**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**42 CFR Part 410**

**[HCFA–3250–P]**

**RIN 0938–AJ53**

# Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B to promote Medicare program integrity and national uniformity, and simplify administrative requirements for clinical diagnostic laboratory services. A Negotiated Rulemaking Committee (the Committee) developed the proposed policies as directed by section 4554(b)(1) of the Balanced Budget Act of 1997 (the BBA).

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 9, 2000.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3250–P, P.O. Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8016.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3250–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

**FOR FURTHER INFORMATION CONTACT:** Jackie Sheridan, (410) 786–4635 (for issues related to coverage policies). Brigid Davison, (410) 786–8794 (for issues related to documentation requirements). Dan Layne, (410) 786–3320 (for issues related to claims processing).

**SUPPLEMENTARY INFORMATION:**

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## Overview

In this proposed rule, we explain the establishment of a negotiated rulemaking committee to develop coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. We set out and explain proposed revisions to regulations on clinical diagnostic laboratory services payable under Medicare Part B, including provisions relating to national administrative policies. The addenda to this proposed rule include the proposed national coverage policies that are proposed as national coverage decisions, and an introduction explaining the uniform format used by the Committee in developing those decisions.

To assist readers in referencing sections contained in this proposed rule, we are providing the following table of contents:

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Due to referral practices in the performance of clinical diagnostic laboratory tests, the laboratory performing the test may not be the entity authorized to bill Medicare for the service. In order to avoid confusion, in this proposed rule we have used the word ''laboratory'' when discussing requirements that apply universally to laboratories and the word ''entity billing Medicare'' (or a similar phrase) to indicate requirements that apply to a laboratory or other entity that is authorized to submit the Medicare claim for the service.

## I. Background

**Note:** Label comments about this section with the subject: ''Background''.

### *A. Current Statutory Authority and Medicare Policies*

Section 1861(s)(3) of the Social Security Act (the Act) provides for payment of, among other things, clinical diagnostic laboratory services under Medicare Part B. Tests must be ordered either by a physician, as described in § 410.32(a), or by a qualified nonphysician practitioner, as described in § 410.32(a)(3). Tests may be furnished by any of the entities listed in § 410.32(d)(1). A laboratory furnishing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100–578), as set forth at 42 CFR part 493. Part 493 applies to laboratories seeking payment under the Medicare and Medicaid programs.

Section 1862(a)(1)(A) of the Act, to which there are certain explicit statutory exceptions, provides that no Medicare payment may be made for expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. We have consistently interpreted this provision to exclude services that are not safe and effective, are experimental, and are not furnished in accordance with accepted standards of medical practice. (Some exceptions exist such as category B devices under evaluation with FDA protocals.) Moreover, section 1862(a)(7) of the Act excludes coverage ''where such expenses are for routine physical checkups, eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examination therefore, or immunizations (except as otherwise allowed under section 1861(s)(10) and paragraph (1)(B) or under paragraph (1)(F).''

We have consistently interpreted these provisions to prohibit coverage of screening services, including clinical laboratory tests furnished in the absence of signs, symptoms, complaints, or personal history of disease or injury, except as explicitly authorized by statute.

Under the above statutory authority, we have issued national coverage decisions and policies in a variety of documents, such as HCFA manual instructions, **Federal Register** notices, and HCFA Rulings. We have issued approximately 20 national coverage decisions pertaining to clinical diagnostic laboratory services in the Medicare Coverage Issues Manual (HCFA Pub. 6). Medicare program manuals are posted on the Internet at http://www. hcfa.gov/pubforms/progman.htm. Program transmittals and program memoranda are posted at http://www.hcfa.gov/pubforms/transmit/transmit.htm.

Under section 1842(a) of the Act, we contract with organizations to perform bill processing and benefit payment functions for Medicare Part B (Supplementary Medical Insurance). These Medicare contractors, who process Part B claims from noninstitutional entities, are called carriers. Under section 1816(a) of the Act, we contract with fiscal intermediaries to perform claims processing and benefit payment functions for Medicare Part A (Hospital Insurance). Fiscal intermediaries also process claims payable from the Medicare Part B trust fund that are submitted by providers that participate in Medicare Part A, such as hospitals and skilled nursing facilities. We use the term ''contractor(s)'' to mean carriers and fiscal intermediaries.

Medicare contractors review and adjudicate claims for services to assure that Medicare payments are made only for services that are covered under Medicare Part A or Part B. In the absence of a specific national coverage decision, coverage decisions are made at the discretion of the local contractors. Frequently, local contractors publish local medical review policies (LMRPs) to provide guidance to the public and medical community that they service. Contractors develop these local medical review polices by considering medical literature, the advice of local medical societies and medical consultants, and public comments. Our instructions regarding the development of local medical review policies appear in section 7500ff of the Medicare Carriers Manual (HCFA Pub. 13–3).

These LMRPs explain when an item or service will (or will not) be considered ''reasonable and necessary'' and thus eligible (or ineligible) for coverage under the Medicare statute. If a contractor develops an LMRP, its LMRP applies only within the area it serves. While another contractor may come to a similar decision, we do not require it to do so. An LMRP may not conflict with a national coverage decision once the national coverage decision is effective. If a national coverage decision conflicts with a previously made LMRP, the contractor must change its LMRP to conform it to the national coverage decision. A contractor may, however, make an LMRP that supplements a national coverage decision where the national coverage decision is silent on an issue. The LMRP may not alter the national coverage decision.

*B. Recent Legislation*

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, mandates use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. Section 4554(b)(2) requires that these national coverage policies be ''designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Medicare Part B in connection with the following:

- Beneficiary information required to be submitted with each claim or order for laboratory services.
- The medical conditions for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Social Security Act).
- The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services.
- The medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test (in accordance with section 1833(e) of the Act).
- Recordkeeping requirements in addition to any information required to be submitted with a claim, including physician's obligations regarding such requirements.
- Procedures for filing claims and for providing remittances by electronic media.
- Limitations on frequency of coverage for the same services performed on the same individual.''

## II. Negotiated Rulemaking Process

**Note:** Label comments about this section with the subject: ''Negotiated Rulemaking Process''.

*A. Convening the Committee*

Negotiated rulemaking under the Negotiated Rulemaking Act (Public Law 101–648) 5 U.S.C. 561–570 is a process by which a committee of representatives of interests that may be significantly affected by a proposed rule, together with an agency representative attempt to reach consensus on the text or content of a proposed rule. The Committee is assisted by an impartial facilitator or mediator.

A convening process was followed to determine the interests likely to be significantly affected by the proposed rule and the individuals who should be appointed to the Committee to represent those interests. Impartial conveners interviewed potential representatives and made recommendations in a convening report. We considered the conveners' recommendations and published a notice of intent to negotiate on June 3, 1998 in the **Federal Register** (63 FR 30166). That notice described the scope of the negotiations and proposed Committee membership. Committee membership is based on responses to the notice, and the Committee is chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). One additional member was added by consensus of the Committee. Committee members represented the following organizations:

- American Association of Bioanalysts.
- American Association for Clinical Chemistry.
- American Association of Retired Persons (AARP).
- American Clinical Laboratory Association.
- American College of Physicians—American Society of Internal Medicine.
- American Health Information Management Association.
- American Hospital Association.
- American Medical Association.
- American Medical Group Association.
- American Society for Clinical Laboratory Science.
- American Society of Clinical Pathologists.
- American Society for Microbiology.
- Clinical Laboratory Management Association.
- American Society for Clinical Laboratory Science.
- College of American Pathologists.
- Health Industry Manufacturers Association.
- Medical Group Management Association.
- National Medical Association.

In addition, we represented the Department of Health and Human Services on the Committee.

*B. Summary of the Committee Process*

The Committee met nine times from July 13, 1998 to January 27, 1999 and again on August 30 and 31. We published notices of meetings in the **Federal Register** on June 3, 1998 (63 FR 30166), August 11, 1998 (63 FR 42796), January 4, 1999 (64 FR 69), and August 10, 1999 (64 FR 43338). We posted detailed agendas and minutes for each of these meetings on the HCFA web page at http://www.hcfa.gov/quality/qlty-8a.htm.

The Committee operated under organizational groundrules that it adopted by consensus. The organizational groundrule on ''consensus'' provided for the following:

- The Committee would operate by consensus.
- The Committee would make decisions with the unanimous concurrence of Committee members.
- Concurrence would mean only that the Committee member could live with the decision being considered by the Committee.
- An abstention would be the same as a concurrence for purposes of determining consensus.

Committee meetings were open to the general public. In addition, the Committee provided opportunities for the general public to submit written and oral comments.

The Committee prepared and signed an agreement at the conclusion of the meetings. The agreement states the provisions for which the Committee reached consensus in a consensus report. The Committee members agreed that they would not submit negative comments on this proposed rule as long as it has the same substance and effect as the consensus report. In addition, the Committee developed proposed national coverage decisions for certain clinical diagnostic laboratory tests or groups of tests. The Committee formed six workgroups to assist with this task and a ''Drafting Workgroup''. Each Committee member was permitted, but not required, to appoint a representative to each workgroup. The agreement signed by Committee Members represents ''consensus'' under the definition set out above. Thus, a Member may have chosen to abstain on some of the matters negotiated, rather than affirmatively indicating concurrence. In particular, the AARP did not participate in the workgroups which developed proposed national coverage policies for specific tests, and in this agreement defers to Committee members with specialized expertise in the areas covered. Therefore, the AARP's general concurrence reflects its abstention on the proposed national coverage policies for specific tests.

## III. Proposed Policy Changes and Clarifications

Section 4554(b)(2) of the BBA explicitly directs that a negotiated rulemaking committee negotiate coverage and administrative policies for clinical diagnostic laboratory services ''payable under part B.'' Therefore, these Medicare policies apply to all laboratory services billed to Medicare Part B regardless of the location of the entity furnishing the service (physicians' office laboratories, hospital laboratories, independent laboratories, etc., or of the type of Medicare contractor processing the claims (carriers or fiscal intermediaries).

Any policy relating to the ordering of clinical diagnostic laboratory tests applies whether the individual ordering the test is a physician or a nonphysician practitioner qualified under § 410.32(a)(3) to order diagnostic tests. Section 410.32(a)(3) provides that nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) who furnish services that would be physicians' services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for purposes of § 410.32. Thus, where this proposed rule discusses ordering clinical laboratory tests and refers to a ''physician,'' it means either a physician or a qualified nonphysician practitioner as defined in § 410.32(a)(3).

These proposed regulations do not purport to provide any immunities or safe harbors. The provisions of this proposed rule are not intended to limit criminal, civil or administrative law enforcement or overpayment recoveries.

*A. Information Required With Each Claim*

**Note:** Label comments about this section with the subject: ''Information Required with Claim.''

1. Required Data Fields

Section 4554(b)(2)(A) of the BBA directs the Committee to negotiate policies that are designed to promote program integrity and national uniformity, and to simplify administrative requirements for beneficiary information that must be submitted with each claim for laboratory services. The Committee reviewed the existing Medicare claims processing requirements that are outlined in the Medicare Carriers Manual (HCFA Pub. 14–3) sections 3005 and 3999, exhibit 10, and in the Medicare Fiscal Intermediary Manual (HCFA Pub. 13–3) section 3605 and Addendum L.

The Committee discussed the existing requirements related to information that must be submitted with the claims. To promote administrative simplicity, some members of the Committee suggested that the preamble to this rule include a listing of the specific data elements that are required for laboratory claims. However, the data elements that are required for a claim for a laboratory service may vary depending on certain factors. For example, required data fields will vary with the individual circumstances of the beneficiary, such as secondary payer situations; and the particular service furnished.

Moreover, claims processing requirements may be subject to change as other program requirements are modified or as the uniform requirements enacted under the Health Insurance Portability and Accountability Act (HIPAA) are implemented. Some members of the Committee expressed concern that having a list in the preamble that may rapidly become inaccurate could generate increased opportunity for errors or confusion. Thus, the Committee agreed to

encourage readers to refer to the claims processing sections of the Medicare Carriers Manual (section 3005 and 3999, exhibit 10) and Medicare Fiscal Intermediary Manual (section 3605 and Addendum L) in order to keep current regarding the specific policies related to data elements. As noted above, these manuals are posted on the Internet at http://www.hcfa.gov/pubforms/progman.htm.

2. Diagnostic Information Requirement

The Committee discussed when diagnostic information to support medical necessity must be submitted with a claim. The discussion focused on whether diagnostic information should be required on claims for all tests, even those not addressed by a national coverage policy or LMRP. Some Committee members emphasized that providing information on the reason for the patient visit or for the test would be useful in evaluating patient outcomes and quality of care and would ensure consistency and simplicity. Physicians' representatives expressed concern, however, about the burden that may be involved in providing the information. Laboratory representatives expressed concern about laboratories' ability to be paid if the physician does not provide the information.

The Committee concurred that this proposed rule would not promulgate a requirement that diagnostic information be submitted with every claim; however, there may be other requirements for a diagnosis code with every claim. The Committee recommended, however, that physicians be encouraged voluntarily to provide diagnosis information (either the reason for the visit or the reason for the test) with the order, and laboratories be encouraged to submit information that they receive with the claim.

3. Date of Service

The date of service is a required data field for laboratory claims. A laboratory service may take place over a period of time. That is, the date the physician orders the test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date of the test, and the date results are produced may not be the same. For example, often several days elapse between taking a sample and producing results in microbiology tests that are cultured. The Committee discussed what ''date of service'' laboratories must report on claims for clinical diagnostic laboratory services. To ensure equitable treatment of beneficiaries and providers, as well as to promote national claims processing consistency, it is necessary that all laboratories report this date consistently.

Laboratory representatives reported that some laboratory computer systems are programmed to report the date of acquisition of the specimen or the date of accession (the date the test is entered into the computer system), in the date of service field on the claim form. In addition, Medicare issued Program Memorandum A–9J–4 in April, 1995 that instructed some laboratories, primarily hospital-based laboratories, to report the date of performance as the date of service on automated multi-channel tests.

After considerable discussion the Committee reached consensus that the date of service for Medicare claim purposes should be the date the tested specimen was collected and that the person obtaining the specimen must furnish the date of collection of the specimen to the entity billing Medicare. However, the Committee felt that further input was needed to make an informed decision to determine appropriate date of service for Medicare claim purposes. We are committed to the concept that we should establish a national policy regarding date of service for Medicare claims that will promote program integrity and national uniformity, yet minimize the burden on laboratories. Therefore, we are specifically soliciting public comment on this issue from organizations serving on the Negotiated Rulemaking as well as others. As discussed below in ''Effective Date of Provisions'', we are proposing to provide a grace period of up to 12 months after the effective date of the final rule to accommodate any system changes required by the policy changes or clarifications resulting from the Committee's negotiations. Laboratories will have up to 24 months (12 months delayed effective date and up to 12 months grace period for system changes) after publication of the final rule to achieve system modification to submit claims in accordance with the final policy on date of service.

*B. Medical Conditions for Which a Test May Be Reasonable and Necessary*

**Note:** Label comments about this section with the subject: ''National Coverage Decisions''.

Section 4554(b)(2) of the Act instructs the Committee to consider the medical conditions for which a laboratory test is considered reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Act) in developing national coverage policies. These policies must be designed to promote program integrity and national uniformity and simplify administrative requirements. We are promulgating these policies as ''national coverage decisions'' under section 1862(a)(1) of the Act, as defined in § 405.732. These decisions are binding upon the claims processing contractors as well as the review and appeal entities.

1. The Committee Process Used for Proposed National Coverage Decisions

The Committee reached consensus to outline the specific medical conditions for which a number of specific clinical laboratory services may be reasonable and necessary. The Committee developed an extensive list of tests for which it believed that a national coverage decision was appropriate. It focused on those services that have a diversity of LMRPs.

Given the large number of tests under consideration, the Committee used workgroups to assist with the development of the coverage decisions. The Committee formed workgroups to address laboratory tests in six major clinical categories and assigned and prioritized tests (or groups of tests) to the workgroups. The six clinical categories of tests were endocrinology and metabolism, cardiology and other therapeutic drug monitoring, hematology and coagulation, oncology and anatomic pathology, infectious diseases, and gastrointestinal and renal.

Each workgroup was co-chaired by two Committee members. Each Committee member was entitled to appoint a designee to each workgroup. In addition, each workgroup had at least one Medicare carrier medical director as a nonvoting technical consultant. Each workgroup included, at a minimum, a pathologist, another specialty physician, a primary care physician, a laboratory expert, a coding expert, and a Medicare expert (HCFA staff).

To ensure that the workgroups approached the task consistently, the Committee negotiated a process to be used by the workgroups to develop draft recommendations for proposed national coverage decisions. The national coverage decisions are based on authoritative evidence. In addition, the national coverage decisions reflect common, generally accepted medical practice through the input of nationally recognized organizations, rather than solely the opinion of individual practitioners. The workgroup process included the following:

- Seeking input from relevant national medical specialty societies and voluntary health agencies through the AMA representative.
- Reviewing relevant scientific literature and practice guidelines.

• Reviewing existing local medical review policies, as well as any existing relevant templates for local policies developed by a task force of carrier medical directors.

Because of the statutory deadline for the Committee's work, the workgroups operated under very tight time constraints. Workgroup members communicated by telephone conference calls, e-mail, and FAX.

Workgroup recommendations were posted on the HCFA website for the negotiations by November 4, 1998 and public comments were solicited through November 11, 1998. At the Committee's November meeting, the full Committee considered each workgroup's recommendations, and any comments from the public or from other Committee members. The Committee modified the draft policies, where necessary, in order to respond to comments and to achieve consensus.

The Committee reached consensus on the 23 proposed national coverage decisions included in Addendum B. In addition, the Committee reached consensus on the introductory explanation of those decisions included in Addendum A. The Committee reached consensus that the decisions should be published in manual form, rather than as a codified regulation. This would ensure that coverage decisions are updated in a timely manner as appropriate (for example, changes in technology, coding, or national practice standards).

2. Uniform Format

The Committee used a uniform format for the proposed national coverage decisions that included a narrative description of the test, panel of tests, or group of tests addressed in the decision; clinical indications for which the test(s) may be considered reasonable and necessary and not screening for Medicare purposes; limitations on use of the test(s); and diagnosis codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM codes).

The lists of ICD–9–CM codes in each policy were derived from the narrative description, indications, and, in some decisions, limitations, and are included in the decisions to achieve the statutory objective to promote national uniformity in processing claims. The codes are listed in one of the following three sections: (1) ICD–9–CM codes covered by Medicare program; (2) ICD–9–CM codes denied; and (3) ICD–9–CM codes that do not support medical necessity.

The first section lists covered codes—those for which there is a presumption of medical necessity. Diagnoses listed in this section may support medical necessity of the claim, but the claim may be subject to review to determine whether the test was in fact reasonable and necessary in the particular circumstances presented. If the policy takes an ''exclusionary'' approach (described below), this section states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM code sections below.''

The second section lists diagnosis codes that are never covered. If an ICD–9–CM code listed in this section is submitted with the claim, the test may be initially billed to the Medicare beneficiary without billing Medicare because the test is a service that is not covered by Medicare under any circumstances, such as a screening service that is not paid for under a statutory screening exception. The beneficiary, however, does have a right to have the claim submitted to Medicare.

The third section lists codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Generally, diagnoses in this section will result in denial. In certain circumstances, however, additional documentation could support a decision of medical necessity and must be submitted by the ordering provider to the billing entity for submission with the claim. In other circumstances, it may be appropriate for the ordering physician or the laboratory to obtain an advance beneficiary notice from the beneficiary consistent with § 7300.5 of the Medicare Carriers Manual and § 3430—3432.1 of the Fiscal Intermediary Manual. If the policy takes an ''inclusionary'' approach (described below), this section of the policy states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.''

Each proposed national coverage decision published in Addendum B includes a section titled ''Reasons for Denial.'' The Committee did not negotiate the language included in this section. The language represents our interpretation of Medicare's longstanding policies. It is included in the national coverage decision for informational purposes.

Each proposed decision contains a section for sources of information on which the decision is based. A national coverage decision must be based on authoritative evidence. Authoritative evidence could include peer-reviewed medical literature, clinical practice guidelines or consensus, and formal opinions of national medical specialty societies and national voluntary health organizations.

Coding guidelines that apply to all tests are included in each proposed policy. Some policies contain additional coding guidelines relevant for the specific test or group of tests addressed in the policy.

To develop national coverage decisions for the tests assigned to each workgroup, the Committee agreed to use one of two approaches, referred to as ''inclusionary'' and ''exclusionary.'' Decisions using the ''inclusionary'' approach list the ICD–9–CM codes in the following two categories: ICD–9–CM Codes Covered by Medicare Program and ICD–9–CM Codes Denied. These decisions do not list the codes that require additional documentation to support medical necessity.

The ''exclusionary'' approach was used for tests for which LMRPs identified a large number of acceptable ICD–9–CM codes. The Committee used this approach to develop a proposed policy on blood counts, including complete blood counts. In lieu of listing all the ICD–9–CM codes that support medical necessity of a test or group of tests, decisions using the ''exclusionary'' approach list ICD–9–CM codes in the following two categories: ICD–9–CM codes denied and ICD–9–CM codes that do not support medical necessity. Any diagnosis code not listed in either of those two categories is presumed to support the medical necessity of the billed services.

3. Explanation of Effect of a National Coverage Decision

A national coverage decision for a diagnostic laboratory test is a document that includes the circumstances under which the test may be considered reasonable and necessary and, therefore payable under Medicare. This decision applies nationwide and is binding on all Medicare carriers, fiscal intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans when published in a HCFA program manual or the **Federal Register**. The decisions published in Addendum B of this proposed rule would, when final, be national coverage decisions under section 1862(a)(1) of the Act and regulations codified at § 405.732. When final, these decisions may not be disregarded, set aside, or otherwise reviewed by an Administrative Law Judge. A court's review of a national coverage decision is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record previously.

4. Proposed Decisions Developed by the Committee

The committee developed proposed national policy decisions for the following tests:

- Urine bacterial culture.
- Human immunodeficiency virus testing (prognosis, including monitoring).
- Human immunodeficiency virus (diagnosis).
- Blood counts.
- Partial thromboplastin time.
- Prothrombin time.
- Iron studies.
- Blood glucose.
- Glycated hemoglobin/glycated protein.
- Thyroid testing.
- Collagen crosslinks.
- Lipids.
- Digoxin.
- Alpha-fetoprotein.
- Carcinoembronic Antigen.
- Human chorionic gonadotropin.
- Tumor antigen by immunoassay-CA 125.
- Tumor antigen by immunoassay-CA 15–3/CA27.29.
- Tumor antigen by immunoassay-CA 19–9.
- Total Prostate specific antigen.
- Gamma glutamyltransferase.
- Hepatitis panel.
- Fecal occult blood.

5. Request for Comments

The Committee encourages comment on these proposed policies. The Committee recognizes that these proposed policies address important and complex questions concerning the medical necessity of clinical diagnostic laboratory services. The Committee sought to develop evidence-based proposed policies for clinical diagnostic laboratory services that promote program integrity. The Committee found it difficult to do this in some cases because generally accepted medical practice may include testing that is excluded by statute from Medicare coverage, for example, blood glucose screening of patients at high risk for diabetes. The Committee believes that its proposed policies address many concerns that have been raised by the variation among LMRPs. In view of the short time period allowed by the BBA for addressing these complicated issues, the Committee requests public comment, particularly from those with evidence that would support any proposed changes. We encourage commenters to submit, with their comments, copies of medical literature supporting their recommendation for change, rather than simply providing the references to appropriate medical sources.

6. Ongoing Coverage Process

The Committee discussed whether there should be an ongoing process to update these policies, once they are final, and/or to develop additional national coverage policies for other diagnostic laboratory tests or groups of tests. We informed the Committee about steps we are taking to develop a process to address coverage issues for all Medicare services, including laboratory tests. See 80 FR 22619 published April 27, 1999.

The Committee discussed how this process could be used to update the national coverage policies resulting from Committee negotiations, as well as to develop additional policies. We assured Committee Members that they would have an opportunity to comment on that process and on any policies being developed using that process. In light of the information provided and recognizing that section 4554(b)(6) of the Balanced Budget Act provides an opportunity for public notice and comment in a biennial review of laboratory coverage policies, the Committee discontinued its discussions about whether there should be a separate coverage process for laboratory tests.

*C. Appropriate Use of Procedure Codes*

**Note:** Label comments about this section with the subject: ''Procedure Codes''.

The Committee also discussed issues related to procedure codes and modifiers under HCFA's Common Procedure Coding System (HCPCS). HCPCS codes include Current Procedural Terminology (CPT) codes developed by the CPT Editorial Panel of the American Medical Association (AMA) that are copyrighted by the AMA. The Committee reached consensus that certain procedure codes or modifiers should be clarified in this preamble.

1. Use of the Word ''Screening'' in Descriptor

Some Committee members noted that use of the words ''screen'' or ''screening'' in the descriptor of some CPT codes may cause confusion in distinguishing between screening for a disease or disease precursors using a laboratory test (which is generally excluded from Medicare coverage), and screening for a specific analyte or group of related analytes using a laboratory test (which may be covered under Medicare). The use of the term ''screening'' or ''screen'' in these CPT code descriptors does not necessarily describe a test performed in the absence of signs or symptoms of an illness, disease, or condition. The failure to make this distinction may lead to inappropriate denial of claims.

If a test is reasonable and necessary for diagnosing or treating a beneficiary's medical condition, Medicare covers testing for a specific analyte or group of related analytes, even though the words ''screen'' or ''screening'' may appear in the CPT code descriptor for the test. Examples of CPT codes where screening for an analyte may be used diagnostically include the following:

- 83068: Hemoglobin; unstable, screen.
- 86255: Fluorescent noninfectious agent antibody; screen, each antibody.
- 87081: Culture bacterial; screening, for single organisms.

We will include this clarification in instructions we issue to the contractors.

2. Multiple Testing

Committee members also noted potential confusion about multiple claim submissions by a laboratory for the same CPT code for the same beneficiary for the same day. Generally, multiple testing is considered to be duplicative and is not payable under Medicare. Under certain circumstances, however, claims for multiple services assigned the same CPT code may be submitted because the multiple services are medically necessary to diagnose or treat the beneficiary's condition. In these circumstances, presently the laboratory must use CPT modifier ''–59.'' CPT modifier ''–59'' is defined in Appendix A of Current Procedural Terminology, Fourth Edition in part, as follows:

> Distinct procedural service: Under certain circumstances, the physician may need to indicate that a procedure or service was distinct or independent from other services performed on the same day. Modifier ''–59'' is used to identify procedures/services that are not normally reported together, but are appropriate under the circumstances. This may represent a different session or patient encounter, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same physician.

This modifier replaced the previous HCPCS modifier ''GB'' (Distinct procedural service).

A few examples of appropriate use of CPT modifier ''–59'' are the following:

- Biochemical studies performed on different samples, for example, renins (CPT code 84244).

• Multiple blood cultures (CPT codes 87040 and 87103), generally 2–3 collected to document etiology of sepsis.

• Multiple lesion samples collected from distinct anatomic sites for culture for bacteria (CPT codes 87070 and 87075).

The American Medical Association's CPT Editorial Panel is considering changes in the modifier codes to indicate multiple services for the year 2000 update. If such changes are implemented, they may alter the clarification discussed above. We will issue instructions to our contractors addressing modifiers to indicate that a procedure or service is distinct or independent from other services performed on the same day.

*D. Documentation and Recordkeeping Requirements*

**Note:** Label comments about this section with the subject: ''Documentation''.

Section 4554(b)(2) of the BBA provides for uniform national coverage and administrative policies in connection with ''[t]he medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test'' and ''[r]ecordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements.'' Section 4317 of the BBA provides, with respect to diagnostic laboratory and certain other services, that ''if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the * * * service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner [ordering the service] shall provide that information to the entity at the time the * * * service is ordered by the physician or practitioner.''

1. Maintenance of Documentation

Since section 1862(a)(1)(A) of the Act prohibits Medicare payment for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, information describing the patient's signs, symptoms or medical condition(s) documenting the circumstances making laboratory services medically necessary must be maintained in a form that can be accessible or retrievable.

The Committee discussed what documentation generally exists with each entity. The Committee's consensus reflects members' understanding of existing responsibilities for maintaining information regarding medical necessity of clinical diagnostic laboratory services and accuracy of claims submissions. Generally, physicians maintain information in the patient's medical record, and laboratories maintain the information provided to them by the ordering physician. To promote uniformity, the Committee's consensus was that we propose a codified regulation addressing documentation and recordkeeping requirements for clinical diagnostic laboratory services consistent with present practices.

We are proposing to add a new paragraph (d)(2)(i) to § 410.32 to clarify that the ordering physician is responsible for maintaining documentation of medical necessity in the beneficiary's medical record. In addition, we are proposing to add paragraph (d)(2)(ii) to § 410.32 to clarify that the entity submitting the claim must maintain the documentation it receives from the ordering physician and the documentation that the claim information that it submitted to the Medicare contractor accurately reflects the documentation received from the ordering physician.

We are also proposing to add a new paragraph (d)(2)(iii) to § 410.32 to clarify that the entity submitting the claim may request additional diagnostic and other information to document that the services it bills are reasonable and necessary. Examples of situations in which a billing entity may wish to seek additional documentation may include, but would not be limited to, situations where diagnostic information is not submitted with an order for a test for which there is a national coverage decision or LMRP; where data analysis indicate that the particular beneficiary may exceed applicable frequency parameters for this particular test, or where there is an indication of potential aberrant utilization. In making requests for additional information, laboratories should focus their requests on material relevant to medical necessity of the services billed. In addition, documentation requests must take into account current rules and regulations related to patient confidentiality that are applicable in the area where the physician is practicing.

2. Submission of Documentation

The Committee discussed who should be responsible for supplying documentation when a Medicare contractor reviews a laboratory claim. The Committee acknowledges that, for program integrity purposes, Medicare make payments only for services that are reasonable and necessary under Medicare. The Committee consensus is based on the general principle that physicians and laboratories may each be requested to provide the information that they maintain (as described below) but does not alter the responsibility of the entity submitting the claim.

Specifically, the Committee consensus was that, upon request, laboratories must supply documentation that they maintain, such as the requisition from the ordering physician. We are proposing to add a new paragraph (d)(3)(i) to § 410.32(d) to specify that, upon request, the entity submitting the claim must provide the following information: (1) Documentation of the physician's order for the service billed, including information sufficient to enable us to identify and contact the ordering physician; (2) documentation showing accurate processing of the order and submission of the claim; and, (3) diagnostic and other medical information that supports medical necessity supplied to the laboratory by the ordering physician or qualified nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

The entity submitting a claim is responsible for documentation of medical necessity of the services to justify and support Medicare payment of the claim. Some Committee members, however, expressed concerns about protecting beneficiary confidentiality if laboratories are required to handle beneficiary medical records. The Committee agreed that if the information supplied by the entity submitting the claim (laboratory) was not sufficient to demonstrate that the services were reasonable and necessary, then we would seek additional information directly from the ordering physician. If the ordering physician does not supply the information, we will notify the laboratory and deny the claim.

We are proposing to add a new paragraph (d)(3)(ii) to § 410.32 to specify that, if the documentation provided under paragraph (d)(3)(i) by the entity submitting the claim does not demonstrate that the service is reasonable and necessary, we would take the following actions: (1) provide the ordering physician information sufficient to identify the claim being reviewed; (2) request from the ordering physician those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed; and (3) if the ordering physician does not supply the documentation requested, inform the entity submitting the claim(s) that the documentation has not been supplied and deny the claim.

Since the entity submitting the claim would be the entity to experience a

payment denial if documentation does not support the medical necessity of the claim, the Committee agreed that the basic premise that Medicare would seek additional diagnostic and other medical information from the entity that usually maintains that documentation—the ordering physician—does not preclude the laboratory from requesting additional diagnostic or other medical information from the ordering provider. In making requests for additional information, laboratories must focus their request for additional information on material relevant to medical necessity. In addition, documentation requests must take into account current rules and regulations related to patient confidentiality that are applicable in the area where the physician is practicing.

Similar to proposed paragraph (d)(2)(iii) of § 410.32, we are proposing to add a new paragraph (d)(3)(iii) to § 410.32 to state that the entity submitting the claim may request additional diagnostic and other medical information to document that the services for which it bills are reasonable and necessary. When such a request is made, it must be focused on material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

3. Signature on Requisition

Section 410.32(a) requires that all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Some have interpreted this regulation to require a physician's signature on the requisition as documentation of the physician's order. Regulations implementing the Clinical Laboratory Improvement Act (CLIA) at § 493.1105, relating to the requisition specify that a laboratory must perform services only at the written or electronic request of an authorized person. Further, this section permits oral requests for laboratory services only if the laboratory subsequently requests written authorization for the testing within 30 days. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered.

The Committee consensus is that this issue would be resolved by our publication of an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test. We will issue a program instruction that reiterates this point.

4. Retention of Records

The Committee discussed the length of time that records to document medical necessity for clinical diagnostic laboratory services must be retained. The Committee consensus was to identify, in this preamble, current record retention requirements in Federal law. The provisions of the Federal statutes and regulations that pertain specifically to retention of records related to laboratory testing, including a brief summary of those provisions are set forth as follows:

- 42 CFR 482.24(b)(1), ''Condition of Participation for Hospitals—Standard: Form and Retention of Record'' specifies that medical records must be retained in their original or legally reproduced form for at least 5 years.
- 42 CFR 488.5(a) and 488.6, which discuss accreditation standards for hospitals or other providers or suppliers deemed to meet applicable Medicare conditions of participation, include record retention standards.
- 42 CFR 493.1105, which implements the Clinical Laboratory Improvement Amendments of 1988 (CLIA), specifies that records of test requisitions or test authorizations must be retained for a minimum of 2 years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of 2 years and must be available to the laboratory at the time of testing and be available to us upon request.
- 42 CFR 493.1107 specifies that records of patient testing, including, if applicable, instrument printouts, must be retained for at least 2 years. Immunohematology and transfusion records must be retained for no less than 5 years in accordance with 21 CFR part 606, subpart I.
- 42 CFR 493.1107 and 1109 state that records of blood and blood product testing must be maintained for a period not less than 5 years after processing records have been completed, or 6 months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).
- 42 CFR 493.1257(g) specifies that the laboratory must retain all slide preparation for cytology exams for 5 years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period.
- 42 CFR 1003.132, related to civil monetary penalties, assessments, and exclusions, states that an action must begin within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

*E. Procedures for Filing Claims*

**Note:** Label comments about this section with the subject: ''Claims Processing''.

1. Coding of Narrative Diagnoses

Most laboratory claims are submitted to us electronically. Laboratories that receive narrative diagnosis information from an ordering physician must translate that information into an appropriate diagnosis code (ICD–9-CM code) to submit the claim electronically. The Committee discussed policies for assigning an ICD–9-CM code if there is not an exact match between the code descriptor and the narrative the laboratory received from the ordering physician. The Committee consensus was that an appropriate diagnosis code may be assigned to a narrative, even if the wording of the narrative does not exactly match the code descriptor for the ICD–9-CM code. If an ICD–9-CM code is submitted by the ordering physician, laboratories must use that code in submitting the claim unless the laboratory has obtained documentation from the physician to support altering the code. For example, if a physician submits an incomplete code (that is, only 3 digits of a code that requires 5 digits), the laboratory must document the appropriate subclassification if it is required to report a code on the claim. We will include this clarification in future program instructions.

2. Limitation on Number of Diagnoses

The Committee discussed variation among Medicare contractor's in the number of ICD–9–CM codes on a claim form that the contractor's computer systems will accept. If a contractor's system accepts a limited number of codes, a claim may be denied even if the physician who ordered the test supplied a code that would support the medical necessity of the test. The Committee was informed that, when proposed HIPAA standards are implemented, eight ICD–9–CM codes will be permitted on electronic claims. Committee members provided information indicating that this number would be sufficient for the vast majority of claims.

Until HIPAA standards permitting eight ICD–9–CM codes are implemented, Medicare contractors, whose systems accept fewer than eight ICD–9–CM codes in the diagnoses field, would permit the laboratory to submit additional codes in the narrative field. If it would require the Medicare contractor to make a change in its

claims processing system in order to use this information for automated claims processing, the additional diagnoses would only be used by the contractor in processing claims that were suspended for manual review.

3. Matching of Diagnosis to Procedure

All Medicare contractors presently process claims using any diagnosis-to-procedure code matching supplied by the laboratory. Some Committee members wished to find a way to have contractors examine all submitted codes. The Committee consensus was that, in the absence of matching of codes supplied by the laboratory, Medicare contractors must examine all submitted codes on prepayment review, taking into account program integrity concerns. Claims will not be denied solely because there is no matching of diagnosis and procedure codes on the claim form. We will include this clarification in future instructions to our contractors.

The Committee also discussed ways of avoiding denial of an entire claim if it is submitted with diagnosis codes for multiple procedures (tests) and one of the diagnosis codes indicates screening, but the laboratory does not link the diagnosis and procedure codes. The Committee was concerned that absent information indicating which test(s) is performed for which diagnosis, the contractor may deny all of the claimed services after examining the diagnosis codes.

The Committee consensus was that laboratories have the option of submitting a separate claim for the procedure that is not covered by Medicare. We would instruct the Medicare contractors to allow this option.

In order to ensure that noncovered procedures can be identified, ordering providers must supply to the laboratory the necessary information to specifically identify any noncovered test ordered, such as a test ordered for screening purposes. When this information is supplied to the laboratory, the laboratory must supply this information with any claim for the noncovered service. For example, when an ICD–9–CM code that indicates screening is provided by the physician, the laboratory must either submit a separate claim for the procedure that is not covered by Medicare or match that code on a claim form with the CPT code(s) provided for that purpose.

*F. Limitation on Frequency*

**Note:** Label comments about this section with the subject: ''Frequency''.

Section 4554(b)(2) of the BBA instructs the Committee to negotiate policies that take into consideration ''Limitations on frequency of coverage for the same tests performed on the same individual.''

1. Notice of Frequency Screens

The Committee discussed the use of frequency screens and their impact on the laboratory community. Some Committee members noted that, since frequency screens are a program integrity tool and therefore are not published, there is no means for a laboratory to know when a claim would be reviewed and perhaps denied in the absence of additional documentation of medical necessity. After studying the data on frequency denials and discussing the issue, we agreed that a frequency screen would not result in a frequency-based denial unless information published by us or our contractor includes an indication of the frequency that is generally considered reasonable utilization of that test for Medicare payment purposes.

We will issue instructions to Medicare contractors through a revision to the program integrity sections of the Medicare Carriers Manual and Fiscal Intermediary Manual. In the future, we will be moving this information to the Program Integrity Manual. These instructions will provide that, except for egregious utilization, contractors may not use a frequency screen that could result in a frequency-based denial unless the contractor has published information about the appropriate frequency for the service or unless we have published information about the appropriate frequency in a national coverage decision. The information regarding appropriate frequency either may include the frequency with which the service is generally considered reasonable utilization for Medicare purposes or may be an absolute limit on coverage. The information must be published in advance of implementation of a frequency screen in a form, such as a contractor bulletin, that is widely disseminated to affected providers and suppliers. The contractor must consult with appropriate advisors, including medical specialty and other organizations before developing and publishing local frequency information for a clinical diagnostic laboratory test. Local frequency information for a particular test may not conflict with a national coverage decision or policy that includes frequency information for that test.

If a Medicare contractor has been applying a frequency screen in the absence of published information about the frequency expectation, the contractor must either publish information about the appropriate frequency or stop using the frequency screen. Frequency screens that can result in denial must not be more restrictive than the frequency described in the published information. Contractors may, however, continue to deal with egregious utilization without prior publication of frequency information by using Category III edits described in section 7506.2 of the Medicare Carriers Manual, which are typically provider specific.

2. Automatic Denial and Manual Review

The Committee discussed Medicare policy on automatic denials of laboratory claims as the policy applies to frequency screens. The Committee consensus is that the current policy regarding automatic denial and manual review of claims as stated in Medicare Carriers Manual sections 7505.1 and 7506 is appropriate and should be codified in regulations.

We are proposing to add a new paragraph (d)(4) to § 410.32 to provide that, except in limited and specified circumstances as described below, we will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim (for example, justifications prepared by providers or suppliers, primary and secondary diagnoses, and copies of medical records). We, however, may automatically deny a claim without any manual review under the following circumstances: (1) If a national coverage decision or policy or LMRP review policy specifies the circumstances under which a service is denied and those circumstances exist, or the service is specifically excluded from Medicare coverage by statute; or (2) if we determine that a specific provider or supplier has engaged in egregious overutilization of a particular service and the claim is for that service.

3. Notice to Beneficiaries

The Committee discussed the impact of frequency screens on laboratories furnishing services to beneficiaries who use multiple laboratories. Several Committee members suggested proposals for notifying beneficiaries of frequency denials and requesting that they advise their physicians of the denial in an effort to encourage the physician to obtain an advance beneficiary notice. Such a notification mechanism would be costly to Medicare, would frequently and inaccurately identify potential denial situations due to time lags between

receipt of services, and may be confusing to beneficiaries. Some members of the Committee expressed concern that such a mechanism may have the unintended effect of beneficiaries failing to receive necessary services. The Committee could not agree to a specific proposal and therefore we are soliciting new ideas for addressing this problem from Committee members as well as others. We are especially interested in ideas that include shared responsibility for solving the problem.

4. Consistent Remittance Message

Some Committee Members expressed concern that HCFA may not be using a consistent denial message to indicate claims that are denied for excess frequency. We agreed to instruct the Medicare claims processing contractors (carriers and fiscal intermediaries) to consistently use remittance advice language that identifies the reason for denial as excessive frequency. The language would read as follows: ''Claim/service denied/reduced because the payer deems the information submitted does not support this level of service, this many services, this length of service or this dosage.''

## IV. Other Topics Discussed by the Committee

The Committee also discussed some topics that we identified as outside the scope of the negotiations, but are of concern to some Committee members. The Committee discussed Medicare provisions on limitation of liability (sometimes called waiver of liability) in the context of laboratory services. These provisions are currently found in section 1879 of the Social Security Act, 42 CFR part 411, subpart K, section 7330 of the Medicare Carriers Manual, section 3440—3446.9 of the Fiscal Intermediary Manual, and any currently applicable rulings. If prerequisites for waiver of liability in these provisions are met, these provisions are equally applicable to laboratory services. If we issue revisions or clarifications of these policies in the future, the revisions would be applicable to all providers/suppliers, including laboratories, unless otherwise stated.

## V. Provisions of the Proposed Regulations

This proposed rule would establish uniform national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. This proposed rule would promote Medicare program integrity and national uniformity and would simplify administrative requirements for clinical diagnostic laboratory services. These regulations do not provide, or purport to provide, any immunities or safe harbors. Additionally, these regulations do not limit any criminal, civil, or administrative law enforcement and overpayment actions. These Medicare policies apply to all Medicare contractors processing Part B laboratory claims, including fiscal intermediaries. The changes we would make to 42 CFR part 410 are set forth as follows:

- We are proposing to redesignate paragraph (d) introductory text as paragraph (d)(1) and adding a heading.
- We are proposing to redesignate paragraphs (d)(1) through (d)(7) as paragraphs (d)(1)(i) through (d)(1)(vii).
- We are proposing to add a new paragraph (d)(2) to § 410.32 that would outline documentation and recordkeeping requirements related to clinical diagnostic laboratory tests. The proposed documentation and recordkeeping requirements read as follows:

+ Paragraph (d)(2)(i) would specify that the physician (or qualified nonphysician practitioner) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

+ Paragraph (d)(2)(ii) would require the entity submitting the claim to maintain documentation it receives from the ordering physician and information documenting that the claim submitted accurately reflects the information it received from the ordering physician.

+ Paragraph (d)(2)(iii) would authorize the entity submitting the claim to request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. This request must be relevant to the medical necessity of the specific test(s), and take into consideration current rules and regulations on patient confidentiality.

- We are proposing to add a new paragraph (d)(3) to § 410.32 relating to claims review.

+ Paragraph (d)(3)(i) would specify that the entity submitting the claim must provide documentation of the physician's order for the service billed, showing accurate processing and submission of the claim, and diagnostic or other medical information supplied to the laboratory by the ordering physician or qualified nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

+ Paragraph (d)(3)(ii) would specify that if the documentation submitted by the laboratory does not demonstrate that the service is reasonable and necessary, we will provide the ordering physician information sufficient to identify the claim being reviewed and request from the ordering physician those parts of the beneficiary's medical record that are relevant to the claim(s) being reviewed. If the documentation is not provided timely, we will notify the billing entity and deny the claim.

+ Paragraph (d)(3)(iii) would authorize the entity submitting the claim to request additional diagnostic and other medical information that is relevant to the medical necessity of the specific services from the ordering physician consistent with applicable patient confidentiality laws and regulations.

- We are proposing to add a new paragraph (d)(4) to § 410.32 to outline when we may deny a claim without manual review.

+ Paragraph (d)(4)(i) would state that unless indicated in paragraph (d)(4)(ii), we will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim.

+ Paragraph (d)(4)(ii) would permit automatic denial of claims when there is a national coverage decision, or LMRP that specifies the circumstances under which the service is denied, the statute excludes Medicare coverage for the service, or the specific provider or supplier has engaged in egregious overutilization of the service and the claim is for that service.

## VI. Effective Date of Provisions

The Committee discussed the appropriate effective date of the provisions for which it reached consensus. Changes or clarifications resulting from the Committee's negotiations will impact each entity submitting the claim differently (for example, variance in the time frame for computer systems and software updates in accordance with this proposed regulation, compliance with the comprehensive HIPAA administrative simplification regulations, etc.). We especially are concerned about smaller entities because of the lack of resources at their disposal to identify and implement changes. Due to such differences among laboratories and physician offices, the Committee recommended that HCFA provide an extended period of advance notification prior to implementation. We note that the national coverage decisions included in addendum B effect approximately 60 percent of the total volume of laboratory services billed to the Medicare program. The Committee is concerned that there be an adequate opportunity to educate the community

regarding the decisions and their impact upon claims payment. They were also concerned that there be adequate opportunity to modify computer systems to accommodate these provisions.

The Committee reached consensus to recommend that changes arising from these actions would become effective 12 months after publication of the final regulation. Further, it recommended a grace period of not more than 12 months after the effective date of the changes be available for any system changes any party is required to make. In modifying claims processing systems for the proposed changes, we will give priority to implementation of the national coverage decisions. We are proposing to delay the effective date of this proposed rule and national coverage decisions in accordance with the Committee's consensus recommendation.

The Committee also discussed a strategy to communicate the changes to affected parties. Many members of the Committee will continue to work together in further developing a plan through which they could adequately inform the community, especially physicians and laboratories, of the provisions of this proposed rule and the national coverage decisions. We will instruct the contractors to issue a bulletin to notify affected providers, such as physicians, hospitals, and laboratories, of the policies. Within 90 days of receiving this instruction from us, contractors must issue the bulletin at least 90 days before the effective date of the policy and national coverage decision.

## VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

*Documentation and Recordkeeping Requirements*

In summary, § 410.32(d)(2)(i) requires the physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service to maintain documentation of medical necessity in the beneficiary's medical record.

While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2), because this requirement is considered a usual and customary business practice.

*Submitting the Claim*

In summary, § 410.32(d)(2)(ii) requires an entity submitting the claim to maintain the following documentation:

- The documentation that it receives from the ordering physician.
- The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician.

While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2), because this requirement is considered a usual and customary business practice.

*Entity Request for Additional Information*

In summary, § 410.32(d)(2)(iii) requires that an entity submitting a claim may request additional diagnostic and other information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

The burden associated with this requirement is the time and effort for the physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service, to disclose additional diagnostic and other information to the entity submitting the claim that demonstrates that the services it bills are reasonable and necessary. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2), because this requirement is considered a usual and customary business practice.

*Claims Review: Documentation Requirements*

In summary, § 410.32(d)(3)(i) requires that an entity submitting a claim provide to HCFA upon request; 1) documentation of the physician's order for the service billed (including information sufficient to enable HCFA to identify and contact the ordering physician), 2) documentation showing accurate processing of the order and submission of the claim and, 3) any diagnostic or other medical information supplied to the laboratory by the ordering physician, including any ICD–9–CM code or narrative description supplied.

In summary, § 410.32(d)(3)(iii) authorizes the entity submitting the claim to request additional diagnostic and other medical information that is relevant to the medical necessity of the specific services from the ordering physician consistent with applicable patient confidentiality laws and regulations.

Since these reporting requirements would be imposed pursuant to the conduct of an administrative action and/or audit, these requirements are not subject to the PRA as defined under 5 CFR 1320.4(a)(2).

If you have any comments on any of these information collection and recordkeeping requirements, please mail the original and 3 copies directly to the following:

Health Care Financing Administration, Office of Information Services, Standards and Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: John Burke HCFA–3250–P

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, HCFA Desk Officer.

## VIII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

## IX. Regulatory Impact Analysis

We have examined the impacts of this proposed rule as required by Executive

Order (EO) 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

Section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

*A. Executive Order 12866*

The intent of this Proposed rule is to promote program integrity and national uniformity and simplify administrative procedures for clinical diagnostic laboratory services. We do not expect the provisions of this proposed rule to have a significant cost effect upon providers or suppliers. The provisions of the proposed rule, for the most part, are administrative and state explicitly and codify practices that are currently in effect. That is, physicians maintain documentation in the medical record and laboratories maintain the information that is provided to them. We expect no cost consequence of codifying this common practice.

Similarly, we do not anticipate a cost effect of the provision related to the documentation that must be submitted upon claims review. While some Medicare contractors presently request medical record information directly from laboratories, the laboratories must in turn seek the information from the physicians. Requiring Medicare contractors to seek medical record information directly from physicians may result in a minimal increase in the administrative cost of conducting claims review. We anticipate that there would be offsetting savings from reduced Medicare contractor requests to laboratories for documentation. This would result in a decreased documentation burden to the laboratories.

The provision in § 410.32(d)(4) merely codifies policies that are presently included in the Medicare program manuals. Since these provisions are currently operational, there is no cost effect to their codification.

The national coverage decisions published as Addendum B to this proposed rule potentially may give rise to a cost effect. Approximately 60 percent of the total volume of laboratory claims would be subject to a national coverage decision if these decisions become effective unchanged. Implementation of the national coverage decisions would result in some adjustments in the amount and degree of coverage (that is, there would be some increases and some decreases). However, we do not have data available to precisely quantify the amounts involved. We estimate that the net cost effect of these coverage decisions would not be significant.

If there is currently an LMRP for a test for which we issue a national coverage decision, and the LMRP was more liberal than the national coverage decisions, this would result in a cost savings to the Medicare program . If an LMRP was more restrictive than an national coverage decision, it would result in a cost increase for the Medicare program. After careful analysis of the information available regarding LMRPs, we estimate that the costs and savings are likely to offset each other, and that the proposed national coverage decisions would have a negligible cost impact.

We should point out, however, that clinical diagnostic laboratory services are considered as part of the calculation of the sustained growth factor used in determining changes in the Medicare payment amounts under the Medicare physician fee schedule. Should there be a significant increase in Medicare payment for laboratory services, Medicare may recover these costs through reductions in the otherwise applicable physician payments.

*B. The Unfunded Mandates Reform Act*

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. As noted above, we do not anticipate that this proposed rule would have a significant cost impact. Thus, we certify that this proposed rule would not result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million.

**C. Regulatory Flexibility Act (RFA)**

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Intermediaries and carriers, physicians, and many laboratories are considered small entities.

This proposed rule would affect all clinical laboratories located in physician offices, hospitals, other health facilities, Medicare contractors, and independent laboratories. There are approximately 160,000 labs affected. We believe the impact of this proposed rule on these entities, for the most part, would be positive. As stated above, this proposed rule would, for the most part, explicitly state and codify existing policies. Having a clear statement of policies would be beneficial to entities submitting Medicare claims because they can avoid unintentional errors. The provision relating to Medicare seeking medical record information directly from physicians would reduce the burden of recordkeeping and reporting on laboratories without increasing the burden on physicians.

Publication of clear and consistent national coverage decisions would assist physicians and laboratories in knowing in advance situations where additional documentation may be needed to support payment on a claim. The documentation may be submitted with the initial claim, thus avoiding the increased cost of appealing a denied claim. National coverage decisions relating to laboratory claims would result in consistent coverage determination regardless of geography, and consequently, less confusion for beneficiaries, who often do not understand the present situations of coverage for a service in one area and not in other areas. Reduced confusion for the beneficiary results in reduced inquiry workloads for Medicare contractors.

As noted above, there may be some areas where implementation of the national coverage decisions would result in denial of payment in situations where payment is presently made. We believe that the proposed policies, developed in partnership with the physician and laboratory community and based on authoritative evidence, reflect the appropriate treatment of

clinical diagnostic laboratory services. Thus, to the extent that payment is presently being made for these services, we believe it is inappropriate and should be curtailed.

We do not expect any beneficiary to be deprived of medically necessary services as a result of these provisions. Nor do we expect that there would be an impact upon the availability of covered services to beneficiaries. Beneficiaries may, however, experience a minimal increase in out-of-pocket costs if they choose to have testing that is not covered by Medicare. That is, publication of clear decisions regarding when a test is considered medically necessary may prompt physicians and laboratories to execute advanced beneficiary notices and charge patients for noncovered services, when they may not have followed these procedures due to ambiguity regarding whether the service would be covered by Medicare.

If Medicare were to fail to implement the policies proposed in the rule and addendum, inconsistency among the contractors would continue. The inconsistency would cause confusion on the part of laboratories, physicians, and beneficiaries in predicting Medicare coverage decisions and anticipating documentation needs. In debating the provisions of the proposed rule, the Committee considered a broad range of alternatives and their impact upon all affected parties. In light of the explicit language of section 4554(b) of the BBA to use negotiated rulemaking to pursue recommendations relating to the problems of program inconsistency, program abuse, and administrative complexity in Medicare payment of clinical diagnostic laboratory services, we have not independently considered other alternatives. Rather, we have accepted the consensus recommendations of the Committee, which included representatives of laboratories, physicians, and beneficiaries. Because the provisions of this proposed rule have the support of these organizations, we do not anticipate adverse reactions to this proposal.

For these reasons, the Secretary certifies, that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

We have reviewed this proposed rule under the threshold criteria of Executive Order 13132. We have determined that it does not significantly affect States' rights, roles, and responsibilities.

**List of Subjects in Part 410**

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

For the reasons set forth in the preamble, 42 CFR chapter IV would be amended as follows:

## PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

### Subpart B—Medical and Other Health Services

1. The authority citation for Part 410 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 410.32:

A. Paragraph (d) introductory text is redesignated as paragraph (d)(1) and a heading is added;

B. Paragraphs (d)(1) through (d)(7) are redesignated as paragraphs (d)(1)(i) through (d)(1)(vii); and

C. Paragraphs (d)(2) through (d)(4) are added to read as follows:

**§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.**

* * * * *

(d) *Diagnostic laboratory tests*—(1) *Who may furnish services.* * * *

(2) *Documentation and recordkeeping requirements.* (i) *Ordering the service.* The physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* The entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) Claims review. (i) *Documentation requirements.* Upon request by HCFA, the entity submitting the claim must provide the following information :

(A) Documentation of the physician's order for the service billed (including information sufficient to enable HCFA to identify and contact the ordering physician).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, HCFA takes the following actions:

(A) Provides the ordering physician information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review*—(i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, HCFA does not deny a claim for services that exceeds utilization parameters without reviewing all relevant documentation submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* HCFA may automatically deny a claim without manual review under the following circumstances:

(A) A national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by statute.

(B) HCFA determines that a specific provider or supplier has engaged in egregious overutilization of a particular service, and the claim is for that service.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 9, 1999.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration.*

Dated: November 24, 1999.

**Donna E. Shalala,**

*Secretary.*

**Note:** The following addendums A-C will not appear in the Code of Federal Regulations.

*Addendum A—Introduction to National Coverage Policies for Diagnostic Laboratory Tests*

**Purpose**

This addendum provides an introduction to national coverage policies for diagnostic laboratory tests payable under Part B of Medicare. This addendum explains what a national coverage policy is, what effect a national coverage policy has, and describes the various sections in the policies. In addition, it explains the two approaches used to develop these national coverage policies.

**What Is a National Coverage Policy?**

Part B of title XVIII of the Social Security Act (the Act) provides for Supplementary Medical Insurance (SMI) for certain Medicare beneficiaries, specifying what health care items or services will be covered by the Medicare Part B program. Diagnostic laboratory tests are generally covered under Part B, unless excluded from coverage by the Act. Services that are generally excluded from coverage include routine physical examinations and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. HCFA interprets these provisions to prohibit coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute. A test may be considered medically appropriate, but nonetheless be excluded from Medicare coverage by statute.

A national coverage policy for diagnostic laboratory test(s) is a document stating HCFA's policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide. A national coverage policy is neither a practice parameter nor a statement of the accepted standard of medical practice. Words such as ''may be indicated'' or ''may be considered medically necessary'' are used for this reason. Where a policy gives a general description and then lists examples (following words like ''for example'' or ''including''), the list of examples is not meant to be all inclusive but merely to provide some guidance.

**What Is the Effect of a National Coverage Policy?**

A national coverage policy to which this introduction applies is a National Coverage Decision (NCD) under section 1862(a)(1) of the Social Security Act. Regulations on National Coverage Decisions are codified at 42 CFR 405.732(b)–(d). A Medicare contractor may not develop a local policy that conflicts with a national coverage policy.

**What Is the Format for These National Coverage Policies?**

Below are the headings for national coverage policies, developed by the Negotiated Rulemaking Committee on Clinical Diagnostic Laboratory Tests.

*National Coverage Policy For*

This section identifies the official title of the policy.

*Other Names/Abbreviations*

This section identifies other names for the policy. It generally reflects more colloquial terminology.

*Description*

This section includes a description of the test(s) addressed by the policy and provides a general description of the appropriate uses of the test(s).

*Descriptor(s)*

The descriptor(s) used in this section is (are) the Current Procedural Terminology (CPT) or other HCFA Common Procedure Coding System (HCPCS). The CPT is developed and copyrighted by the American Medical Association (AMA). If a descriptor does not accurately or fully describe the test, a more complete description may be included elsewhere in the policy, such as in the *Indications* section.

*Indications*

This section lists detailed clinical indications for Medicare coverage of the test(s).

*Limitations*

This section lists any national frequency expectations, as well as other limitations on Medicare coverage of the specific test(s) addressed in the policy—for example, if it would be unnecessary to perform a particular test with a particular combination of diagnoses.

*ICD–9–CM Codes Covered by Medicare Program*

Code: Description

This section includes covered codes—those where there is a presumption of medical necessity, but the claim is subject to review to determine whether the test was in fact reasonable and necessary. The diagnosis codes are from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). Where the policy takes an ''exclusionary'' approach, as described below, this section states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM code sections below.''

*Reasons for Denial*

This section includes standard language reflecting national policy with respect to all tests—such as denial of screening services and denial if medical necessity is not documented in the patient's medical record. This section may also include reasons for denial related to the specific test(s). This section was not negotiated by the Negotiated Rulemaking Committee, but rather reflects HCFA policy.

*ICD–9–CM Codes Denied*

Code: Description

This section lists codes that are never covered. If a code from this section is given as the reason for the test, the test may be billed to the Medicare beneficiary without billing Medicare first because the service is not covered by statute, in most instances because it is performed for screening purposes and is not within an exception. The beneficiary, however, does have a right to have the claim submitted to Medicare, upon request.

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

This section lists/describes generally non-covered codes for which there are only limited exceptions. However, additional documentation could support a determination of medical necessity in certain circumstances. Subject to section 1879 of the Social Security Act (the Act), 42 CFR 411, subpart K, section 7330 of the Medicare Carriers Manual section 3440–3446.9 of the Medicare Fiscal Intermediary Manual and any applicable rulings, it would be appropriate for the ordering physician or the laboratory to obtain an advance beneficiary notice from the beneficiary. Where the policy takes an ''inclusionary'' approach, as described below, this section states: ''Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.''

*Sources of Information*

Relevant sources of information used in developing the policy are listed in this section.

*Coding Guidelines*

This section includes coding guidelines that apply generally to all policies, as well any additional coding instructions appropriate for a specific national coverage policy. The coding guidelines may be from or based on a Coding Clinic for ICD–9–CM published by the American Hospital Association.

*Documentation Requirements*

This section refers to documentation requirements for clinical diagnostic laboratory tests at 42 CFR 410.32(d) and includes any specific documentation requirements related to the test(s) addressed in the policy.

*Other Comments*

This section may contain any other relevant comments that are not addressed in the sections described above.

**What Are the Two Approaches Used in Developing a National Coverage Policy?**

To develop national coverage policies for the tests assigned to each Workgroup, the Committee agreed to use one of two approaches, referred to as ''inclusionary'' and ''exclusionary''. Policies using the ''inclusionary'' approach list the ICD–9–CM codes in the following two categories: ICD–9–CM Codes Covered by Medicare Program and ICD–9–CM Codes Denied. These policies do not list the codes that require additional documentation to support medical necessity.

The exclusionary approach was used for tests for which local medical review policies had identified a large number of acceptable ICD–9–CM codes. The Committee used this approach to develop a proposed policy on blood counts. In lieu of listing all the ICD–9–CM codes that support medical necessity of a test or group of tests, policies using the ''exclusionary'' approach list ICD–9–CM codes in the following two categories: ICD–9–CM Codes Denied and ICD–9–CM Codes That Do Not Support Medical Necessity.

**Addendum B—National Coverage Decisions**

*Medicare National Coverage Decision:* Culture, Bacterial, Urine.

*Other Names/Abbreviations:* Urine culture.

*Description.*

A bacterial urine culture is a laboratory procedure performed on a urine specimen to establish the probable etiology of a presumed urinary tract infection. It is common practice to do a urinalysis prior to a urine culture. A urine culture may also be used as part of the evaluation and management of another related condition. The procedure includes aerobic agar-based isolation of bacteria or other cultivable organisms present, and quantitation of types present based on morphologic criteria. Isolates deemed significant may be subjected to additional identification and susceptibility procedures as requested by the ordering physician. The physician's request may be through clearly documented and communicated laboratory protocols.

*HCPCS Codes:* (alpha numeric, CPT © AMA):

| Code: | Descriptor: |
|---|---|
| 87086 | Culture, bacterial, urine; quantitative, colony count. |
| 87087 | Culture, bacterial, urine; commercial kit. |
| 87088 | Culture, bacterial, urine; identification, in addition to quantitative or commercial kit. |
| 87184 | Sensitivity studies, antibiotic; disk method, per plate (12 or fewer disks). |
| 87186 | Sensitivity studies, antibiotic; microtiter, minimum inhibitory concentration (MIC), any number of antibiotics. |

*Indications*

1. A patient's urinalysis is abnormal suggesting urinary tract infection, for example, abnormal microscopic (hematuria, pyuria, bacteriuria); abnormal biochemical urinalysis (positive leukocyte esterase, nitrite, protein, blood); a Gram's stain positive for microorganisms; positive bacteriuria screen by a non-culture technique; or other significant abnormality of a urinalysis. While it is not essential to evaluate a urine specimen by one of these methods before a urine culture is performed, certain clinical presentations with highly suggestive signs and symptoms may lend themselves to an antecedent urinalysis procedure where follow-up culture depends upon an initial positive or abnormal test result.

2. A patient has clinical signs and symptoms indicative of a possible urinary tract infection (UTI). Acute lower UTI may be present with urgency, frequency, nocturia, dysuria, discharge or incontinence. These findings may also be noted in upper UTI with additional systemic symptoms (for example, fever, chills, lethargy); or pain in the costovertebral, abdominal, or pelvic areas. Signs and symptoms may overlap considerably with other inflammatory conditions of the genitourinary tract (for example, prostatitis, urethritis, vaginitis, or cervicitis). Elderly or immunocompromised patients, or patients with neurologic disorders may present atypically (for example, general debility, acute mental status changes, declining functional status).

3. The patient is being evaluated for suspected urosepsis, fever of unknown origin, or other systemic manifestations of infection but without a known source. Signs and symptoms used to define sepsis have been well-established.

4. A test-of cure is generally not indicated in an uncomplicated infection. However, it may be indicated if the patient is being evaluated for response to therapy and there is a complicating co-existing urinary abnormality including structural or functional abnormalities, calculi, foreign bodies, or ureteral/renal stents or there is clinical or laboratory evidence of failure to respond as described in Indications 1 and 2.

5. In surgical procedures involving major manipulations of the genitourinary tract, preoperative examination to detect occult infection may be indicated in selected cases (for example, prior to renal transplantation, manipulation or removal of kidney stones, or transurethral surgery of the bladder or prostate).

6. Urine culture may be indicated to detect occult infection in renal transplant recipients on immunosuppressive therapy.

*Limitations*

1. CPT 87086 or 87087 may be used one time per encounter. CPT 87086 and 87087 are not used concurrently.

2. Colony count restrictions on coverage of CPT 87088 do not apply as they may be highly variable according to syndrome or other clinical circumstances (for example , antecedent therapy, collection time, degree of hydration).

3. CPT 87088, 87184, and 87186 may be used multiple times in association with or independent of 87086 or 87087, as urinary tract infections may be polymicrobial.

4. Testing for asymptomatic bacteriuria as part of a prenatal evaluation may be medically appropriate but is considered screening and therefore not covered by Medicare. The US Preventive Services Task Force has concluded that screening for asymptomatic bacteriuria outside of the narrow indication for pregnant women is generally not indicated. There are insufficient data to recommend screening in ambulatory elderly patients including those with diabetes. Testing may be clinically indicated on other grounds including likelihood of recurrence or potential adverse effects of antibiotics, but is considered screening in the absence of clinical or laboratory evidence of infection.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Descriptor |
|---|---|
| 003.1 | Salmonella septicemia. |
| 038.0–038.9 | Septicemia. |
| 276.2 | Acidosis. |
| 276.4 | Metabolic acidosis/alkalosis. |
| 286.6 | Defibrination syndrome/disseminated intravascular coagulation. |
| 288.0 | Agranulocytosis/neutropenia. |
| 288.8 | Other specified disease of white blood cells including leukemoid reaction/leukocytosis. |
| 306.53 | Psychogenic dysuria. |
| 306.59 | Other psychogenic genitourinary malfunction. |
| 518.82 | Other pulmonary insufficiency, not elsewhere classified. |
| 570 | Acute and subacute necrosis of liver. |

| Code | Descriptor |
|---|---|
| 580.0–580.9 | Acute glomerulonephritis. |
| 583.0–583.9 | Nephritis and Nephropathy, not specified as acute or chronic. |
| 584.5 | Acute renal failure, with lesion of tubular necrosis. |
| 584.9 | Acute renal failure, unspecified. |
| 585 | Chronic renal failure. |
| 586 | Renal failure, unspecified. |
| 590.00–590.9 | Infections of kidney/pyelonephritis acute and chronic. |
| 592.0–592.9 | Calculus of kidney and ureter. |
| 593.0–593.9 | Other disorders of kidney and ureter (cyst, stricture, obstruction, reflux, etc.). |
| 594.0–594.9 | Calculus of lower urinary tract. |
| 595.0–595.9 | Cystitis. |
| 597.0 | Urethritis, not sexually transmitted and urethral syndrome. |
| 597.80–597.89 | Other urethritis. |
| 598.00–598.01 | Urethral stricture due to infection. |
| 599.0 | Urinary tract infection, site not specified. |
| 599.7 | Hematuria. |
| 600 | Hyperplasia of prostate. |
| 601.0–601.9 | Inflammatory diseases of prostate. |
| 602.0–602.9 | Other disorders of prostate (calculus, congestion, atrophy, etc.). |
| 604.0–604.99 | Orchitis and epididymitis. |
| 608.0–608.9 | Other disorders of male genital organs (seminal vesiculitis, spermatocele, etc.). |
| 614.0–614.9 | Inflammatory disease of ovary, fallopian tube, pelvic cellular tissue, and peritoneum. |
| 615.0–615.9 | Inflammatory disease of uterus, except cervix. |
| 616.0 | Cervicitis and endocervicitis. |
| 616.10–616.11 | Vaginitis and vulvovaginitis. |
| 616.2–616.9 | Other inflammatory conditions of cervix, vagina and vulva. |
| 619.0–619.9 | Fistula involving female genital tract. |
| 625.6 | Stress incontinence, female. |
| 639.0 | Genital tract and pelvic infection complicating abortion, ectopic or molar pregnancies. |
| 639.5 | Shock complicating abortion, ectopic or molar pregnancies. |
| 646.60–.64 | Infections of genitourinary tract in pregnancy. |
| 670.00–.04 | Major puerperal infection. |
| 672.00–.04 | Pyrexia of unknown origin during the puerperium. |
| 724.5 | Backache, unspecified. |
| 780.2 | Syncope and collapse. |
| 780.6 | Fever (Hyperthermia). |
| 780.79 | Other malaise and fatigue. |
| 780.9 | Other general symptoms (altered mental status, chills, generalized pains). |
| 785.0 | Tachycardia, unspecified. |
| 785.50–.59 | Shock without mention of trauma. |
| 788.0–788.9 | Symptoms involving urinary system. (renal colic, dysuria, retention of urine, incontinence of urine, frequency, polyuria, nocturia, oliguria, anuria, other abnormality of urination, urethral discharge, extravasation of urine, other symptoms of urinary system). |
| 789.00–789.09 | Abdominal pain. |
| 789.60–789.69 | Abdominal tenderness. |
| 790.7 | Bacteremia. |
| 791.0–791.9 | Nonspecific findings on examination of urine (proteinuria, chyluria, hemoglobinuria, myoglobinuria, biliuria, glycosuria, acetonuria, other cells and casts in urine, other nonspecific findings on examination of urine). |
| 799.3 | Debility, unspecified (only for declining functional status). |
| 939.0 | Foreign body in genitourinary tract, bladder and urethra. |
| 939.3 | Foreign body in genitourinary tract, penis. |
| V44.50–V44.6 | Artificial cystostomy or other artificial opening of urinary tract status. |
| V55.5–V55.6 | Attention to cystostomy or other artificial opening of urinary tract. |
| V58.69 | Long-term (current) use of other medications. |
| V72.84 | Pre-operative examination, unspecified. |

*Reasons for Denial*

**Note:** This section has not been negotiated by the Negotiated Rulemaking Committee. It includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. The documentation may include notes documenting relevant signs, symptoms, or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating

nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995).

*ICD–9–CM Codes Denied..*

| Code | Descriptor |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Descriptor

Any ICD–9–CM code not listed in either of the ICD–9–CM sections.

*Sources of Information*

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Sodeman, TM. 1995. A practical strategy for diagnosis of urinary tract infections. Clin. Lab. Med. 15:235–250.

Stamm WE, and TM Hooton. 1993. Management of urinary tract infections in adults. N. Engl. J. Med. 329:1328–1334.

United States Preventive Services Task Force (1996). Guidelines for screening for asymptomatic bacteriuria.

Lachs MS, Nachamkin I, Edelstein PH et al. 1992. Spectrum bias in the evaluation of diagnostic tests: lessons from the rapid dipstick test for urinary tract infection. Ann. Int. Med. 117:135–140.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS Codes'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43).

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52).

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44).

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as

though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. In the case of pre-operative examination (V72.84), the following codes may support medical necessity: 585, 586, 592.0–592.9, 594.0–594.9, 600, 602.0–602.9, 939.0, 939.3.

7. Specific coding guidelines:

a. Use CPT 87086 Culture, bacterial, urine; quantitative, colony count where a urine culture colony count is performed to determine the approximate number of bacteria present per milliliter of urine. The number of units of service is determined by the number of specimens.

b. Use CPT 87087 Culture, bacterial, urine; commercial kit where a commercial kit uses manufacturer defined media for isolation, presumptive identification, and quantitation of morphotypes present. The number of units of service is determined by the number of specimens.

c. Use CPT 87088 Culture, bacterial, urine; identification in addition to quantitative or commercial kit where identification of morphotypes recovered by quantitative culture or commercial kits and deemed to represent significant bacteriuria requires the use of additional testing, for example, biochemical test procedures on colonies. Identification based solely on visual observation of the primary media is usually not adequate to justify use of this code. The number of units of service is determined by the number of isolates.

d. Use CPT 87184 or 87186, Sensitivity studies where susceptibility testing of isolates deemed to be significant is performed concurrently with identification. The number of units of service is determined by the number of isolates. These codes are not exclusively used for urine cultures but are appropriate for isolates from other sources as well.

e. Appropriate combinations are as follows: CPT 87086 or 87087, 1 per specimen with 87088, 1 per isolate and 87184 or 87186 where appropriate.

f. Culture for other specific organism groups not ordinarily recovered by media used for aerobic urine culture may require use of additional CPT codes (for example, anaerobes from suprapubic samples).

g. Identification of isolates by non-routine, nonbiochemical methods may be coded appropriately (for example, immunologic identification of streptococci, nucleic acid techniques for identification of N. gonorrhoeae).

h. While infrequently used, sensitivity studies by methods other than CPT 87184 or 87186 are appropriate. CPT 87181, agar dilution method, each antibiotic or CPT 87188, macrotube dilution method, each antibiotic may be used. The number of units of service is the number of antibiotics multiplied by the number of unique isolates.

8. ICD–9–CM code 780.02, 780.9 or 799.3 should be used only in the situation of an elderly patient, immunocompromised patient or patient with neurologic disorder who presents without typical manifestations of a urinary tract infection but who presents with one of the following signs or symptoms, not otherwise explained by another co-existing condition: increasing debility; declining functional status; acute mental changes; changes in awareness; or hypothermia.

9. In cases of post renal-transplant urine culture used to detect clinically significant occult infection in patients on long term immunosuppressive therapy, use code V58.69.

*Documentation Requirements*

Appropriate HCPCS/CPT code(s) must be used as described.

*National Coverage Decision for:* Human Immunodeficiency Virus Testing (Prognosis including monitoring).

*Other Names/Abbreviations:* HIV–1 or HIV–2 quantification or viral load.

*Description*

HIV quantification is achieved through the use of a number of different assays which measure the amount of circulating viral RNA. Assays vary both in methods used to detect viral RNA as well as in ability to detect viral levels at lower limits. However, all employ some type of nucleic acid amplification technique to enhance sensitivity, and results are expressed as the HIV copy number.

Quantification assays of HIV plasma RNA are used prognostically to assess relative risk for disease progression and predict time to death, as well as to assess efficacy of antiretroviral therapies over time.

HIV quantification is often performed together with CD4+ T cell counts which provide information on extent of HIV induced immune system damage already incurred.

*HCPCS Codes* (alpha numeric, CPT© AMA)

| Code | Descriptor |
|---|---|
| 87536 | Infectious agent detection by nucleic acid (DNA or RNA); HIV–1, quantification. |
| 87539 | Infectious agent detection by nucleic acid (DNA or RNA); HIV–2, quantification. |

*Indications*

1. A plasma HIV RNA baseline level may be medically necessary in any patient with confirmed HIV infection.

2. Regular periodic measurement of plasma HIV RNA levels may be medically necessary to determine risk for disease progression in an HIV-infected individual and to determine when to initiate or modify antiretroviral treatment regimens.

3. In clinical situations where the risk of HIV infection is significant and initiation of therapy is anticipated, a baseline HIV quantification may be performed. These situations include:

a. Persistence of borderline or equivocal serologic reactivity in an at-risk individual.

b. Signs and symptoms of acute retroviral syndrome characterized by fever, malaise, lymphadenopathy and rash in an at-risk individual.

*Limitations*

1. Viral quantification may be appropriate for prognostic use including baseline determination, periodic monitoring, and monitoring of response to therapy. Use as a diagnostic test method is not indicated.

2. Measurement of plasma HIV RNA levels should be performed at the time of establishment of an HIV infection diagnosis. For an accurate baseline, 2 specimens in a 2-week period are appropriate.

3. For prognosis including antiretroviral therapy monitoring, regular, periodic measurements are appropriate. The frequency of viral load testing should be consistent with the most current Centers for Disease Control and Prevention guidelines for use of antiretroviral agents in adults and adolescents or pediatrics.

4. Because differences in absolute HIV copy number are known to occur using different assays, plasma HIV RNA levels should be measured by the same analytical method. A change in assay method may necessitate re-establishment of a baseline.

5. Nucleic acid quantification techniques are representative of rapidly emerging and evolving new technologies. As such, users are advised to remain current on FDA-approval status.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Descriptor |
|---|---|
| 042 | Human immunodeficiency virus [HIV] disease. |
| 079.53 | Human immunodeficiency virus, type 2 [HIV–2]. |
| 647.60–.64 | Other viral diseases complicating pregnancy (including HIV–I and II). |
| 795.71 | Nonspecific serologic evidence of human immunodeficiency virus [HIV]. |
| V08 | Asymptomatic human immunodeficiency virus [HIV] infection status. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. It includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. The documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Descriptor |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| DV16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

CDC. 1998. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. MMWR 47 (RR–5).

CDC. 1998. Guidelines for the use of antiretroviral agents in pediatric HIV infection. MMWR 47 (RR–4).

CDC. 1998. Public Health Service Task Force recommendations for the use of antiretroviral drugs in pregnant women infected with HIV–1 for maternal health and for reducing perinatal HIV–1 transmission in the United States. MMWR 47 (RR–2).

Carpenter, C.C., M.A. Fischi, S.M. Hammer, et . al. 1998. Antiretroviral therapy for HIV infection in 1998. Updated recommendations of the international AIDS society-USA panel. .A.M.A. 280:78–86.

Saag, M.S., M. Holodniy, D.R. Kuritzkes, et al. 1996. HIV viral load markers in clinical practice. Nature Medicine 2(6): 625–629.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be

provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. Specific coding guidelines:

a. Temporary code G0100 has been superseded by code 87536 effective January 1, 1998.

b. CPT codes for quantification should not be used simultaneously with other nucleic acid detection codes for HIV–1 (that is, 87534, 87535) or HIV–2 (that is, 87537, 87538).

7. Codes 647.60–.64 should only be used for HIV infections complicating pregnancy.

*Other Comments*

Assessment of CD4+ T cell numbers is frequently performed in conjunction with viral load determination. When used in concert, the accuracy with which the risk for disease progression and death can be predicted is enhanced.

*Medicare National Coverage Decision For:* Human Immunodeficiency Virus Testing (Diagnosis).

*Other Names/Abbreviations:* HIV, HIV–1, HIV–2, HIV1/2, HTLV III, Human T-cell lymphotrophic virus, AIDS, Acquired immune deficiency syndrome.

*Description*

Diagnosis of Human Immunodeficiency Virus (HIV) infection is primarily made through the use of serologic assays. These assays take one of two forms: antibody detection assays and specific HIV antigen (p24) procedures. The antibody assays are usually enzyme immunoassays (EIA) which are used to confirm exposure of an individual's immune system to specific viral antigens. These assays may be formatted to detect HIV–1, HIV–2, or HIV–1 and 2 simultaneously and to detect both IgM and IgG. When the initial EIA test is repeatedly positive or indeterminant, an alternative test is used to confirm the specificity of the antibodies to individual viral components. The most commonly used method is the Western Blot.

The HIV–1 core antigen (p24) test detects circulating viral antigen which may be found prior to the development of antibodies and may also be present in later stages of illness in the form of recurrent or persistent antigenemia. Its prognostic utility in HIV infection has been diminished as a result of development of sensitive viral RNA assays, and its primary use today is as a routine screening tool in potential blood donors.

In several unique situations, serologic testing alone may not reliably establish an HIV infection. This may occur because the antibody response (particularly the IgG response detected by Western Blot) has not yet developed (that is, acute retroviral syndrome), or is persistently equivocal because of inherent viral antigen variability. It is also an issue in perinatal HIV infection due to transplacental passage of maternal HIV antibody. In these situations, laboratory evidence of HIV in blood by culture, antigen assays, or proviral DNA or viral RNA assays, is required to establish a definitive determination of HIV infection.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 86689 | Qualitative or semiquantitative immunoassays performed by multiple step methods; HTLV or HIV antibody, confirmatory test (for example, Western Blot). |
| 86701 | Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV–1. |
| 86702 | Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV–2. |
| 86703 | Qualitative or semiquantitative immunoassays performed by multiple step methods; HIV–1 and HIV–2, single assay. |
| 87390 | Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple step; HIV–1. |
| 87391 | Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple step; HIV–2. |
| 87534 | Infectious agent detection by nucleic acid (DNA or RNA); HIV–1, direct probe technique. |
| 87535 | Infectious agent detection by nucleic acid (DNA or RNA); HIV–1, direct probe technique HIV–1, amplified probe technique. |
| 87537 | Infectious agent detection by nucleic acid (DNA or RNA); HIV–2, direct probe technique. |
| 87538 | Infectious agent detection by nucleic acid (DNA or RNA); HIV–2, amplified probe technique. |

*Indications*

Diagnostic testing to establish HIV infection may be indicated when there is a strong clinical suspicion supported by one or more of the following clinical findings:

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.

2. The patient has another documented sexually transmitted disease which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.

3. The patient has documented acute or chronic hepatitis B or C infection which identifies a significant risk of exposure to HIV and the potential for an early or subclinical infection.

4. The patient has a documented AIDS-defining or AIDS-associated neoplasm.

5. The patient has a documented AIDS-associated neurologic disorder or otherwise unexplained dementia.

6. The patient has another documented AIDS-defining clinical condition, or a history of other severe, recurrent, or persistent conditions which suggest an underlying immune deficiency (for example, cutaneous or mucosal disorders).

7. The patient has otherwise unexplained generalized signs and symptoms suggestive of a chronic process with an underlying immune deficiency (for example, fever, weight loss, malaise, fatigue, chronic diarrhea, failure to thrive, chronic cough, hemoptysis, shortness of breath, or lymphadenopathy).

8. The patient has otherwise unexplained laboratory evidence of a chronic disease process with an underlying immune deficiency (for example, anemia, leukopenia,

pancytopenia, lymphopenia, or low CD4+ lymphocyte count).

9. The patient has signs and symptoms of acute retroviral syndrome with fever, malaise, lymphadenopathy, and skin rash.

10. The patient has documented exposure to blood or body fluids known to be capable of transmitting HIV (for example, needlesticks and other significant blood exposures) and antiviral therapy is initiated or anticipated to be initiated.

11. The patient is undergoing treatment for rape. (HIV testing is a part of the rape treatment protocol.)

For a comprehensive tabulation of AIDS-defining and AIDS associated conditions, refer to information source document #5.

*Limitations*

1. HIV antibody testing in the United States is usually performed using HIV–1 or HIV–½ combination tests. HIV–2 testing is indicated if clinical circumstances suggest HIV–2 is likely (that is, compatible clinical findings and HIV–1 test negative). HIV–2 testing may also be indicated in areas of the country where there is greater prevalence of HIV–2 infections.

2. The Western Blot test should be performed only after documentation that the initial EIA tests are repeatedly positive or equivocal on a single sample.

3. The HIV antigen tests currently have no defined diagnostic usage.

4. Direct viral RNA detection may be performed in those situations where serologic testing does not establish a diagnosis but strong clinical suspicion persists (for example, acute retroviral syndrome, nonspecific serologic evidence of HIV, or perinatal HIV infection).

5. If initial serologic tests confirm an HIV infection, repeat testing is not indicated.

6. If initial serologic tests are HIV EIA negative and there is no indication for confirmation of infection by viral RNA detection, the interval prior to retesting is 3–6 months.

7. Testing for evidence of HIV infection using serologic methods may be medically appropriate in situations where there is a risk of exposure to HIV. However, in the absence of a documented AIDS defining or HIV associated disease, an HIV associated sign or symptom, or documented exposure to a known HIV-infected source, the testing is considered by Medicare to be screening and thus is not covered by Medicare (for example, history of multiple blood component transfusions, exposure to blood or body fluids not resulting in consideration of therapy, history of transplant, history of illicit drug use, multiple sexual partners, same-sex encounters, prostitution, or contact with prostitutes).

8. The CPT Editorial Panel has issued a number of codes for infectious agent detection by direct antigen or nucleic acid probe techniques that have not yet been developed or are only being used on an investigational basis. Laboratory providers are advised to remain current on FDA-approval status for these tests.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 003.1 | Salmonella septicemia. |
| 007.2 | Coccidiosis (Isoporiasis). |
| 007.4 | Cryptosporidiosis. |
| 007.8 | Other specified protozoal intestinal diseases. |
| 010.00–010.96 | Primary tuberculous infection. |
| 011.00–011.96 | Pulmonary tuberculosis. |
| 012.00–012.86 | Other respiratory tuberculosis. |
| 013.00–013.96 | Tuberculosis of meninges and central nervous system. |
| 014.00–014.86 | Tuberculosis of intestines, peritoneum and mesenteric glands. |
| 015.00–015.96 | Tuberculosis of bones and joints. |
| 016.00–016.96 | Tuberculosis of genitourinary system. |
| 017.00–017.96 | Tuberculosis of other organs. |
| 018.00–018.96 | Miliary tuberculosis. |
| 027.0 | Listeriosis. |
| 031.0–031.9 | Diseases due to other mycobacteria. |
| 038.2 | Pneumococcal septicemia. |
| 038.43 | Septicemia (Pseudomonas). |
| 039.0–.9 | Actinomycotic infections (includes Nocardia). |
| 041.7 | Pseudomonas infection. |
| 042 | HIV disease (Acute retroviral syndrome, AIDS-related complex). |
| 046.3 | Progressive multifocal leukoencephalopathy. |
| 049.0–049.9 | Other non-arthropod-borne viral diseases of central nervous system. |
| 052.0–052.8 | Chickenpox (with complication). |
| 053.0–053.9 | Herpes zoster. |
| 054.0–054.9 | Herpes simplex. |
| 055.0–055.8 | Measles (with complication). |
| 070.20–070.23 | Viral hepatitis B with hepatic coma. |
| 070.30–070.33 | Viral hepatitis B without mention of hepatic coma. |
| 070.41 | Acute or unspecified hepatitis C with hepatic coma. |
| 070.42 | Hepatitis delta without mention of active hepatitis B disease with hepatic coma. |
| 070.44 | Chronic hepatitis C with hepatic coma. |
| 070.49 | Other specified viral hepatitis with hepatic coma. |
| 070.51 | Acute or unspecified hepatitis C without hepatic coma. |
| 070.52 | Hepatitis delta without mention of active hepatitis B disease without hepatic coma. |
| 070.54 | Chronic hepatitis C without hepatic coma. |
| 070.59 | Other specified viral hepatitis without hepatic coma. |
| 070.6 | Unspecified viral hepatitis with hepatic coma. |
| 070.9 | Unspecified viral hepatitis without hepatic coma. |
| 078.0 | Molluscum contagiosum. |
| 078.10–078.19 | Viral warts. |
| 078.3 | Cat-scratch disease. |
| 078.5 | Cytomegaloviral disease. |
| 078.88 | Other specified diseases due to Chlamydiae. |
| 079.50 | Retrovirus unspecified. |
| 079.51 | HTLV–I. |
| 079.52 | HTLV–II. |
| 079.53 | HTLV–III. |
| 079.59 | Other specified Retrovirus. |

| Code | Description |
|---|---|
| 079.88 | Other specified chlamydial infection. |
| 079.98 | Unspecified chlamydial infection. |
| 085.0–085.9 | Leishmaniasis. |
| 088.0 | Bartonellosis. |
| 090.0–090.9 | Congenital syphilis. |
| 091.0–091.9 | Early syphilis symptomatic. |
| 092.0–092.9 | Early syphilis, latent. |
| 093.0–093.9 | Cardiovascular syphilis. |
| 094.0–094.9 | Neurosyphilis. |
| 095.0–095.9 | Other forms of late syphilis, with symptoms. |
| 096 | Late syphilis, latent. |
| 097.0–097.9 | Other and unspecified syphilis. |
| 098.0–098.89 | Gonococcal infections. |
| 099.0 | Chancroid. |
| 099.1 | Lymphogranuloma venereum. |
| 099.2 | Granuloma inguinale. |
| 099.3 | Reiter's disease. |
| 099.40–099.49 | Other nongonococcal urethritis. |
| 099.50–099.59 | Other venereal diseases due to Chlamydia trachomatis. |
| 099.8 | Other specified venereal disease. |
| 099.9 | Venereal disease unspecified. |
| 110.1 | Dermatophytosis of nail. |
| 111.0 | Pityriasis versicolor. |
| 112.0–112.9 | Candidiasis. |
| 114.0–114.9 | Coccidioidomycosis. |
| 115.00–115.99 | Histoplasmosis. |
| 116.0–116.2 | Blastomycotic infection. |
| 117.3 | Aspergillosis. |
| 117.5 | Cryptococcosis. |
| 118 | Opportunistic mycoses. |
| 127.2 | Strongyloidiasis. |
| 130.0–130.9 | Toxoplasmosis. |
| 131.01 | Trichomonal vulvovaginitis. |
| 132.2 | Phthirus pubis. |
| 133.0 | Scabies. |
| 136.2 | Specific infections by free living amebae. |
| 136.3 | Pneumocystosis. |
| 136.8 | Other specified infectious and parasitic disease (for example, microsporidiosis). |
| 176.0–176.9 | Kaposi's sarcoma. |
| 180.0–180.9 | Malignant neoplasm of cervix uteri. |
| 200.20–200.28 | Burkitt's tumor or lymphoma. |
| 200.80–200.88 | Lymphosarcoma, other named variants. |
| 201.00–201.98 | Hodgkin's disease. |
| 280.0–280.9 | Iron deficiency anemias. |
| 285.9 | Anemia, unspecified. |
| 287.3 | Primary thrombocytopenia. |
| 288.0 | Agranulocytosis. |
| 288.8 | Other specified disease of white blood cells. |
| 294.8 | Other specified organic brain syndromes (chronic). |
| 310.1 | Organic personality syndrome. |
| 322.2 | Chronic meningitis. |
| 336.9 | Unspecified disease of spinal cord. |
| 348.3 | Encephalopathy unspecified. |
| 354.0–354.9 | Mononeuritis of upper limbs and mononeuritis multiplex. |
| 356.8 | Other specified idiopathic peripheral neuropathy. |
| 363.20 | Chorioretinitis, unspecified. |
| 425.4 | Other primary cardiomyopathies. |
| 473.0–473.9 | Chronic sinusitis. |
| 481 | Pneumococcal pneumonia. |
| 482.0–482.9 | Other bacterial pneumonia. |
| 484.1 | Pneumonia in cytomegalic inclusion disease. |
| 512.8 | Other spontaneous pneumothorax. |
| 516.8 | Other specified alveolar and parietoalveolar pneumonopathies. |
| 528.2 | Oral aphthae. |
| 528.6 | Leukoplakia of oral mucosa. |
| 530.2 | Ulcer of esophagus. |
| 583.9 | Nephropathy with unspecified pathological lesion in kidney. |
| 588.8 | Other specified disorders resulting from impaired renal function. |
| 647.60–.64 | Other viral diseases complicating pregnancy (use for HIV I and II). |
| 682.0–682.9 | Other cellulitis and abscess. |
| 690.10–690.18 | Seborrheic dermatitis. |
| 696.1 | Other psoriasis. |
| 698.3 | Lichenification and lichen simplex chronicus. |
| 704.8 | Other specified diseases of hair and hair follicles. |

| Code | Description |
|---|---|
| 706.0–706.9 | Diseases of sebaceous glands. |
| 780.6 | Fever. |
| 780.79 | Other malaise and fatigue. |
| 783.2 | Abnormal loss of weight. |
| 783.4 | Lack of expected normal physiological development. |
| 785.6 | Enlargement of lymph nodes. |
| 786.00 | Respiratory abnormality, unspecified. |
| 786.05 | Shortness of breath. |
| 786.2 | Cough. |
| 786.3 | Hemoptysis. |
| 786.4 | Abnormal sputum. |
| 787.91 | Diarrhea. |
| 795.71 | Nonspecific serologic evidence of human immunodefiency virus. |
| 799.4 | Wasting disease. |
| V01.7 | Contact with or exposure to communicable diseases, other viral diseases. |
| V71.5 | Rape. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |

| Code | Description |
|---|---|
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in neither of the ICD–9–CM sections above.

*Sources of Information*

CDC, 1993. Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 41 (No. RR17).

CDC, 1994. Revised classification system for human immunodeficiency virus infection in children less than 13 years of age.

CDC, 1998. Guidelines for treatment of sexually transmitted diseases. MMWR 47 (RR1):11–17.

Piatak, M., M.S. Saag, L.C. Yang, *et al.* 1993. High levels of HIV–1 in plasma during all stages of infection determined by competitive PCR. Science 259:1749–1754.

Rhame, R.S. 1994. Acquired immunodeficiency syndrome, p. 628–652. *In Infectious Diseases;* P.D. Hoeprich, M.C. Jordan, and A.R. Ronald (J.B. Lippincott Co., Philadelphia).

Vasudevachari, M.D., R.T. Davey, Jr., J.A. Metcalf, and H.C. Lane. 1997. Principles and procedures of human immunodeficiency virus serodiagnosis. *In Manual of Clinical Laboratory Immunology* (Fifth ed.); N.R. Rose, E.C. de Macario, J.D. Folds, H.C. Lane, and R.M. Nakamura (ASM Press, Washington, DC).

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. Specific coding guidelines:

a. CPT 86701 or 86703 is performed initially. CPT 86702 is performed when 86701 is negative and clinical suspicion of HIV–2 exists.

b. CPT 86689 is performed only on samples repeatedly positive by 86701, 86702, or 86703.

c. CPT 87534 or 87535 is used to detect HIV–1 RNA where indicated. CPT 87537 or 87538 is used to detect HIV–2 RNA where indicated.

*Documentation Requirements*

Appropriate HCPCS/CPT codes must be used as described.

*Medicare National Coverage Decision:* Blood Counts.

*Other Names/Abbreviations:* CBC.

*Description*

Blood counts are used to evaluate and diagnose diseases relating to abnormalities of the blood or bone marrow. These include primary disorders such as anemia, leukemia, polycythemia, thrombocytosis and thrombocytopenia. Many other conditions secondarily affect the blood or bone marrow, including reaction to inflammation and infections, coagulopathies, neoplasms and exposure to toxic substances. Many treatments and therapies affect the blood or bone marrow, and blood counts may be used to monitor treatment effects.

The complete blood count (CBC) includes a hemogram and differential white blood count (WBC). The hemogram includes enumeration of red blood cells, white blood cells, and platelets, as well as the determination of hemoglobin, hematocrit, and indices.

The symptoms of hematological disorders are often nonspecific, and are commonly encountered in patients who may or may not prove to have a disorder of the blood or bone marrow. Furthermore, many medical conditions that are not primarily due to abnormalities of blood or bone marrow may have hematological manifestations that result from the disease or its treatment. As a result, the CBC is one of the most commonly indicated laboratory tests.

In patients with possible hematological abnormalities, it may be necessary to determine the hemoglobin and hematocrit, to calculate the red cell indices, and to measure the concentration of white blood cells and platelets. These measurements are usually performed on a multichannel analyzer that measures all of the parameters on every sample. Therefore, laboratory assessments routinely include these measurements.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 85007 | Blood count; manual differential WBC count (includes RBC morphology and platelet estimation). |
| 85008 | Blood counts, manual blood smear examination without differential parameters. |
| 85013 | Blood counts, Spun microhematocrit. |
| 85014 | Blood counts, Other than spun hematocrit. |
| 85018 | Blood counts, Hemoglobin. |
| 85021 | Blood counts, Hemogram, automated (RBC, WBC, Hgb, Hct, and indices only). |
| 85022 | Blood counts, Hemogram, automated, and manual differential WBC count (CBC). |
| 85023 | Blood counts, Hemogram and platelet count, automated, and manual differential WBC count (CBC). |
| 85024 | Blood counts, Hemogram and platelet count, automated, and automated partial differential WBC count (CBC). |

| Code | Descriptor |
|---|---|
| 85025 | Hemogram and platelet count, automated and automated complete differential WBC count (CBC). |
| 85027 | Blood counts, Hemogram and platelet count, automated. |
| 85031 | Blood count; hemogram, manual, complete CBC (RBC, Hgb, Hct, differential and indices. |
| 85048 | Blood counts, White blood cell (WBC). |
| 85590 | Platelet; manual count. |
| 85595 | Platelet, automated count. |

*Indications*

Indications for a CBC or hemogram include red cell, platelet, and white cell disorders. Examples of these indications are enumerated individually below.

1. Indications for a CBC generally include the evaluation of bone marrow dysfunction as a result of neoplasms, therapeutic agents, exposure to toxic substances, or pregnancy. The CBC is also useful in assessing peripheral destruction of blood cells, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic, or lymphoproliferative processes, and immune disorders.

2. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with anemia or other red blood cell disorder (e.g., pallor, weakness, fatigue, weight loss, bleeding, acute injury associated with blood loss or suspected blood loss, abnormal menstrual bleeding, hematuria, hematemesis, hematochezia, positive fecal occult blood test, malnutrition, vitamin deficiency, malabsorption, neuropathy, known malignancy, presence of acute or chronic disease that may have associated anemia, coagulation or hemostatic disorders, postural dizziness, syncope, abdominal pain, change in bowel habits, chronic marrow hypoplasia or decreased RBC production, tachycardia, systolic heart murmur, congestive heart failure, dyspnea, angina, nailbed deformities, growth retardation, jaundice, hepatomegaly, splenomegaly, lymphadenopathy, ulcers on the lower extremities).

3. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with polycythemia (for example, fever, chills, ruddy skin, conjunctival redness, cough, wheezing, cyanosis, clubbing of the fingers, orthopnea, heart murmur, headache, vague cognitive changes including memory changes, sleep apnea, weakness, pruritus, dizziness, excessive sweating, visual symptoms, weight loss, massive obesity, gastrointestinal bleeding, paresthesias, dyspnea, joint symptoms, epigastric distress, pain and erythema of the fingers or toes, venous or arterial thrombosis, thromboembolism, myocardial infarction, stroke, transient ischemic attacks, congenital heart disease, chronic obstructive pulmonary disease, increased erythropoetin production associated with neoplastic, renal or hepatic disorders, androgen or diuretic use, splenomegaly, hepatomegaly, diastolic hypertension.)

4. Specific indications for CBC with differential count related to the WBC include signs, symptoms, test results, illness, or disease associated with leukemia, infections or inflammatory processes, suspected bone marrow failure or bone marrow infiltrate, suspected myeloproliferative, myelodysplastic or lymphoproliferative disorder, use of drugs that may cause leukopenia, and immune disorders (e.g., fever, chills, sweats, shock, fatigue, malaise, tachycardia, tachypnea, heart murmur, seizures, alterations of consciousness, meningismus, pain such as headache, abdominal pain, arthralgia, odynophagia, or dysuria, redness or swelling of skin, soft tissue bone, or joint, ulcers of the skin or mucous membranes, gangrene, mucous membrane discharge, bleeding, thrombosis, respiratory failure, pulmonary infiltrate, jaundice, diarrhea, vomiting, hepatomegaly, splenomegaly, lymphadenopathy, opportunistic infection such as oral candidiasis.)

5. Specific indications for CBC related to the platelet count include signs, symptoms, test results, illness, or disease associated with increased or decreased platelet production and destruction, or platelet dysfunction.(e.g., gastrointestinal bleeding, genitourinary tract bleeding, bilateral epistaxis, thrombosis, ecchymosis, purpura, jaundice, petechiae, fever, heparin therapy, suspected DIC, shock, pre-eclampsia, neonate with maternal ITP, massive transfusion, recent platelet transfusion, cardiopulmonary bypass, hemolytic uremic syndrome, renal diseases, lymphadenopathy, hepatomegaly, splenomegaly, hypersplenism, neurologic abnormalities, viral or other infection, myeloproliferative, myelodysplastic, or lymphoproliferative disorder, thrombosis, exposure to toxic agents, excessive alcohol ingestion, autoimmune disorders (SLE, RA and other).

6. Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include, in addition to those already listed, thalassemia, suspected hemoglobinopathy, lead poisoning, arsenic poisoning, and spherocytosis.

7. Specific indications for CBC with differential count related to the WBC include, in addition to those already listed, storage diseases/mucopolysaccharidoses, and use of drugs that cause leukocytosis such as G–CSF or GM–CSF.

8. Specific indications for CBC related to platelet count include, in addition to those already listed, May-Hegglin syndrome and Wiskott-Aldrich syndrome.

*Limitations*

1. Testing of patients who are asymptomatic, or who do not have a condition that could be expected to result in a hematological abnormality, is screening and is not a covered service.

2. In some circumstances it may be appropriate to perform only a hemoglobin or hematocrit to assess the oxygen carrying capacity of the blood. When the ordering provider requests only a hemoglobin or hematocrit, the remaining components of the CBC are not covered.

3. When a blood count is performed for an end-stage renal disease (ESRD) patient, and is billed outside the ESRD rate, documentation of the medical necessity for the blood count must be submitted with the claim.

4. In some patients presenting with certain signs, symptoms or diseases, a single CBC may be appropriate. Repeat testing may not be indicated unless abnormal results are found, or unless there is a change in clinical condition. If repeat testing is performed, a more descriptive diagnosis code (*e.g.,* anemia) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a continued risk for the development of hematologic abnormality.

*ICD–9–CM Codes Covered by Medicare Program*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9-CM code sections below.

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and

necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

| Code | Description |
|---|---|
| 078.10–078.19 | Viral warts. |
| 210.0–210.9 | Benign neoplasm of lip, oral cavity, and pharynx. |
| 214.0 | Lipoma, skin and subcutaneous tissue of face. |
| 216.0–216.9 | Benign neoplasm of skin. |
| 217 | Benign neoplasm of breast. |
| 222.0–222.9 | Benign neoplasm of male genital organs. |
| 224.0 | Benign neoplasm of eye. |
| 230.0 | Carcinoma in situ of lip, oral cavity and pharynx. |
| 232.0–232.9 | Carcinoma in situ of skin. |
| 300.00–300.09 | Neurotic disorders. |
| 301.0–301.9 | Personality disorders. |
| 302.0–302.9 | Sexual deviations and disorders. |
| 307.0 | Stammering and stuttering. |
| 307.20–307.23 | Tics. |
| 307.3 | Stereotyped repetitive movements. |
| 307.80–307.89 | Psychalgia. |
| 312.00–312.9 | Disturbance of conduct, not elsewhere classified. |
| 313.0–313.9 | Disturbance of emotions specific to childhood and adolescence. |
| 314.00–314.9 | Hyperkinetic syndrome of childhood. |
| 363.30–363.35 | Chorioretinal scars. |
| 363.40–363.43 | Choroidal degeneration. |

| Code | Description |
|---|---|
| 363.50–363.57 | Hereditary choroidal dystrophies. |
| 363.70–363.9 | Choroidal detachment. |
| 366.00–366.9 | Cataract. |
| 367.0–367.9 | Disorders of refraction and accommodation. |
| 371.00–371.9 | Corneal opacity and other disorders of cornea. |
| 373.00–373.9 | Inflammation of eyelids. |
| 375.00–375.9 | Disorders of lacrimal system. |
| 376.21–376.9 | Disorders of the orbit, *except 376.3 Other exophthalmic conditions.* |
| 377.10–377.16 | Optic atrophy. |
| 377.21–377.24 | Other disorders of optic disc. |
| 384.20–384.25 | Perforation of tympanic membrane. |
| 384.81–384.82 | Other specified disorders of tympanic membrane. |
| 385.00–385.90 | Other disorders of middle ear and mastoid. |
| 387.0–387.9 | Otosclerosis. |
| 388.00–388.5 | Other disorders of ear. |
| 389.00–389.9 | Hearing loss. |
| 440.0–440.1 | Atherosclerosis of aorta and renal artery. |
| 443.8–443.9 | Peripheral vascular disease. |
| 448.1 | Capillary nevus, non neoplastic. |
| 457.0 | Postmastectomy lymphedema syndrome. |
| 470 | Deviated nasal septum. |
| 471.0–471.9 | Nasal polyps. |
| 478.0 | Hypertrophy of nasal turbinates. |
| 478.4 | Polyp of vocal cord or larynx. |
| 520.0–520.9 | Disorders of tooth development and eruption. |
| 521.0–521.9 | Diseases of hard tissues of teeth. |
| 524.00–524.9 | Dentofacial anomalies, including malocclusion. |
| 525.0–525.9 | Other diseases and conditions of teeth and supporting structures. |
| 526.0–526.3 | Diseases of the jaws. |
| 527.6–527.9 | Diseases of the salivary glands. |
| 575.6 | Cholesterolosis of gallbladder. |
| 600 | Hyperplasia of prostate. |
| 603.0 | Encysted hydrocele. |
| 603.8 | Other specified types of hydrocele. |
| 603.9 | Hydrocele, unspecified. |
| 605 | Redundant prepuce and phimosis. |
| 606.0–606.1 | Infertility, male. |
| 608.1 | Spermatocoele. |
| 608.3 | Atrophy of testis. |
| 610.0–610.9 | Benign mammary dysplasia. |
| 611.1–611.6 | Other disorders of breast. |
| 611.9 | Unspecified breast disorder. |
| 616.2 | Cyst of Bartholin's gland. |
| 618.0–618.9 | Genital prolapse. |
| 620.0–620.3 | Noninflammatory disorders of ovary, fallopian tube, and broad ligament. |
| 621.6–621.7 | Malposition or inversion of uterus. |
| 627.2–627.9 | Menopausal and post menopausal disorders. |
| 628.0–628.9 | Infertility, female. |
| 676.00–676.94 | Other disorders of breast associated with childbirth and disorders of lactation. |
| 691.0–691.8 | Atopic dermatitis and related disorders. |
| 692.0–692.9 | Contact dermatitis and other eczema. |
| 700 | Corns and callosities. |
| 701.0–701.9 | Other hypertrophic and atrophic conditions of skin. |
| 702.0–702.8 | Other dermatoses. |
| 703.9 | Unspecified disease of nail. |
| 706.0–706.9 | Diseases of sebaceous glands. |
| 709.00–709.4 | Other disorders of skin and subcutaneous tissue. |
| 715.00–715.98 | Osteoarthrosis. |
| 716.00–716.99 | Other and unspecified arthropathies. |
| 718.00–718.99 | Other derangement of joint. |
| 726.0–726.91 | Peripheral esthesiopathies and allied syndromes. |
| 727.00–727.9 | Other disorders of synovium, tendon, and bursa. |
| 728.10–728.85 | Disorders of muscle ligament and fascia. |
| 732.0–732.9 | Osteochondropathies. |
| 733.00–733.09 | Osteoporosis. |
| 734 | Flat foot. |
| 735.0–735.9 | Acquired deformities of toe. |
| 736.00–736.9 | Other acquired deformities of limb. |
| 737.0–737.9 | Curvature of spine. |
| 738.0–738.9 | Other acquired deformity. |
| 739.0–739.9 | Nonallopathic lesions, not elsewhere classified. |
| 830.0–839.9 | Dislocations. |
| 840.0–848.9 | Sprains and strains. |
| 905.0–909.9 | Late effects of musculoskeletal and connective tissue injuries. |

| Code | Description |
|---|---|
| 910.0–919.9 | Superficial injuries. |
| 930.0–932 | Foreign body on external eye, in ear, in nose. |
| 955.0–957.9 | Injury to peripheral nerve. |
| V03.0–V06.9 | Need for prophylactic vaccination. |
| V11.0–V11.9 | Personal history of mental disorder. |
| V14.0–V14.8 | Personal history of allergy to medicinal agents. |
| V16.0 | Family history of malignant neoplasm, gastrointestinal tract. |
| V16.3 | Family history of malignant neoplasm, breast. |
| V21.0–V21.9 | Constitutional states in development. |
| V25.01–V25.9 | Encounter for contraceptive management. |
| V26.0–V26.9 | Procreative management. |
| V40.0–V40.9 | Mental and behavioral problems. |
| V41.0–V41.9 | Problems with special senses and other special functions. |
| V43.0–V43.1 | Organ or tissue replaced by other means, eye globe or lens. |
| V44.0–V44.9 | Artificial opening status. |
| V45.00–V45.89 | Other post surgical states. |
| V48.0–V48.9 | Problems with head, neck, and trunk. |
| V49.0–V49.9 | Problems with limbs. |
| V51 | Aftercare involving the use of plastic surgery. |
| V52.0–V52.9 | Fitting and adjustment of prosthetic device and implant. |
| V53.01–V53.09 | Fitting and adjustment of devices related to nervous system and special senses. |
| V53.1 | Fitting and adjustment of spectacles and contact lenses. |
| V53.31–V53.39 | Fitting and adjustment of cardiac device. |
| V53.4 | Fitting and adjustment of orthodontic devices. |
| V53.5 | Fitting and adjustment of other intestinal appliance. |
| V53.6 | Fitting and adjustment of urinary devices. |
| V53.7 | Fitting and adjustment of orthopedic devices. |
| V53.8 | Fitting and adjustment of wheelchair. |
| V53.9 | Fitting and adjustment of other and unspecified device. |
| V54.0–V54.9 | Other orthopedic aftercare. |
| V55.0–V55.9 | Attention to artificial openings. |
| V57.0–V57.9 | Care involving use of rehabilitation procedures. |
| V58.5 | Orthodontics. |
| V59.0–V59.9 | Donors. |
| V61.0–V61.9 | Other family circumstances. |
| V62.2–V62.9 | Other psychosocial circumstances. |
| V65.2 | Person feigning illness. |
| V65.3 | Dietary surveillance and counseling. |
| V65.40–V65.49 | Other counseling, not elsewhere classified. |
| V65.5 | Person with feared complaint in whom no diagnosis was made. |
| V65.8 | Other reasons for seeking consultation. |
| V65.9 | Unspecified reason for consultation. |
| V66.0-V66.9 | Convalescence and palliative care. |
| V67.3 | Follow-up examination following psychotherapy. |
| V67.4 | Follow-up examination following treatment of healed fracture. |
| V69.3 | Problems related to lifestyle, gambling and betting. |
| V71.01–V71.09 | Observation and evaluation for suspected conditions not found, mental. |
| V72.0–V72.2 | Special investigations, examination of eyes and vision, ears and hearing, dental. |
| V72.4–V72.7 | Special investigations, radiologic exam, laboratory exam, diagnostic skin and sensitization tests. |
| V72.9 | Special investigation, unspecified. |
| V76.10–V76.19 | Special screening for malignant neoplasms, breast. |
| V76.2 | Special screening for malignant neoplasms, cervix. |

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*Cecil Textbook of Medicine,* Bennett, et al., 20th edition, Philadelphia: W.B. Saunders, 1996.

*Williams Hematology,* Beutler, et al., 5th editiion, New York: McGraw-Hill, 1995.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding

Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Partial Thromboplastin Time*

*Other Names/Abbreviations:* PTT.

*Description*

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: The partial thromboplastin time (PTT), prothrombin time (PT), thrombin time (TT), or a quantitative fibrinogen determination. The partial thromboplastin time (PTT) test is an in vitro laboratory test used to assess the intrinsic coagulation pathway and monitor heparin therapy.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 85730 | Thromboplastin time, partial (PTT); plasma or whole blood. |

*Indications*

1. The PTT is most commonly used to quantitate the effect of therapeutic unfractionated heparin and to regulate its dosing. Except during transitions between heparin and warfarin therapy, in general both the PTT and PT are not necessary together to assess the effect of anticoagulation therapy. PT and PTT must be justified separately. (See ''Limitations'' section for further discussion.)

2. A PTT may be used to assess patients with signs or symptoms of hemorrhage or thrombosis. For example:

- Abnormal bleeding, hemorrhage or hematoma petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation
- Swollen extremity with or without prior trauma

3. A PTT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of hemorrhage or thrombosis that is related to the intrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example:

- Dysfibrinogenemia.
- Afibrinogenemia (complete).
- Acute or chronic liver dysfunction or failure, including Wilson's disease.
- Hemophilia.
- Liver disease and failure.
- Infectious processes.
- Bleeding disorders.
- Disseminated intravascular coagulation.
- Lupus erythematosus or other conditions associated with circulating inhibitors, e.g., Factor VIII Inhibitor, lupus-like anticoagulant, etc.
- Sepsis.
- Von Willebrand's disease.
- Arterial and venous thrombosis, including the evaluation of hypercoagulable states.
- Clinical conditions associated with nephrosis or renal failure.
- Other acquired and congenital coagulopathies as well as thrombotic states.

4. A PTT may be used to assess the risk of thrombosis or hemorrhage in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. An example is as follows:

- Evaluation prior to invasive procedures or operations of patients with personal or family history of bleeding or who are on heparin therapy

*Limitations*

1. The PTT is not useful in monitoring the effects of warfarin on a patient's coagulation routinely. However, a PTT may be ordered on a patient being treated with warfarin as heparin therapy is being discontinued. (See coding guidelines for instructions on the use of code V58.61 in this situation.) A PTT may also be indicated when the PT is markedly prolonged due to warfarin toxicity.

2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of heparin.

3. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 002.0–002.9 | Typhoid and paratyphoid. |
| 003.0–003.9 | Other Salmonella infections. |
| 042 | Human immunodeficiency virus (HIV) disease. |
| 038.9 | Unspecified Septicemia. |
| 060.0–060.9 | Yellow fever. |
| 65.0–065.9 | Arthopod borne hemorrhagic fever. |
| 070.0–070.9 | Viral Hepatitis. |
| 075 | Infectious mononucleosis. |
| 078.6 | Hemorrhagic nephrosonephritis. |
| 078.7 | Arenaviral hemorrhagic fever. |
| 120.0 | Schistosomiasis haematobium. |
| 121.1 | Clonorchiasis. |
| 121.3 | Fascioliasis. |
| 124 | Trichinosis. |
| 135 | Sarcoidosis. |
| 155.0–155.2 | Malignant neoplasm of liver and intrahepatic bile ducts. |
| 197.7 | Malignant neoplasm of liver, specified as secondary. |
| 238.4 | Polycythemia vera. |
| 238.7 | Other lymphatic and hemapoietic tissues. |
| 239.9 | Neoplasm of unspecified nature, site unspecified. |
| 246.3 | Hemorrhage and infarction of thyroid. |
| 250.40–250.43 | Diabetic with renal manifestations. |
| 269.0 | Deficiency of Vitamin K. |

| Code | Description |
|---|---|
| 273.0–273.9 | Disorders of plasma protein metabolism. |
| 273.2 | Other paraproteinemias. |
| 275.0–275.9 | Disorders of iron metabolism. |
| 277.1 | Disorders of porphyrin metabolism. |
| 277.3 | Amyloidosis. |
| 285.1 | Acute posthemorrhagic anemia. |
| 286.0 | Congenital factor VIII disorder—Hemophilia A. |
| 286.1 | Congenital factor IX disorder—Hemophilia B. |
| 286.2–286.3 | Other congenital factor deficiencies. |
| 286.4 | von Willebrand's disease. |
| 286.5 | Hemorrhagic disorder due to circulating anticoagulants. |
| 286.6 | Defibrination syndrome. |
| 286.7 | Acquired coagulation factor deficiency. |
| 286.8–.9 | Other and unspecified coagulation defects. |
| 287.0–287.9 | Purpura and other hemorrhagic conditions. |
| 289.0 | Polycythemia, secondary. |
| 325 | Phlebitis and thrombophlebitis of intracranial ventricles sinuses. |
| 360.43 | Hemophthalmos, except current injury. |
| 362.34 | Amaurosis fugax. |
| 362.43 | Hemorrhagic detachment of retinal pigment epithelium. |
| 362.81 | Retinal hemorrhage. |
| 363.6 | Choroidal hemorrhage. |
| 363.72 | Choroidal detachment. |
| 368.9 | Unspecified Visual Disturbances. |
| 372.72 | Conjunctive hemorrhage. |
| 374.81 | Hemorrhage of eyelid. |
| 376.32 | Orbital hemorrhage. |
| 377.42 | Hemorrhage in optic nerve sheaths. |
| 379.23 | Vitreous hemorrhage. |
| 380.31 | Hematoma of auricle or pinna. |
| 403.01, 403.11, 403.91 | Hypertensive Renal Disease with renal failure. |
| 404.02, 404.12, 404.92 | Hypertensive Heart and Renal Disease with renal failure. |
| 423.0 | Hemopericardium. |
| 427.31 | Atrial fibrillation. |
| 427.9 | Cardiac dysrhythmias, unspecified. |
| 428.0 | Congestive heart failure. |
| 429.79 | Mural thrombus. |
| 430–432.9 | Cerebral hemorrhage. |
| 433.00–433.91 | Occlusion and stenosis of precerebral arteries. |
| 434.00–434.91 | Occlusion of cerebral arteries. |
| 435.9 | Focal neurologic deficit. |
| 444.0–444.9 | Arterial embolism and thrombosis. |
| 446.6 | Thrombotic microangiopathy. |
| 447.2 | Rupture of artery. |
| 448.0 | Hereditary Hemorrhagic telangiectasia. |
| 451.0–451.9 | Phlebitis and thrombophlebitis. |
| 453.0–453.9 | Other Venous emboli and thrombosis. |
| 456.0 | Esophageal varices with bleeding. |
| 456.1 | Esophageal varices without bleeding. |
| 459.89 | Ecchymosis. |
| 530.7 | Gastroesophageal laceration—hemorrhage syndrome. |
| 531.00–535.61 | Gastric-Duodenal ulcer disease. |
| 537.83 | Angiodysplasia of stomach and duodenum with hemorrhage. |
| 556.0–557.9 | Hemorrhagic bowel disease. |
| 562.02–562.03 | Diverticulosis of small intestine with hemorrhage. |
| 562.12 | Diverticulosis of colon with hemorrhage. |
| 562.13 | Diverticulitis of colon without hemorrhage. |
| 568.81 | Hemoperitoneum (nontraumatic). |
| 569.3 | Hemorrhage of rectum and anus. |
| 570 | Acute and subacute necrosis of liver. |
| 571.0–573.9 | Liver disease (in place of specific codes listed). |
| 576.0–576.9 | Biliary tract disorders. |
| 577.0 | Acute pancreatitis. |
| 578.0–578.9 | Gastrointestinal Hemorrhage. |
| 579.0–579.9 | Malabsorption. |
| 581.0–581.9 | Nephrotic Syndrome. |
| 583.9 | Nephritis, with unspecified pathological lesion in kidney. |
| 584.5–584.9 | Acute Renal Failure. |
| 585 | Chronic Renal Failure. |
| 586 | Renal failure. |
| 593.81–593.89 | Other disorders of kidney and ureter, with hemorrhage. |
| 596.7 | Hemorrhage into bladder wall. |
| 596.8 | Other disorders of bladder, with hemorrhage. |
| 599.7 | Hematuria. |

| Code | Description |
|---|---|
| 607.82 | Penile hemorrhage. |
| 608.83 | Vascular disorders of male genital organs. |
| 611.8 | Hematoma of breast. |
| 620.7 | Hemorrhage of broad ligament. |
| 621.4 | Hematometra. |
| 622.8 | Other specified disorders of cervix, with hemorrhage. |
| 623.6 | Vaginal hematoma. |
| 623.8 | Other specified diseases of the vagina, with hemorrhage. |
| 624.5 | Hematoma of vulva. |
| 626.6 | Metrorrhagia. |
| 626.7 | Postcoital bleeding. |
| 627.0 | Premenopausal bleeding. |
| 627.1 | Postmenopausal bleeding. |
| 629.0 | Hematocele female not elsewhere classified. |
| 632 | Missed abortion. |
| 634.00–634.92 | Spontaneous abortion. |
| 635.10–635.12 | Legally induced abortion, complicated by delayed or excessive hemorrhage. |
| 636.10–636.12 | Illegally induced abortion, complicated by delayed or excessive hemorrhage. |
| 637.10–637.12 | Abortion unspecified, complicated by delayed or excessive hemorrhage. |
| 638.1 | Failed attempt abortion, complicated by delayed or excessive hemorrhage. |
| 639.1 | Delayed or excessive hemorrhage following abortion and ectopic and molar pregnancies. |
| 639.6 | Complications following abortion and ectopic and molar pregnancies, embolism. |
| 640.00–640.93 | Hemorrhage in early pregnancy. |
| 641.00–641.93 | Antepartum hemorrhage. |
| 642.00–642.94 | Hypertension complicating pregnancy, childbirth, and the puerperium. |
| 646.70–646.73 | Liver disorders in pregnancy. |
| 656.00–656.03 | Fetal maternal hemorrhage. |
| 658.40–658.43 | Infection of amniotic cavity. |
| 666.00–666.34 | Postpartum hemorrhage. |
| 671.20–671.54 | Phlebitis in pregnancy. |
| 673.00–673.84 | Obstetrical pulmonary embolus. |
| 674.30–674.34 | Other complications of surgical wounds, with hemorrhage. |
| 710.0 | Systemic Lupus erythematosus. |
| 713.2 | Arthropathy associated with hematologic disorders (note: may not be used without indicating associated condition first). |
| 713.6 | Arthropathy associated with Henoch Schoenlein (note: may not be used without indicating associated condition first). |
| 719.10–.19 | Hemarthrosis. |
| 729.5 | Leg pain/calf pain. |
| 733.1 | Pathologic fracture associated with fat embolism. |
| 762.1 | Other forms of placental separation with hemorrhage (affecting newborn code—do not assign to mother's record). |
| 764.90–764.99 | Fetal intrauterine growth retardation. |
| 767.0–767.1 | Subdural and cerebral hemorrhage. |
| 767.8 | Other specified birth trauma, with hemorrhage. |
| 770.3 | Fetal and newborn pulmonary hemorrhage. |
| 772.0–.9 | Fetal and neonatal hemorrhage. |
| 774.0–.7 | Other perinatal jaundice. |
| 776.0–776.9 | Hemorrhagic disease of the newborn. |
| 780.2 | Syncope. |
| 782.4 | Jaundice, unspecified, not of newborn. |
| 782.7 | Spontaneous ecchymoses Petechiae. |
| 784.7 | Epistaxis. |
| 784.8 | Hemorrhage from throat. |
| 785.4 | Gangrene. |
| 785.50 | Shock. |
| 786.05 | Shortness of breath. |
| 786.3 | Hemoptysis. |
| 786.59 | Chest pain. |
| 789.00–.09 | Abdominal pain. |
| 790.92 | Abnormal coagulation profile. |
| 800.00–800.99 | Fracture of vault of skull. |
| 801.00–801.99 | Fracture of base of skull. |
| 802.20–802.9 | Fracture of face bones. |
| 803.00–.99 | Other fracture, skull. |
| 804.00–.99 | Multiple fractures, skull. |
| 805.00–806.9 | Fracture, vertebral column. |
| 807.00–807.09 | Fractures of rib(s), closed. |
| 807.10–807.19 | Fracture of rib(s), open. |
| 808.8–.9 | Fracture of pelvis. |
| 809.0–.1 | Fracture of trunk. |
| 810.00–.13 | Fracture of clavicle. |
| 811.00–.19 | Fracture of scapula. |
| 812.00–.59 | Fracture of humerus. |
| 813.10–.18 | Fracture of radius and ulna, upper end, open. |

| Code | Description |
|---|---|
| 813.30–.38 | Fracture of radius and ulna, shaft, open. |
| 813.50–813.58 | Fracture of radius and ulna, lower end, open. |
| 813.90–.98 | Fracture of radius and ulna, unspecified part, open |
| 819.0–819.1 | Multiple fractures. |
| 820.00– 821.39 | Femur. |
| 823.00–.92 | Tibia and fibula. |
| 827.0–829.1 | Other multiple lower limb. |
| 852.00–853.19 | Subarachnoid subdural, and extradural hemorrhage, following injury, Other and specified intracranial hemorrhage following injury. |
| 860.0–860.5 | Traumatic pneumothorax and hemothorax. |
| 861.00–.32 | Injury to heart and lung. |
| 862.0–.862.9 | Injury to other and unspecified intrathoracic organs. |
| 863.0–.9 | Injury to gastrointestinal tract. |
| 864.00–.19 | Injury to liver. |
| 865.00–.19 | Injury to spleen. |
| 866.00–.13 | Injury to kidney. |
| 867.0–.9 | Injury to pelvic organs. |
| 868.00–.19 | Injury to other intra-abdominal organs. |
| 869.0–.1 | Internal injury to unspecified or ill defined organs. |
| 900.00–.9 | Injury to blood vessels of head and neck. |
| 901.0–.9 | Injury to blood vessels of the thorax. |
| 902.0–.9 | Injury to blood vessels of the abdomen and pelvis. |
| 903.00–.9 | Injury to blood vessels of upper extremity. |
| 904.0–.9 | Injury to blood vessels of lower extremity and unspecified sites. |
| 920–924.9 | Contusion with intact skin surface. |
| 925.1–929.9 | Crushing injury. |
| 958.2 | Secondary and recurrent hemorrhage. |
| 959.9 | Injury, unspecified site. |
| 964.2 | Poisoning by anticoagulants. |
| 964.5 | Poisoning by anticoagulant antagonists. |
| 964.7 | Poisoning by natural blood and blood products. |
| 980.0 | Toxic effects of alcohol. |
| 989.5 | Snake venom. |
| 995.2 | Unspecified adverse effect of drug, medicinal and biological substance (due to correct medicinal substance properly administered). |
| 996.7 | Other complications of internal prosthetic device. |
| 997.02 | Iatrogenic cerbrovascular infarction or hemorrhage. |
| 998.11 | Hemorrhage or hematoma complicating a procedure. |
| 999.2 | Other vascular complications of medical care. |
| V12.3 | Personal history of diseases of blood and blood forming organs. |
| V58.2 | Admission for Transfusion of blood products. |
| V58.61 | Long term (current use) of anticoagulants. |
| V72.81 | Pre-operative cardiovascular examination. |
| V72.83 | Other specified pre-operative examination. |
| V72.84 | Pre-operative examination, unspecified. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–09–CM Codes That Do Not Support Medical Necessity:*

Code: Description

Any ICD–9–09CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

CMD Clinical Laboratory Workgroup

1999 CPT Physicians' Current Procedural Terminology, American Medical Association

Blue Book of Diagnostic Tests; PL Liu; Saunders

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''College of American Pathologists Conference XXXI on Laboratory Monitoring of Anticoagulant Therapy,'' Arch Pathol Lab Med, Vol 122, Sep 1998, P 782–798.

Lupus Anticoagulants/Antiphospholipid-protein Antibodies: The Great Imposters, Triplett DA, Lupus 1996:5:431

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. When patients are being converted from heparin therapy to warfarin therapy, use code V58.61 to document the medical necessity of the PTT.

7. When coding for Disseminated Intravascular Coagulation (DIC), use 286.6 or code for the signs and symptoms clinically indicating DIC.

8. If a specific condition is known and is the reason for a pre-operative test, submit the clinical text description or ICD–9–CM code describing the condition with the order/referral. If a specific condition or disease is not known, and the pre-operative test is for pre-operative clearance only, assign code V72.84.

9. Assign codes 289.8—other specified disease of blood and blood-forming organs only when a specific disease exists and is indexed to 289.8, (for example, myelofibrosis). Do not assign code 289.8 to report a patient on long term use of anticoagulant therapy (for example, to report a PTT value or re-check need for medication adjustment.) Assign code V58.61 to referrals for PTT checks or re-checks. (Reference AHA's Coding Clinic, March–April, pg 12—1987, 2nd quarter pg 8—1989)

*Medicare National Coverage Decision for Prothrombin Time*

*Other Names/Abbreviations:* PT

*Description*

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: the partial thromboplastin time (PTT), prothrombin time (PT), thrombin time (TT), or a quantitative fibrinogen determination. The prothrombin time (PT) test is one in-vitro laboratory test used to assess coagulation. While the PTT assesses the intrinsic limb of the coagulation system, the PT assesses the extrinsic or tissue factor dependent pathway. Both tests also evaluate the common coagulation pathway involving all the reactions that occur after the activation of factor X. Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of factors may be related to decreased production or increased consumption of coagulation factors. The PT/INR is most commonly used to measure the effect of warfarin and regulate its dosing. Warfarin blocks the effect of vitamin K on hepatic production of extrinsic pathway factors.

A prothrombin time is expressed in seconds and/or as an international normalized ratio (INR). The INR is the PT ratio that would result if the WHO reference thromboplastin had been used in performing the test.

Current medical information does not clarify the role of laboratory PT testing in patients who are self monitoring. Therefore, the indications for testing apply regardless of whether or not the patient is also PT self-testing.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 85610 .. | Prothrombin Time. |

*Indications*

1. A PT may be used to assess patients taking warfarin. The prothrombin time is generally not useful in monitoring patients receiving heparin who are not taking warfarin.

2. A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example:

- swollen extremity with or without prior trauma
- unexplained bruising
- abnormal bleeding, hemorrhage or hematoma
- petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation

3. A PT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example:

- dysfibrinogenemia
- afibrinogenemia (complete)
- acute or chronic liver dysfunction or failure, including Wilson's disease and Hemochromatosis
- disseminated intravascular coagulation (DIC)
- congenital and acquired deficiencies of factors II, V, VII, X;
- vitamin K deficiency
- lupus erythematosus
- hypercoagulable state
- paraproteinemia
- lymphoma
- amyloidosis
- acute and chronic leukemias
- plasma cell dyscrasia
- HIV infection
- malignant neoplasms
- hemorrhagic fever
- salicylate poisoning
- obstructive jaundice
- intestinal fistula
- malabsorption syndrome
- colitis
- chronic diarrhea
- presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction
- patients with bleeding or clotting tendencies
- organ transplantation
- presence of circulating coagulation inhibitors

4. A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example:

- evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy.
- prior to the use of thrombolytic medication

*Limitations*

1. When an ESRD patient is tested for PT, testing more frequently than weekly (the frequency authorized by 3171.2, Fiscal Intermediary Manual, or 2231.3 Medicare Carrier Manual) requires documentation of medical necessity [e.g. other than ''Chronic Renal Failure'' (ICD–9–CM 585) or ''Renal Failure, Unspecified'' (ICD–9–CM 586)]

2. The need to repeat this test is determined by changes in the underlying medical condition and/or the dosing of warfarin. In a patient on stable warfarin therapy, it is ordinarily not necessary to repeat testing more than every two to three weeks. When testing is performed to evaluate a patient with signs or symptoms of abnormal bleeding or thrombosis and the initial test result is normal, it is ordinarily not necessary to repeat testing unless there is a change in the patient's medical status.

3. Since the INR is a calculation, it will not be paid in addition to the PT when expressed in seconds, and is considered part of the conventional prothrombin time, 85610.

4. Testing prior to any medical intervention associated with a risk of bleeding and thrombosis (other than thrombolytic therapy) will generally be considered medically necessary only where there are signs or symptoms of a bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis or a condition associated with a coagulopathy. Hospital/clinic-specific policies, protocols, *etc.,* in and of themselves, cannot alone justify coverage.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 002.0–002.9 | Typhoid and paratyphoid. |
| 003.0–003.9 | Other Salmonella infections. |
| 038.9 | Unspecified Septicemia. |
| 042 | Human Immunodeficiency virus (HIV) disease. |
| 060.0–060.9 | Yellow fever |
| 065.0–065.9 | Arthropod-borne hemorrhagic fever. |
| 070.0–070.9 | Viral hepatitis. |
| 075 | Infectious mononucleosis. |
| 078.6 | Hemorrhagic nephrosonephritis. |
| 078.7 | Arenaviral hemorrhagic fever. |
| 84.8 | Blackwater fever. |
| 120.0 | Schistosomiasis. |
| 121.1 | Clonorchiasos. |
| 121.3 | Fascioliasis. |

| Code | Description |
|---|---|
| 124 | Trichinosis. |
| 134.2 | Hirudiniasis. |
| 135 | Sarcoidosis. |
| 152.0–152.9 | Malignant neoplasm of small intestine, including duodenum. |
| 155.0–155.2 | Malignant neoplasm of liver and intrahepatic bile ducts. |
| 156.0–156.9 | Malignant neoplasm of gallbladder and extrahepatic bile ducts. |
| 157.0–157.9 | Malignant neoplasm of pancreas. |
| 188.0–189.9 | Malignant neoplasm of bladder, kidney, and other and unspecified urinary organs. |
| 198.0 | Secondary malignant neoplasm, kidney. |
| 198.1 | Secondary malignant neoplasm, other urinary organs. |
| 200.00–200.88 | Lymphosarcoma and reticulosarcoma. |
| 202.0–202.98 | Nodular and other Lymphomas. |
| 223.0–223.9 | Benign neoplasm of kidney and other urinary organs. |
| 238.4 | Polycythemia vera. |
| 238.5 | Histocytic and mast cells—neoplasm of uncertain behavior. |
| 238.6 | Plasma cells—neoplasm of uncertain behavior. |
| 238.7 | Other lymphatic and hematopoietic tissues. |
| 239.4 | Neoplasm of unspecified nature, bladder. |
| 239.5 | Neoplasm of unspecified nature, other genitourinary organs. |
| 239.9 | Neoplasm of unspecified nature, site unspecified. |
| 246.3 | Hemorrhage and infarction of thyroid. |
| 250.40–250.43 | Diabetic with renal manifestations. |
| 263.0–263.9 | Other and unspecified protein/calorie malnutrition. |
| 269.0 | Deficiency of Vitamin K. |
| 269.2. | Unspecified vitamin deficiency. |
| 273.0–273.9 | Disorders of plasma protein metabolism. |
| 275.0 | Disorders of iron metabolism. |
| 277.1 | Disorders of porphyrin metabolism. |
| 277.3 | Amyloidosis. |
| 280.0 | Iron deficiency anemia, secondary to blood loss—chronic. |
| 280.9 | Iron deficiency anemia, unspecified. |
| 281.0 | Pernicious anemia. |
| 281.1 | Other Vitamin B12 Deficiency Anemia, NEC. |
| 281.9 | Unspecified Deficiency Anemia, NOS. |
| 285.0 | Sideroblastic anemia. |
| 285.1 | Acute posthemorrhagic anemia. |
| 286.0– 286.9 | Coagulation defects. |
| 287.0–287.9 | Purpura and other hemorrhagic conditions. |
| 290.40–290.43 | Arteriosclerotic dementia. |
| 325 | Phlebitis and thrombophlebitis of intracranial venous sinuses. |
| 342.9 | Hemiplegia NOS. |
| 42.90 | Hemiplegia NOS, Side NEC. |
| 360.43 | Hemophthalmios, except current injury. |
| 362.18 | Retinal vasculitis. |
| 362.30–362.37 | Retinal vascular occlusion. |
| 362.43 | Hemorrhagic detachment of retnal pigment epithelium. |
| 362.81 | Retinal hemorrhage. |
| 363.61–363.72 | Choroidal hemorrhage and rupture, detachment. |
| 368.9 | Unspecified Visual Disturbances. |
| 372.72 | Conjunctival hemorrhage. |
| 374.81 | Hemorrage in optic nerve sheaths. |
| 376.32 | Orbital hemorrhage. |
| 377.42 | Hemorrhage in optic nerve sheaths. |
| 377.53 | Disorders of optic chiasm associated with vascular disorders. |
| 377.62 | Disorders of visual pathways associated with vascular disorders. |
| 377.72 | Disorders of visual cortex associated with vascular disorders. |
| 379.23 | Vitreous hemorrhage. |
| 380.31 | Hematoma of auricle or pinna. |
| 386.2 | Vertigo of central origin. |
| 386.50 | Labyrinthine dysfunction, unspecified. |
| 394.0–394.9 | Diseases of the mitral valve. |
| 395.0 | Rheumatic aortic stenosis. |
| 395.2 | Rheumatic aortic stenosis with insufficiency. |
| 396.0–396.9 | Diseases of mitral and aortic valves. |
| 397.0–397.9 | Diseases of other endocardial structures. |
| 398.0–398.99 | Other rheumatic heart disease. |
| 403.01, 403.11,. | |
| 403.91 | Hypertensive Renal Disease with renal failure. |
| 404.02, 404.12,. | |
| 404.92 | Hypertensive Heart and Renal Disease with renal failure. |
| 410.00–410.92 | Acute myocardial infarction. |
| 411.1 | Intermediate coronary syndrome. |
| 411.81 | Coronary occlusion without myocardial infarction. |
| 411.89 | Other acute and subacute forms of ischemic heart disease. |

| Code | Description |
|---|---|
| 413.0–413.9 | Angina pectoris. |
| 414.00–414.05 | Coronary atherosclerosis. |
| 414.8 | Other specified forms of chronic ischemic heart disease. |
| 414.9 | Chronic ischemic heart disease, unspecified. |
| 415.0–415.19 | Acute pulmonary heart disease. |
| 416.9 | Chronic pulmonary heart disease, unspecified. |
| 423.0 | Hemopericardium. |
| 424.0 | Mitral valve disorders. |
| 424.1 | Aortic valve disorder. |
| 424.90 | Endocarditis, valve unspecified, unspecified cause. |
| 425.0–425.9 | Cardiomyopathy. |
| 427.0–427.9 | Cardiac dysrhythmias. |
| 428.0–428.9 | Heart failure. |
| 429.0–429.4 | Ill-defined descriptions and complications of heart disease. |
| 429.79 | Other certain sequelae of myocardial infarction, not elsewhere classified. |
| 430 | Subarachnoid hemorrhage. |
| 431 | Intracerebral hemorrhage. |
| 432.0–432.9 | Other and unspecified intracranial hemorrhage. |
| 433.00–433.91 | Occlusion and stenosis of precerebral arteries. |
| 434.00–434.91 | Occlusion of cerebral arteries. |
| 435.0–435.9 | Transient cerebral ischemia. |
| 436 | Acute, but ill-defined cerebrovascular disease. |
| 437.0 | Cerebral atherosclerosis. |
| 437.1 | Other generalized ischemic cerebrovascular disease. |
| 437.6 | Nonpyogenic thrombosis of intracranial venous sinus. |
| 440.0–440.9 | Atherosclerosis. |
| 441.0–441.9 | Aortic aneurysm and dissection. |
| 443.0–443.9 | Other peripheral vascular disease. |
| 444.0–444.9 | Arterial embolism and thrombosis. |
| 447.1 | Stricture of artery. |
| 447.2 | Rupture of artery. |
| 447.6 | Arteritis, unspecified. |
| 448.0 | Hereditary hemorrhagic telangiectasia. |
| 448.9 | Other and unspecified capillary diseases. |
| 451.0–451.9 | Phlebitis and thrombophlebitis. |
| 452 | Portal vein thrombosis. |
| 453.0–453.9 | Other venous embolism and thrombosis. |
| 455.2 | Internal hemorrhoids with other complication. |
| 455.5 | External hemorrhoids with other complication. |
| 455.8 | Unspecified hemorrhoids with other complication. |
| 456.0–456.1 | Esophageal varices. |
| 456.8 | Varices of other sites. |
| 459.0 | Hemorrhage, unspecified. |
| 459.1 | Postphlebitis syndrome. |
| 459.2 | Compression of vein. |
| 459.81 | Venous (peripheral) insufficiency, unspecified. |
| 459.89 | Other, other specified disorders of circulatory system. |
| 511.8 | Other specified forms of effusion, except tuberculosis. |
| 514 | Pulmonary congestion and hypostasis. |
| 530.7 | Gastroesophageal laceration—hemorrhage syndrome. |
| 530.82 | Esophageal hemorrhage. |
| 531.00–535.61 | Gastric ulcer, duodenal ulcer, peptic ulcer, gastrojejunal ulcer, gastritis and duodenitis. |
| 555.0–555.9 | Regional enteritis. |
| 556.0–556.9 | Ulcerative colitis. |
| 557.0–557.9 | Vascular insufficiency of intestine. |
| 562.02—562.03 | Diverticulosis of small intestine with hemorrhage. |
| 562.10 | Diverticulosis of colon w/o hemorrhage. |
| 562.11 | Diverticulitis of colon w/o hemorrhage. |
| 562.12 | Diverticulosis of colon with hemorrhage. |
| 562.13 | Diverticulitis of colon without hemorrhage. |
| 568.81 | Hemoperitoneum (nontraumatic). |
| 569.3 | Hemorrhage of rectum and anus. |
| 571.0–571.9 | Chronic liver disease and cirrhosis. |
| 572.2 | Hepatic coma. |
| 572.4 | Hepatorenal syndrome. |
| 572.8 | Other sequelae of chronic liver disease. |
| 573.1–573.9 | Hepatitis in viral diseases, other and unspecified disorder of liver. |
| 576.0–576.9 | Other disorders of Biliary tract. |
| 577.0 | Acute pancreatitis. |
| 578.0–578.9 | Gastrointestinal hemorrhage. |
| 579.0–579.9 | Intestinal Malabsorption. |
| 581.0—581.9 | Nephrotic Syndrome. |
| 583.9 | Nephritis, with unspecified pathological lesion in kidney. |
| 584.5–584.9 | Acute Renal Failure. |

| Code | Description |
|---|---|
| 585 | Chronic Renal Failure. |
| 586 | Renal failure, unspecified. |
| 593.81–593.89 | Other specified disorders of kidney and ureter. |
| 596.7 | Hemorrhage into bladder wall. |
| 596.8 | Other specified disorders of bladder. |
| 599.7 | Hematuria. |
| 607.82 | Vascular disorders of penis. |
| 608.83 | Vascular disorders of male genital organs. |
| 611.8 | Other specified disorders of breast—hematoma. |
| 620.7 | Hemorrhage of broad ligament. |
| 621.4 | Hematometra. |
| 622.8 | Other specified noninflammatory disorders of cervix. |
| 623.6 | Vaginal hematoma. |
| 623.8 | Other specified noninflammatory disorders of the vagina. |
| 624.5 | Hematoma of vulva. |
| 626.2–626.9 | Abnormal bleeding from female genital tract. |
| 627.0 | Premenopausal menorrhagia. |
| 627.1 | Postmenopausal bleeding. |
| 629.0 | Hematocele female, not classified elsewhere. |
| 632 | Missed abortion. |
| 634.10–634.12 | Spontaneous abortion, complicated by excessive hemorrhage. |
| 635.10–635.12 | Legally induced abortion, complicated by delayed or excessive hemorrhage. |
| 636.10–636.12 | Illegally induced abortion, complicated by delayed or excessive hemorrhage. |
| 637.10–637.12 | Abortion unspecified, complicated by delayed or excessive hemorrhage. |
| 638.1 | Failed attempted abortion, complicated by delayed or excessive hemorrhage. |
| 639.1 | Delayed or excessive hemorrhage following abortion and ectopic and molar pregnancies. |
| 639.6 | Complications following abortion and ectopic and molar pregnancies with embolism. |
| 640.00–640.93 | Hemorrhage in early pregnancy. |
| 641.00–641.93 | Antepartum hemorrhage, abruptio placentae, and placenta previa. |
| 642.00–642.94 | Hypertension complicating pregnancy, childbirth, and the puerperium. |
| 646.70–646.73 | Liver disorders in pregnancy. |
| 656.00–656.03 | Fetal maternal hemorrhage. |
| 658.40–658.43 | Infection of amniotic cavity. |
| 666.00–666.34 | Postpartum hemorrhage. |
| 671.20–671.94 | Venous complications in pregnancy and the puerperium. |
| 673.00–673.84 | Obstetrical pulmonary embolism. |
| 674.30–674.34 | Other complications of obstetrical surgical wounds. |
| 713.2 | Arthropathy associated with hematological disorders. |
| 713.6 | Arthropathy associated with hypersensitivity reaction. |
| 719.15 | Hemarthrosis (5th digits 5, 6, and 9 allowed only). |
| 719.16 | Lower leg. |
| 719.19 | Multiple sites. |
| 729.5 | Pain in limb. |
| 733.1 | Patholgic fracture, unspecified site. |
| 746.00–746.9 | Other Congenital anomalies of heart. |
| 762.1 | Other forms of placental separation and hemorrhage. |
| 767.0–767.1 | Subdural and cerebral hemorrhage. |
| 767.8 | Other specified birth trauma. |
| 770.3 | Pulmonary hemorrhage. |
| 772.0–772.9 | Fetal and neonatal hemorrhage. |
| 774.6 | Unspecified fetal and neonatal jaundice. |
| 776.0–776.9 | Hemorrhagic disease of the newborn. |
| 780.2 | Syncope an collapse. |
| 782.3 | Edema. |
| 782.4 | Jaundice, unspecified, not of newborn. |
| 782.7 | Spontaneous ecchymosis. |
| 784.7 | Epistaxis. |
| 784.8 | Hemorrhage from throat. |
| 785.4 | Gangrene. |
| 785.50 | Shock without mention of trauma. |
| 786.05 | Shortness of breath. |
| 786.3 | Hemoptysis. |
| 786.59 | Chest pain, other. |
| 789.00–789.09 | Abdominal pain. |
| 789.1 | Hepatomegaly. |
| 789.5 | Ascites. |
| 790.92 | Abnormal coagulation profile. |
| 790.94 | Euthyroid sick syndrome. |
| 791.2 | Hemoglobinuria. |
| 794.8 | Abnormal Liver Function Study. |
| 800.00–800.99 | Fracture of vault of skull. |
| 801.00–801.99 | Fracture of base of skull. |
| 802.20–802.9 | Fracture of face bones. |
| 803.00–803.99 | Other and unqualified skull fractures. |

| Code | Description |
|---|---|
| 804.00–804.99 | Multiple fractures involving skull or face with other bones. |
| 805.00–806.9 | Fracture, vertebral column. |
| 807.00–807.09 | Fractures of rib(s), closed. |
| 807.10–807.19 | Fracture of rib(s), open. |
| 808.8–808.9 | Fracture of Pelvis. |
| 809.0–809.1 | Ill-defined fractures of bones of Trunk. |
| 810.00–810.13 | Fracture of Clavicle. |
| 811.00–811.19 | Fracture of Scapula. |
| 812.00–812.59 | Fracture of Humerus. |
| 813.10–18 | Fracture of radius and ulna, upper end, open. |
| 813.30–38 | Shaft, open. |
| 813.50–813.58 | Lower end, open. |
| 813.90–98 | Fracture unspecified part, open. |
| 819.0–819.1 | Multiple fractures involving both upper limbs, closed and open. |
| 820.00–821.39 | Fracture of neck of femur. |
| 823.00–823.92 | Fracture of tibia and fibula. |
| 827.0–829.1 | Other multiple lower limb. |
| 852.00–852.59 | Subarachnoid, subdural, and extradural hemorrhage, following injury. |
| 853.00–853.19 | Other and specified intracranial hemorrhage following injury. |
| 852.00–853.19 | Subarachnoid subdural, and extradural hemorrhage, following injury, Other and specified intracranial hemorrhage following injury. |
| 860.0–860.5 | Traumatic pneumothorax and hemothorax. |
| 861.00–.32 | Injury to heart and lung. |
| 862.0–.862.9 | Injury to other and unspecified intrathoracic organs. |
| 863.0–.9 | Injury to gastrointestinal tract. |
| 864.00–.19 | Injury to liver. |
| 865.00–.19 | Injury to spleen. |
| 866.00–.13 | Injury to kidney. |
| 867.0–.9 | Injury to pelvic organs. |
| 868.00–.19 | Injury to other intra-abdominal organs. |
| 869.0–.1 | Internal injury to unspecified or ill defined organs. |
| 900.00–.9 | Injury to blood vessels of head and neck. |
| 901.0–.9 | Injury to blood vessels of the thorax. |
| 902.0–.9 | Injury to blood vessels of the abdomen and pelvis. |
| 903.00–.9 | Injury to blood vessels of upper extremity. |
| 904.0–.9 | Injury to blood vessels of lower extremity and unspecified sites. |
| 920—924.9 | Contusion with intact skin surface. |
| 925.1—929.9 | Crushing injury. |
| 958.2 | Secondary and recurrent hemorrhage. |
| 959.9 | Injury, unspecified site. |
| 964.0–964.9 | Poisoning by agents primarily affecting blood constituents. |
| 980.0–980.9 | Toxic effect of alcohol. |
| 981 | Toxic effect of petroleum products. |
| 982.0–982.8 | Toxic effects of solvents other than petroleum-based. |
| 987.0–987.9 | Toxic effect of other gases, fumes or vapors. |
| 989.0–989.9 | Toxic effect of other substances chiefly non-medicinal as to source. |
| 995.2 | Unspecified adverse effect of drug, medicinal and biological substance (due to correct medicinal substance properly administered). |
| 996.82 | Complication of transplanted liver. |
| 997.4 | Digestive system complications. |
| 998.11–998.12 | Hemorrhage or hematoma complicating a procedure. |
| 997.02 | Iatrogenic cerbrovascular infarction or hemorrhage. |
| 999.2 | Other vascular complications. |
| 999.8 | Other transfusion reactions. |
| V08 | Asymptomatic HIV infection. |
| V12.1 | History of nutritional deficiency. |
| V12.3 | Personal history of diseases of blood and blood-forming organs. |
| V15.1 | Personal history of surgery to heart and great vessels. |
| V15.2 | Personal history of surgery of other major organs. |
| V42.0 | Kidney replaced by transplant. |
| V42.1 | Heart replaced by transplant. |
| V42.2 | Heart valve replaced by transplant. |
| V42.6 | Lung replaced by transplant. |
| V42.7 | Liver replaced by transplant. |
| V42.8 | Other specified organ or tissue replaced by transplant. |
| V43.2 | Heart replaced by other means. |
| V43.3 | Heart valve replaced by other means. |
| V43.4 | Blood vessel replaced by other means. |
| V43.60 | Unspecified joint replaced by other means. |
| V58.2 | Transfusion of blood products. |
| V58.61 | Long-term (current) use of anticoagulants. |
| V72.84 | Pre-operative examination, unspecified. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0—798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

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''Monitoring Oral Anticoagulation Therapy with Point-of-Care Devices. Correlation and

Caveats''. Clinical Chemistry: No. 9, 1997, pp 1785–1786.

''College of American Pathologists Conference XXXI on Laboratory Monitoring of Anticoagulant Therapy''. Arch. Pathol. Lab. Med. Vol. 122. September 1998. pp 768–780.

''A Structured Teaching and Self-management Program for Patients Receiving Oral Anti-coagulation''. JAMA; 1999; 281: 145–150.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

6. If a specific condition is known and is the reason for a pre-operative test, submit the text description or ICD–9–CM code describing the condition with the order/referral. If a specific condition or disease is not known, and the pre-operative test is for pre-operative clearance only, assign code V72.84.

7. Assign codes 289.8—other specified disease of blood and blood-forming organs only when a specific disease exists and is indexed to 289.8 (for example, myelofibrosis). Do not assign code 289.8 to report a patient on long term use of anticoagulant therapy (e.g. to report a PT value or re-check need for medication adjustment.) Assign code V58.61 to referrals for PT checks or re-checks. (Reference AHA's Coding Clinic, March–April, pg 12—1987, 2nd quarter pg 8—1989)

*Medicare National Coverage Decision for Serum Iron Studies*

*Other Names/Abbreviations*

*Description*

Serum iron studies are useful in the evaluation of disorders of iron metabolism, particularly iron deficiency and iron excess. Iron studies are best performed when the patient is fasting in the morning and has abstained from medications that may influence iron balance.

Iron deficiency is the most common cause of anemia. In young children on a milk diet, iron deficiency is often secondary to dietary deficiency. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary deficiency or malabsorption. Following major surgery the patient may have iron deficient erythropoiesis for months or years if adequate iron replacement has not been given. High doses of supplemental iron may cause the serum iron to be elevated. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions.

Total iron binding capacity (TIBC) is an indirect measure of transferrin, a protein that binds and transports iron. TIBC quantifies transferrin by the amount of iron that it can bind. TIBC and transferrin are elevated in iron deficiency, and with oral contraceptive use, and during pregnancy. TIBC and transferrin may be decreased in malabsorption syndromes or in those affected with chronic diseases. The percent saturation represents the ratio of iron to the TIBC.

Assays for ferritin are also useful in assessing iron balance. Low concentrations are associated with iron deficiency and are highly specific. High concentrations are found in hemosiderosis (iron overload without associated tissue injury) and hemochromatosis (iron overload with associated tissue injury). In these conditions the iron is elevated, the TIBC and transferrin are within the reference range or low, and the percent saturation is elevated. Serum ferritin can be useful for both initiating and monitoring treatment for iron overload.

Transferrin and ferritin belong to a group of serum proteins known as acute phase reactants, and are increased in response to stressful or inflammatory conditions and also can occur with infection and tissue injury due to surgery, trauma or necrosis. Ferritin and iron/TIBC (or transferrin) are affected by acute and chronic inflammatory conditions, and in patients with these disorders, tests of iron status may be difficult to interpret.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82728 | Ferritin. |
| 83540 | Iron. |
| 83550 | Iron Binding capacity. |
| 84466 | Transferrin. |

*Indications*

1. Ferritin (82728), iron (83540) and either iron binding capacity (83550) or transferrin (84466) are useful in the differential diagnosis of iron deficiency, anemia, and for iron overload conditions.

A. The following presentations are examples that may support the use of these studies for evaluating iron deficiency:

- Certain abnormal blood count values (i.e., decreased mean corpuscular volume (MCV), decreased hemoglobin/hematocrit when the MCV is low or normal, or increased red cell distribution width (RDW) and low or normal MCV).
- Abnormal appetite (pica)
- Acute or chronic gastrointestinal blood loss
- Hematuria
- Menorrhagia
- Malabsorption
- Status post-gastrectomy
- Status post-gastrojejunostomy
- Malnutrition
- Preoperative autologous blood collection(s)
- Malignant, chronic inflammatory and infectious conditions associated with anemia which may present in a similar manner to iron deficiency anemia
- Following a significant surgical procedure where blood loss had occurred and had not been repaired with adequate iron replacement.

B. The following presentations are examples that may support the use of these studies for evaluating iron overload:

- Chronic Hepatitis
- Diabetes
- Hyperpigmentation of skin
- Arthropathy
- Cirrhosis
- Hypogonadism
- Hypopituitarism
- Impaired porphyrin metabolism

- Heart failure
- Multiple transfusions
- Sideroblastic anemia
- Thalassemia major
- Cardiomyopathy, cardiac dysrhythmias and conduction distrubances

2. Follow-up testing may be appropriate to monitor response to therapy, *e.g.,* oral or parenteral iron, ascorbic acid, and erythropoietin.

3. Iron studies may be appropriate in patients after treatment for other nutritional deficiency anemias, such as folate and vitamin B12, because iron deficiency may not be revealed until such a nutritional deficiency is treated.

4. Serum ferritin may be appropriate for monitoring iron status in patients with chronic renal disease with or without dialysis.

5. Serum iron may also be indicated for evaluation of toxic effects of iron and other metals (*e.g.,* nickel, cadmium, aluminum, lead) whether due to accidental, intentional exposure or metabolic causes.

*Limitations*

1. Iron studies should be used to diagnose and manage iron deficiency or iron overload states. These tests are not to be used solely to assess acute phase reactants where disease management will be unchanged. For example, infections and malignancies are associated with elevations in acute phase reactants such as ferritin, and decreases in serum iron concentration, but iron studies would only be medically necessary if results of iron studies might alter the management of the primary diagnosis or might warrant direct treatment of an iron disorder or condition.

2. If a normal serum ferritin level is documented, repeat testing would not ordinarily be medically necessary unless there is a change in the patient's condition, and ferritin assessment is needed for the ongoing management of the patient. For example, a patient presents with new onset insulin-dependent diabetes mellitus and has a serum ferritin level performed for the suspicion of hemochromatosis. If the ferritin level is normal, the repeat ferritin for diabetes mellitus would not be medically necessary.

3. When an End Stage Renal Disease (ESRD) patient is tested for ferritin, testing more frequently than every three months (the frequency authorized by 3167.3, Fiscal Intermediary manual) requires documentation of medical necessity [*e.g.,* other than ''Chronic Renal Failure'' (ICD–9–CM 585) or ''Renal Failure, Unspecified'' (ICD–9–CM 586)].

4. It is ordinarily not necessary to measure both transferrin and TIBC at the same time because TIBC is an indirect measure of transferrin. When transferrin is ordered as part of the nutritional assessment for evaluating malnutrition, it is not necessary to order other iron studies unless iron deficiency or iron overload is suspected as well.

5. It is not ordinarily necessary to measure both iron/TIBC (or transferrin) and ferritin in initial patient testing. If clinically indicated after evaluation of the initial iron studies, it may be appropriate to perform additional iron studies either on the initial specimen or on a subsequently obtained specimen. After a diagnosis of iron deficiency or iron overload is established, either iron/TIBC (or transferrin) or ferritin may be medically necessary for monitoring, but not both.

6. It would not ordinarily be considered medically necessary to do a ferritin as a preoperative test except in the presence of anemia or recent autologous blood collections prior to the surgery.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 002.0–002.9 | Typhoid and paratyphoid fevers. |
| 003.0–003.9 | Other salmonella infections. |
| 006.0–006.9 | Amebiasis. |
| 007.0–007.9 | Other protozoal intestinal diseases. |
| 008.00–008.8 | Intestinal infections due to other organisms. |
| 009.0–009.3 | Ill-defined intestinal infections. |
| 011.50–011.56 | Tuberculous bronchiectasis. |
| 014.00–014.86 | Tuberculosis of intestines, peritoneum, and mesenteric glands. |
| 015.00–015.96 | Tuberculosis of bones and joints. |
| 016.00–016.06 | Tuberculosis of kidney. |
| 016.10–016.16 | Tuberculosis of bladder. |
| 016.20–016.26 | Tuberculosis of ureter. |
| 016.30–016.36 | Tuberculosis of other urinary organs. |
| 042 | Human Immunodeficiency virus (HIV) disease. |
| 070.0–070.9 | Viral hepatitis. |
| 140.0–149.9 | Malignant neoplasm of lip oral cavity and pharynx. |
| 150.0–159.9 | Malignant neoplasm of digestive organs and peritoneum. |
| 160.0–165.9 | Malignant neoplasm of respiratory and intrathoracic organs. |
| 170.0–176.9 | Malignant neoplasm of bone, connective tissue, skin and breast. |
| 179–189.9 | Malignant neoplasm of genitourinary organs. |
| 190.0–199.1 | Malignant neoplasm of other and unspecified sites. |
| 200.0–208.91 | Malignant neoplasm of lymphatic and hematopoietic tissue. |
| 210.0–229.9 | Benign neoplasms. |
| 230.0–234.9 | Carcinoma in situ. |
| 235.0–238.9 | Neoplasms of uncertain behavior. |
| 239.0–239.9 | Neoplasms of unspecified nature. |
| 250.00–250.93 | Diabetes mellitus. |
| 253.2 | Panhypopituitarism. |
| 253.7 | Iatrogenic pituitary disorders. |
| 253.8 | Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin. |
| 256.3 | Other ovarian failure. |
| 257.2 | Other testicular hypofunction. |
| 260 | Kwashiorkor. |
| 261 | Nutritional marasmus. |
| 262 | Other severe protein-calorie malnutrition. |
| 263.0–263.9 | Other and unspecified protein-calorie malnutrition. |
| 275.0 | Disorders of iron metabolism. |
| 277.1 | Disorders of porphyrin metabolism. |
| 280.0–280.9 | Iron deficiency anemias. |
| 281.0–281.9 | Other deficiency anemias. |
| 282.4 | Thalassemias. |
| 285.0 | Sideroblastic anemia (includes hemochromatosis with refractory anemia). |
| 285.1 | Acute post-hemorrhagic anemia. |

| Code | Description |
|---|---|
| 285.9 | Anemia, unspecified. |
| 286.0–286.9 | Coagulation defects (congenital factor disorders). |
| 287.0–287.9 | Purpura and other hemorrhagic conditions. |
| 306.4 | Physiological malfunction arising from mental factors, gastrointestinal. |
| 307.1 | Anexoria nervosa. |
| 307.50–307.59 | Other and unspecified disorders of eating. |
| 425.4 | Other primary cardiomyopathies. |
| 425.5 | Alcoholic cardiomyopathy. |
| 425.7 | Nutritional and metabolic cardiomyopathy. |
| 425.8 | Cardiomyopathy in other diseases classified elsewhere. |
| 425.9 | Secondary cardiomyopathy, unspecified. |
| 426.0–426.9 | Conduction disorders. |
| 427.0–427.9 | Cardiac dysrhythmias. |
| 428.0–428.9 | Heart Failure. |
| 530.7 | Gastroesophageal laceration-hemorrhage syndrome. |
| 530.82 | Esophageal hemorrhage. |
| 531.00–531.91 | Gastric ulcer. |
| 532.00–532.91 | Duodenal ulcer. |
| 533.00–533.91 | Peptic ulcer, site unspecified. |
| 534.00–534.91 | Gastrojejunal ulcer. |
| 535.00–535.61 | Gastritis and duodenitis. |
| 536.0–536.9 | Disorders of function of stomach. |
| 537.83 | Angiodysplasia of stomach and duodenum with hemorrhage. |
| 555.0–555.9 | Regional enteritis. |
| 556.0–556.9 | Ulcerative colitis. |
| 557.0 | Acute vascular insufficiency of intestine. |
| 557.1 | Chronic vascular insufficiency of intestine. |
| 562.02 | Diverticulosis of small intestine with hemorrhage. |
| 562.03 | Diverticulitis of small intestine with hemorrhage. |
| 562.12 | Diverticulosis of colon with hemorrhage. |
| 562.13 | Diverticulitis of colon with hemorrhage. |
| 569.3 | Hemorrhage of rectum and anus. |
| 569.85 | Angiodysplasia of intestine with hemorrhage. |
| 570 | Acute and subacute necrosis of liver. |
| 571.0–571.9 | Chronic liver disease and cirrhosis. |
| 572.0–572.8 | Liver abscess and sequelae of chronic liver disease. |
| 573.0–573.9 | Other disorders of liver. |
| 578.0–578.9 | Gastrointestinal hemorrhage. |
| 579.0–579.3 | Intestinal malabsorption. |
| 581.0–581.9 | Nephrotic syndrome. |
| 585 | Chronic renal failure. |
| 586 | Renal failure, unspecified. |
| 608.3 | Atrophy of testis. |
| 626.0–626.9 | Disorders of menstruation and other abnormal bleeding from female genital tract. |
| 627.0 | Premenopausal menorrhagia. |
| 627.1 | Postmenopausal bleeding. |
| 648.20–648.24 | Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium: Anemia. |
| 698.0–698.9 | Pruritis and related conditions. |
| 704.00–704.09 | Alopecia. |
| 709.00–709.09 | Dyschromia. |
| 719.40–719.49 | Pain in joint. |
| 773.2 | Hemolytic disease due to other and unspecified isoimmunization. |
| 773.3 | Hydrops fetalis due to isoimmunization. |
| 773.4 | Kernicterus due to isoimmunization. |
| 773.5 | Late anemia due to isoimmunization. |
| 783.9 | Other symptoms concerning nutrition, metabolism and development. |
| 790.0 | Abnormality of red blood cells. |
| 790.4 | Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase [LDH]. |
| 790.5 | Other nonspecific abnormal serum enzymelevels. |
| 790.6 | Other abnormal blood chemistry. |
| 799.4 | Cachexia. |
| 964.0 | Poisoning by agents primarily affecting blood constituents, iron compounds. |
| 984.0–984.9 | Toxic effect of lead and its compounds (including fumes). |
| 996.85 | Complications of transplanted organ, bone marrow. |
| 999.8 | Other transfusion reaction. |
| V08 | Asymptomatic HIV infection. |
| V12.1 | Personal history of nutritional deficiency. |
| V12.3 | Personal history of diseases of blood and blood forming organs. |
| V15.1 | Personal history of surgery to heart and great vessels. |
| V15.2 | Personal history of surgery to other major organs. |
| V43.2 | Heart replaced by other means. |
| V43.3 | Heart valve replaced by other means. |
| V43.4 | Blood vessel replaced by other means. |

| Code | Description |
|---|---|
| V43.60 | Unspecified joint replaced by other means. |
| V72.84 | Pre-operative examination, unspecified. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied:*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs |
| V16.6 | Family history of malignant neoplasm, leukemia |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment |
| V62.1 | Adverse effects of work environment |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special screening for disorders of blood and blood-forming organs. |
| V79.0–V79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

*Sources of Information*

CDC. Recommendations to prevent and control iron deficiency in the United States. MMWR 1998; 47(RR–3):1–29.

Powell LW, George DK, McDonnell SM, Kowdley KV. Diagnosis of hemochromatosis. Ann.Intern.Med. 1998; 129:925–931.

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Wallach JB. Handbook of Interpretation of Diagnostic Tests. Lippincott-Raven Publishers (Philadelphia) 1998, pp. 170–180.

Van Walraven C, Goel V, Chan B. Effect of Population-Based Interventions on Laboratory Utilization. JAMA. 1998; 280:2028–2033.

Guyatt GH, Patterson C, Ali M, Singer J, Levine M, Turpie I, Meyer R. Diagnosis of Iron-Deficiency Anemia in the Elderly. AmJMed. 1990; 88:205–209.

Burns ER, Goldberg SN, Lawrence C, Wenz B. AJCP. 1990; 3:240–245.

**Burns ER, *et al.* Brief Clinical Observations. AmJMed. 1991; 90:653–654.**

Yang Q, *et al.* Hemochromatosis-associated Mortality in the United States from 1979 to 1992: An Analysis of Multiple-Cause Mortality Data. AnIntMed. 1998; 129:946–953.

*Coding Guidelines:*

1. Any claim for a test listed in AHCPCS CODES@ above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. ICD–9–CM code V82.9 (special screening of other conditions, unspecified condition), or comparable narratives should be used to indicate screening tests performed in the absence of a specific sign, symptom, or complaint. Use of V82.9 or comparable narrative will result in the denial of claims as non covered screening services. (Note: this language may be inappropriate for screening tests that are specifically covered by statute, such as pap smears.) All ICD–9–CM diagnosis codes must be coded to the highest level of specificity.

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit or fifth-digit classifications are provided, they must be assigned. From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Collagen Crosslinks, Any Method*

*Other Names/Abreviations*

*Description*

Collagen crosslinks, part of the matrix of bone upon which bone mineral is deposited, are biochemical markers the excretion of which provide a quantitative measurement of bone resorption. Elevated levels of urinary collagen crosslinks indicate elevated bone resorption. Elevated bone resorption contributes to age-related and postmenopausal loss of bone leading to osteoporosis and increased risk of fracture. The collagen crosslinks assay can be performed by immunoassay or by high performance liquid chromatography (HPLC). Collagen crosslink immunoassays measure the pyridinoline crosslinks and associated telopeptides in urine.

Bone is constantly undergoing a metabolic process called turnover or remodeling. This includes a degradation process, bone resorption, mediated by the action of osteoclasts, and a building process, bone formation, mediated by the action of osteoblasts. Remodeling is required for the maintenance and overall health of bone and is tightly coupled; that is, resorption and formation must be in balance. In abnormal states of bone remodeling, when resorption exceeds formation, it results in a net loss of bone. The measurement of specific, bone-derived resorption products provides analytical data about the rate of bone resorption.

Osteoporosis is a condition characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures of the hip, spine, and wrist. The term primary osteoporosis is applied where the causal factor in the disease is menopause or aging. The term secondary osteoporosis is applied where the causal factor is something other than menopause or aging, such as long-term administration of glucocorticosteroids, endocrine-related disorders (other than loss of estrogen due to menopause), and certain bone diseases such as cancer of the bone.

With respect to quantifying bone resorption, collagen crosslink tests can provide adjunct diagnostic information in concert with bone mass measurements. Bone mass measurements and biochemical markers may have complementary roles to play in assessing effectiveness of osteoporosis treatment. Proper management of osteoporosis patients, who are on long-term therapeutic regimens, may include laboratory testing of biochemical markers of bone turnover, such as collagen crosslinks, that provide a profile of bone turnover responses within weeks of therapy. Changes in collagen crosslinks are determined following commencement of antiresorptive therapy. These can be measured over a shorter time interval, such as three months, when compared to bone mass density. If bone resorption is not elevated, repeat testing is not medically necessary.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82523 ..... | Collagen cross links, any method. |

*Indications*

Generally speaking, collagen crosslink testing is useful mostly in ''fast losers'' of bone. The age when these bone markers can help direct therapy is often pre-Medicare. By the time a fast loser of bone reaches age 65, she will most likely have been stabilized by appropriate therapy or have lost so much bone mass that further testing is useless. Coverage for bone marker assays may be established, however, for younger Medicare beneficiaries and for those who might become fast losers because of some other therapy such as glucocorticoids. Safeguards should be incorporated to prevent excessive use of tests in patients for whom they have no clinical relevance.

Collagen crosslinks testing is used to:

- identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored;
- predict response (as assessed by bone mass measurements) to FDA approved antiresorptive therapy in postmenopausal women;
- assess response to treatment of patients with osteoporosis, Paget's disease of the bone, or risk for osteoporosis where

treatment may include FDA approved antiresorptive agents, anti-estrogens or selective estrogen receptor moderators.

*Limitations*

Because of significant specimen to specimen collagen crosslink physiologic variability (15–20%), current recommendations for appropriate utilization include: one or two base-line assays from specified urine collections on separate days; followed by a repeat assay about three months after starting anti-resorptive therapy; followed by a repeat assay in 12 months after the three-month assay; and thereafter not more than annually, unless there is a change in therapy in which circumstance an additional test may be indicated three months after the initiation of new therapy.

Some collagen crosslink assays may not be appropriate for use in some disorders, according to FDA labeling restrictions.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 203.00–.01 | Multiple myeloma. |
| 242.00–242.91 | Thyrotoxicosis. |
| 245.2 | Chronic lymphocytic thyroiditis (only if thyrotoxic). |
| 246.9 | Unspecified disorder of thyroid. |
| 252.0 | Hyperparathyroidism. |
| 256.2 | Postablative ovarian failure. |
| 256.3 | Other ovarian failure. |
| 256.8 | Other ovarian dysfunction. |
| 256.9 | Unspecified ovarian dysfunction. |
| 268.9 | Unspecified vitamin D deficiency. |
| 269.3 | Mineral deficiency, not elsewhere classified. |
| 627.0 | Premenopausal menorrhagia. |
| 627.1 | Postmenopausal bleeding. |
| 627.2 | Menopausal or female climacteric state. |
| 627.4 | States associated with artificial menopause. |
| 627.8 | Other specified menopausal and postmenopausal disorders. |
| 627.9 | Unspecified menopausal & postmenopausal disorder. |
| 731.0 | Osteitis deformans without mention of bone tumor (Paget's disease of bone). |
| 733.00–733.09 | Osteoporosis |
| 733.10–733.19 | Pathological fracture |
| 733.90 | Disorder of bone and cartilage, unspecified |
| 805.8 | Fracture of vertebral column without mention of spiral cord injury, unspecified, closed |
| V58.69 | Long-term (current) use of other medications. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.
- Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |

| Code | Description |
|---|---|
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections.

*Sources of Information*

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Harper KD, Weber TJ. Secondary osteoporosis—Diagnostic considerations. Endocrinol. Metab.Clin. North Am. 1998;27:325–48.

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Schneider DL, Barrett-Connor EL. Urinary N-Telopeptide levels discriminate normal, osteopenic, and osteoporotic bone mineral density. Arch. Intern. Med. 1997; 157:1241–5.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. When the indication for the test is long-term administration of glucocorticosteroids, use ICD–9–CM code V58.69.

*Medicare National Coverage Decision for Blood Glucose Testing*

*Description*

This policy is intended to apply to blood samples used to determine glucose levels.

Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. The method for assay may be by color comparison of an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82947 | Glucose; quantitative. |
| 82948 | Glucose; blood, reagent strip. |
| 82962 | Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use. |

*Indications*

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110–125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause). Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

*Limitations*

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually.

Depending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary. Repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition. If repeat testing is performed, a specific diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 011.00–011.96 | Tuberculosis. |
| 038.0–038.9 | Septicemia. |
| 112.1 | Recurrent vaginal candidiasis. |
| 112.3 | Interdigital candidiasis. |
| 118 | Opportunistic mycoses. |
| 157.4 | Malignant neoplasm of Islets of Langerhans. |
| 158.0 | Malignant neoplasm of retroperitoneum. |
| 211.7 | Benign neoplasm of Islets of Langerhans. |
| 242.00–242.91 | Thyrotoxicosis. |
| 250.00–250.93 | Diabetes mellitus. |
| 251.0–251.9 | Disorders of pancreatic internal secretion. |
| 253.0–253.9 | Disorders of the pituitary gland. |
| 255.0 | Cushing syndrome. |
| 263.0–263.9 | Malnutrition. |
| 271.0–271.9 | Disorders of carbohydrate transport and metabolism. |
| 272.0–272–4 | Disorders of lipoid metabolism. |
| 275.0 | Hemochromotosis. |
| 276.0–276.9 | Disorders of fluid, electrolyte and acid-base balance. |
| 278.3 | Hypercarotinemia. |
| 293.0 | Acute delirium. |
| 294.9 | Unspecified organic brain syndrome. |
| 298.9 | Unspecified psychosis. |
| 300.9 | Unspecified neurotic disorder. |
| 310.1 | Organic personality syndrome. |
| 337.9 | Autonomic nervous system neuropathy. |
| 345.10–345.11 | Generalized convulsive epilepsy. |
| 348.3 | Encephalopathy, unspecified. |
| 355.9 | Neuropathy, not otherwise specified. |
| 356.9 | Unspecified hereditary and idiopathic peripheral neuropathy. |
| 357.9 | Unspecified inflammatory and toxic neuropathy. |
| 362.10 | Background retinopathy. |
| 362.18 | Retinal vasculitis. |
| 362.29 | Nondiabetic proliferative retinopathy. |
| 362.50–362.57 | Degeneration of macular posterior pole. |
| 362.60–362.66 | Peripherial retinal degeneration. |
| 362–81–362.89 | Other retinal disorders. |
| 362.0 | Unspecified retinal disorders. |
| 365.–04 | Borderline glaucoma. |
| 365.32 | Corticosteriod-induced glaucoma residual. |
| 366.00–366.09 | Presenile cataract. |
| 366.10–366.19 | Senile cataract. |
| 367.1 | Acute myopia. |
| 368.8 | Other specified visual disturbance. |

| Code | Description |
|---|---|
| 373.00 | Blepharitis. |
| 377.24 | Pseudopapilledema. |
| 377.9 | Autonomic nervous system neuropathy. |
| 378.50–378.55 | Paralytic strabiamus. |
| 379.45 | Argyll-Robertson pupils. |
| 410.00–410.92 | Acute myocardial infarctions. |
| 414.00–414.19 | Coronary atherosclerosis and aneurysm of heart. |
| 425.9 | Secondary cardiomyopathy, unspecified. |
| 440.23 | Arteriosclerosis of extremities with ulceration. |
| 440.24 | Arteriosclerosis of extremities with gangrene. |
| 440.9 | Arteriosclerosis, not otherwise specified. |
| 458.0 | Postural hypotension. |
| 462 | Acute pharyngitis. |
| 466.0 | Acute bronchitis. |
| 480.0–486 | Pneumonia. |
| 490 | Recurrent bronchitis, not specified as acute or chronic. |
| 491.0–491.9 | Chronic bronchitis. |
| 527.7 | Disturbance of salivory secretion (drymouth). |
| 528.0 | Stomatitis. |
| 535.50–535.51 | Gastritis. |
| 536.8 | Dyspepsia. |
| 571.8 | Other chronic nonalcoholic liver disease. |
| 572.0–.8 | Liver abscess and sequelae of chronic liver disease. |
| 574.50–574.51 | Choledocholitiasis. |
| 575.0–575.12 | Cholecystitis. |
| 576.1 | Cholangitis. |
| 577.0 | Acute pancreatitis. |
| 577.1 | Chronic pancreatitis. |
| 577.8 | Pancreatic multiple calculi. |
| 590.00–590.9 | Infections of the kidney. |
| 595.9 | Recurrent cystitis. |
| 596.4 | Bladder atony. |
| 596.53 | Bladder paresis. |
| 599.0 | Urinary tract infection, recurrent. |
| 607.84 | Impotence of organic origin. |
| 608.89 | Other disorders male genital organs. |
| 616.10 | Vulvovaginitis. |
| 626.0 | Amenorrhea. |
| 626.4 | Irregular menses. |
| 628.9 | Infertility—female. |
| 648.00 | Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable. |
| 648.03 | Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antipartum condition or complication. |
| 648.04 | Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication. |
| 648.80 | Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable. |
| 648.83 | Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antipartum condition or complication. |
| 648.84 | Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication. |
| 656.60–656.63 | Fetal problems affecting management of mother—large for-date of fetus. |
| 657.00–657.03 | Polyhydramnios. |
| 680.0–680.9 | Carbuncle and furuncle. |
| 686.00–686.9 | Infections of skin and subcutaneous tissue. |
| 698.0 | Pruritis ani. |
| 698.1 | Pruritis of genital organs. |
| 704.1 | Hirsutism. |
| 705.0 | Anhidrosis. |
| 707.0–707.9 | Chronic ulcer of skin. |
| 709.3 | Degenerative skin disorders. |
| 729.1 | Myalgia. |
| 730.07–730.27 | Osteomyelitis of tarsal bones. |
| 780.01 | Coma. |
| 780.02 | Transcient alteration of awareness. |
| 780.09 | Alteration of consciousness, other. |
| 780.2 | Syncope and collapse. |
| 780.39 | Seizures, not otherwise specified. |
| 780.4 | Dizziness and giddiness. |
| 780.71–.79 | Malaise and fatigue. |
| 780.8 | Hyperhidrosis. |
| 782.0 | Loss of vibratory sensation. |
| 783.1 | Abnormal weight gain. |
| 783.2 | Abnormal loss of weight. |
| 783.5 | Polydipsia. |

| Code | Description |
|---|---|
| 785.0 | Tachycardia. |
| 785.4 | Gangrene. |
| 786.01 | Hyperventilation. |
| 786.09 | Dyspnea. |
| 786.50 | Chest pain, unspecified. |
| 787.6 | Fecal incontinence. |
| 787.91 | Diarrhea. |
| 788.41–788.43 | Frequency of urination and polyuria. |
| 789.1 | Hepatomegaly. |
| 790.2 | Abnormal glucose tolerance test. |
| 790.6 | Other abnormal blood chemistry (hyperglycemia). |
| 791.0 | Proteinuria. |
| 791.5 | Glycosuria. |
| 796.1 | Abnormal reflex. |
| 799.4 | Cachexia. |
| V23.0–.9 | Supervision of high risk pregnancy. |
| V67.2 | Follow-up examination, following chemotherapy. |
| V67.51 | Follow up examination with high-risk medication not elsewhere classified. |
| V58.69 | Long term current use of other medication. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9-CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |

| Code | Description |
|---|---|
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD– 9–CM sections above.

*Sources of Information*

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Bower, Bruce F. And Robert E. Moore, Endocrine Function and Carbohydrates.

Clinical Laboratory Medicine, Kenneth D. McClatchy, editor. Baltimore/Williams & Wilkins, 1994. Pp 321–323.

Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, Diabetes Care, Volume 20, Number 7, July 1997, pages 1183 *et seq.*

Roberts, H.J., Difficult Diagnoses. W. B. Saunders Co., pp 69–70.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD–9–CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6—other abnormal blood chemistry. If the provider bases the diagnostic statement of ''impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2—normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

7. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD–9–CM code that best describes the condition is most frequently listed as the reason for the test.

8. When laboratory testing is done solely to monitor response to medication, the most accurate ICD–9–CM code to describe the reason for the test would be V58.69—long term use of medication.

9. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category—follow-up examination.

10. According to ICD–9–CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD–9–CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement, ''thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0–242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD–9–CM must be expanded to include the underlying disease in order to accurately code the condition.

*Documentation Requirements*

The ordering physician must include evidence in the patient's clinical record that an evaluation of history and physical preceded the ordering of glucose testing and that manifestations of abnormal glucose levels were present to warrant the testing.

*Medicare National Coverage Decision for Glycated Hemoglobin/glycated Protein*

*Description*

The management of diabetes mellitus requires regular determinations of blood glucose levels. Glycated hemoglobin/protein levels are used to assess long-term glucose control in diabetes. Alternative names for these tests include glycated or glycosylated hemoglobin or Hgb, hemoglobin glycated or glycosylated protein, and fructosamine.

Glycated hemoglobin (equivalent to hemoglobin A1) refers to total glycosylated hemoglobin present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. Hemoglobin A1c refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis. Fructosamine or glycated protein refers to glycosylated protein present in a serum or plasma sample. Glycated protein refers to measurement of the component of the specific protein that is glycated usually by colorimetric method or affinity chromatography.

Glycated hemoglobin in whole blood assesses glycemic control over a period of 4–8 weeks and appears to be the more appropriate test for monitoring a patient who is capable of maintaining long-term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient's metabolic control has been on average within the target range. More frequent assessments, every 1–2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). Glycated protein in serum/plasma assesses glycemic control over a period of 1–2 weeks. It may be reasonable and necessary to monitor glycated protein monthly in pregnant diabetic women. Glycated hemoglobin/protein test results may

be low, indicating significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the patient's hypoglycemic state in those conditions.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82985 | Glycated protein. |
| 83036 | Hemoglobin; glycated. |

*Indications*

Glycated hemoglobin/protein testing is widely accepted as medically necessary for the management and control of diabetes. It is also valuable to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. Glycated protein testing may be used in place of glycated hemoglobin in the management of diabetic patients, and is particularly useful in patients who have abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

*Limitations*

It is not considered reasonable and necessary to perform glycated hemoglobin tests more often than every three months on a controlled diabetic patient to determine whether the patient's metabolic control has been on average within the target range. It is not considered reasonable and necessary for these tests to be performed more frequently than once a month for diabetic pregnant women. Testing for uncontrolled type one or two diabetes mellitus may require testing more than four times a year. The above Description Section provides the clinical basis for those situations in which testing more frequently than four times per annum is indicated, and medical necessity documentation must support such testing in excess of the above guidelines.

Many methods for the analysis of glycated hemoglobin show significant interference from elevated levels of fetal hemoglobin or by variant hemoglobin molecules. When the glycated hemoglobin assay is initially performed in these patients, the laboratory may inform the ordering physician of a possible analytical interference. Alternative testing, including glycated protein, for example, fructosamine, may be indicated for the monitoring of the degree of glycemic control in this situation. It is therefore conceivable that a patient will have both a glycated hemoglobin and glycated protein ordered on the same day. This should be limited to the initial assay of glycated hemoglobin, with subsequent exclusive use of glycated protein.

These tests are not considered to be medically necessary for the diagnosis of diabetes.

*ICD–9–CM Codes Covered by The Medicare Program*

| Code | Description |
|---|---|
| 211.7 | Benign neoplasm of islets of Langerhans. |
| 250.00–250.93 | Diabetes mellitus & various related codes. |
| 251.0 | Hypoglycemic coma. |
| 251.1 | Other specified hypoglycemia. |
| 251.2 | Hypoglycemia unspecified. |
| 251.3 | Post-surgical hypoinsulinemia. |
| 251.4 | Abnormality of secretion of glucagon. |
| 251.8 | Other specified disorders of pancreatic internal secretion. |
| 251.9 | Unspecified disorder of pancreatic internal secretion. |
| 258.0–.9 | Polyglandular dysfunction. |
| 271.4 | Renal glycosuria. |
| 275.0 | Hemochromatosis. |
| 577.1 | Chronic pancreatitis. |
| 579.3 | Other and unspecified postsurgical nonabsorption. |
| 648.00 | Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable. |
| 648.03 | Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antepartum condition or complication. |
| 648.04 | Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication. |
| 648.80 | Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable. |
| 648.83 | Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antepartum condition or complication. |
| 648.84 | Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication. |
| 790.2 | Abnormal glucose tolerance test. |
| 790.6 | Other abnormal blood chemistry (hyperglycemia.) |
| 962.3 | Poisoning by insulin and antidiabetic agents. |
| V12.2 | Personal history of endocrine, metabolic, and immunity disorders. |
| V58.69 | Long-term use of other medication. |

*Reasons For Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and

necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

*Sources of Information*

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Foster, Daniel W., Diabetes Mellitus, Harrison's Principles of Internal Medicine. 13th ed., Kurt J. Isselbacher *et al.* Editors, New York/McGraw-Hill, 1994, pg. 1990.

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Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, Diabetes Care, Volume 20, Number 7, July 1997, pp. 1183 *et seq.*

Sacks, David B., Carbohydrates. In Tietz Textbook of Clinical Chemistry, 2nd Ed., Carl A. Burtis and Edward R. Ashwood, editors. Philadelphia, W.B. Saunders Co., 1994. pp. 980–988.

Tests of Glycemia in Diabetes, American Diabetes Association, Diabetes Care, Volume 20, Supplement I, January 1997, pp. 518–520.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43)

2. Screening is the testing for disease or disease precursors in seemingly well individuals so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no related sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the

reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52).

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. A diagnostic statement of impaired glucose tolerance must be evaluated in the context of the documentation in the medical record in order to assign the most accurate ICD–9–CM code. An abnormally elevated fasting blood glucose level in the absence of the diagnosis of diabetes is classified to Code 790.6—other abnormal blood chemistry. If the provider bases the diagnostic statement of ''impaired glucose tolerance'' on an abnormal glucose tolerance test, the condition is classified to 790.2—normal glucose tolerance test. Both conditions are considered indications for ordering glycated hemoglobin or glycated protein testing in the absence of the diagnosis of diabetes mellitus.

*Medicare National Coverage Decision For Thyroid Testing*

*Other Names/Abbreviations*

*Description*

Thyroid function studies are used to delineate the presence or absence of hormonal abnormalities of the thyroid and pituitary glands. These abnormalities may be either primary or secondary and often but not always accompany clinically defined signs and symptoms indicative of thyroid dysfunction.

Laboratory evaluation of thyroid function has become more scientifically defined. Tests can be done with increased specificity, thereby reducing the number of tests needed to diagnose and follow treatment of most thyroid disease. Measurements of serum sensitive thyroid-stimulating hormone (TSH) levels, complemented by determination of thyroid hormone levels [free thyroxine (fT–4) or total thyroxine (T4) with Triiodothyronine (T3) uptake] are used for diagnosis and follow-up of patients with thyroid disorders. Additional tests may be necessary to evaluate certain complex diagnostic problems or on hospitalized patients, where many circumstances can skew tests results. When a test for total thyroxine (total T4 or T4 radioimmunoassay) or T3 uptake is performed, calculation of the free thyroxine index (FTI) is useful to correct for abnormal results for either total T4 or T3 uptake due to protein binding effects.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 84436 | Thyroxine; total. |
| 84439 | Thyroxine; free. |
| 84443 | Thyroid stimulating hormone (TSH). |
| 84479 | Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR). |

*Indications*

Thyroid function tests are used to define hyper function, euthyroidism, or hypofunction of thyroid disease. Thyroid testing may be reasonable and necessary to:

- distinguish between primary and secondary hypothyroidism;
- confirm or rule out primary hypothyroidism;
- monitor thyroid hormone levels (for example, patients with goiter, thyroid nodules, or thyroid cancer);
- monitor drug therapy in patients with primary hypothyroidism;
- confirm or rule out primary hyperthyroidism; and
- monitor therapy in patients with hyperthyroidism.

Thyroid function testing may be medically necessary in patients with disease or neoplasm of the thyroid and other endocrine glands. Thyroid function testing may also be medically necessary in patients with metabolic disorders; malnutrition; hyperlipidemia; certain types of anemia; psychosis and non-psychotic personality disorders; unexplained depression; ophthalmologic disorders; various cardiac arrhythmias; disorders of menstruation; skin conditions; myalgias; and a wide array of signs and symptoms, including alterations in consciousness; malaise; hypothermia; symptoms of the nervous and musculoskeletal system; skin and integumentary system; nutrition and metabolism; cardiovascular; and gastrointestinal system.

It may be medically necessary to do follow-up thyroid testing in patients with a personal history of malignant neoplasm of the endocrine system and in patients on long-term thyroid drug therapy.

*Limitations*

Testing may be covered up to two times a year in clinically stable patients; more frequent testing may be reasonable and necessary for patients whose thyroid therapy has been altered or in whom symptoms or signs of hyperthyroidism or hypothyroidism are noted.

*ICD–9–CM Codes Covered by Medicare Program.*

| Code | Description |
|---|---|
| 017.50–017.56 | Tuberculosis of the thyroid gland. |
| 183.0 | Malignant neoplasm of ovary. |
| 193 | Malignant neoplasm of thyroid gland. |
| 194.8 | Malignant neoplasm of other endocrine glands and related structures, other. |
| 198.89 | Secondary malignant neoplasm of the thyroid. |
| 220 | Benign neoplasm of ovary. |
| 226 | Benign neoplasm of thyroid gland. |
| 227.3 | Benign neoplasm of pituitary gland and craniopharyngeal duct. |
| 234.8 | Carcinoma in situ of other and unspecified sites. |
| 237.4 | Neoplasm of uncertain behavior of other and unspecified endocrine glands. |
| 239.7 | Neoplasm of unspecified nature, thyroid gland. |
| 240.0–240.9 | Goiter specified and unspecified. |
| 241.0–241.9 | Nontoxic nodular goiter. |
| 242.00–242.91 | Thyrotoxicosis with or without goiter. |
| 243 | Congenital hypothyroidism. |

| Code | Description |
|---|---|
| 244.0–244.9 | Acquired hypothyroidism. |
| 245.0–245.9 | Thyroiditis. |
| 246.0–246.9 | Other disorders of thyroid. |
| 250.00–250.93 | Diabetes mellitus. |
| 252.1 | Hypoparathyroidism. |
| 253.1 | Other and unspecified anterior pituitary hyper function. |
| 253.2 | Panhypopituitarism. |
| 253.3–253.4 | Pituitary dwarfism. |
| 253.4 | Other anterior pituitary disorders. |
| 253.7 | Iatrogenic pituitary disorders. |
| 255.2 | Adrenogenital disorders. |
| 255.4 | Corticoadrenal insufficiency. |
| 256.3 | Ovarian failure. |
| 257.2 | Testicular hypofunction. |
| 258.0–258.9 | Polyglandular dysfunction. |
| 262 | Malnutrition, severe. |
| 263.0–263.9 | Malnutrition, other and unspecified. |
| 266.0 | Ariboflavinosis. |
| 272.0 | Pure hypercholesterolemia. |
| 272.2 | Mixed hyperlipidemia. |
| 272.4 | Other and unspecified hyperlipidemia. |
| 275.40–275.49 | Calcium disorders. |
| 276.0 | Hyposmolality andor hypernatremia. |
| 276.1 | Hyposmolality andor hyponatremia. |
| 278.3 | Hypercarotinemia. |
| 279.4 | Autoimmune disorder, not classified elsewhere. |
| 281.0 | Pernicious anemia. |
| 281.9 | Unspecified deficiency anemia. |
| 283.0 | Autoimmune hemolytic anemia. |
| 285.9 | Anemia, unspecified. |
| 290.0 | Senile dementia, uncomplicated. |
| 290.10–290.13 | Presenile dementia. |
| 290.20–290.21 | Senile dementia with delusional or depressive features. |
| 293.0–293.1 | Delirium. |
| 293.81–293.89 | Transient organic mental disorders. |
| 294.8 | Other specified organic brain syndromes. |
| 296.00–296.99 | Affective psychoses. |
| 297.0 | Paranoid state, simple. |
| 297.9 | Unspecified paranoid state. |
| 298.3 | Acute paranoid reaction. |
| 300.00–300.09 | Anxiety states. |
| 307.9 | Agitation—other and unspecified special symptoms or syndromes, not elsewhere classified. |
| 310.1 | Organic personality syndrome. |
| 311 | Depressive disorder, not elsewhere classified. |
| 331.0–331.2 | Alzheimer's, pick's disease, Senile degeneration of brain. |
| 333.1 | Essential and other specified forms of tremor. |
| 354.0 | Carpal Tunnel syndrome. |
| 356.9 | Idiopathic peripheral neuropathy, unspecified polyneuropathy. |
| 359.9 | Myopathy, unspecified. |
| 368.2 | Diplopia. |
| 372.71 | Conjunctival hyperemia. |
| 372.73 | Conjunctival edema. |
| 374.41 | Lid retraction or lag. |
| 374.82 | Eyelid edema. |
| 376.30–376.31 | Exophthalmic conditions, unspecified and constant. |
| 376.33–376.34 | Orbital edema or congestion, intermittent exophthalmos. |
| 378.50–378.55 | Paralytic strabismus. |
| 401.0–401.9 | Essential hypertension. |
| 403.00–403.91 | Hypertensive renal disease. |
| 404.00–404.93 | Hypertensive heart and renal disease. |
| 423.9 | Unspecified disease of pericardium. |
| 427.0 | Paroxysmal supraventricular tachycardia. |
| 427.2 | Paroxysmal tachycardia, unspecified. |
| 427.31 | Atrial fibrillation. |
| 427.89 | Other specified cardiac dysrhythmia. |
| 427.9 | Cardiac dysrhythmia, unspecified. |
| 428.0 | Congestive heart failure. |
| 428.1 | Left heart failure. |
| 429.3 | Cardiomegaly. |
| 511.9 | Unspecified pleural effusion. |
| 518.81 | Acute respiratory failure. |
| 529.8 | Other specified conditions of the tongue. |
| 560.1 | Paralytic ileus. |
| 564.0 | Constipation. |

| Code | Description |
|---|---|
| 564.7 | Megacolon, other than Hirschsprung's. |
| 568.82 | Peritoneal effusion (chronic). |
| 625.3 | Dysmenorrhea. |
| 626.0–626.2 | Disorders of menstruation. |
| 626.4 | Irregular menstrual cycle. |
| 648.10–648.14 | Other current conditions in the mother, classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium, thyroid dysfunction. |
| 676.20–676.24 | Engorgement of breast associated with childbirth and disorders of lactation. |
| 698.9 | Unspecified pruritic disorder. |
| 701.1 | Keratoderma, acquired (dry skin). |
| 703.8 | Other specified diseases of nail (Brittle nails). |
| 704.00–704.09 | Alopecia. |
| 709.01 | Vitiligo. |
| 710.0–710.9 | Diffuse disease of connective tissue. |
| 728.2 | Muscle wasting. |
| 728.9 | Unspecified disorder of muscle, ligament, and fascia. |
| 729.1 | Myalgia and myositis, unspecified. |
| 729.82 | Musculoskeletal cramp. |
| 730.30–.39 | Periostitis without osteomyelitis. |
| 733.09 | Osteoporosis, drug induced. |
| 750.15 | Macroglossia, congenital. |
| 759.2 | Anomaly of other endocrine glands. |
| 780.01 | Coma. |
| 780.02 | Transient alteration of awareness. |
| 780.09 | Alteration of consciousness, other. |
| 780.50–780.52 | Insomnia. |
| 780.6 | Fever. |
| 780.71–.79 | Malaise and fatigue. |
| 780.8 | Hyperhidrosis. |
| 780.9 | Other general symptoms (hyperthermia). |
| 781.0 | Abnormal involuntary movements. |
| 781.3 | Lack of coordination, ataxia. |
| 782.0 | Disturbance of skin sensation. |
| 782.3 | Localized edema. |
| 782.8 | Changes in skin texture. |
| 782.9 | Other symptoms involving skin and integumentary tissues. |
| 783.1 | Abnormal weight gain. |
| 783.2 | Abnormal lost of weight. |
| 783.6 | Polyphagia. |
| 784.1 | Throat pain. |
| 784.49 | Voice disturbance. |
| 784.5 | Other speech disturbance. |
| 785.0 | Tachycardia, unspecified. |
| 785.1 | Palpitations. |
| 785.9 | Other symptoms involving cardiovascular system. |
| 786.09 | Other symptoms involving respiratory system. |
| 786.1 | Stridor. |
| 787.2 | Dysphagia. |
| 787.91–787.99 | Other symptoms involving digestive system. |
| 789.5 | Ascites. |
| 793.9 | Nonspecific abnormal findings on radiological and other examination, other (neck). |
| 794.5 | Thyroid, abnormal scan or uptake. |
| 796.1 | Other nonspecific abnormal findings, abnormal reflex. |
| 799.2 | Nervousness. |
| 990 | Effects of radiation, unspecified. |
| V10.87 | Personal history of malignant neoplasm of the thyroid. |
| V10.88 | Personal history of malignant neoplasm of other endocrine gland. |
| V12.2 | Personal history of endocrine, metabolic and immunity disorders. |
| V58.69 | Long term (current) use of other medications. |
| V67.0–V67.9 | Follow-up examination. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

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*ICD–9–CM Codes Denied:*

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| V62.1 | Adverse effects of work environment. |
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| V79.0–V.79.9 | Special screening for mental disorders. |
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| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

AACE Clinical Practice Guidelines for the Diagnosis and Management of Thyroid Nodules, Endocrine Practice (1996) 2:1, pp. 78–84.

AACE Clinical Practice Guidelines for the Evaluation and Treatment of Hyperthyroidism and Hypothyroidism, Endocrine Practice (1995) 1:1, pp. 54–62.

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Larsen PR, Ingbar SH. The Thyroid Gland. In: Wilson JD, Foster DW, eds. Williams Textbook of Endocrinology. 9th ed. Philadelphia, Pa: WB Saunders Co; 1992:357–487.

The Merck Manual, 16th Edition, pp. 1072–1081.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a

screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. When a patient is under treatment for a condition for which the tests in this policy are applicable, the ICD–9–CM code that best describes the condition is most frequently listed as the reason for the test.

7. When laboratory testing is done solely to monitor response to medication, the most accurate ICD–9–CM code to describe the reason for the test would be V58.69—long term use of medication.

8. Periodic follow-up for encounters for laboratory testing for a patient with a prior history of a disease, who is no longer under treatment for the condition, would be coded with an appropriate code from the V67 category—follow-up examination.

9. According to ICD–9–CM coding conventions, codes that appear in italics in the Alphabetic and/or Tabular columns of ICD–9–CM are considered manifestation codes that require the underlying condition to be coded and sequenced ahead of the manifestation. For example, the diagnostic statement ''thyrotoxic exophthalmos (376.21),'' which appears in italics in the tabular listing, requires that the thyroid disorder (242.0–242.9) is coded and sequenced ahead of thyrotoxic exophthalmos. Therefore, a diagnostic statement that is listed as a manifestation in ICD–9–CM must be expanded to include the underlying disease in order to accurately code the condition.

10. Use code 728.9 to report muscle weakness as the indication for the test. Other diagnoses included in 728.9 do not support medical necessity.

11. Use code 194.8 (Malignant neoplasm of other endocrine glands and related structures, Other) to report multiple endocrine neoplasia syndromes (MEN–1 and MEN–2). Other diagnoses included in 194.8 do not support medical necessity.

*Documentation Requirements*

When these tests are billed at a greater frequency than the norm (two per year), the ordering physician's documentation must support the medical necessity of this frequency.

*Medicare National Coverage Decision for Lipids*

*Other Names/Abbreviations*

*Description*

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise, genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease (including diabetes), and kidney disease.

In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoprotein cholesterol (LDL–C) and high density lipoprotein cholesterol (HDL–C), are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Blood levels of the above cholesterol components including triglyceride have been separated into desirable, borderline and high risk categories by the National Heart, Lung and Blood Institute in their report in 1993. These categories form a useful basis for evaluation and treatment of patients with hyperlipidemia (See Reference). Therapy to reduce these risk parameters includes diet, exercise and medication, and fat weight loss, which is particularly powerful when combined with diet or exercise.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 80061 | Lipid panel. |
| 82465 | Cholesterol, serum, total. |
| 83715 | Lipoprotein, blood; electrophoretic separation and quantitation. |
| 83716 | Lipoprotein, blood: high resolution fractionation and quantitation of lipoprotein cholesterols (for example, electrophoretic, nuclear magnetic resonance, ultracentrifugation). |
| 83718 | Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol). |
| 83721 | Lipoprotein, direct measurement, LDL cholesterol. |
| 84478 | Triglycerides. |

*Indications*

The medical community recognizes lipid testing as appropriate for evaluating atherosclerotic cardiovascular disease. Conditions in which lipid testing may be indicated include:

- assessment of patients with atherosclerotic cardiovascular disease;
- evaluation of primary dyslipidemias;
- any form of atherosclerotic disease;
- diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism;
- secondary dyslipidemias, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure; and
- signs or symptoms of dyslipidemias, such as skin lesions.
- as follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200–240 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol <35 mg/dl.

To monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for the treatment of elevated blood lipid disorders, total cholesterol, HDL cholesterol and LDL cholesterol may be used. Triglycerides may be obtained if this lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.

When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total

cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD–9–CM code 272.1, Pure hyperglyceridemia).

Any one component of the panel or a measured LDL may be reasonable and necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

Electrophoretic or other quantitation of lipoproteins (CPT codes 83715 and 83716) may be indicated if the patient has a primary disorder of lipoid metabolism (ICD–9–CM codes 272.0 to 272.9).

*Limitations*

Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid estretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis.

Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc.

Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it is reasonable to perform the lipid panel annually. A lipid panel (CPT code 80061) at a yearly interval will usually be adequate while measurement of the serum total cholesterol (CPT code 82465) or a measured LDL (CPT code 83721) should suffice for interim visits if the patient does not have hypertriglyceridemia (for example, ICD–9–CM code 272.1, Pure hyperglyceridemia).

Any one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

If no dietary or pharmacological therapy is advised, monitoring is not necessary.

When evaluating non-specific chronic abnormalities of the liver (for example, elevations of transaminase, alkaline phosphatase, abnormal imaging studies, *etc.*), a lipid panel would generally not be indicated more than twice per year.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 242.00–245.9 | Disorders of the thyroid gland with hormonal dysfunction. |
| 250.00–.93 | Diabetes mellitus. |
| 255.0 | Cushing's syndrome. |
| 260 | Kwashiorkor. |
| 261 | Nutritional marasmus. |
| 262 | Other severe, protein-calorie malnutrition. |
| 263.0 | Malnutrition of moderate degree. |
| 263.1 | Malnutrition of mild degree. |
| 263.8 | Other protein-calorie malnutrition. |
| 263.9 | Unspecified protein-calorie malnutrition. |
| 270.0 | Disturbances of amino-acid transport. |
| 271.1 | Galactosemia. |
| 272.0 | Pure hypercholesterolemia. |
| 272.1 | Hyperglyceridemia. |
| 272.2 | Mixed hyperlipidemia (tuberous xanthoma). |
| 272.3 | Hyperchylomicronemia. |
| 272.4 | Other and unspecified hyperlipidemia (unspecified xanthoma). |
| 272.5 | Lipoprotein deficiencies. |
| 272.6 | Lipodystrophy. |
| 272.7 | Lipidoses. |
| 272.8 | Other disorders of lipoid metabolism. |
| 272.9 | Unspecified disorders of lipoid metabolism. |
| 277.3 | Amyloidosis. |
| 278.01 | Morbid obesity. |
| 303.90–303.92 | Alcoholism. |
| 362.10–362.16 | Other background retinopathy and retinal vascular change. |
| 362.30–362.34 | Retinal vascular occlusion. |
| 362.82 | Retinal exudates and deposits. |
| 371.41 | Corneal arcus, juvenile. |
| 374.51 | Xanthelasma. |
| 379.22 | Crystalline deposits in vitreous. |
| 388.00 | Degenerative & vascular disorder of ear, unspecified. |
| 388.02 | Transient ischemic deafness. |
| 410.00–410.92 | Acute myocardial infarction. |
| 411.0–411.1 | Other acute & subacute forms of ischemic heart disease. |
| 411.81 | Coronary occlusion without myocardial infarction. |
| 411.89 | Other acute and subacute ischemic heart disease. |
| 412 | Old myocardial infarction. |
| 413.0–413.1 | Angina pectoris. |
| 413.9 | Other and unspecified angina pectoris. |
| 414.00–414.03 | Coronary atherosclerosis. |
| 414.04 | Coronary athrscl-artery bypass graft. |
| 414.05 | Coronary athrscl-unspec graft. |
| 414.10 | Aneurysm, heart (wall). |
| 414.11 | Coronary vessel aneurysm. |

| Code | Description |
|---|---|
| 414.19 | Other aneurysm of heart. |
| 414.8 | Other specified forms of chronic ischemic heart disease. |
| 414.9 | Chronic ischemic heart disease, unspecified. |
| 428.0–428.9 | Heart failure. |
| 429.2 | Arteriosclerotic cardiovascular disease. |
| 429.9 | Heart disease NOS. |
| 431 | Intracerebral hemorrhage. |
| 433.00-.91 | Occlusion & stenosis of precerebral arteries. |
| 434.00-.91 | Occlusion of cerebral arteries. |
| 435.0-.9 | Transient cerebral ischemia. |
| 437.0 | Other & ill-defined cerebrovascular disease. |
| 437.1 | Other generalized ischemic cerebrovascular disease. |
| 437.5 | Moyamoya disease. |
| 438.0-.9 | Late effects of cerebrovascular disease. |
| 440.0–440.9 | Arteriosclerosis. |
| 441.00–441.9 | Aortic aneurysms. |
| 442.0 | Upper extremity aneurysm. |
| 442.1 | Renal artery aneurysm. |
| 442.2 | Iliac artery aneurysm. |
| 444.0-.9 | Arterial embolism & thrombosis. |
| 557.1 | Chronic vascular insufficiency of intestine. |
| 571.8 | Other chronic non-alcoholic liver disease. |
| 571.9 | Unspecified chronic liver disease without mention of alcohol. |
| 573.8 | Other specified disorders of liver. |
| 573.9 | Unspecified disorders of liver. |
| 577.0–577.9 | Pancreatic disease. |
| 579.3 | Other & unspecified postsurgical nonabsorption. |
| 579.8 | Other specified intestinal malabsorption. |
| 581.0–581.9 | Nephrotic syndrome. |
| 584.5 | Acute renal failure with lesion of tubular necrosis. |
| 585 | Chronic renal failure. |
| 588.0 | Renal osteodystrophy. |
| 588.1 | Nephrogenic diabetes insipidus. |
| 588.8 | Other specified disorders resulting from impaired renal function. |
| 588.9 | Unspecified disorder resulting from impaired renal function. |
| 607.84 | Impotence of organic origin, penis disorder. |
| 646.70–646.71 | Liver disorders in pregnancy. |
| 646.73 | Liver disorder antepartum. |
| 648.10–648.14 | Thyroid disfunction in pregnancy and the puerperium. |
| 6.0 | Psoriatic arthropathy. |
| 696.1 | Other psoriasis. |
| 751.61 | Biliary atresia. |
| 764.10–764.19 | ''Light for dates'' with signs of fetal malnutrition. |
| 786.50 | Chest pain unspecified. |
| 786.51 | Precordial pain. |
| 786.59 | Chest pain, other. |
| 789.1 | Hepatomegaly. |
| 790.4 | Abnormal transaminase. |
| 790.5 | Abnormal alkaline phosphatase. |
| 790.6 | Other abnormal blood chemistry. |
| 793.4 | Abnormal imaging study. |
| 987.9 | Toxic effect of unspecified gas or vapor. |
| 996.81 | Complication of transplanted organ, kidney, failure. |
| V42.0 | Transplanted organ, kidney. |
| V58.69 | Long term (current) use of other medications. |

*Reasons For Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.]

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating

nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

American Diabetes Association. Management of Dyslipidemia in Adults with Diabetes. J. Florida M.A. 1998, 85:2 30–34.

Jialal, I. Evolving lipoprotein risk factors: lipoprotein (a) and oxidizing low-density lipoprotein. Clin Chem 1998; 44:8(B) 1827–1832.

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National Institutes of Health. Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. NIH Publication 93–3095. September 1993.

Bierman EL. Atherosclerosis and other forms of arteriosclerosis. Harrison's Principles of Internal Medicine. Eds. Isselbacher KJ, Braunwald E, Wilson JD, *et al.* McGraw-Hill. New York. 1994; 2058–2069.

Brown MS and Goldstein JL. The hyperlipoproteinemias and other disorders of lipid metabolism. Harrison's Principles of Internal Medicine. Eds. Isselbacher KJ, Braunwald E, Wilson JD, *et al.* McGraw-Hill. New York. 1994; 1106–1116.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9-CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Digoxin Therapeutic Drug Assay*

*Other Names/Abbreviations*

*Description*

A digoxin therapeutic drug assay is useful for diagnosis and prevention of digoxin toxicity, and/or prevention for under dosage of digoxin.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 80162 | Digoxin (Therapeutic Drug Assay) |

*Indications*

Digoxin levels may be performed to monitor drug levels of individuals receiving digoxin therapy because the margin of safety between side effects and toxicity is narrow or because the blood level may not be high enough to achieve the desired clinical effect.

Clinical indications may include individuals on digoxin:

- With symptoms, signs or electrocardiogram (ECG) suggestive of digoxin toxicity;
- Taking medications that influence absorption, bioavailability, distribution, and/or elimination of digoxin;
- With impaired renal, hepatic, gastrointestinal, or thyroid function;
- With pH and/or electrolyte abnormalities;
- With unstable cardiovascular status, including myocarditis;
- Requiring monitoring of patient compliance.

Clinical indications may include individuals:

- Suspected of accidental or intended overdose; or
- Who have an acceptable cardiac diagnosis (as listed) and for whom an accurate history of use of digoxin is unobtainable

The value of obtaining regular serum digoxin levels is uncertain, but it may be reasonable to check levels once yearly after a steady state is achieved. In addition, it may be reasonable to check the level if:

- Heart failure status worsens;
- Renal function deteriorates;
- Additional medications are added that could affect the digoxin level; or
- Signs or symptoms of toxicity develop.

Steady state will be reached in approximately 1 week in patients with normal renal function, although 2–3 weeks may be needed in patients with renal impairment. After changes in dosages or the addition of a medication that could affect the digoxin level, it is reasonable to check the digoxin level one week after the change or addition. Based on the clinical situation, in cases of digoxin toxicity, testing may need to be done more than once a week.

Digoxin is indicated for the treatment of patients with heart failure due to systolic dysfunction and for reduction of the ventricular response in patients with atrial fibrillation or flutter. Digoxin may also be indicated for the treatment of other supraventricular arrhythmias, particularly in the presence of heart failure.

*Limitations*

This test is not appropriate for patients on digitoxin or treated with digoxin FAB (fragment antigen binding) antibody.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 242.00–242.91 | Thyrotoxicosis with or without goiter. |
| 243 | Congenital hypothyroidism. |
| 244.0–244.9 | Acquired hypothyroidism. |
| 245.0–245.9 | Thyroiditis. |
| 275.2 | Disorders of magnesium metabolism. |
| 275.40–.49 | Disorders of calcium metabolism. |
| 276.0 | Hyperosmolality. |
| 276.1 | Hyposmolality. |
| 276.2 | Acidosis. |
| 276.3 | Alkalosis. |
| 276.4 | Mixed acid-base balance disorder. |
| 276.5 | Volume depletion. |
| 276.6 | Fluid overload. |
| 276.7 | Hyperpotassemia. |
| 276.8 | Hypopotassemia. |
| 276.9 | Electrolyte and fluid disorder (not elsewhere classified). |
| 293.0 | Acute delirium. |
| 293.1 | Subacute delirium. |
| 307.47 | Other dysfunctions of sleep stages or arousal from sleep. |
| 368.16 | Psychophysical visual disturbances. |
| 368.8 | Other specified visual disturbances. |
| 368.9 | Unspecified visual disturbances. |
| 397.9 | Rheumatic diseases of endocardium. |
| 398.0 | Rheumatic myocarditis. |
| 398.91 | Rheumatic heart Failure. |
| 402.01 | Hypertensive heart disease, malignant with CHF. |
| 402.11 | Hypertensive heart disease, benign with CHF. |
| 402.91 | Hypertensive heart disease, unspecified with CHF. |
| 403.00–403.91 | Hypertensive renal disease. |
| 404.00–404.93 | Hypertensive heart & renal disease. |
| 410.00–410.92 | Acute myocardial infarction. |
| 411.0–411.89 | Other acute & subacute forms of ischemic heart disease. |
| 413.0–413.9 | Angina pectoris. |

| Code | Description |
|---|---|
| 422.0–422.99 | Acute myocarditis. |
| 425.0–425.9 | Cardiomyopathy. |
| 426.0–426.9 | Conduction disorders. |
| 427.0–427.9 | Cardiac dysrhythmias. |
| 428.0–428.9 | Heart failure. |
| 429.4 | Heart disturbances postcardiac surgery. |
| 429.5 | Rupture chordae tendinae. |
| 429.6 | Rupture papillary muscle. |
| 429.71 | Acquired cardiac septal defect. |
| 514 | Pulmonary congestion & hypostasis. |
| 579.9 | Unspecified intestinal malabsorption. |
| 584.5–584.9 | Acute renal failure. |
| 585 | Chronic renal failure. |
| 586 | Renal failure, unspecified. |
| 587 | Renal sclerosis, unspecified. |
| 588.0 | Renal osteodystrophy. |
| 588.1 | Nephrogenic Diabetes Insipidus. |
| 588.8 | Impaired renal function (not elsewhere classified). |
| 588.9 | Unspecified disorder resulting from impaired renal function. |
| 780.01 | Coma. |
| 780.02 | Transient alteration of awareness. |
| 780.09 | Other ill-defined general symptoms (drowsiness, semicoma, somnolence, stupor, unconsciousness). |
| 780.1 | Hallucinations. |
| 780.2 | Syncope & collapse. |
| 780.4 | Dizziness and giddiness. |
| 780.71–.79 | Malaise & fatigue. |
| 783.0 | Anorexia. |
| 784.0 | Headache. |
| 787.01–787.03 | Nausea & vomiting. |
| 787.91 | Diarrhea. |
| 794.31 | Abnormal electrocardiogram. |
| 799.2 | Nervousness. |
| 972.1 | Poisoning by cardiotonic glycosides & drugs of similar action. |
| 995.2 | Unspecified adverse effect of drug, medicinal and biological substance. |
| *E942.1 | Adverse effect of cardiotonic glycosides and drugs of similar action. |
| V58.69 | Encounter long term—medication use (not elsewhere classified). |

*Code may not be reported as a stand-alone or first-listed code on the claim.

*Reasons For Denial*

**Note:** Note: This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.
- Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |

| Code | Description |
|---|---|
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

*Sources of Information*

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Konstam M, Dracup K, Baker D, *et al.* Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction. Clinical Practice Guideline No. 11. AHCPR Publication No. 94–0612. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. June 1994.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9-CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9-CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9-CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Alpha-fetoprotein*

*Other Names/Abbreviations:* Afp.

*Description*

Alpha-fetoprotein (AFP) is a polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82105 | Alpha-fetoprotein; serum. |

*Indications*

AFP is useful for the diagnosis of hepatocellular carcinoma in high-risk patients (such as alcoholic cirrhosis, cirrhosis of viral etiology, hemochromatosis, and alpha $_1$-antitrypsin deficiency) and in separating patients with benign hepatocellular neoplasms or metastases from those with hepatocellular carcinoma and, as a non-specific tumor associated antigen, serves in marking germ cell neoplasms of the testis, ovary, retro peritoneum, and mediastinum.

*Limitations*

*ICD–9–09CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 070.22–070.23 | Chronic viral hepatitis B with hepatic coma, with or without mention of hepatitis delta |
| 070.32–070.33 | Chronic viral hepatitis B without mention of hepatic coma, with or without mention of hepatitis delta |
| 070.44 | Chronic hepatitis C with hepatic coma |
| 070.54 | Chronic hepatitis C without mention of hepatic coma |
| 095.3 | Syphilis of liver |
| 121.1 | Clonorchiasis |
| 121.3 | Fascioliasis |
| 155.0–155.2 | Malignant neoplasm of the liver and intrahepatic bile ducts |
| 164.2–164.9 | Malignant neoplasm of the mediastinum |
| 183.0 | Malignant neoplasm, ovary |
| 186.0 | Malignant neoplasm of undescended testis |
| 186.9 | Malignant neoplasm, other and unspecific testis |
| 197.1 | Secondary malignant neoplasm of mediastinum |
| 197.7 | Secondary malignant neoplasm of liver |
| 198.6 | Secondary malignant neoplasm of ovary |
| 198.82 | Secondary malignant neoplasm, genital organs |
| 211.5 | Benign neoplasm of liver and biliary passages |
| 235.3 | Neoplasm of uncertain behavior of liver and biliary passages |
| 272.2 | Mixed hyperlipidemia |
| 275.0 | Disorder of iron metabolites |
| 275.1 | Disorder of copper metabolism |
| 277.00 | Cystic Fibrosis without mention of meconium ileus |
| 277.6 | Other deficiencies of circulating enzymes |
| 285.0 | Sideroblastic Anemia |
| 571.2 | Alcoholic cirrhosis of liver |
| 571.40 | Chronic hepatitis, unspecified |
| 571.41 | Chronic persistent hepatitis |
| 571.49 | Other chronic hepatitis |
| 571.5 | Cirrhosis of liver without mention of alcohol |
| 608.89 | Other specified disorders of male genital organs |
| 793.1 | Non-specific abnormal findings of lung field |
| 793.2 | Non-specific abnormal findings of other intrathoracic organs |
| 793.3 | Non-specific abnormal findings of biliary tract |
| 793.6 | Non-specific abnormal findings of abdominal area, including retro peritoneum |
| V10.07 | Personal history of malignant neoplasm, liver |
| V10.43 | Personal history of malignant neoplasm, ovary |
| V10.47 | Personal history of malignant neoplasm, testis |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.
- Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE

devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995).

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–099–09CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

*Sources of Information*

Tatsuta M. Yamamura H. Iishi H. Kasugai H. Okuda S.Value of serum alpha-fetoprotein and ferritin in the diagnosis of hepatocellular carcinoma. Oncology. 43(5):306–10, 1986.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition described by that code must be related to the above indications for the test.

*Medicare National Coverage Decision for Carcinoembryonic Antigen*

*Other Names/Abbreviations*: CEA.

*Description*

Carcinoembryonic antigen (CEA) is a protein polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82378 | Carcinoembryonic antigen (CEA). |

*Indications*

CEA may be medically necessary for follow-up of patients with colorectal carcinoma. It would however only be medically necessary at treatment decision-making points. In some clinical situations (*e.g.* adenocarcinoma of the lung, small cell carcinoma of the lung, and some gastrointestinal carcinomas) when a more specific marker is not expressed by the tumor, CEA may be a medically necessary alternative marker for monitoring. Preoperative CEA may also be helpful in determining the post-operative adequacy of surgical resection and subsequent medical management. In general, a single tumor marker will suffice in following patients with colorectal carcinoma or other malignancies that express such tumor markers.

In following patients who have had treatment for colorectal carcinoma, ASCO guideline suggests that if resection of liver metastasis would be indicated, it is recommended that post-operative CEA testing be performed every two to three months in patients with initial stage II or stage III disease for at least two years after diagnosis.

For patients with metastatic solid tumors which express CEA, CEA may be measured at the start of the treatment and with subsequent treatment cycles to assess the tumor's response to therapy.

*Limitations*

Serum CEA determinations are generally not indicated more frequently than once per chemotherapy treatment cycle for patients with metastatic solid tumors which express CEA or every two months post-surgical treatment for patients who have had colorectal carcinoma. However, it may be proper to order the test more frequently in certain situations, for example, when there has been a significant change from prior CEA level or a significant change in patient status which could reflect disease progression or recurrence.

Testing with a diagnosis of an in situ carcinoma is not reasonably done more frequently than once, unless the result is abnormal, in which case the test may be repeated once.

*ICD–9–09–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 150.0–150.9 | Malignant neoplasm of the esophagus. |
| 151.0–151.9 | Malignant neoplasm of stomach. |
| 152.0–154.8 | Malignant neoplasm of small intestine, including duodenum, rectum, rectosigmoid junction and anus. |
| 157.0–157.9 | Primary malignancy of pancreas. |
| 159.0 | Malignant neoplasm of intestinal tract, part unspecified. |
| 162.0–162.9 | Malignant neoplasm of trachea, bronchus, lung. |
| 174.0–174.9 | Malignant neoplasm of female breast. |
| 175.0–175.9 | Malignant neoplasm of male breast. |
| 183.0 | Malignant neoplasm of ovary. |
| 197.0 | Secondary malignant neoplasm of neoplasm of lung. |
| 197.4 | Secondary malignant neoplasm of small intestine. |
| 197.5 | Secondary malignant neoplasm of large intestine and rectum. |
| 230.3 | Carcinoma in situ of colon. |
| 230.4 | Carcinoma in situ of rectum. |
| 230.7 | Carcinoma in situ of other/unspecified parts of intestine. |
| 230.9 | Carcinoma in situ other and unspecified digestive organs. |
| 235.2 | Neoplasm of uncertain behavior of stomach, intestines, rectum. |
| 790.99 | Other nonspecific findings on examination of blood. |
| V10.00 | Personal history of malignant neoplasm of gastro-intestinal tract, unspecified. |
| V10.3 | Personal history of malignant neoplasm, breast. |
| V10.05 | Personal history of malignant neoplasm, large intestine. |
| V10.06 | Personal history of malignant neoplasm, rectum, rectosigmoid junction, anus. |
| V10.11 | Personal history of malignant neoplasm, bronchus, and lung. |
| V10.43 | Personal history of malignant neoplasm, ovary. |
| V67.2 | Follow-up examination following chemotherapy. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.
- Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device

Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995).

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 S | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

*Sources of Information*

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Grem J. The prognostic importance of tumor markers in adenocarcinomas of the gastrointestinal tract. [Review] [38 refs] Current Opinion in Oncology. 9(4):380–7, 1997 Jul.

Bergamaschi R. Arnaud JP. Routine compared with nonscheduled follow-up of patients with ''curative'' surgery for colorectal cancer. Annals of Surgical Oncology. 3(5):464–9, 1996 Sep.

Kim YH. Ajani JA. Ota DM. Lynch P. Roth JA. Value of serial carcinoembryonic antigen levels in patients with resectable adenocarcinoma of the esophagus and stomach Cancer. 75(2):451–6, 1995 Jan 15.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

6. To show elevated CEA, use ICD–9–CM 790.99 (Other nonspecific findings on examination of blood) only if a more specific diagnosis has not been made. If a more specific diagnosis has been made, use the code for that diagnosis.

*Medicare National Coverage Decision for Human Chorionic Gonadotropin*

*Other Names/Abbreviations:* hCG.

*Description*

Human chorionic gonadotropin

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 84702 | Gonodotropin, chorionic (hCG); quantitative. |

*Indications*

hCG is useful for monitoring and diagnosis of germ cell neoplasms of the ovary, testis, mediastinum, retroperitoneum, and central nervous system. In addition, it is useful for diagnosis of pregnancy and pregnancy-associated conditions.

*Limitations*

Not more than once per month for diagnostic purposes. As needed for monitoring of patient progress and treatment. Qualitative hCG assays (CPT 84703) are not appropriate for medically managing patients with known or suspected germ cell neoplasms.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 158.0 | Malignant neoplasm of retroperitoneum. |
| 158.8 | Malignant neoplasm of specified parts of peritoneum. |
| 164.2 | Malignant neoplasm of anterior mediastinum. |
| 164.3 | Malignant neoplasm of posterior mediastinum. |
| 164.8 | Malignant neoplasm, other (includes malignant neoplasm of contiguous overlapping sites of thymus, heart, and mediastinum whose point of origin cannot be determined. |
| 164.9 | Malignant neoplasm of mediastinum, part unspecified. |
| 181 | Malignant neoplasm of placenta. |
| 183.0 | Malignant neoplasm of ovary. |
| 183.8 | Other specified sites of uterine adnexas. |
| 186.0 | Malignant neoplasm of undescended testes. |
| 186.9 | Malignant neoplasm of other and unspecified testis. |
| 194.4 | Malignant neoplasm of pineal gland. |
| 197.1 | Secondary malignant neoplasm of mediastinum. |
| 197.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum. |
| 198.6 | Secondary malignant neoplasm of ovary. |
| 198.82 | Secondary malignant neoplasm of other genital organs. |
| 236.1 | Neoplasm of uncertain behavior, placenta. |
| 623.8 | Vaginal bleeding. |
| 625.9 | Pelvic pain. |
| 630 | Hydatidiform mole. |
| 631 | Pregnancy, molar. |
| 632 | Missed abortion. |
| 633.9 | Ectopic pregnancy. |
| 640.00– | Threatened abortion. |
| V10.09 | Personal history of malignant neoplasm, other gastrointestinal sites. |
| V10.29 | Personal history of malignant neoplasm of other respiratory and intrathoracic organs. |
| V10.43 | Personal history of malignant neoplasm, ovary. |
| V10.47 | Personal history of malignant neoplasm, testis. |
| V22.0–.1 | Pregnancy. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.
- Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied:*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

O'Callaghan A. Mead GM. Testicular carcinoma. [Review] [23 Refs] Postgraduate Medical Journal. 73(862):4816, 1997 Aug.

Sawamura Y. Current diagnosis and treatment of central nervous system germ cell tumours. [Review] [47 Refs] Current Opinion in Neurology. 9(6):41923, 1996 Dec.

Wilkins M. Horwich A. Diagnosis and treatment of urological malignancy: The testes. [Review] [23 Refs] British Journal of Hospital Medicine. 55(4): 199203, 1996. Feb 21, Mar 5.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45).

5. When a nonspecific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Tumor Antigen by Immunoassay—CA125*

*Other Names/Abbreviations*

*Description*

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses tumor antigen CA125.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| Not yet assigned | Tumor antigen 125. |

*Indications*

CA125 is a high molecular weight serum tumor marker elevated in 80% of patients who present with epithelial ovarian carcinoma. It is also elevated in carcinomas of the fallopian tube, endometrium, and endocervix. An elevated level may also be associated with the presence of a malignant mesothelioma.

A CA125 level may be obtained as part of the initial pre-operative work-up for women presenting with a suspicious pelvic mass to be used as a baseline for purposes of post-operative monitoring. Initial declines in CA125 after initial surgery and/or chemotherapy for ovarian carcinoma are also measured by obtaining three serum levels during the first month post treatment to determine the patient's CA125 half-life, which has significant prognostic implications.

CA125 levels are again obtained at the completion of chemotherapy as an index of residual disease. Surveillance CA125 measurements are generally obtained every 3 months for 2 years, every 6 months for the next 3 years, and yearly thereafter. CA125 levels are also an important indicator of a patient's response to therapy in the presence of advanced or recurrent disease. In this setting, CA125 levels may be obtained prior to each treatment cycle.

*Limitations*

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

CA125 is specifically not covered for aiding in the differential diagnosis of patients with a pelvic mass as the sensitivity and specificity of the test is not sufficient. In general, a single ''tumor marker'' will suffice in following a patient with one of these malignancies.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 180.0 | Malignant neoplasm, endocervix. |
| 182.0 | Malignant neoplasm of corpus uteri, except isthmus. |
| 183.0 | Malignant neoplasm,ovary. |
| 183.2 | Malignant neoplasm, fallopian tube. |
| 183.8 | Malignant neoplasm, other specified sites of uterine adnexa. |
| 184.8 | Malignant neoplasm, other specified sites of female genital organs. |
| 198.6 | Secondary malignant neoplasm, ovary. |
| 198.82 | Secondary malignancy of genital organs. |
| 236.0–236.3 | Neoplasm of uncertain behavior of female genital organs. |
| V10.43–V10.44 | Personal history of malignant neoplasm of female genital organs. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.
- Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |

| Code | Description |
|---|---|
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Chan DW, Beveridge RA, Muss H, *et al.* Use of Triquant BR Radioimmunoassay for Early Detection of Breast Cancer Recurrence in Patients with Stage II and Stage III Disease. J Clin Oncol 1977, 15(6):2322–2328.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

*Documentation Requirements*

Indicated if service request for CA125 is requested more frequently than stipulated.

*Medicare National Coverage Decision for Tumor Antigen by Immunoassay CA15–3/CA27.29*

*Other Names/Abbreviations*

*Description*

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses the following tumor antigens: CA15–3 and CA27.29

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| Not yet assigned | Tumor antigen CA15–3/CA27.29. |

*Indications*

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists postsurgical therapy.

CA 15–3 is often medically necessary to aid in the management of patients with breast cancer. Serial testing must be used in conjunction with other clinical methods for monitoring breast cancer. For monitoring, if medically necessary, use consistently either CA 15–3 or CA 27.29, not both.

CA 27.29 is equivalent to CA 15–3 in its usage in management of patients with breast cancer.

*Limitations*

These services are not covered for the evaluation of patients with signs or

symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 174.0–174.9 | Breast, primary (female)—malignant neoplasm of female breast. |
| 175.0–175.9 | Breast, primary (male)—malignant neoplasm of male breast |
| 198.2 | Secondary malignant neoplasm (male breast). |
| 198.81 | Secondary malignant neoplasm (female breast). |
| V10.3 | Personal history of malignant neoplasm, breast. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

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• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemi. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Chan DW, Beveridge RA, Muss H, *et al.* Use of Triquant BR Radioimmunoassay for Early Detection of Breast Cancer Recurrence in Patients with Stage II and Stage III Disease. J Clin Oncol 1977, 15(6):2322–2328.

Bone GG, von Mensdorff-Pouilly S, Kenemans P, van Kamp GJ, *et al.* Clinical and Technical Evaluation of ACS BR Serum Assay of MUC–1 Gene Derived Glycoprotein in Breast Cancer, and Compared with CA15–3 Assays. Clin Chem 1997, 43(4):585–593.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Tumor Antigen by Immunoassay CA19–9*

*Other Names/Abbreviations*

*Description*

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This policy specifically addresses the following tumor antigen: CA19–9.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| Not yet assigned ..... | Tumor antigen CA19–9. |

*Indications*

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy.

Levels are useful in following the course of patients with established diagnosis of pancreatic and biliary ductal carcinoma. The test is not indicated for diagnosing these two diseases.

*Limitations*

These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 155.1 ..... | Malignant neoplasm, intrahepatic bile ducts. |
| 156.1 ..... | Malignant neoplasm, extrahepatic bile ducts. |
| 156.8 ..... | Malignant neoplasm, other specified sites of gallbladder and extrahepatic bile ducts. |
| 156.9 ..... | Malignant neoplasm, unspecified part of biliary tract. |
| 157.0–157.9 ..... | Malignant neoplasm, pancreas. |
| 197.8 ..... | Secondary malignant neoplasm, other digestive organs and spleen. |
| 235.3 ..... | Neoplasm of uncertain behavior, liver and biliary passages. |
| 235.5 ..... | Neoplasm of uncertain behavior, other and unspecified digestive organs. |
| V10.09 ..... | Other personal history of cancer. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that

exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

Clinical Pancreatic Guideline for the Use of Tumor Markers in Breast and Colorectal Cancer, American Society of Clinical Oncology. J Clin Oncol 14:2843–2877, 1996.

Richter JM, Christensen MR, Rustgi AK, and Silverstein MD. The Clinical Utility of the CA19–9 Radioimmunoassay for the Diagnosis of Pancreatic Cancer Presenting as Pain or Weight Loss: A Cost Effective Analysis. Arch Intern Med 1989, 149:2292–2297.

Safi F, SchlosseW, Falkenreck S, *et al.* Prognostic Value of CA 19–9 Serum Course in Pancreatic Cancer. Hepaetogastroenterology 1998 Jan–Feb; 45(19):253–9.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs,

symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Prostate Specific Antigen*

*Other Names/Abbreviations:* Total PSA.

*Description*

PSA, a tumor marker for adenocarcinoma of the prostate, can predict residual tumor in the post-operative phase of prostate cancer. Three to six months after radical prostatectomy, PSA is reported to provide a sensitive indicator of persistent disease. Six months following introduction of antiandrogen therapy, PSA is reported as capable of distinguishing patients with favorable response from those in whom limited response is anticipated.

PSA when used in conjunction with other prostate cancer tests, such as digital rectal examination, may assist in the decision making process for diagnosing prostate cancer. PSA also, serves as a marker in following the progress of most prostate tumors once a diagnosis has been established. This test is also an aid in the management of prostate cancer patients and in detecting metastatic or persistent disease in patients following treatment.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 84153 | Prostate Specific Antigen (PSA), total |

*Indications*

PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms (*e.g.,* hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and incontinence) as well as with patients with palpably abnormal prostate glands on physician exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder. PSA is also a marker used to follow the progress of prostate cancer once a diagnosis has been established, such as in detecting metastatic or persistent disease in patients who may require additional treatment. PSA testing may also be useful in the differential diagnosis of men presenting with as yet undiagnosed disseminated metastatic disease.

*Limitations*

Generally, for patients with lower urinary tract signs or symptoms, the test is performed only once per year unless there is a change in the patient's medical condition.

Testing with a diagnosis of in situ carcinoma is not reasonably done more frequently than once, unless the result is abnormal, in which case the test may be repeated once.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 185 | Malignant neoplasm of prostate. |
| 188.5 | Malignant neoplasm of bladder neck. |
| 196.5 | Secondary malignant neoplasm, lymph nodes inguinal region and lower limb. |
| 196.6 | Secondary malignant neoplasm, intrapelvic lymph nodes. |
| 196.8 | Secondary malignant neoplasm, lymph nodes of multiple sites. |
| 198.5 | Secondary malignant neoplasm, bone and bone marrow. |
| 198.82 | Secondary malignant neoplasm, genital organs. |
| 233.4 | Carcinoma in situ, prostate. |
| 239.5 | Neoplasm of unspecified nature, other genitourinary organs. |
| 596.0 | Bladder neck obstruction. |
| 599.7 | Hematuria. |
| 601.9 | Unspecified prostatitis. |
| 602.9 | Unspecified disorder of prostate. |
| 788.20 | Retention of urine, unspecified. |
| 788.21 | Incomplete bladder emptying. |
| 790.93 | Elevated prostate specific antigen. |
| 793.6/793.7 | Non-specific abnormal result of radiologic examination, evidence of malignancy. |
| 794.9 | Bone scan evidence of malignancy. |
| V10.46 | Personal history of malignant neoplasm; prostate. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
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- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
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has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
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| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
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| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

Laboratory Test Handbook, 3rd edition, pp. 338–340.

Cooner WH, Mosley BR, Rutherford CL, *et al*. Prostate Cancer Detection in a Clinical Urological Practice by Ultrasonography, Digital Rectal Examination and Prostate Specific Antigen. J.Urol.1990;143: 1146–1154.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom or condition must be related to the indications for the test above.

6. To show elevated PSA, use ICD–9–CM code 790.93 (Elevated prostate specific antigen). If a more specific diagnosis code has been made, use the code for that diagnosis.

*Medicare National Coverage Decision for Gamma Glutamyl Transferase*

Other Names/Abbreviations: GGT.

*Description*

Gamma glutamyltransferase (GGT) is an intracellular enzyme that appears in blood following leakage from cells. Renal tubules, liver, and pancreas contain high amounts, although the measurement of GGT in serum is almost always used for assessment of

hepatobiliary function. Unlike other enzymes which are found in heart, skeletal muscle, and intestinal mucosa as well as liver, the appearance of an elevated level of GGT in serum is almost always the result of liver disease or injury. It is specifically useful to differentiate elevated alkaline phosphatase levels when the source of the alkaline phosphatase increase (bone, liver, or placenta) is unclear. The combination of high alkaline phosphatase and a normal GGT does not, however, rule out liver disease completely.

As well as being a very specific marker of hepatobiliary function, GGT is also a very sensitive marker for hepatocellular damage. Abnormal concentrations typically appear before elevations of other liver enzymes or bilirubin are evident. Obstruction of the biliary tract, viral infection (e.g., hepatitis, mononucleosis), metastatic cancer, exposure to hepatotoxins (e.g., organic solvents, drugs, alcohol), and use of drugs that induce microsomal enzymes in the liver (e.g., cimetidine, barbiturates, phenytoin, and carbamazepine) all can cause a moderate to marked increase in GGT serum concentration. In addition, some drugs can cause or exacerbate liver dysfunction (e.g., atorvastatin, troglitazone, and others as noted in FDA Contraindications and Warnings.)

GGT is useful for diagnosis of liver disease or injury, exclusion of hepatobiliary involvement related to other diseases, and patient management during the resolution of existing disease or following injury.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82977 | Glutamyltransferase, gamma (GGT). |

*Indications*

1. To provide information about known or suspected hepatobiliary disease, for example:
   a. following chronic alcohol or drug ingestion;
   b. following exposure to hepatotoxins;
   c. when using medication known to have a potential for causing liver toxicity (e.g., following the drug manufacturer's recommendations); or
   d. following infection (e.g., viral hepatitis and other specific infections such as amebiasis, tuberculosis, psittacosis, and similar infections)
2. To assess liver injury/function following diagnosis of primary or secondary malignant neoplasms
3. To assess liver injury/function in a wide variety of disorders and diseases known to cause liver involvement (e.g., diabetes mellitus, malnutrition, disorders of iron and mineral metabolism, sarcoidosis, amyloidosis, lupus, and hypertension)
4. To assess liver function related to gastrointestinal disease
5. To assess liver function related to pancreatic disease
6. To assess liver function in patients subsequent to liver transplantation
7. To differentiate between the different sources of elevated alkaline phosphatase activity

*Limitations*

When used to assess liver dysfunction secondary to existing non-hepatobiliary disease with no change in signs, symptoms, or treatment, it is generally not necessary to repeat a GGT determination after a normal result has been obtained unless new indications are present.

If the GGT is the only ''liver'' enzyme abnormally high, it is generally not necessary to pursue further evaluation for liver disease for this specific indication.

When used to determine if other abnormal enzyme tests reflect liver abnormality rather than other tissue, it generally is not necessary to repeat a GGT more than one time per week.

Because of the extreme sensitivity of GGT as a marker for cytochrome oxidase induction or cell membrane permeability, it is generally not useful in monitoring patients with known liver disease.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 003.1 | Salmonella septicemia. |
| 006.0–.9 | Amebiasis. |
| 014.00–.86 | Tuberculosis of intestines, peritoneum, and mesenteric glands. |
| 017.90–.96 | Tuberculosis of other specified organs. |
| 018.90–.96 | Miliary tuberculosis, unspecified. |
| 020.0–.9 | Plague. |
| 022.3 | Anthrax septicemia. |
| 027.0 | Listeriosis. |
| 027.1 | Erysipelothrix infection. |
| 030.1 | Tuberculoid leprosy [Type T]. |
| 032.83 | Diphtheritic peritonitis. |
| 036.1 | Meningococcal encephalitis. |
| 036.2 | Meningococcemia. |
| 038.0–.9 | Septicemia. |
| 039.2 | Actinomycotic infections, abdominal. |
| 040.0 | Gas gangrene. |
| 042 | Human immunodeficiency virus (HIV) disease. |
| 054.0 | Eczema herpeticum. |
| 054.5 | Herpetic septicemia. |
| 060.0–.1 | Yellow fever. |
| 070.0–.9 | Viral hepatitis. |
| 072.71 | Mumps hepatitis. |
| 073.0 | Ornithosis, with pneumonia. |
| 074.8 | Other specified diseases due to Coxsackie virus. |
| 075 | Infectious mononucleosis. |
| 078.5 | Cytomegaloviral disease. |
| 079.99 | Unspecified viral infection. |
| 082.0–.9 | Tick-borne rickettsioses, stet. |
| 084.9 | Other pernicious complications of malaria. |
| 086.1 | Chagas disease with organ involvement other than heart. |
| 088.81 | Lyme disease. |
| 091.62 | Secondary syphilitic hepatitis. |
| 095.3 | Syphilis of liver. |
| 100.0 | Leptospirosis icterohemorrhagica. |

| Code | Description |
|---|---|
| 112.5 | Candidiasis, disseminated. |
| 115.00 | Infection by Histoplasma capsulatum without mention of manifestation. |
| 120.9 | Schistosomiasis, unspecified. |
| 121.1 | Clonorchiasis. |
| 121.3 | Fascioliasis. |
| 122.0 | Echinococcus granulosus infection of liver. |
| 122.5 | Echinococcus multilocularis infection of liver. |
| 122.8 | Echinococcosis, unspecified, of liver. |
| 122.9 | Echinococcus, other and unspecified. |
| 130.5 | Hepatitis due to toxoplasmosis. |
| 135 | Sarcoidosis. |
| 150.0–159.9 | Malignant neoplasm of digestive organs and peritoneum. |
| 160.0–165.9 | Malignant neoplasm of respiratory and intrathoracic organs. |
| 170.0–176.9 | Malignant neoplasm of bone, connective tissue, skin, and breast. |
| 179–189.9 | Malignant neoplasm of genitourinary organs. |
| 200.00–208.91 | Malignant neoplasm of lymphatic and hematopoietic tissue. |
| 211.5 | Benign neoplasm of liver and biliary passages. |
| 211.6 | Benign neoplasm of pancreas, except islets of Langerhans. |
| 211.7 | Benign neoplasm of islets of Langerhans. |
| 228.04 | Hemangioma of intra-abdominal structures. |
| 230.8 | Carcinoma in situ of liver and biliary system. |
| 235.0–238.9 | Neoplasms of uncertain behavior. |
| 239.0 | Neoplasm of unspecified nature of digestive system. |
| 250.00–.93 | Diabetes mellitus. |
| 252.0 | Hyperparathyroidism. |
| 263.1 | Malnutrition of mild degree. |
| 263.9 | Unspecified protein-calorie malnutrition. |
| 268.0 | Rickets, active. |
| 268.2 | Osteomalacia, unspecified. |
| 269.0 | Deficiency of vitamin K. |
| 270.2 | Other disturbances of aromatic amino acid metabolism. |
| 270.9 | Unspecified disorder of amino acid metabolism. |
| 271.0 | Glycogenosis. |
| 272.0 | Pure hypercholesterolemia. |
| 272.1 | Pure hyperglyceridemia. |
| 272.2 | Mixed hyperlipidemia. |
| 272.4 | Other and unspecified hyperlipidemia. |
| 272.7 | Lipidoses. |
| 272.9 | Unspecified disorder of lipoid metabolism. |
| 275.0 | Disorders of iron metabolism. |
| 275.1 | Disorders of copper metabolism. |
| 275.3 | Disorders of phosphorus metabolism. |
| 275.40–.49 | Disorders of calcium metabolism. |
| 277.1 | Disorders of porphyrin metabolism. |
| 277.3 | Amyloidosis. |
| 277.4 | Disorders of bilirubin excretion. |
| 277.6 | Other deficiencies of circulating enzymes. |
| 282.60–.69 | Sickle cell anemia. |
| 286.6 | Defibrination syndrome. |
| 286.7 | Acquired coagulation factor deficiency. |
| 289.4 | Hypersplenism. |
| 291.0–.9 | Alcoholic psychoses. |
| 303.00–.03 | Acute alcoholic intoxication. |
| 303.90–.93 | Other and unspecified alcohol dependence. |
| 304.0–.9 | Drug dependence. |
| 305.00–.93 | Non-dependent abuse of drugs. |
| 357.5 | Alcoholic polyneuropathy. |
| 359.2 | Myotonic disorders. |
| 452 | Portal vein thrombosis. |
| 453.0–.9 | Other vein embolism and thrombosis. |
| 456.0–.21 | Esophageal varices. |
| 555.0–.9 | Regional enteritis. |
| 556.0–.9 | Ulcerative colitis. |
| 557.0 | Acute vascular insufficiency of intestine. |
| 558.1–.9 | Other noninfectious gastroenteritis and colitis. |
| 560.0–.9 | Intestinal obstruction without mention of hernia. |
| 562.01 | Diverticulitis of small intestine (without mention of hemorrhage). |
| 562.03 | Diverticulitis of small intestine with hemorrhage. |
| 562.11 | Diverticulitis of colon (without mention of hemorrhage). |
| 562.13 | Diverticulitis of colon with hemorrhage. |
| 567.0–.9 | Peritonitis. |
| 569.83 | Perforation of intestine. |
| 570 | Acute and subacute necrosis of liver. |
| 571.0–.9 | Chronic liver disease and cirrhosis. |

| Code | Description |
|---|---|
| 572.0–.8 | Liver abscess and sequelae of chronic liver disease. |
| 573.0–.9 | Other disorders of liver. |
| 574.00–.91 | Cholelithiasis. |
| 575.0–.9 | Other disorders of gallbladder. |
| 576.0–.9 | Other disorders of biliary tract. |
| 581.0–.9 | Nephrotic syndrome. |
| 582.0–.9 | Chronic glomerulonephritis. |
| 583.0–.9 | Nephritis and nephropathy not specified as acute or chronic. |
| 584.5–.9 | Acute renal failure. |
| 585 | Chronic renal failure. |
| 586 | Renal failure, unspecified. |
| 587 | Renal sclerosis, unspecified. |
| 588.0–.9 | Disorders resulting from impaired renal function |
| 590.00–.9 | Infections of kidney. |
| 646.7 | Liver disorders in pregnancy. |
| 960.0–979.9 | Poisoning by drugs, medicinal, and biological substances. |
| 980.0–989.89 | Toxic effects of substances chiefly nonmedical as to source. |
| V58.61–.69 | Long term (current) drug use. |
| V67.1 | Follow-up examination, radiotherapy. |
| V67.2 | Follow-up examination, chemotherapy. |
| V67.51 | Follow-up examination after completed treatment with high-risk medications, not elsewhere classified. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |

| Code | Description |
|---|---|
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above.

*Sources of Information*

Ockner, R.K., ''Clinical approach to liver disease,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 808–809.

Ockner, R.K., ''Laboratory tests in liver disease,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 814–817.

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*Illustrated Guide to Diagnostic Tests* (2nd ed.), 1997, Springhouse Corporation.

*Sleisenger and Fordtrans's Gastrointestinal and Liver Disease* (6th ed.), 1997, W.B. Saunders.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52.)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Hepatitis Panel*

*Description*

This panel consists of the following tests:

Hepatitis B surface antigen (HBsAg) (CPT 87340).

Hepatitis C antibody (CPT 86803).

Hepatitis B core antibody (HBcAb), IgM Antibody (CPT 86705).

Hepatitis A antibody (HAAb), IgM Antibody (CPT 86709).

Hepatitis is an inflammation of the liver resulting from viruses, drugs, toxins, and other etiologies. Viral hepatitis can be due to one of at least five different viruses, designated Hepatitis A, B, C, D, and E. Most cases are caused by Hepatitis A virus (HAV), Hepatitis B virus (HBV), or Hepatitis C virus (HCV).

HAV is the most common cause of hepatitis in children and adolescents in the United States. Prior exposure is indicated by a positive IgG anti-HAV. Acute HAV is diagnosed by IgM anti-HAV, which typically appears within four weeks of exposure, and which disappears within three months of its appearance. IgG anti-HAV is similar in the timing of its appearance, but it persists indefinitely. Its detection indicates prior effective immunization or recovery from infection. Although HAV is spread most commonly by fecal-oral exposure, parenteral infection is possible during the acute viremia stage of the disease. After exposure, standard immune globulin may be effective as a prophylaxis.

HBV produces three separate antigens (surface, core, and e (envelope) antigens) when it infects the liver, although only hepatitis B surface antigen (HBsAg) is included as part of this panel. Following exposure, the body normally responds by producing antibodies to each of these antigens; one of which is included in this panel: Hepatitis B surface antibody (HBsAb)-IgM antibody , HBsAg is the earlier marker, appearing in serum four to eight weeks after exposure, and typically disappearing within six months after its appearance. If HBsAg remains detectable for greater than six months, this indicates chronic HBV infection. HBcAb, in the form of both IgG and IgM antibodies, are next to appear in serum, typically becoming detectable two to three months following exposure. The IgM antibody gradually declines or disappears entirely one to two years following exposure, but the IgG usually remains detectable for life. Because HBsAg is present for a relatively short period and usually displays a low titer, a negative result does not exclude an HBV diagnosis. HBcAb, on the other hand, rises to a much higher titer and remains elevated for a longer period of time, but a positive result is not diagnostic of acute disease, since it may be the result of a prior infection. The last

marker to appear in the course of a typical infection is HBsAb, which appears in serum four to six months following exposure, remains positive indefinitely, and confers immunity. HBV is spread exclusively by exposure to infected blood or body fluids; in the U.S., sexual transmission accounts for 30% to 60% of new cases of HBV infection.

The diagnosis of acute HBV infection is best established by documentation of a positive IgM antibody against the core antigen (HBcAb-IgM) and by identification of a positive hepatitis B surface antigen (HBsAg). The diagnosis of chronic HBV infection is established primarily by identifying a positive hepatitis B surface antigen (HBsAg) and demonstrating positive IgG antibody directed against the core antigen (HBcAb-IgG). Additional tests such as Hepatitis B e antigen (HBeAg) and Hepatitis B e antibody (HBeAb), the envelope antigen and antibody, are not included in the Hepatitis Panel, but may be of importance in assessing the infectivity of patients with HBV. Following completion of a HBV vaccination series, HBsAb alone may be used monthly for up to six months, or until a positive result is obtained, to verify an adequate antibody response.

HCV is the most common cause of post-transfusion hepatitis; overall HCV is responsible for 15% to 20% of all cases of acute hepatitis, and is the most common cause of chronic liver disease. The test most commonly used to identify HCV measures HCV antibodies, which appear in blood two to four months after infection. False positive HCV results can occur. For example, a patient with a recent yeast infection may produce a false positive anti-HCV result. For this reason, at present positive results usually are confirmed by a more specific technique. Like HBV, HCV is spread exclusively through exposure to infected blood or body fluids.

This panel of tests is used for differential diagnosis in a patient with symptoms of liver disease of injury. When the time of exposure or the stage of the disease is not known, a patient with continued symptoms of liver disease despite a completely negative Hepatitis Panel may need a repeat panel approximately two weeks to two months later to exclude the possibility of hepatitis. Once a diagnosis is established, specific tests can be used to monitor the course of the disease.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 80059 | Hepatitis Panel. |

*Indications*

1. To detect viral hepatitis infection when there are abnormal liver function test results, with or without signs or symptoms of hepatitis.

2. Prior to and subsequent to liver transplantation.

*Limitations*

After a hepatitis diagnosis has been established, only individual tests, rather than the entire panel, are needed.

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 070.0–.9 | Viral hepatitis. |
| 456.0–.21 | Esophageal varices with or without mention of bleeding. |
| 570 | Acute and subacute necrosis of liver. |
| 571.5 | Cirrhosis of liver without mention of alcohol. |
| 572.0–.8 | Liver abscess and sequelae of chronic liver disease. |
| 573.3 | Hepatitis, unspecified. |
| 780.31 | Febrile convulsions. |
| 780.71 | Chronic fatigue syndrome. |
| 780.79 | Other malaise and fatigue. |
| 782.4 | Jaundice, unspecified, not of newborn. |
| 783.0–.6 | Symptoms concerning nutrition, metabolism, and development. |
| 784.69 | Other symbolic dysfunction. |
| 787.01–.03 | Nausea and vomiting. |
| 789.00–.09 | Abdominal pain. |
| 789.1 | Hepatomegaly. |
| 789.6 | Localized abdominal tenderness (RUQ). |
| 794.8 | Nonspecific abnormal results of function studies, liver. |
| 999.3 | Other infection following infusion, injection, trans fusion, or vaccination. |
| 996.82 | Complications of transplanted organ, liver. |
| V72.85 | Liver transplant recipient evaluation. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.
- Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.
- A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.
- If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the laboratory performing the test to have the appropriate Clinical

Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms, (sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9-CM code not listed in either of the ICD–9-CM sections above

*Sources of Information*

Ockner, R.K., ''Approaches to the diagnosis of jaundice,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 817–818.

Ockner, R.K., ''Acute viral hepatitis,'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 818–826.

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Wallach, J., *Interpretation of Diagnostic Tests,* 1996, Little Brown and Co.

*Illustrated Guide to Diagnostic Tests* (2nd ed.), 1997, Springhouse Corporation.

*Sleisenger and Fordtrans's Gastrointestinal and Liver Disease* (6th ed.), 1997, W.B. Saunders.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9-CM diagnosis code or comparable narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are

provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

*Medicare National Coverage Decision for Fecal Occult Blood*

*Description*

The fecal occult blood test detects the presence of trace amounts of blood in stool. The procedure is performed by testing one or several small samples of one, two or three different stool specimens.

This test may be performed with or without evidence of iron deficiency anemia, which may be related to gastrointestinal blood loss. The range of causes for blood loss include inflammatory causes, including acid-peptic disease, non-steroidal anti-inflammatory drug use, hiatal hernia, Crohn's disease, ulcerative colitis, gastroenteritis, and colon ulcers. It is also seen with infectious causes, including hookworm, stronglyoidal ascariasis, tuberculosis, and enteroamebiasis. Vascular causes include angiodysplasia, hemangiomas, varices, blue rubber bleb nevus syndrome, and watermelon stomach. Tumors and neoplastic causes include lymphoma, leiomyosarcoma, lipomas, adenocarcinoma and primary and secondary metastases to the GI tract. Drugs such as nonsteroidal anti-inflammatory drugs also cause bleeding. There are extra gastrointestinal causes such as hemoptysis, epistaxis, and oropharyngeal bleeding. Artifactual causes include hematuria, and menstrual bleeding. In addition, there may be other causes such as coagulopathies, gastrostomy tubes or other appliances, factitial causes, and long distance running.

Three basic types of fecal hemoglobin assays exist, each directed at a different component of the hemoglobin molecule.

(1) Immunoassays recognize antigenic sites on the globin portion and are least affected by diet or proximal gut bleeding, but the antigen may be destroyed by fecal flora.

(2) The heme-porphyrin assay measures heme-derived porphyrin and is least influenced by enterocolic metabolism or fecal storage. This assay does not discriminate dietary from endogenous heme. The capacity to detect proximal gut bleeding reduces its specificity for colorectal cancer screening but makes it more useful for evaluating overall GI bleeding in case finding for iron deficiency anemia.

(3) The guaiac-based test is the most widely used. It requires the peroxidase activity of an intact heme moiety to be reactive. Positivity rates fall with storage. Fecal hydration such as adding a drop of water increases the test reactivity but also increases false positivity.

Of these three tests, the guaiac-based test is the most sensitive for detecting lower bowel bleeding. Because of this sensitivity, it is advisable, when it is used for screening, to defer the guaiac-based test if other studies of the colon are performed prior to the test. Similarly, this test's sensitivity may result in a false positive if the patient has recently ingested meat. Both of these cautions are appropriate when the test is used for screening, but when appropriate indications are present, the test should be done despite its limitations.

*HCPCS Codes* (Alpha numeric, CPT © AMA):

| Code | Descriptor |
|---|---|
| 82270 | Blood, occult; feces, 1–3 simultaneous determinations. |

*Indications*

1. To evaluate known or suspected alimentary tract conditions that might cause bleeding into the intestinal tract.

2. To evaluate unexpected anemia.

3. To evaluate abnormal signs, symptoms, or complaints that might be associated with loss of blood.

4. To evaluate patient complaints of black or red-tinged stools.

*Limitations*

1. Code 82270 is reported once for the testing of up to three separate specimens (comprising either one or two tests per specimen).

2. In patients who are taking non-steroidal anti-inflammatory drugs and have a history of gastrointestinal bleeding but no other signs, symptoms, or complaints associated with gastrointestinal blood loss, testing for occult blood may generally be appropriate no more than once every three months.

3. When testing is done for the purpose of screening for colorectal cancer in the absence of signs, symptoms, conditions, or complaints associated with gastrointestinal blood loss, HCPCS code G0107 (Colorectal cancer screening; fecal-occult blood test, 1–3 simultaneous determinations) should be used. Coverage of colorectal cancer screening is described in HCFA Program Memorandum Transmittal No. AB–97–24 (November, 1997).

*ICD–9–CM Codes Covered by Medicare Program*

| Code | Description |
|---|---|
| 004.0–.9 | Shigellosis. |
| 005.0–.9 | Other food poisoning (bacterial). |
| 006.0–.9 | Amebiasis. |
| 007.0–.9 | Other protozoal intestinal diseases. |
| 008.41–.49 | Intestinal infections due to other specified bacteria. |
| 009.0–.3 | Ill defined intestinal infections. |
| 014.00–.86 | Tuberculosis of intestines, peritoneum, and mesenteric glands. |
| 022.2 | Gastrointestinal anthrax. |
| 040.2 | Whipple's disease. |
| 123.0–.9 | Other cestode infection. |
| 124 | Trichinosis. |
| 127.0–.9 | Other intestinal helminthiases. |
| 150.0–157.9 | Malignant neoplasm of digestive organisms. |
| 176.3 | Kaposi's sarcoma, gastrointestinal sites. |
| 197.4–.5 | Secondary malignant neoplasm of intestines. |
| 197.8 | Secondary malignant neoplasm of other digestive organs and spleen. |
| 199.0 | Disseminated malignant neoplasm. |
| 204.00–.91 | Lymphoid leukemia. |
| 205.00–208.91 | Leukemia. |
| 211.0–.9 | Benign neoplasm of other parts of digestive system. |
| 228.04 | Hemangioma of intra-abdominal structures. |
| 230.2–.9 | Carcinoma in situ of digestive organs. |

| Code | Description |
|---|---|
| 235.2 | Neoplasm of uncertain behavior of stomach, intestines, and rectum. |
| 235.5 | Neoplasm of uncertain behavior of other and unspecified digestive organs. |
| 239.0 | Neoplasm of unspecified nature, digestive system. |
| 280.0–.9 | Iron deficiency anemias. |
| 285.0–.9 | Other and unspecified anemias. |
| 286.0–.9 | Coagulation defects. |
| 287.0–.9 | Purpura and other hemorrhagic conditions. |
| 448.0 | Hereditary hemorrhagic telangiectasia. |
| 455.0–.8 | Hemorrhoids. |
| 456.0–.21 | Esophageal varices with or without mention of bleeding. |
| 530.10–535.61 | Diseases of the esophagus, stomach, and duodenum. |
| 536.2 | Persistent vomiting. |
| 536.8–.9 | Dyspepsia and other specified and unspecified functional disorders of the stomach. |
| 537.0–.4 | Other disorders of stomach and duodenum. |
| 537.82–.83 | Angiodysplasia of stomach and duodenum. |
| 537.89 | Other specified disorders of stomach and duodenum. |
| 555.0–558.9 | Non-infectious enteritis and colitis. |
| 560.0–.39 | Intestinal obstruction/impaction without mention of hernia. |
| 562.10–.13 | Diverticulosis/diverticulitis of colon. |
| 564.0–.9 | Functional digestive disorders, not elsewhere classified. |
| 565.0–.1 | Anal fissure and fistula. |
| 569.0 | Anal and rectal polyp. |
| 569.1 | Rectal prolapse. |
| 569.3 | Hemorrhage of rectum and anus. |
| 569.41–.49 | Other specified disorders of rectum and anus. |
| 569.84–.85 | Angiodysplasia of intestine with or wihout mention of hemorrhage. |
| 571.0–.9 | Chronic liver disease and cirrhosis. |
| 577.0 | Acute pancreatitis. |
| 577.0–.9 | Diseases of the pancreas. |
| 578.0–.9 | Gastrointestinal hemorrhage. |
| 579.0 | Celiac disease. |
| 579.8 | Other specified intestinal malabsorption. |
| 617.5 | Endometriosis of intestine. |
| 780.71 | Chronic fatigue syndrome. |
| 780.79 | Other malaise and fatigue. |
| 783.0 | Anorexia. |
| 783.2 | Abnormal loss of weight. |
| 787.01–.03 | Nausea and vomiting. |
| 787.1 | Heartburn. |
| 787.2 | Dysphagia. |
| 787.7 | Abnormal feces. |
| 787.91 | Diarrhea. |
| 787.99 | Other symptoms involving digestive system. |
| 789.00–.09 | Abdominal pain. |
| 789.30–.39 | Abdominal or pelvic swelling, mass, or lump. |
| 789.40–.49 | Abdominal rigidity. |
| 789.5 | Ascites. |
| 789.60–.69 | Abdominal tenderness. |
| 790.92 | Abnormal coagulation profile. |
| 792.1 | Nonspecific abnormal findings in stool contents. |
| 793.6 | Nonspecific abnormal findings on radiological and other examination, abdominal area, including retroperitoneum. |
| 794.8 | Nonspecific abnormal results of function studies, liver. |
| 863.0–.90 | Injury to gastrointestinal tract. |
| 864.00–.09 | Injury to liver without mention of open wound into cavity. |
| 864.11–.19 | Injury to liver with open wound into cavity. |
| 866.00–.03 | Injury to kidney without mention of open wound into cavity. |
| 866.10–.13 | Injury to kidney with open wound into cavity. |
| 902.0 –.9 | Injury to blood vessels of abdomen and pelvis. |
| 926.11–.19 | Crushing injury of trunk, other specified sites. |
| 926.8 | Crushing injury of trunk, multiple sites. |
| 926.9 | Crushing injury of trunk, unspecified site. |
| 964.2 | Poisoning by agents primarily affecting blood constituents, anticoagulants. |
| 995.2 | Unspecified adverse effect of drug, medicinal, and biological substance. |
| V10.00–.09 | Personal history of malignant neoplasm, gastrointestinal tract. |
| V12.00 | Personal history of unspecified infectious and parasitic disease. |
| V12.72 | Personal history of colonic polyps. |
| V58.61 | Long term (current) use of anticoagulants. |
| V58.69 | Long term (current) use of other medications. |
| V67.51 | Following treatment with high risk medication, not elsewhere specified. |

*Reasons for Denial*

**Note:** This section was not negotiated by the Negotiated Rulemaking Committee. This section includes HCFA's interpretation of its longstanding policies and is included for informational purposes.

• Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute. These include exams required by insurance companies, business establishments, government agencies, or other third parties.

• Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered according to the statute.

• Failure to provide documentation of the medical necessity of tests may result in denial of claims. Such documentation may include notes documenting relevant signs, symptoms or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office may result in denial.

• A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it is submitted without an ICD–9–CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

• If a national or local policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

• Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

• Failure of the laboratory performing the test to have the appropriate Clinical Laboratory Improvement Act of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

• Tests that require an FDA approval or clearance will be denied as not reasonable and necessary if FDA approval or clearance has not been obtained, except for those having a Category B Investigational Device Exemption (IDE). Coverage of Category B IDE devices is left to contractor discretion. (See 60 FR 48425, Sept. 19, 1995)

*ICD–9–CM Codes Denied*

| Code | Description |
|---|---|
| 798.0–798.9 | Sudden death, cause unknown. |
| V15.85 | Exposure to potentially hazardous body fluids. |
| V16.1 | Family history of malignant neoplasm, trachea, bronchus, and lung. |
| V16.2 | Family history of malignant neoplasm, other respiratory and intrathoracic organs. |
| V16.4 | Family history of malignant neoplasm, genital organs. |
| V16.5 | Family history of malignant neoplasm, urinary organs. |
| V16.6 | Family history of malignant neoplasm, leukemia. |
| V16.7 | Family history of malignant neoplasm, other lymphatic and hematopoietic neoplasms. |
| V16.8 | Family history of malignant neoplasm, other specified malignant neoplasm. |
| V16.9 | Family history of malignant neoplasm, unspecified malignant neoplasm. |
| V17.0–V17.8 | Family history of certain chronic disabling diseases. |
| V18.0–V18.8 | Family history of certain other specific conditions. |
| V19.0–V19.8 | Family history of other conditions. |
| V20.0–V20.2 | Health supervision of infant or child. |
| V28.0–V28.9 | Antenatal screenings. |
| V50.0–V50.9 | Elective surgery for purposes other than remedying health states. |
| V53.2 | Fitting and adjustment of hearing aid. |
| V60.0–V60.9 | Housing, household, and economic circumstances. |
| V62.0 | Unemployment. |
| V62.1 | Adverse effects of work environment. |
| V65.0 | Healthy persons accompanying sick persons. |
| V65.1 | Persons consulting on behalf of another person. |
| V68.0–V68.9 | Encounters for administrative purposes. |
| V70.0–V70.9 | General medical examinations. |
| V73.0–V73.99 | Special screening examinations for viral and chlamydia diseases. |
| V74.0–V74.9 | Special screening examinations for bacterial and spirochetal diseases. |
| V75.0–V75.9 | Special screening examination for other infectious diseases. |
| V76.0 | Special screening for malignant neoplasms, respiratory organs. |
| V76.3 | Special screening for malignant neoplasms, bladder. |
| V76.42–V76.9 | Special screening for malignant neoplasms,(sites other than breast, cervix, and rectum). |
| V77.0–V77.9 | Special screening for endocrine, nutrition, metabolic, and immunity disorders. |
| V78.0–V78.9 | Special Screening for disorders of blood and blood-forming organs. |
| V79.0–V.79.9 | Special screening for mental disorders. |
| V80.0–V80.3 | Special screening for neurological, eye, and ear diseases. |
| V81.0–V81.6 | Special screening for cardiovascular, respiratory, and genitourinary diseases. |
| V82.0–V82.9 | Special screening for other conditions. |

*ICD–9–CM Codes That Do Not Support Medical Necessity*

Code: Description

Any ICD–9–CM code not listed in either of the ICD–9–CM sections above

*Sources of Information*

Ahlquist, D.A., ''Approach to the patient with occult gastrointestinal bleeding,'' in Tadatake, Y. (ed.), *Textbook of Gastroenterology* (2nd ed.), 1995, J.B. Lippincott, pp. 699–717.

Tietz, N.W. (ed.), *Clinical guide to Laboratory Tests* (3rd ed.), 1995, pp.452–454.

Schleisenger, M.H., Wall, S.D., *et al.,* ''Part X. Gastrointestinal Diseases'' in Wyngaarden, J.B., and Smith, L.H. (eds.), *Cecil Textbook of Medicine* (18th ed.), 1988, W.B. Saunders, pp. 656–807.

*Harrison's Principles of Internal Medicine* (14th ed.), 1998, McGraw Hill.

Wallach, J., *Interpretation of Diagnostic Tests,* 1996, Little Brown and Co.

*Illustrated Guide to Diagnostic Tests* (2nd ed.), 1997, Springhouse Corporation.

*Sleisenger and Fordtrans's Gastrointestinal and Liver Disease* (6th ed.), 1997, W.B. Saunders.

*Coding Guidelines*

1. Any claim for a test listed in ''HCPCS CODES'' above must be submitted with an ICD–9–CM diagnosis code or comparable

narrative. Codes that describe symptoms and signs, as opposed to diagnoses, should be provided for reporting purposes when a diagnosis has not been established by the physician. (Based on Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 43.)

2. Screening is the testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test. When the reason for performing a test is because the patient has had contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned, not a screening code, but the test may still be considered screening and not covered by Medicare. For screening tests, the appropriate ICD–9–CM screening code from categories V28 or V73–V82 (or comparable narrative) should be used. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1996, pages 50 and 52)

3. A three-digit code is to be used only if it is not further subdivided. Where fourth-digit and/or fifth-digit subclassifications are provided, they must be assigned. A code is invalid if it has not been coded to the full number of digits required for that code. (From Coding Clinic for ICD–9–CM. Fourth Quarter, 1995, page 44.)

4. Diagnoses documented as ''probable,'' ''suspected,'' ''questionable,'' ''rule-out,'' or ''working diagnosis'' should not be coded as though they exist. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, exposure to communicable disease or other reasons for the visit. (From Coding Clinic for ICD–9–CM, Fourth Quarter 1995, page 45.)

5. When a non-specific ICD–9 code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test above.

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