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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS–3250–F]

RIN 0938–AL03

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

AGENCY: Center for Medicare & Medicaid Services, (CMS) HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes 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. This rule addresses public comments received on the proposed rule that was published March 10, 2000. A Negotiated Rulemaking Committee (the Committee) developed the policies as directed by section 4554(b)(1) of the Balanced Budget Act of 1997 (the BBA).

DATES: Effective November 25, 2002, except for sections 410.28(f), 410.32(d) redesignations, (d)(1) heading, (d)(4) and (e), which are effective February 21, 2002. See the effective date section of the preamble for a discussion of the effective dates for provisions that were discussed in the preamble but not codified in the rule.

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: The sections contained within this document have been constructed according to the framework outlined in the table of contents that follows. We summarized pertinent material from our proposed rule that was published on March 10, 2000 (65 FR 13082) followed by public comments and our responses.

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I. Background

A. Current Statutory Authority and Medicare Policies

Section 1833 and 1861 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. 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).

Under the above statutory authority, we have issued national coverage decisions and policies in a variety of documents, such as Centers for Medicare & Medicaid Services manual instructions, **Federal Register** notices, and Centers for Medicare & Medicaid Services Rulings. We have issued approximately 20 national coverage decisions pertaining to clinical diagnostic laboratory services in the Medicare Coverage Issues Manual (CMS Pub. 6). Medicare program manuals are posted on the Internet at *http://www.cms.gov/pubforms/progman.htm.* Program transmittals and program memoranda are posted at *http://www.cms.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 (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 ensure 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 policies 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 2.3 of the Program Integrity Manual (CMS Pub. 83).

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 established LMRP, the contractor must change its LMRP to conform 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) of the BBA 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 condition for which a laboratory tests is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the 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 physicians' obligations regarding these 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. Provisions of the March 10, 2000 Proposed Rule

In the March 10, 2000 proposed rule, we set forth uniform national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B. These proposed policies were designed to promote Medicare program integrity and national uniformity and 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 preamble to the March 10, 2000 proposed rule discussed the composition of the Committee, the guidelines the Committee followed in making recommendations, and the consensus of the negotiating Committee. Most of the provisions of the rule will be implemented through our instructional issuance system rather than codified in regulations, but were discussed in the preamble to the March 10, 2000 proposed rule nonetheless. A summary of the preamble of the March 10, 2000 proposed rule is as follows:

- Information required with each claim.

—Claims processing requirements change regularly; therefore, we encourage readers to refer to the claims processing sections of the Medicare Carriers Manual (sections 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. These manuals are posted on the Internet at *http://www.cms.gov/pubforms/progman.htm.*

—We proposed not to require that diagnostic information be submitted with every claim at this time. However, we encourage physicians to voluntarily provide diagnosis information (either the reason for the visit or the reason for the test) with the order, and we encourage laboratories to submit information that they receive with the claim.

—In order to promote uniformity, we proposed that the date of service for laboratory tests that is reported on the claim be the date the tested specimen was collected. The person obtaining the specimen must furnish the date of collection of the specimen to the entity billing Medicare.

- Medical conditions for which a test may be reasonable and necessary.

—The March 10, 2000 proposed rule discussed the uniform process that the Committee used in developing 23 national coverage decisions. We are not codifying the national coverage decisions (NCDs) so that they could be updated in a timely manner as appropriate to accommodate changes in technology, coding, or national practice standards. We used the following process to develop the NCDs:

++ Seeking input from relevant national medical specialty societies and voluntary health agencies through the American Medical Association 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.

++ Soliciting comments on the draft policies through an Internet posting from November 4 through 11, 1998.

—The policies followed a uniform format that Included a narrative description of the test, panel of tests, or group of tests addressed in the NCD; 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); reasons for denial (the content of which was not negotiated by the Committee); sources of information on which the decision is based; and coding guidelines.

The ICD–9–CM codes were displayed in one of three sections. The first section lists covered codes—those for which there is a presumption of medical necessity but the claim may be subject to review. The second section lists diagnosis codes that are never covered. 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. Additional documentation could support a decision of medical necessity and must be submitted by the ordering provider and accompany the claim.

The national coverage decisions apply nationwide and are binding on all Medicare carriers, fiscal intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans for purposes of Medicare coverage. In accordance with section 522 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Beneficiaries who file for review of NCDs on or after October 1, 2001 may appeal to the Department of Health and Human Services Appeals Board for review.

—The policies may be updated and new laboratory policies developed under the Medicare national coverage process that was published April 27, 1999 (see 64 FR 22619). A copy of this general notice is posted on the Centers for Medicare & Medicaid Services Internet site at *http://www.cms.gov/coverage/8a1.htm*

- Appropriate use of procedure codes.

—We clarified that the term screening or screen in Current Procedure Terminology (CPT) Codes does not necessarily describe a test performed in the absence of signs or symptoms of an illness, disease, or condition.
—We clarified use of the −59 modifier as an indication for claims for multiple billings of the same CPT code for the same beneficiary for the same day when those services are medically necessary.

• Documentation and recordkeeping requirements.

—We proposed adding language to the Code of Federal Regulations (CFR) to clarify the documentation physicians and laboratories, respectively, are required to maintain.
—We proposed CFR provisions clarifying that if the documentation submitted by the entity submitting the claim is inadequate, we will seek information directly from the ordering physician.
—We clarified that we do not require the signature of the ordering physician on a requisition for laboratory tests. However, documentation that the physician ordered the test must be available upon our request.
—We summarized the various record retention requirements that presently exist.

• Procedures for filing claims.

—We clarified that the entity submitting the claim may assign an appropriate diagnosis code to a narrative, even if there is not an exact match between the code descriptor and the narrative the laboratory received from the ordering physician.
—We clarified that until 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.
—We encourage matching of procedures to diagnoses, but we clarified that claims would not be denied solely because there is no matching of diagnosis and procedure codes on the claim form. In lieu of identifying a noncovered service through matching noncovered diagnoses to specific procedures on a claim, we also proposed that laboratories have the option of submitting a separate claim for a procedure that is not covered by Medicare.

• Limitation on frequency.

—We proposed to issue instructions that state February 21, 2002 that contractors may not use a frequency screen that could result in a frequency-based denial unless information published by us or our contractors includes an indication of the frequency that is generally considered reasonable utilization of that test for Medicare purposes.
—We proposed to clarify the CFR provision by including the existing requirements related to automatic denials from the manual in the CFR.
—We solicited new ideas for addressing the problem of notification of beneficiaries of potential overutilization of testing.
—We proposed to issue instructions February 21, 2002 that all Medicare contractors consistently use remittance advice language that identifies the reason for denial as excess frequency when that is the reason for denial.

• We clarified that the limitation on liability provisions that are currently found in section 1879 of the Act, 42 CFR part 411, subpart K, section 7330 of the Medicare Carriers Manual, section 3440 through 3446.9 of the Fiscal Intermediary Manual, and any currently applicable rules are equally applicable to laboratory services.

The changes we proposed to make to § 410.32 are set forth as follows:

• We proposed to redesignate paragraph (d) introductory text as paragraph (d)(1), and we proposed to add a heading.

• We proposed to redesignate paragraphs (d)(1) through (d)(7) as paragraphs (d)(1)(i) through (d)(1)(vii).

• We proposed to add a new paragraph (d)(2) to § 410.32 that would outline documentation and recordkeeping requirements related to clinical diagnostic laboratory tests. The 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 for the service 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 from the ordering physician 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 applicable rules and regulations on patient confidentiality.

• We proposed adding a new paragraph (d)(3) to § 410.32 relating to claims review.

++ Paragraph (d)(3)(i) will 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) will 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) will 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. h We proposed adding a new paragraph (d)(4) to § 410.32 to outline when we may deny a claim without manual review.

++ Paragraph (d)(4)(i) will 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) will permit automatic denial of claims when there is a national coverage decision, or LMRP that specifies the circumstances under which the service is denied, or 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.

III. Comments and Responses Based on the March 10, 2000 Proposed Rule

We received responses from 61 commenters during the public comment period. The commenters included many of the members of the negotiation

committee; other national and State organizations, such as the American Society of Hematology, and the Iowa Association of Pathologists; representatives of various laboratories and hospitals; individual physicians and other health care practitioners; a seniors' legal advocate; and a Medicare contractor medical director.

Information Required With Each Claim

Comment: Eighteen commenters expressed concern that the proposed rule did not specifically require physicians to provide information necessary to support medical necessity. The commenters believe that laboratories billing Medicare will have to collect information from various sources to support medical necessity. The commenters proposed that the final rule should clearly state that physicians are required to provide the information necessary to support medical necessity with the order, if that information is needed for claims processing.

Response: The Committee discussed when diagnostic information to support medical necessity must be submitted with a claim. The Committee's 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 related to 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. While we recognize the concerns of the commenters, we believe that such a requirement would present significant burdens on some physicians. We will continue to study this issue and weigh the benefits of requiring diagnostic information on every claim for laboratory services against the burden that it would impose on physicians and laboratories. We welcome the public to share with us any specific suggestions they have for mitigating the burden on physicians inherent with instituting a mandatory diagnostic information requirement.

In addition, we encourage physicians voluntarily to provide diagnostic information (either the reason for the visit or the reason for the test) with the order. Likewise, we encourage laboratories to submit information that they receive with the claim. Of course, if the diagnostic information is required for claims payment, such as where there is published national or local policy, physicians and practitioners are required under section 4317(b) of the BBA to provide diagnostic information at the time that the test is ordered.

Comment: One commenter expressed concern about the proper procedure with which to handle patients who have no referring diagnosis but can provide complaint, symptoms, or diagnosis. The commenter believes that not having a process to handle those situations may result in the patient experiencing delay or postponement of the service.

Response: For situations in which the patient does not present with a referring diagnosis but is able to provide complaint, symptom(s), or diagnosis, the proposed rule stated that the patient should be coded to the highest level of specificity that corresponds to his/her state of health. That is, the physician should provide this information (in narrative or code) to the laboratory, and the laboratory should report the complaint or symptom as one of the diagnoses on the claim. The national coverage decisions in this final rule include appropriate ICD–9–CM codes for relevant signs and symptoms in the sections entitled ''ICD–9–CM Codes Covered by Medicare Program.''

Comment: Twenty-eight commenters addressed the issue of date of service, which is defined in the proposed rule as the date of specimen collection. Twenty-one of the commenters generally agreed with the proposed rule's definition, but made suggestions for additional information or clarifications, such as the following in the definition: include the time the specimen was collected; clarify how to handle archived specimens and collections that span a 24-hour time period; specify that the entity collecting the specimen be responsible for reporting the date of service; and ensure that the laboratory is not held liable if an inaccurate date was reported on Medicare claims.

One commenter suggested that laboratories should be given the flexibility to also define date of service as the date of accession in cases for which date of collection is not available.

Six commenters were not in favor of the proposed definition on date of service and submitted suggestions about how the date of collection may be redefined. Three commenters suggested that the definition be changed to the date of accession. Two commenters suggested that the definition be changed to the date the test results were reported. In addition, one commenter suggested that laboratories be given the flexibility to choose the date of service as either the date of collection, date test results were reported or the date of accession in the laboratory. One commenter suggested that we reserve the dates of service issue for further study and not proceed with finalization of the proposal in this rule.

Response: 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.

We are committed to establishing a national coverage policy regarding the date of service for Medicare claims that will promote program integrity and national uniformity, yet minimize the burden on laboratories. 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–95–4 in April 1995 that instructed hospital-based laboratories to report the date of performance as the date of service for automated multi-channel tests.

We believe that the date of collection most closely relates to the date the test was ordered and that the use of only one date of service is consistent with the goal of promoting program integrity and national uniformity. We also agree that in order to promote national uniformity, the claims processing instruction implementing this provision needs to include clarifications regarding handling of special circumstances, such as archived specimens and tests requiring extended acquisition time.

For specimen collections that span more than a 24-hour period, the

implementing instructions will clarify that the entity performing the collection should define the date of service as the date the collection began. For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.

One commenter suggested that the time of specimen collection also be reported. We do not see the need for this information in processing Medicare claims. Further, the computer software used by the industry and us for claims processing does not include a field to report this information. Thus, the addition of specimen collection time as a required element on Medicare laboratory claims would result in a substantial cost for all involved parties. The commenter did not identify benefits from this addition that were commensurate with the costs. Consequently, we are not adopting this change.

Several of the laboratory representatives commenting on this issue expressed concerns with the potential problems that may arise when the entity collecting the specimen fails to comply with the requirement to supply the specimen collection date. The implementing instruction for this provision will carefully emphasize the requirement to those collecting specimens to report the date of collection. We are optimistic that after adequate education from us and the Committee member organizations, such as the American Medical Society and national laboratory organizations, most of those collecting specimens for laboratory testing will take care to report required information. We do not believe that it is consistent with the statutory requirement to promote national uniformity to permit a variety of means to report the date of service.

We note, however, that we are providing 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 provisions of this rule. Entities that want to obtain the benefit of a grace period to permit additional time to implement computerized system changes must contact us in writing 90 days before the effective date of the provision(s) they are not able to implement timely.

The request for a grace period must include a description of the nature of the system change not able to be implemented timely, a description of the actions the entity has taken in an effort to implement timely, date upon that the entity will be able to implement fully, and a workplan with a timeline providing a detailed description of the acts which the entity shall undertake to accomplish full implementation and the dates by which acts shall be performed. We will review the submittal and advise the entity if we grant or deny the request for a grace period. We may grant or deny the request for a grace period at our discretion. Notwithstanding the foregoing, we may terminate at any time any grace period already provided if we determine that the entity has not acted in good faith or we determine the entity has failed to perform any of the conditions upon which we agreed to extend a grace period.

If we need additional time to implement system changes associated with a particular provision of this rule on a nationwide basis, we well issue a program memorandum detailing the rationale for the extension and provide a new effective date.

Thus, 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. We believe this extended time before implementation will ease any anticipated problems with the reporting of the specimen collection date.

Medical Conditions for Which a Test May Be Reasonable and Necessary

Comment: One commenter expressed concern about designating the coverage policies included in the addendum to the proposed rule as national coverage determinations. The commenter requested that national coverage determination status not be conferred to the 23 coverage policies because this would render them unchallengeable.

Response: Section 4554 of the BBA specifies that the negotiated rulemaking develop national coverage policies for clinical diagnostic laboratory services. The statute goes on to state that the rules consider the medical conditions for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Act).

Our regulations do not use the term ''national coverage policies'' in developing policies that describe the medical conditions for which a test is reasonable and necessary. Rather, § 405.860 defines national coverage decisions (NCDs) in this fashion. Specifically, the section of the regulation states, ''CMS makes NCDs either granting, limiting, or excluding Medicare coverage for a specific medical service, procedure, or device. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.'' We believe that the Congress by requiring the Secretary to adopt ''national coverage and administrative policies for clinical diagnostic laboratory tests under part B of title XVIII,'' clearly intended the coverage policies developed under this rule to be considered as NCDs. We believe that to not confer NCD status on these policies would conflict with the statutory intent of section 4554(b) of the BBA.

We note, however, that the policies are developed to provide flexibility in all but a very limited number of diagnoses. That is, the policies have been constructed in a fashion to permit a Medicare contractor to consider coverage of additional indications on a case-by-case basis.

The Committee consensus includes the restatement of existing Medicare program requirements that contractors consider all information that is submitted with a claim. The policies include very few diagnoses that may not be covered under any circumstances in the section entitled ''ICD–9–CM Codes Denied.'' Codes included in the list entitled ''Codes That Do Not Support Medical Necessity'' may be covered when they are accompanied by sufficient medical justification for the test for a particular patient's condition.

Thus, the commenter's concern that NCD status would establish an irrefutable barrier to coverage is not inherent in the NCDs as negotiated. Moreover, section 522 of BIPA includes a provision to provide for review of NCDs with regard to requests for review of NCDs filed on or after October 1, 2001. Under the provisions of section 522 of BIPA, a beneficiary who is adversely affected by an NCD may request a review with the Department of Health and Human Services Appeals Board (DAB). The DAB may take evidence, consult with appropriate scientific and clinical experts and will look at the reasonableness of the determination. Final decisions of the DAB are subject to judicial review. Thus, the policies will be reviewable.

Comment: One commenter expressed concern that the March 10, 2000 proposed rule did not specifically state that a laboratory is not required to provide an advance beneficiary notice with respect to the ICD–9–CM codes that are listed in the category ''ICD–9–CM Codes Denied.''

Response: The diagnoses listed in the section entitled ''ICD–9–CM Codes Denied'' are codes that are not covered by Medicare for a variety of reasons. For example, some codes are excluded because they are screening services;

others are listed because they are services to caretakers rather than beneficiaries; another is based on the hearing aid exclusion. Advance Beneficiary Notices (ABNs), with respect to laboratory services, are required only for claims that the provider or supplier believes may not be covered by Medicare based on section 1862(a)(1) of the Act (reasonable and necessary exclusion).

Historically, Medicare's exclusion of screening services has been attributed to section 1862(a)(7) of the Act. In a 1988 Program Memorandum (AB–88–2), we stated that we consider the 1862(a)(7) of the Act exclusion to be the basis for denial of screening services. Thus, under current policy, providers or suppliers are not required to provide the beneficiary with an ABN before to billing them for screening tests that are provided for the diagnoses listed in the section entitled ''ICD–9–CM Codes Denied.'' However, we believe that advance notice to beneficiaries of that liability is prudent, and we encourage providers and suppliers to voluntarily notify beneficiaries that they will be liable for the cost of the tests.

We are, however, reconsidering whether to exclude screening tests based on section 1862(a)(7) of the Act rather than section 1862(a)(1)(A) of the Act. We are concerned that it may not be in the best interest of our beneficiaries to permit providers and suppliers to bill them for screening services without advance notice. Should we issue a change to the policy, laboratories will be required to issue ABNs for services that are not covered based on the diagnoses in the list that are screening services. Any such change would be prospectively effective.

Comment: Two commenters addressed the fact that the 23 tests identified in the national coverage decision represented 60 percent of the volume of Medicare outpatient laboratory testing. The commenters requested information about what percentage of Medicare outpatient laboratory payments is represented by the 23 laboratory services.

Response: We performed an analysis on the 1999 bills that were processed by the Medicare carriers. This database does not include the laboratory claims processed by hospital-based laboratories. In this data set, the 63 laboratory tests that make up the 23 services represent 43 percent of carrier lab services and 51 percent of carrier laboratory payments.

Comment: Two commenters expressed concern with the development of policies using both an inclusionary and exclusionary basis. They noted that using two different forms of logic in the development of computer edits is costly. They suggested that we re-evaluate the benefits of this approach relative to the benefits.

Response: We decided to display the diagnosis codes in the coverage policy for blood tests on an exclusionary basis. That is, rather that list the ICD–9–CM diagnosis codes than presumptively support medical necessity of a blood count, they listed the codes for which a blood count would not be presumptively medically necessary. We decided to use the exclusionary approach for listing the codes when the list of codes that supported medical necessity was considerably larger than the list of those that did not. Thus, blood counts was the only test that was developed using the exclusionary approach.

We note that the coverage policy for blood counts was developed in the same manner as all other tests. That is, based on scientific evidence, we listed those conditions that are indications for the test, or the inclusionary approach. It was for reasons of administrative simplicity that we displayed the codes in an exclusionary manner. Thus, any organization developing its own internal edits is free to edit using an inclusionary approach of computer logic by listing the codes that are not displayed as excluded.

Comment: One commenter suggested that the narrative indications and the ICD–9–CM codes contained in the policies needed to be reviewed for consistency in all sections. The commenter believes that not all codes that can be used for the indications have been included in the list for ''ICD–9–CM Codes Covered by Medicare Program.'' However, the commenter did not make specific suggestions for changes.

Response: During the development of the proposed policies, we made a valiant effort to ensure that the coding corresponded to the indications included in the NCDs. This effort included development of the initial list of codes by an interdisciplinary workgroup that included at least one ICD–9–CM coding expert designated by the American Health Information Management Association, as well as multiple physicians, including Medicare contractor medical directors who are familiar with coding from their claims analysis activities. After the workgroup produced the draft NCDs, they were posted on the Internet for public comments.

Several of the public comments related to coding suggestions, which the Committee took under advisement in making its final recommendations. We assigned a team of coders and physicians to review the recommended policies as well before they were published as proposed policies in the **Federal Register**.

In addition, to help ensure a complete listing of codes, we specifically solicited comments on the policies from the public in the preamble to the proposed rule. However, in that preamble we explicitly stated that requests for changes should be accompanied by scientific evidence supporting the request. We encouraged commenters ''to submit, with their comments, copies of medical literature supporting their recommendation for change * * *''

We received a number of comments regarding specific codes that members of the public believe were appropriate changes to the lists. None of the requests or comments regarding coding changes was accompanied by supporting scientific evidence, however. As discussed more fully in subsequent comments, we carefully reviewed each of these suggestions using a team of our physicians and coding experts and made appropriate decisions regarding their inclusion in the list based on the indications described in the policies.

We believe the use of the Committee to develop the initial list of covered codes, together with the opportunity for public comment both during the Committee meetings and in response to the March 10, 2000 proposed rule provides adequate assurances that the list of codes is appropriate. If members of the public have additional suggestions, we invite them to use the national coverage process to request specific changes for the future.

Comment: One commenter expressed concern with the language in the ''Reasons for Denial'' section relating to Food and Drug Administration (FDA) approval or clearance of tests. The commenter believes that there are additional exceptions beyond the Category B Investigation Device Exemption (IDE) noted in the March 10, 2000 proposed rule. The commenter suggested that the language provide for other exceptions. Further, the commenter requested that we specify the procedures that would apply to this section through an additional document that would be subject to notice and comment.

Response: The last bullet in the Reasons for Denial section of the proposed policies states that ''Tests that require 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, September 19, 1995).'' The purpose of including the reasons for denial was to provide information that may be helpful to users of the policy. We note that this section was not negotiated by the Committee and included general policies of Medicare that apply to various types of services rather than being specific to laboratory services.

Subsequent to the publication of the March 10, 2000 proposed rule we published a policy on Medicare coverage of services under clinical trials. This policy was published on our coverage web site on the Internet (http://www.cms.gov/coverage/8d.htm) and in Program Memorandum AB–00–89 and Coverage Issues Manual Section 30–1. The national coverage decision that related to clinical trials provides for coverage of routine costs incurred during certain clinical trials. Thus, as the commenter noted, there are other exceptions to FDA approval. As part of implementation of this policy, we will be modifying our regulations governing coverage of IDEs that was referenced in this bullet. We believe it is appropriate to remove this bullet from the reasons for denial section at this time. We should point out, however, that we will continue to consider FDA approval when appropriate in making coverage determinations on Medicare claims.

Comment: One commenter noted that none of the coverage policies considered family history as a medically necessary reason for a test. The commenter believes that in a limited number of diseases family history should be included as a basis for diagnostic testing, but did not identify any specific conditions.

Response: The policies have been developed based on Medicare's long-standing interpretation of sections 1862(a)(1)(A) and 1862(a)(7) of the Act. Section 1862(a)(1)(A) of the Act provides that Medicare payment may only be made for services that are reasonable and necessary for the diagnosis or treatment of illness or injury. Section 1862(a)(7) of the Act excludes Medicare coverage of routine physical checkups. We have interpreted this to exclude routine testing provided during such a physical checkup. Thus, all of the policies were developed based on the concept that tests that are performed when no specific sign, symptom, or diagnosis is present and when the patient has not been exposed to a disease are excluded from coverage as screening services. (See Coding Guideline #2.)

We, as well as many members of the Committee, recognize that there may be many instances when testing of beneficiaries in the absence of specific signs, symptoms, diagnosis, or exposure to disease is good health care. The value of many preventive services and screening tests, particularly in the case of family history of disease is well documented. The exclusion of family history was not based on a belief by the Committee or us that such testing should not be performed.

We are considering generating an internal request for a national coverage decision addressing the role of family history as a medical justification for a test being reasonable and necessary under our national coverage decision process. National coverage decisions are evidence-based decisions. If, after careful analysis, we believe there is a basis for covering screening services, we will post a notice on our coverage page on the Internet to allow the public an opportunity to participate by submitting evidence for our further consideration.

Comment: One commenter expressed concern that certain pre-operative tests were not included in the proposed policies. The commenter explained that surgeons and other involved physicians will be bound by unreasonable and inflexible protocols that impose barriers to prudent management of an individual patient about to undergo surgery.

Response: The coverage policies negotiated by the Committee are evidence-based policies. In situations in which the scientific evidence supports the administration of tests, such as blood counts, prothrombin time and partial thromboplastin time, before surgery, the policies provide for coverage of these tests.

There are a number of other tests, however, that are routinely administered to all patients about to undergo surgery in some hospitals. We note that the value of that routine testing for all patients undergoing all surgery is questionable. For example, a recent study of pre-operative testing of cataract patients showed that the routine testing did not affect the outcome of the patients. (*The New England Journal of Medicine* 342 (2000): 168). Based on our discussion with physicians on this issue, we have concluded that there is not consensus among physicians regarding the appropriateness of furnishing a broad spectrum of tests to seemingly well individuals merely because they are about to undergo surgery.

We believe that the proposed policies developed by the Committee appropriately handle the issue of pre-operative surgery given the constraints of the law related to screening that are discussed above. That is, tests furnished to patients who present with signs, symptoms, or history of disease are covered for those conditions. Although screening individuals without signs, symptoms, or past history may be good medical practice, we do not believe it is a service that is covered by the Medicare program.

However, we are interested in continuing to study this issue. We encourage the public to use the national coverage process discussed elsewhere in this document to forward to us any scientific literature related to improvements in outcomes associated with administering specific pre-operative laboratory tests routinely to Medicare patients.

Comment: One commenter expressed concern that the proposed policies may not be appropriate for certain populations. The commenter was particularly concerned that the proposed policies did not address the specific needs of certain socioeconomic or ethnic groups.

Response: We acknowledge that the proposed policy does not generally address specific socioeconomic or ethnic groups. Generally, additional testing of particular socioeconomic or ethnic groups is based on higher propensity for a disease state, which is considered screening. Rather, the policies were designed to identify the specific medical indications (signs, symptoms, or disease) for testing that were supported by the scientific literature. However, the policies were not designed to be an irrefutable list of diagnoses that may warrant a particular test. Diagnoses, other than those listed in the section entitled ''ICD–9–CM Codes Denied,'' or more frequent tests may be covered on an individual basis when they are supported by medical justification submitted with the claim.

Comment: One commenter suggested that the title of the list of codes called ''ICD–9–CM Codes Denied'' be changed to ''ICD–9–CM Codes Denied as Not a Benefit of Medicare'' to clarify that these are not medical necessity denials.

Response: As noted above, we are re-evaluating our policy related to screening services. Thus, we do not believe it is in the best interest of the users of the policy to change the title of this section at this time.

Comment: One commenter requested that the coding guidelines remain in the Coding Clinic of the American Hospital Association (AHA), rather than in the **Federal Register**. The commenter explained that AHA's Coding Clinic for ICD–9–CM is a more flexible means of updating codes than is the **Federal Register**, in which changes would be

subject to administrative processes such as notice and comment periods.

Response: Several of the coding guidelines from the AHA Coding Clinic were printed in the proposed coverage policies for purposes of providing assistance to the users of the policies. We believe that repeating certain coding guidelines in the policies would clarify coding policies for users and would be beneficial because users would not need to consult alternative manuals for expeditious resolution of common coding questions.

The incorporation of existing coding guidelines in the national coverage determinations was not intended to imply that future changes to the coding guidelines would be subject to publication in the **Federal Register** or make composite coding guidelines subject to the Administrative Procedure Act. If one of the coding guidelines that was printed in the proposed policies is changed in the future, the revised guideline may be incorporated into a national coverage decision through the NCD coverage process without publication in the **Federal Register**.

Comment: One commenter expressed concern with coding guideline 2 on screening services. The commenter believes that the V01 codes, contact with or exposure to communicable diseases should be denied under all circumstances as screening. Further, the commenter suggested clarification of coding when a screening test shows an abnormal finding.

Response: We believe that confirmed exposure to disease is not considered a screening test in all circumstances. For example, the proposed policy does not consider HIV testing of patients who have been exposed to HIV through needlesticks from an HIV-positive patient as screening. Further, Medicare Program Memorandum AB–99–04 details that we do not consider testing for hepatitis C infection screening when it is performed on patients who have been exposed to hepatitis C through a blood transfusion from a patient that later is determined to have hepatitis C. Thus, we are not adopting the commenter's first recommendation.

We acknowledge that the appropriate coding for tests that were ordered as screening, but show abnormal findings, is an issue that needs clarification. We have learned that there are significant differences in the common coding practices between hospitals and nonhospital settings. We believe, however, that this issue is most appropriately handled by the ICD–9–CM Coding Committee. The ICD–9–CM Coding Committee is comprised of representatives from Centers for Medicare & Medicaid Services, the AHA and the National Center for Health Statistics, who are experts in the coding field. They are best able to discuss the differences among the various uses of coding guidelines and issue clarifications. We will ask the ICD–9–CM Coding Committee to include this issue on an upcoming agenda. Clarification will be published through the AHA Coding Clinic when the differences are resolved.

Comment: One commenter made reference to coding guideline #5, which refers to nonspecific codes. The commenter believes the guideline does not define nonspecific codes, nor is the appropriate meaning of the term clear. The commenter requested that the final rule clarify whether the term ''non-specific codes'' refers to the ICD–9–CM code ''not otherwise specified'' (codes ending in an 8) or ''unspecified'' (codes ending in 9) or something else.

Response: Coding guideline #5 states, ''When a non-specific ICD–9–CM code is submitted, the underlying sign, symptom, or condition must be related to the indication for the test above.'' In including this statement in the coding guideline, the Committee was not addressing the ''not otherwise specified'' or ''unspecified'' codes exclusively. Rather, the list of covered codes frequently includes codes that are very broad and encompass several related but different conditions, only a few of which would justify the test in question.

For example, assume that a given code (X) is appropriate for three conditions (A, B, and C). An indication for test 1 is condition A. The coding guideline is intended to remind users that if you report code X for test 1, it is expected that the patient have condition A. In other words, if upon medical review of the chart, the contractor finds that the patient only has condition B, which is not included in the indications, it may deny the claim despite the fact that code X is included in the list of codes that support medical necessity.

Comment: Many commenters suggested additional

ICD–9–CM diagnosis codes be added to the various policies. The commenters generally did not provide rationale for the suggestions and none of the requests were supported with scientific evidence as we specifically requested in the preamble of the March 10, 2000 proposed rule. In short, the commenters asserted the policies were incorrect or incomplete without providing explanation or support for their concern.

Response: As described in the preamble to the March 10, 2000 proposed rule and in response to another comment above, the Committee developed the policies in a systematic and uniform manner. The Committee developed the narrative portion of the NCDs based on scientific evidence. That is, the narrative indications for a test were evidence based. Once the narrative indications were developed, the Committee attempted to identify the ICD–9–CM codes that appropriately translated the narrative.

The Committee provided a brief public comment period on the policies as developed by the workgroups before the full Committee discussion of the issue and before the rule was published by Centers for Medicare & Medicaid Services on March 10, 2000. During this public comment period, numerous suggestions for coding changes, similar to those received during this public comment period, were made. In considering these public comments, the Committee decided that unless the coding changes were supported by medical evidence, the Committee would continue to look to the narrative indications and make a determination if the suggested code was an appropriate translation of the narrative.

It is critical that the narrative indications for the proposed policy and the ICD–9–CM codes that support medical necessity be consistent. Thus, in order for us to add codes to the list of ICD–9–CM codes that support medical necessity, those codes must either be determined to be an appropriate translation of an existing indication, or we must add a new indication for the test in the policy narrative. The preamble to the March 10, 2000 proposed rule in soliciting public comments on the policies clearly requested that any suggested changes be accompanied by scientific literature supporting the change. Since both the Medicare NCD process and the negotiating committee use evidence-based decision making, it would not be appropriate to use opinion-based decision making to change the proposed policies in responding to the public comments. Therefore, we believe the approach similar to that taken by the negotiating committee in handling the comments it received from the public is a reasonable and appropriate means of addressing the suggestion for coding changes that were submitted to us during the public comment period on the March 10, 2000 proposed rule.

Since none of the suggested coding changes we received on the proposed coverage policies was accompanied by scientific literature, we looked to the

proposed narrative indications in determining if the code was an appropriate addition to the ICD–9–CM list in the policy. We used a team of our physicians and coding experts to evaluate each of the codes that was suggested during the public comment period. The team carefully studied the narrative descriptions of the indications for the test in the proposed NCDs. When the suggested code was a reasonable application of the existing narrative, we added the code to the list.

Our physicians acknowledged that many of the ICD–9–CM codes that were suggested might be clinically understandable in certain situations. However, gathering the scientific-evidence and conducting the analysis necessary to make a reasonable determination as to the appropriateness of adding indications to the proposed policies for each of the multitude of codes suggested would be a daunting task and would have resulted in unreasonable delay in the finalization of the policies. We do not believe it is appropriate to further delay adoption of the proposed policies to conduct this search for medical evidence to support unsubstantiated suggestions. However, requestors are free to use the national coverage decision process (published in the April 27, 1999 **Federal Register** (64 FR 22619) and on the Internet at *http://www.cms.gov/coverage/8a1.htm*) to request further refinement of the national coverage decisions.

The following codes were suggested for addition to specific policies. We believe these codes are an appropriate translation of the indications listed in the policy and we are adding them to the ICD–9–CM codes covered by Medicare.

Blood glucose: 780.31, 781.0, 783.6
Digoxin: 429.2, 972.0
Fecal Occult Blood Test: 003.0, 003.1, 095.2, 095.3, 098.0, 098.7, 098.84, 139.8, 159.0–159.9, 569.82, 569.83, 596.1, 751.1
Gamma Glutamyl Transferase: 230.7, 230.9, 642.5, 782.4, 789.1, 790.4, 790.5, V42.7
Lipids: 278.00, 401.0–401.9, 402.00–402.91, 403.00–403.91, 404.00–404.93, 405.01–405.99, V42.7
Prostate Specific Antigen: 236.5, 599.6, 788.30, 788.41, 788.43, 788.62
Human immunodeficiency virus testing (Diagnosis): 263.0, 263.1, 263.9, 486
Partial thromboplastin time: 362.30, 362.31, 362.32, 362.33, 362.34, 362.35, 362.36, 362.37, 410.0–.9, 456.8, 530.82,
Prothrombin time: 786.50, V12.51–V12.59
Iron studies: 579.8, 579.9, 713.0, 716.4–716.9, V56.0, V56.8
Thyroid: 290.3, 297.1, 333.99, 358.1, 359.5, 376.21, 376.22, 425.7

The following codes were suggested for changes to the NCDs.

Our physician staff and coding experts reviewed these codes. Based on their clinical judgment and knowledge of coding guidelines, we do not believe these codes appropriately stem from the indications included in the respective policies.

Blood counts: 300.00, 300.01, 575.6, V45.89, 715.00–715.98, 716.00, 716.99
Blood glucose: 279.9, 357.2, 357.8, 785.1, 800.00–804.99, 805.00–806.79, 850.00–854.19, V22.0–V22.2, V72.73–V72.84, V72.81
Iron studies: 253.5, 276.0, 276.1, 278, 282.0, 282.1, 282.2, 282.3, 282.4, 282.5, 282.60–282.63, 282.69, 282.7, 282.8, 282.9, 283.0–283.9, 289.0–289.9, 333.99, 564.5, 607.84, 708.8, 714.0–714.9, 715.0–715.9, 716.0–716.3, 733, 758.0, 758.1–758.9, 775.3, 780.4, 790.4
Partial thromboplastin time: 036, 040, 041, 050, 054, 056, 078.5, 081, 082, 083, 084, 085, 086, 087, 115, 117.3, 152.0–152.9, 162, 171, 174, 183, 185, 188.0–188.9, 198.1, 204, 205, 206, 207, 208, 239.4, 239.5, 250.1, 282, 283, 285.0, 287.3, 289.5, 290.40–290.43, 331.81, 345.3, 369.1–369.9, 377.53. 377.62, 386.2, 386.5, 394.0–394.9, 395.0, 395.2, 396.0–396.9, 397.0–397.9, 398.0, 398.90–398.99, 411.1, 411.81, 411.89, 413.0, 413.1, 413.9, 414.00–414.05, 414.8, 414.9, 415.0, 415.11, 415.99, 416.9, 424.0, 424.1, 424.90, 424.2, 424.3, 424.91, 425.0–425.9, 427.0–427.9, 436, 437, 440.0–440.9, 443.0–443.9, 447.6, 452, 459.2, 514, 555.0–555.9, 577.0, 671.9, 710, 746.00, 746.01–746.09, 746.1–746.89, 747.1, 786.50, 789.1, 789.5, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 958.1, 958.4, 991.6, 992.0, 994.1, 995.0, 996.85, V12.51, V15.1, V42.2, V42.7, V43.2, V43.4, V43.60–V43.69
Prothrombin time: 036, 040, 050, 054, 056, 078.5, 081, 082, 083, 084, 085, 086, 087, 115, 117.3, 162, 171, 174, 183, 185, 204, 205, 206, 207, 208, 250.1, 282, 283, 287.3, 331.81, 410.0–410.9, 435.3, 427.5, 447.6, 577.0, 630, 710, 747.1, 785.5, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 958.1, 958.4, 991.6, 994.1, 995.0, 996.85, V43.60–V43.69, V72.81, V72.82, V72.83, V72.84
Thyroid: 198.82, 518.5, 611.6, 780.53–780.57, 786.05, 790.6, 790.94, 793.2, 995.0, V58.0
Digoxin: 402.00, 402.10, 402.90, 414.01, 412, 414.02, 414.03, 414.04, 414.05, 414.10, 414.11, 414.19, 557.1, 746.1–746.6, 746.81–746.89, 747.22, V78.8
Fecal Occult Blood: 003.20–003.24, 003.8, 003.9, 095.4–095.9, 096, 097.0, 097.1, 097.9, 098.10–098.19, 098.2, 098.3–098.39, 098.40–098.49, 098.50–098.59, 098.6, 098.81–098.83, 098.85, 098.89, 139.0, 139.1, 751.2, V12.79, V82.8
Gamma Glutamyl Transferase: 230.0–230.6, 231.0–231.9, 232.0–232.9, 233.0–233.8, 234.0, 234.9, 790.6, V11.3
Lipids: 427.0–427.2, 427.31, 427.32, 427.41, 427.42, 427.5, 427.60–427.69, 436, 443.0, 443.1, 443.8, 443.89, 443.9, 574.00, 574.01. 574.10. 574.11, 574.20, 574.21, 574.30, 574.31, 574.40, 574.41, 574.50, 574.51, 574.60, 574.61, 574.70, 574.71, 574.80, 574.81, 574.90, 574.91, 575.2–575.8, 783.1, V67.51
Glycated Hemoglobin/Protein: 359.6
Prostate Specific Antigen: 188.8, 222.2, 584.5–584.9, 596.0–596.9, 599.1, 600, 606.0, V71.1, V76.44

Comment: One commenter submitted a list of pregnancy-related codes for addition to the codes identified as medically necessary for human chorionic gonadotropin (HCG), quantitative.

Response: In analyzing requests for additions of codes to the list, we have generally looked to the indication section of the proposed policies. The indication section of the HCG proposed policy states that HCG is useful for diagnosis of pregnancy and pregnancy-associated conditions. We note that the proposed policy is exclusively quantitative HCG (CPT code 84702). The proposed policy is not applicable for qualitative HCG. Based on review of scientific evidence, such as textbooks (Clinical Interpretation of Laboratory Tests by Frances K. Widen, M.D.) and advice of medical consultants, we believe the language in the indications of the proposed policy relative to the utility of quantitative hCG for diagnosing pregnancy is overly broad and inaccurate. Pregnancy tests for the diagnosis of pregnancy use qualitative methods of identifying HCG, rather than quantitative methods. Quantitative HCG in pregnant patients is useful to monitor patients with suspected complications of pregnancy, such as ectopic or molar pregnancy.

We believe the Committee had this understanding of the policy in that the list of covered codes included vaginal bleeding, molar pregnancy, missed abortion, ectopic pregnancy, threatened abortion, and pregnancy. Thus, the codes do not coincide with the language of the test being useful for diagnosing pregnancy. That is, codes that indicate suspected pregnancy, such as the

absence of menstruation, are not included.

Consequently, we are altering the indications for the policy for HCG in this final rule to more precisely describe the utility of quantitative HCG. The final policy will read, ''In addition, HCG is useful for monitoring pregnant patients with vaginal bleeding, hypertension and/or suspected fetal loss.'' Given this revised indication, we believe the following codes suggested by the commenter should be added to the list of codes covered by Medicare: 634.0, 636.0, 642.3, 642.4, 642.5, 642.6, 642.7, 642.9. The following codes, suggested by the commenter are not being included at this time: 623.8, 626.0, 626.1, 646.5, 658.1, 658.2, 658.3, 658.4, 659.2, 659.3, V22.2. Further, we are deleting codes V22.0 and V22.1 from the list of covered codes. These codes indicate normal pregnancy. We do not believe that quantitative HCG is reasonable and necessary for a pregnancy that is confirmed as normal.

Comment: Seventeen commenters addressed the proposed NCD on the collagen crosslinks test. Fifteen of the commenters generally expressed support for adopting the NCD on the collagen crosslinks test in the final rule but suggested clarification and revision in a number of different areas. One other commenter questioned the clinical usefulness and reliability of the test and concluded that Medicare should not reimburse it.

Another commenter did not indicate whether or not he supported the proposed national policy, but expressed the view that there were internal inconsistencies in the policy that needed to be clarified before publication in the final rule. Only one of the commenters produced scientific evidence for their views; however, much of this evidence had already been reviewed the rest of the negotiating committee and us during the deliberations.

Response: There was considerable discussion at the November 1998 meeting of the negotiation Committee on this proposed policy as well. It also noted that this was a field that was changing rapidly. We believe that the evidence available supports the policy. Since the field is rapidly changing and there are limited and inconsistent findings in the literature, it is not surprising that we received several inconsistent comments on this proposed policy. That is, some commenters believe the policy is too restrictive, and others believe it goes beyond what is supported by the science. We note, however, that most of the commenters believe that the policy is basically sound, but they were requesting refinements. After careful studying of the comments and the limited additional scientific literature submitted by the commenters, we do not believe that the public comments have presented such a radically different view as to undermine the policy we had proposed and which was recommended by the Committee.

Therefore, we are including the collagen crosslinks policy in the final rule with only minor clarification as we explain in our response to several of the more specific comments summarized below. We invite commenters to use the NCD process that was published in the April 27, 1999 **Federal Register** (64 FR 22619) to request further changes in the policy.

Comment: Some of the commenters expressed concern that the NCD on the collagen crosslinks test did not recognize that these tests may be useful in men who have degenerative bone loss. The commenters noted that while the majority of bone loss patients are women, bone loss can also affect men as well—especially those over 70 years of age.

Response: We agree that the collagen crosslinks test may be useful in assessing or monitoring the treatment regimens of men who have osteoporosis, Paget's disease, or are otherwise at risk for degenerative bone loss. We did not intend to exclude, nor do we believe that the proposed NCD should be interpreted to preclude men from coverage of collagen crosslinks tests as long as one of the applicable medical indications for coverage is met. Nonetheless, we have clarified this point in the final rule by revising the fourth sentence of the ''Indications'' section of the NCD to provide that ''Coverage for bone marker assays should be established * * * for younger beneficiaries and for those men and women who might become fast losers because of some other therapy such as glucocorticoids.''

Comment: Nine commenters indicated that the proposed NCD on the collagen crosslinks test reflects that these tests may be performed on urine, but not on serum samples. One of these commenters stated that the FDA had approved the serum-based technique as ''substantially equivalent'' to the urine-based version and offered documentation in support of adding it to the urine-based collagen crosslinks test in the final rule. Another commenter mentioned that the serum-based technique might be a more reliable test of bone turnover than the urine test, but suggested that there was insufficient information available to determine whether either test was clinically useful for monitoring drug therapy for individuals with or at risk for bone loss.

Response: We recognize that since the proposed Medicare NCD on urine-based collagen was negotiated, the FDA approved the serum collagen crosslinks test in February 1999 for the purpose of assessing or monitoring drug therapy for individuals with or at risk for bone loss. However, serum collagen crosslinks test was not part of the negotiated rulemaking. We do not believe it is appropriate to include additional tests that were not subject to negotiation in this final rule. That is, the negotiated rulemaking committee carefully selected the tests for which it wished to negotiate a coverage NCD.

The commenter noted that the FDA had determined that the serum-based technique is ''substantially equivalent'' to the urine-based version. The criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug and Cosmetic Act is significantly different from the scientific evidence we consider in making ''reasonable and necessary'' determinations under Medicare. FDA does not require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare evidence-base decisions consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage.

When sufficient clinical studies have been done on the serum tests, we encourage the commenters to use the NCD process published in the April 27, 1999 **Federal Register** to request inclusion of serum version of the test in the collagen crosslinks NCD. In the meantime, in the absence of an NCD on the serum collagen crosslink test, Medicare contractors will have local discretion in deciding whether this type of collagen crosslinks test is medically necessary for assessing or monitoring bone loss therapy.

Comment: Fifteen commenters indicated that available scientific evidence and clinical expert opinion support the view that contrary to the first paragraph of the ''Indications'' section of the proposed NCD on the coverage of collagen crosslinks tests, rapid bone loss frequently does occur

after age 65. In view of their concerns, the commenters have recommended that the first paragraph of the ''Indications section'' be deleted or substantially revised in the final rule.

Response: In response to the commenters' concerns, we re-examined the scientific evidence considered by the negotiating Committee and that was submitted during the public comment period on the collagen crosslinks proposed NCD. In the studies we reviewed, the sensitivity and specificity of the biochemical markers was relatively low, and there are wide confidence intervals associated with the results. We believe these factors demonstrate the clinical utility of biochemical markers only for patients who are rapid bone losers.

The commenters do not appear to dispute the determination that collagen crosslinks are most clinically useful only for rapid bone losers. Rather, the commenters believe that many patients over age 65 are considered rapid bone losers. While several practicing physicians indicated that in their clinical judgment patients over age 65 frequently are rapid bone losers, this clinical judgment was not supported with clinical studies to indicate the extent to which rapid bone loss may be a significant problem for Medicare beneficiaries age 65 and older.

Further, in our review of the literature, we did not find scientific evidence either supporting or disputing this assertion. In the absence of evidence to support this clinical judgment, we are not convinced that the policy negotiated by the Committee is inappropriate. In short, we find no persuasive reason to revise the proposed policy. Therefore, we believe that the first paragraph of the ''Indications'' section of the proposed NCD on this test should be included unchanged in the final rule except for the clarification discussed above with respect to men.

We would point out, however, that the age limitation is not an absolute exclusion from coverage. The language in the NCD states, ''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.'' Thus, physicians who encounter an occasional patient age 65 and over for whom they have reason to believe collagen crosslinks testing is clinically useful, may obtain Medicare coverage through documentation that the service is reasonable and necessary for that patient.

Comment: One commenter noted that there appears to be an inconsistency in the proposed NCD for collagen crosslink tests because the list of ICD–9 codes for this policy includes multiple myeloma, but this condition is not included in the ''Indications'' section for this policy. It is suggested that these two portions of the policy be made consistent.

Response: We agree that the two portions of the policy should be made consistent. The Committee operated under the ground rules that the codes included under the ''List of ICD–9–CM Codes Covered by Medicare'' should be an appropriate representation of the narrative indications. In addressing all requests for changes to the codes that were received during the comment period, we have consistently held that the codes must be a codification of a condition that was included in the indication section of the NCD. Therefore, we have removed ICD–9–CM codes 203.00 and 203.01 from the list of ICD–9–CM codes covered by Medicare for collagen crosslinks. If commenters believe this is an appropriate indication for collagen crosslinks, they may use the NCD process described in the April 27, 1999 **Federal Register** to submit scientific evidence in support of the change.

Comment: One commenter also stated that if the purpose of the proposed NCD for collagen crosslink tests is to permit this test to be used to diagnose the presence of osteoporosis or the risk of developing it, we should determine how frequently this test may be used for this purpose and whether collagen crosslinks and bone mineral density tests may be done in the same period for diagnosing osteoporosis. Otherwise, the commenter noted that the predisposing conditions for osteoporosis should be deleted as acceptable conditions for coverage of this test, and only the conditions for coverage of monitoring known osteoporosis treatment should be allowed.

Response: The purpose of the proposed NCD for the collagen crosslinks test was not to permit coverage of the test to diagnose the presence of osteoporosis or the risk of developing it. Rather, the purpose of the test, as stated in the proposed NCD, was to (1) identify individuals with elevated bone resorption, who have osteoporosis in whom response to treatment is being monitored, (2) predict response (as assessed by bone measurements) to FDA-approved antiresorptive therapy in postmenopausal women, and (3) assess response to treatment of patients with osteoporosis, Paget's disease of the bone, or at risk for osteoporosis for which treatment may include FDA approved antiresorptive agents, anti-estrogens or selective estrogen receptor moderators. We are including this language unchanged in the final rule. It should be interpreted to mean that all covered indications for collagen crosslinks in the final rule relate solely to the assessment or monitoring of treatment regimens for postmenopausal women, patients with osteoporosis, Paget's disease of the bone, or others who are at risk for osteoporosis. None of the covered conditions relate to the diagnosis of osteoporosis or the risk of developing osteoporosis.

Comment: Fifteen commenters expressed the view that the proposed NCD on collagen crosslinks tests should be implemented immediately upon publication of the final rule without the 12-month delay in the effective date and the additional grace period of up to 12-months beyond the effective date called for in the March 10, 2000 proposed rule. One of the commenters stated that our reasoning in the March 10, 2000 proposed rule for the delayed implementation that referenced the need for time to allow for educational efforts and computer systems changes to be made for the various new policies was not applicable to the collagen crosslinks test for several reasons. First, the commenter suggested that the volume of Medicare collagen crosslink test claims anticipated is so negligible that the immediate implementation of the NCD on the test would not disrupt the Medicare claims process or cause related education or computer systems problems. Second, the commenter believes that the collagen crosslinks test has a unique legal status that necessitates that it be excluded from the delay in the effective date that has been proposed for all of the clinical diagnostic test NCDs that have been developed. Specifically, the commenter suggested that the collagen crosslinks test is subject to the provisions of section 4106 of the BBA, which mandated national coverage for bone mass measurements effective July 1, 1998.

Response: We continue to believe that the concerns expressed by the negotiating committee relative to the need for the delayed effective date to allow for important education and systems changes to be completed is appropriate and should be applied in the final rule to all of the 23 NCDs, including the one on collagen crosslink tests. We recognize that the volume of Medicare collagen crosslink test claims that may be anticipated may be small in comparison to the volume of Medicare

claims for the other 22 clinical laboratory tests, but the lower volume of claims expected will not preclude the need for important educational efforts and systems changes to be made for the collagen crosslinks test.

As for the commenter's suggestion that the collagen crosslinks test has a unique legal status under section 4106 of the BBA that should allow it to be excluded from the delay in the effective date of the various policies, we disagree that this is the case. Section 4106(b) of the BBA amended the law to provide that payment for bone mass measurements that are covered under the new benefit must be made under the Medicare physician fee schedule, as provided in section 1848(j)(3) of the Act. We have interpreted these provisions in the interim final rule that was published on June 24, 1998 (63 FR 34320) on coverage and payment for bone mass measurements to mean that the scope of the benefit includes bone densitometry or bone sonometry procedures that are performed with devices that have been approved or cleared for marketing by the FDA. We did not include coverage of crosslink tests within the bone mass measurement benefit. Collagen crosslink tests are, in fact, clinical laboratory tests that are paid for under the Medicare clinical laboratory fee schedule, and Medicare coverage of these tests has been addressed under section 4554 of the BBA, which, of course, mandated this negotiated rulemaking process for the coverage of certain clinical laboratory tests. Collagen crosslinks measure bone resorption and are used to monitor the effectiveness of antiresorptive therapy. We do not believe collagen crosslinks tests are appropriately considered bone mass measurements.

Comment: Ten commenters suggested that we develop a specific process for updating policies and to introduce additional national coverage decisions without having to wait for the biennial review.

Response: It is not necessary to wait for the biennial review in order to request changes in the Medicare national coverage decisions. As we noted in the preamble to the March 10, 2000 proposed rule, Medicare has announced a new process for making requests for new Medicare national coverage decisions or for requesting changes to current coverage decisions. The coverage process was delineated in a notice in the **Federal Register** published April 27, 1999, and is available on the Internet at *http://www.cms.gov/coverage/8a1.htm*

We should point out that the new coverage process includes an opportunity for members of the public to participate in coverage decisions. We post all pending coverage issues on the Internet and welcome the submission of evidence related to every issue. In addition, for some issues, we hold public meetings of the Medicare Coverage Advisory Committee (MCAC) to assist us in assessing the evidence. We have established a specific MCAC panel to address diagnostic issues, such as clinical diagnostic laboratory tests.

We intend to solicit changes in the laboratory policies biennially, as directed in section 4554 of the BBA. In addition, we will accept requests for changes to current policies at any time, as long as they comply with the requirements in the coverage notice.

Comment: One commenter was concerned that implementation of the final rule may result in denial of payment for laboratory services that are currently being paid by Medicare. The commenter suggested that a laboratory should be able to rely on the existing local medical review policies (LMRP) without fear of claims denial and potential government enforcement action until the applicable contractor changes its LMRP or until the proposed rule is effective.

Response: We agree with the commenter that the final rule should not be enforced before its effective date. Contractors should be using their existing local policies until these policies become effective. Once these national coverage decisions become effective, contractors will need to use these policies as they are published. LMRPs may not conflict with the 23 national coverage decisions outlined. If a LMRP conflicts with a national coverage decision, the contractor is required to change it so it complies with the national coverage decision. When a national coverage decision is silent on an issue, such as frequency guidance, a contractor may develop an LMRP that supplements the national coverage decision. However, the LMRP may not conflict with the national coverage decision.

Appropriate Use of Procedure Code

Comment: Three commenters expressed the view that it is not appropriate to use modifier −59 for medically necessary repeat clinical laboratory tests for the same CPT code for the same beneficiary on the same day because that modifier applies to physician procedures and not clinical laboratory tests. They indicated that modifier −91 is specifically designed for clinical laboratory tests, and is a more appropriate modifier to use in billing for medically necessary repeat tests of this type.

Response: The issue of use of modifiers −59 and −91 can be confusing. Both modifiers have a place in coding repeat clinical diagnostic laboratory tests. Modifier −91 is appropriate when in the course of treatment of the patient it is necessary to repeat the same laboratory test on the same day to obtain subsequent test results, such as when a beneficiary requires repeated blood tests that were performed at different intervals during the same day.

The commenters are correct that the new modifier −91 that was added by the American Medical Association's CPT Editorial Panel, as part of its year 2000 update, is specifically designed for the reporting of that type of repeated test. For example, if an arterial blood sample is drawn from a patient at three different intervals on the same day, and the blood testing is performed three times that same day, then CPT code 82803, Gas, blood, any combination of pH, PCO2, P02, CO2, HC03 (including calculated oxygen saturation), should be reported as follows: 82803, 82803–91, and 82803–91. We believe one of the examples provided in the March 10, 2000 proposed rule—Biochemical studies performed on different samples, for example, renins (CPT code 84244)—is an example of when the modifier −91 is appropriate.

The purpose of the Committee consensus on the use of modifier −59 was to resolve coding situations that were presented to the Committee by the microbiology community that do not meet the definition of repeated tests for which modifier −91 is appropriate. They cited situations, for example, in which samples or cultures are taken from a patient from different anatomical sites, or even different wounds, and then are tested the same day. We believe that the use of modifier −59 in reporting multiple claims submissions by a clinical laboratory for the same CPT code for the same beneficiary on the same day is the appropriate way to handle these situations and is consistent with established CPT coding conventions. We have consulted with the American Medical Association, the proprietors of the CPT coding system including modifier, in ensuring that modifier −59 is the appropriate means of indicating repeat laboratory test coding when there are two tests involving different sites. As mentioned in the preamble to the March 10, 2000 proposed rule, a few examples of appropriate use of modifier −59 would be the following:

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

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

Comment: One commenter noted that it is the experience of its organizations members that some Medicare contractors are not currently accepting the use of modifier −59, and it is suggested that we should issue an instruction to its contractors to ensure that they will accept multiple claims submitted by laboratories using modifier −59.

Response: We agree that all Medicare contractors processing laboratory claims should be accepting both modifier −59 and modifier −91 when used appropriately in billing for medically necessary laboratory services for the same CPT code for the same beneficiary on the same day, as described above in our reply to the previous comment. We will clarify the use of these two modifiers in the instructions that we will be issuing to our contractors.

Comment: One commenter indicated that there was a need for us to identify all of those clinical laboratory tests that frequently result in multiple tests being billed.

Response: We do not believe that we have the expertise or experience to attempt to identify all of the various clinical laboratory tests that might warrant the use of modifier −59. If we were to attempt this action and make errors in omission, laboratories would not be able to receive payment when it may become necessary to perform repeat testing on patients to attend to their specific medical needs. We believe that it is sufficient to provide a few examples of appropriate use of the modifier, which we will repeat in our instructional issuance.

Moreover, the Committee believes that there was not sufficient time and information available for them to attempt to identify all the various clinical laboratory tests that might warrant use of modifier −59. As a result, the Committee agreed that it would be sufficient to provide a few examples are of appropriate use of the modifier. We agree with the Committee that a few examples are sufficient to address the concern with the −59 modifier. Moreover, we believe that any attempt on our part to identify a comprehensive list of situations that would warrant the use of the −59 modifier is likely to be incomplete due to our lack of field experience and would thus generate additional concerns.

Documentation and Recordkeeping Requirements

Comment: Three commenters expressed concern about the process by which diagnostic information supporting medical necessity is to be collected from the ordering physician. Two of the commenters suggested that we publish a guideline for collecting additional information from the ordering physician. Another commenter further suggested that our guideline state the baseline effort required for obtaining documentation by the entity submitting the claim. The commenter suggested that claims should be denied only if the required effort for obtaining the documentation has been met.

Response: We acknowledge the burden that accompanies the task of collecting diagnostic information to support medical necessity. However, the Act requires that Medicare only pay for services that are reasonable and necessary. Medicare cannot pay for services that do not meet this standard simply because the laboratory has expended a specified amount of effort to obtain documentation. We have, however, identified a process for requesting documentation that we believe reduces the burden on the laboratories for collecting and submitting information to us.

As part of the negotiated rulemaking process, the Committee established a consensus to the guidelines for documentation that appeared in the preamble to the March 10, 2000 proposed rule. Specifically, the consensus statement and proposed rule provide that the laboratory is responsible for maintaining information it receives from the ordering practitioner, and the practitioner, is responsible for maintaining the information in the medical record. Our initial request for information is made to the entity submitting the claim. That entity should submit whatever documentation it has in support of the claim.

If the documentation provided by the entity submitting the claim does not demonstrate that the service is reasonable and necessary, we will take the following action: (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 will be the entity to experience a payment denial if documentation does not support the medical necessity of the claim, we agreed laboratories should not be precluded 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 applicable laws and regulations related to patient confidentiality.

Comment: One commenter requested that we publish a quarterly summary that specifies the total number of tests ordered and the total number of tests not paid by Medicare due to lack of medical necessity by the ordering physician.

Response: We question the utility of quarterly reports that specify the total number of tests and total number denied due to lack of medical necessity. We fail to see how this report would assist laboratories without identification of the laboratories and/or physicians involved. Furthermore, the commenter did not identify a method of distribution of this information that would be beneficial and reasonably priced. We are not convinced that the benefits of such a report would outweigh the costs.

Laboratories are free to prepare any reports for their own use with the payment information they receive. For example, laboratories can link denial rates for failure to provide medical necessity information to specific clients and target educational efforts toward those specific problems.

Comment: Twenty-six commenters expressed concern that the March 10, 2000 proposed rule makes it possible for laboratories to be held liable for claims denial due to the lack of information supporting medical necessity. That is, the commenters were concerned that the laboratories would be the entity experiencing the loss if the physician does not submit the information supporting medical necessity. The commenters believe that the March 10, 2000 proposed rule will result in unfairness and financial hardships for the laboratory industry. Several commenters suggested that in the final rule, laboratories should not be financially responsible in this situation. Some commenters believe that the situation may be best addressed if (1) we simultaneously notify both the entity submitting the claim and the ordering physician that additional information is

being requested; (2) we tracks which physicians have failed to comply with requests for additional information; and (3) we identify a time frame that specifies when responses to requests need to be made. One commenter suggested that we create a database of medical records that service providers may access for claims purposes.

Response: The commenters do not seem to recognize that the March 10, 2000 proposed rule does not change the current provisions for liability on claims due to lack of information supporting medical necessity. Section 1862(a)(1)(A) of the Act provides that, notwithstanding any other provision of the Act, payment may not be made for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service. Although the Committee discussed at length the special circumstances related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that the law does not provide the authority to exempt laboratories from the provision related to medical necessity.

In addition, we do not agree that the provision related to denial of claims for laboratory services when documentation is not provided is unfair. Rather, we believe it would be unfair to exempt laboratories from this provision while continuing to require it for other providers and suppliers. For example, durable medical equipment (DME) suppliers frequently do not have direct contact with beneficiaries but are dependent upon physician documentation of medical need in order to receive payment.

Some commenters suggested that we simultaneously notify both the entity submitting the claims and the ordering physician that additional information is being requested. We are not accepting this suggestion for several reasons. First, in many cases, we do not have the address of the ordering physician at the time the initial request for information is made. This information will be supplied by the entity that submitted the claim following our initial request so that we can directly request additional information from the physician as is contemplated in § 410.32(d)(3)(ii). Moreover, we believe that it would be confusing to request information from both the ordering physician and laboratory simultaneously because both the laboratory and the physician could send information or both can believe that the other is handling it. Finally, duplicate mailings to both the laboratory and physician are costly to the program. This appears to be a cost without benefit.

Some commenters suggested that we track which physicians have failed to comply with requests for additional information. Similarly, this is a suggestion that would result in significant cost to the program if adopted. The commenters were not clear about how this information ought to be used. We do not agree that tracking these physicians would be beneficial. Several of the commenters suggested that we identify a time frame between a request for documentation from the carrier and denial of the claim for lack of documentation. We agree that physicians should be advised of the period of time that they have to respond to the Medicare contractor's request. Section 521 of the BIPA requires that the carrier or fiscal intermediary must make initial determinations on claims within 45 days of receipt of the claim.

Claims subject to additional information requests on prepayment review must be handled within the statutory mandated time frame. In cases for which the initial request would have been made to the entity submitting the claim before the request to the physician, it is very likely that there will be minimal time for the physician to respond. Requests for additional information made on a postpayment basis is not subject to the time frames contained in section 521 of BIPA. In issuing instructions implementing this provision of the rule, we will instruct the contractors to identify the date by which they need information on claims that have not received an initial determination and provide 60 days notice before denying a claim for failure to supply requested information when claims are identified for development based on postpayment review.

Comment: One commenter addressed the process that would allow physicians to justify additional tests that may not be deemed by local medical review policy (LMRP) as medically necessary.

Response: Most local medical review policy is written in a fashion similar to that employed by the Committee in development of the 23 national coverage decisions contained in the addendum to the March 10, 2000 proposed rule. That is, most LMRPs provide a list of codes for which medical necessity is presumed, a list of codes that are not covered, and a list of codes that are presumed not medically necessary. Contractors are required to consider any documentation that is submitted with the claim. Thus, a process already exists for physicians to justify tests that are not presumed medically necessary. Further, LMRPs are not binding upon the Administrative Law Judges that adjudicate appeals of contractor denials. Physicians may use the appeal process to seek payment for claims that the contractor determines are not justified.

Comment: One commenter requested that a form be produced that would allow physicians to justify additional clinical laboratory tests that may not be considered medically necessary by the local LMRP.

Response: Under current Medicare guidelines, clinical laboratories are already allowed, if they choose, to require that their ordering physicians use a specified medical documentation form in support of claims as the commenter has suggested. We, however, are obligated under the Paperwork Reduction Act to limit the reporting burden placed upon providers unless there is a demonstrated need for it to carry out the provisions of the applicable law and regulations. Since clinical laboratories already have the ability to require their clients to use a specified medical documentation form, we do not believe that it is necessary to require the use of such a form by all physicians for all of the tests that they order for their Medicare beneficiaries. It is possible for us to engage in this type of documentation gathering through use of a national certificate of medical necessity for clinical laboratory services. However, before we actively consider imposing this type of reporting burden on the public, we believe we need to research this proposal carefully.

Signature on Requisition

Comment: Twelve commenters addressed the March 10, 2000 proposed rule's provision about signature requirements on requisitions. Seven of the commenters were in agreement with the March 10, 2000 proposed rule provision that a signature not be required on a claim and did not submit suggestions to us. Two of the commenters requested that we publish other means of indicating that a physician has ordered a laboratory service. Three of the commenters expressed concern that the March 10, 2000 proposed rule was in conflict with CLIA requirements that a written authorization be obtained within 30 days of a verbal request for the laboratory service. One suggested that we should require USER ID instead of physician signature while another suggested that another individual who has the authority to order for the physician be required to sign the requisition in place of the physician.

Response: Regulations set forth at § 410.32(a) require that 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. 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. For example, the physician may document the ordering of specific tests in the patient's medical record. As stated in the preamble to the March 10, 2000 proposed rule, we will publish 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 also do not agree with the commenters that the March 10, 2000 proposed rule conflicts with the CLIA requirements. Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (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.

Authorization does not equate to physician signature; the CLIA regulations provide, for example, that the patient's chart or medical record may be used as the test requisition. The CLIA regulations address this written authorization as a means of ensuring that laboratories are not performing tests that were not authorized. They do not address or conflict with the requirement that there be documentation of the physician's order available upon request of the Medicare contractor. Of course, if the physician signs the requisition himself, it would satisfy both the requirement in § 410.32(a) and § 405.1105.

Procedures for Filing Claims

The Committee discussed concerns expressed by various members of the Committee and reached a consensus on the following three issues relating to ''Procedures in Filing Claims.'' These included (1) Coding of Narrative Diagnoses, (2) Limitation on Number of Diagnoses, and (3) Matching of Diagnosis to Procedure. We received no comments from anyone on these issues.

Limitation on Frequency

Comment: Three commenters cited the lack of frequency limitations in many of the national coverage policies that had been developed in the March 10, 2000 proposed rule. Two commenters requested that we specify the allowed frequency limitations in all of the proposed policies. One commenter expressed support only for screens that are national in scope and suggested that in the absence of these national frequency limitations, local contractors should not be permitted to apply their own frequency limitations at that level.

Response: The Committee discussed this subject and agreed to set as its goal the development of specific language on frequency limitations for the various national coverage policies drafted whenever possible to promote uniformity throughout the country. The Committee spent a great deal of time and worked very diligently on this issue, but they were unable to reach a consensus on specific frequency limitations for most of the proposed national coverage policies.

We have continued to study the scientific evidence related to frequency limitations, and we do not believe that the medical evidence is sufficient to develop national frequency limitations for those policies that do not contain them at present. Further, we note that the public comments on the March 10, 2000 proposed rule did not include information supporting the addition of any specific frequency limitations to the national coverage policies. Contractors analyze data to allow them to identify what is the prevalent practice in the area. In the absence of scientific data to support national frequency limitation, we have decided to defer to local contractors in this regard who will base their determinations on the local practices.

In the absence of a national coverage policy on a particular laboratory procedure that specifies a frequency limitation, Medicare's local contractors are responsible for making individual coverage determinations on the procedure, including, if they choose, establishing appropriate local frequency limitations on the procedure.

The Committee discussed this issue and agreed that a frequency limitation would not result in a frequency-based denial at the local level unless information published by our contractor (or by us in the case of a national frequency limitation) includes an indication of the frequency that is generally considered reasonable use of that test for Medicare payment purposes. The contractor must consult with appropriate advisors, including medical specialty and other organizations, before developing and publishing frequency information for a clinical diagnostic laboratory test.

Comment: One commenter opposed the use of frequency screens that result in automatic denials and believes that the use of these screens conflicts with court cases that have held that their use contravenes the Medicare statute. The commenter believes that this type of frequency screen is used as an absolute denial mechanisms or irrebuttable presumption that forecloses the opportunity for an individualized determination of medical necessity and is, therefore, illegal. The court decisions of *Vorster* v. *Bowen,* 709 F. Supp. 934 (C.D.Cal. 1989); and *Fox* v. *Bowen,* 656 F. Supp. 1236 (D.C.Conn. 1987) are cited in support of the commenter's assertion.

Response: We believe the commenter has misunderstood the March 10, 2000 proposed rule with respect to Medicare policy on automatic denial of laboratory claims as the policy applies to frequency screens. This policy does not provide for automatic denials of laboratory claims based on frequency. Rather, under the proposed policy, contractors will provide frequency guidance before implementation of any frequency screens. Entities submitting claims for laboratory services that exceed the frequency guidance are encouraged to submit documentation of the medical necessity of the service with the claim. Contractors will review all documentation submitted before making a determination on the claim.

We do not believe that this policy is in conflict with the court cases that the commenter has referenced. On the contrary, the Court in *Vorster* expressly determined that the Medicare statute and its legislative history supported the use of utilization screens by carriers in processing claims under Part B. In that case, the plaintiff, a Medicare beneficiary, submitted claims for covered chiropractic services to the carrier that were subsequently denied entirely, based on application of a utilization screen. The plaintiff then sought a review determination from the carrier and submitted additional information to the carrier in support of her claim. The carrier again denied the claims, and the beneficiary then filed suit, alleging that the use of utilization screens was a violation of the Medicare statute.

The Court in *Vorster* rejected the plaintiff's allegation that the use of utilization screens violated the Medicare statute. According to the Court in that case: The Congress instructed the Secretary to use the expertise of private sector carriers in administering the Part B plan, and has acknowledged that the efficient administration of the Part B program includes review of utilization and the control of unnecessary utilization of covered services. [Citations omitted.]

* * * * *

Based upon the foregoing legislative history, it appears that in general, the Congress would approve the use of utilization screens in processing claims. *Vorster,* 709 F. Supp. 940–41. The Court in *Vorster* noted that the use of utilization screens would contravene the Medicare statute if they were used as ''absolute denial mechanisms'' or as ''irrefutable presumptions, which foreclosed any meaningful opportunity to receive an individualized determination of medical necessity.'' *Vorster,* 709 F. Supp. at 941. As we have stated above, however, the use of utilization screens as contemplated in the policy does *not* act as either an ''absolute denial mechanism'' or as an ''irrefutable presumption which foreclose[s] any meaningful opportunity to receive an individualized determination of medical necessity.''

We also do not think that the reasoning in the *Fox* v. *Bowen* case, also cited by the commenter, is applicable to the proposed policy. The *Fox* case involved a challenge to a denial of claims for physical therapy services to skilled nursing facility patients. A fiscal intermediary in that case had established parameters for determining whether physical therapy services would be covered for patients in skilled nursing facilities. The Court characterized those parameters as ''informal presumptions'' or ''rules of thumb,'' applied across the board ''without regard to the therapeutic requirements of the individual patient.'' Fox, 656 F. Supp. at 1248. The regulations promulgated by the Secretary, and the manual that was provided to assist intermediaries in making coverage determinations for physical therapy services, however, contemplated clearly that beneficiaries would receive an individualized assessment of need for physical therapy services. *Id.* Because an intermediary's practice in that case did not conform to the requirements of the regulations calling for an individual assessment of need for covered services, the Court in *Fox* determined that the practice was unlawful. We believe, therefore, that the *Fox* case is inapplicable to the proposed policy. The proposed policy does not constitute a denial of benefits based on ''informal presumptions'' or ''rules of thumb'' applied across the board without regard to the therapeutic requirements of the individual patient.

Comment: One commenter expressed concern that there is little oversight of the LMRP development process, which often results in LMRPs being developed without regard to our coverage guidelines. The commenter indicated that, although the Medicare Carrier's Manual requires, and the March 10, 2000 proposed rule suggests that LMRPs must be based on medical literature and current clinical practice guidelines, many are not. The commenter also stated that because there is no public notice for the development of LMRPs, there is no opportunity for beneficiaries to comment on them, and only limited opportunity for affected practitioners to do so.

Response: An LMRP is primarily a program integrity tool. It is developed to address identified or potential abuse, such as overutilization. In the absence of national policy, it is generally developed to specify criteria that describe whether the item or service is covered and under what clinical circumstances it is considered to be reasonable, necessary, and appropriate. The process for developing LMRPs includes the following: (1) Development of a draft policy based on review of medical literature and the contractor's understanding of local practice; (2) soliciting comments from the medical community, including the Contractor Advisory Committee (CAC); (3) responding to and incorporating into a final policy the comments received; and (4) notifying providers of the policy's effective date.

In accordance with our instructions to contractors, LMRPs must be based on the strongest evidence available. The initial action in gathering evidence in developing an LMRP must always be a search of published scientific literature for any available evidence pertaining to the item or service in question. We instruct contractors to heavily weigh published authoritative evidence derived from randomized clinical trials or other definitive studies. We also instruct contractors to consider as evidence the consensus of expert medical opinion (that is, recognized authorities in the field) or medical opinion derived from consultation with medical associations or other health care experts. We do advise them, however, that acceptance by individual providers or groups of providers does not normally indicate general acceptance by the medical community. Testimonials and limited case studies distributed by sponsors with a financial interest in the outcome is not sufficient evidence of general acceptance by the medical community.

Contractors are required to provide a minimum comment period of 45 days on proposed LMRPs. The 45-day period begins with distribution to the CAC. Contractors are required to make their CAC meetings open to the public, and all interested parties, including beneficiaries, may attend and comment on the proposed policies. Further, the proposed policy is not only distributed to the CAC, but also to representatives of specialty societies, other than those represented on the CAC, when appropriate. Contractors are instructed to remain sensitive to other organizations or groups, which may have an interest in an issue. All comments received are considered and responded to either through the contractor's newsletter or individually to the commenter. The final policy is announced in a contractor bulletin at least 30 days before implementation.

Our regional staffs review the contractors' performance annually. If the commenter has specific details regarding a contractor that is not following the above requirements in the development of its local policies, they should notify us so that it can be investigated.

Comment: Three commenters expressed concern with limitations that might be imposed by the provision for automatic denial for egregious utilization.

Response: After considering the comments, we believes that the March 10, 2000 proposed rule was not sufficiently detailed in respect to this provision to benefit from public comment. Consequently, we are withdrawing the provision of automatic denial for egregious utilization and will study the matter further.

Comment: One commenter believes that the use of frequency screens that results in automatic denials will lead to underutilization of Medicare-covered medically necessary services by encouraging laboratories to give Advance Beneficiary Notices (ABNs) in every situation.

Response: The commenter appears to have misunderstood the March 10, 2000 proposed rule with regard to automatic denials. The proposed policy severely limits automatic denial based on frequency. The proposed policy, which we are incorporating in this final rule, provides that, except in limited and specified circumstances as described in

these regulations, we will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim. For example, before denying a claim, contractors must review and consider justifications prepared by a provider or supplier, primary and secondary diagnosis, and copies of medical records that are submitted with the claim. Contractors may automatically deny a claim without any manual review only if a national coverage decision or LMRP specifies the circumstances under which a service is denied and those circumstances exist, or the service is specifically excluded from Medicare coverage by statute.

We do not believe that application of a Medicare policy on automatic denial of laboratory claims, as described in these regulations, will result in the underutilization of Medicare covered services as the commenter suggested. To the extent that laboratories and physicians may issue additional ABNs to these patients that they would not do otherwise, we believe that this may, in fact, be helpful to beneficiaries. The purpose of the ABN is to give beneficiaries advance notice that a service may not be covered so that they have the opportunity to make an informed choice on whether to have the service or not.

Comment: Four commenters offered suggestions for how the Medicare policy on Advance Beneficiary Notices (ABNs) should be clarified with respect to situations when laboratory tests that are performed exceed frequency limitations. They also made suggestions regarding when ABNs need to be signed by beneficiaries under the Medicare limitation on liability provisions.

Response: As we indicated in the preamble to the March 10, 2000 proposed rule, section IV, Other Topics Discussed by the Committee, the Medicare provisions on limitation on liability (sometimes called waiver of liability) were identified as falling outside the scope of the clinical laboratory negotiations. The limitation on liability provisions (including the related subject of ABNs) are currently found in section 1879 of the Act; 42 CFR part 411, subpart K; section 7330.5.A of the Medicare Carriers Manual; sections 3440 through 3446.9 of the Fiscal Intermediary Manual, and any currently applicable rules. Revised Part B ABNs, including one specifically relating to providers of clinical laboratory services, have been circulated in the Paperwork Reduction Act public comment process since October 26, 2000. All interested parties have had the opportunity to comment on those revised notices.

Comment: One commenter believes that a laboratory should be required to track frequencies only for tests performed for beneficiaries by the clinical laboratory itself and requests that we confirm this in the final rule.

Response: We do not place any requirements on laboratories to track frequencies of tests used by Medicare beneficiaries they serve, whether those services are furnished by a single laboratory or are performed by other laboratories.

Comment: One commenter suggested that laboratories should be allowed to bill the patient for frequency denials regardless of whether an ABN has been issued to the beneficiary.

Response: Under section 1879(a) and (b) of the Act, a provider of clinical laboratory services may bill a Medicare beneficiary for its services that are denied Medicare payment due to lack of medical necessity only if the laboratory informed the patient, before furnishing the service, that Medicare was likely to deny payment for the service. Frequency based denials are made because a contractor has determined that it is not reasonable and necessary for a beneficiary to receive that quantity of services based on the documentation that is presented with the claim. Therefore, the statute does not permit us to authorize laboratories to bill a beneficiary for the services that are denied based on frequency unless the beneficiary has been advised of the potential denial.

Comment: One commenter asked why hospitals performing laboratory tests for outpatients are not allowed to ask their Medicare patients to sign ABNs in circumstances when Medicare coverage is uncertain due to medical necessity considerations.

Response: Since the proposed rule was published on March 10, 2000, we have clarified our Medicare policy on the use of Part B ABNs by hospitals that perform laboratory tests and other Part B services. On July 27, 2000, we issued a Program Memorandum (PM) (PM A–00–43) to our Medicare contractors that explicitly provides for the use of the current Part B ABN in the institutional setting.

Comment: One commenter noted that claims for laboratory services that exceed frequency limitations can only be read by the Medicare contractors if they are able to image attachments that come with the first claim submission. The commenter suggested that we make certain that all of our Medicare contractors image and review attachments submitted with initial claims.

Response: All Medicare contractors have the capability to image hard copy documentation that is submitted with the claim. Unless the claim is suitable for auto-denial because the national of local policy specifies the circumstances under which the service is denied or the service is specifically excluded from Medicare coverage by law, contractors are required to review any such documentation before making a determination on the claim (See section 5.1 of the Program Integrity Manual.)

Comment: One commenter suggested that when Medicare clinical laboratory test specimens are being referred to multiple laboratories, contractors should develop claims that exceed the frequency parameters before denial. Specifically, the commenter proposed the following three-step approach: (1) Use prepayment methods to scrutinize the laboratories involved, particularly those that have billing profiles known to be suspect; (2) directly contact the ordering physicians by mail, suggesting that they review the billing and medical necessity of the tests; and (3) encourage physicians to share laboratory reports among all physicians participating in the care of their respective patients.

Response: In response to our specific request for new ideas on how to respond to the multiple laboratory problems discussed by the Committee and described in detail in the March 10, 2000 proposed rule, the commenter offered several interesting suggestions for doing this, but generally the suggestions are not new ones. As we indicated in the March 10, 2000 proposed rule, it would be very costly for our contractors to undertake the developmental work on clinical laboratory claims that would be required to use the prepayment methods proposed by the commenter. At present, laboratories and ordering physicians are free to submit medical justification that our contractors are required to consider. However, we cannot commit to the development of every claim before a denial based on excessive frequency in the fashion suggested by the commenter. We agreed to require contractors to publish frequency limitation guidance to laboratories and physicians in advance of their use as screens in the claims review process. We recognize that physicians and laboratories may not be aware of the number of times that a given beneficiary has had testing performed during a particular time period due to the use of multiple providers. We do, indeed, encourage physicians to share their patients' laboratory reports with other physicians participating in the care of their

patients, particularly those to whom they make referrals.

Comment: Ten commenters responded to the Committee's request regarding informing beneficiaries of frequency denials by expressing concern that without a Medicare database available, clinical laboratories will be unable to identify patients who are reaching the frequency limitation and, thus, will be unable to inform patients of possible claims denials. Seven of the ten commenters suggested that Medicare provide timely access to the Common Working File (CWF) for monitoring frequencies. Two of the ten commenters suggested that any information-sharing system that relies upon mailing paper notices to beneficiaries to share with their physicians would be inefficient and administratively burdensome to Medicare as well as confusing to beneficiaries. They requested instead that Medicare develop a comprehensive database, ideally electronic, containing patient-specific laboratory test frequency information.

Response: We cannot adopt any of the database proposals for several reasons. Several Committee members during the negotiations suggested similar proposals for notifying beneficiaries of frequency denials and requesting that they advise their physicians of the denials in an effort to encourage their physicians to obtain ABNs. We believed then, and continue to maintain, that it would not be possible for us to implement any of the notification proposals because of the high cost to Medicare. In addition, we believe that even the most sophisticated systems that might be available in the next few years would be likely to inaccurately identify potential denial situations due to time lags between receipt of services. Since the Committee could not agree to a specific proposal for dealing with the problem raised, we did agree to solicit in the March 10, 2000 proposed rule new ideas—especially ideas that included shared responsibility—for addressing this problem from Committee members as well as others. Unfortunately, the database proposals described above do not meet the parameters for shared responsibility that we were seeking, but instead would place a disproportionate responsibility and cost on the Medicare program.

We will continue to consider ideas for assisting Medicare beneficiaries become aware of potential overutilization of clinical diagnostic laboratory testing while protecting the privacy of their medical information. If we discover a mechanism that ensures privacy protections, accurately reflects current proximity to frequency expectations, and is easy for beneficiaries to understand, we will implement the system expeditiously.

Comment: One commenter suggested that the Explanation of Medicare Benefits (EOMB) should indicate to the beneficiary when a frequency limit has been exceeded. In this way, the beneficiary would know that future services for the same test may potentially be denied.

Response: The Committee discussed a similar suggestion. We expressed concern that the proposal would be costly to implement with little assurances that it would be beneficial. Several members of the Committee acknowledged that beneficiaries are not likely to remember the specific tests for which they have received frequency notification nor are they likely to take their EOMB with them when they visit their physician. Thus, we believe we are not likely that notification of beneficiaries in the EOMB would be helpful.

Moreover, frequency screens are applied over a period of time. For example, a contractor may set a frequency screen of four glycated hemoglobin tests per year. However, neither the beneficiary nor the physician is likely to know when the base period is reset, making the notification no longer applicable. Thus, it is possible that armed with incomplete or outdated information, a beneficiary may not be offered a medically necessary test or may decline a medically necessary test because he/she believes the test would not be covered. Consequently, we are not adopting this suggestion because we believe it not only would not be cost-effective, but it has a high risk of having harmful effects on Medicare beneficiaries.

Effective Date

Comment: Several physicians who commented expressed concern with the 12-month delay in effective date proposed in the March 10, 2000 proposed rule. They were particularly interested in earlier implementation of the coverage policies. The commenters urged us to consider earlier implementation, but they did not address the ability of the industry to implement the system changes associated with these policies or the impact of denials upon laboratories if physicians who have not been educated to the policies, order tests for conditions that are not presumed to be reasonable and necessary without submitting medical justification.

Response: The Committee recommended a 12-month delay in the effective date of the rule for several reasons. First, the Committee was concerned that some of the policies involved changes in the computer systems of the entity they represented. The Committee noted that it is not possible for most laboratory, hospital, and physician office computer systems to be modified to accommodate changes quickly. It would not be possible for the industry to be prepared for implementation with only 90 days notice. Second, the Committee noted that a large volume of laboratory claims (approximately 60 percent) is potentially affected by the national coverage decisions.

The Committee expressed concern that implementation of the policies without an adequate prior period of education of the physician and laboratory community could result in a significant volume of denied claims without an opportunity to recover payment from beneficiaries. The Committee voluntarily planned an ambitious educational program and expressed a desire that the policies provide an adequate opportunity to engage those educational activities before implementation. Consequently, the Committee proposed a 12-month delay in effective date.

We believed then, and continue to believe, that the concerns expressed by the many members of the negotiating Committee related to education and system changes are valid and that the delayed effective date of policies that require system changes or educational efforts is necessary and appropriate. Therefore, we are not accepting the commenters' suggestion to move up implementation of the NCDs for laboratory services.

However, we note that a number of provisions that are discussed in the preamble to the March 10, 2000 proposed rule are not likely to require changes to computer systems nor is their implementation likely to result in a significant volume of claims denials if they are implemented without an extended period of prior notice.

Instead, they entail clarification of our policies with regard to processing claims for clinical laboratory tests. For example, we agreed to issue instructions requiring contractors to provide frequency guidance before use of frequency screens, clarify that we do not require a signature to be submitted with claims, and clarify coding guidelines for reporting multiple procedures, etc. These provisions are essentially clarifications of our existing policies and issuing the clarifications sooner as opposed to later will significantly improve the working relationship

between some laboratories and Medicare claims processing contractors. In addition, issuance of these clarifications will restore confidence to laboratories who may have in the past acted in accordance with these policies but, because there has been lack of consistency in the interpretations, are fearful that they will later be advised that the claims are in error and subject to recovery of payment. Moreover, early implementation of these clarifications will result in more rapid consistency among the Medicare contractors in application of our administrative policies for laboratories, which is one of the primary objectives of the legislation (section 4554(b) of BBA) authorizing this rule. Finally, we believe that some of the provisions, such as requiring notice of utilization guidelines before implementation of frequency screens, hold universal benefit to the laboratory industry that should be available as soon as possible.

We do not believe that earlier implementation of these clarifications will adversely affect laboratories. Therefore, provisions of the rule that are not likely to require system changes or result in a significant volume of claims denials if implemented without an extended period of education, will be effective February 21, 2002, and we will issue the program instructions within 90 days of publication of the final rule. We believe that this includes the following provisions related to:

- Clarification that the administrative policies discussed in the preamble to the March 10, 2000 proposed rule and the NCDs in the addendum to the March 10, 2000 proposed rule apply equally to all clinical diagnostic laboratory tests payable under Part B regardless of setting (hospital and nonhospital). (See preamble section III and §410.28 and 410.32 of this final rule.)
- Clarification that use of the term ''screening'' or ''screen'' in a CPT code descriptor does not necessarily describe a test performed in the absence of signs or symptoms of illness, disease or condition. (See preamble section III.C.1.)
- Clarification of the use of modifier codes to indicate multiple services that are medically necessary to diagnose or treat the beneficiary's condition. (See section III.C.2. of the preamble.)
- Clarification that the signature of the ordering physician is not required for Medicare purposes on a laboratory test requisition. (See section III.D.3 of the preamble.)
- Clarification that appropriate diagnosis codes may be assigned to a narrative, even if wording of the narrative does not exactly match the code descriptor for the ICD–9–CM code. (See section III.E.1 of the preamble.)
- Clarification that laboratories may use the narrative field on the claims to report additional diagnoses if the Medicare contractor's system will not accept all of the codes in the diagnoses field. (See section III.E.2 of the preamble.)
- Clarification that in the absence of matching diagnosis to procedure codes supplied by the laboratory, Medicare contractors will examine all submitted codes on prepayment review, taking into account program integrity. (See section III.E.3 of the preamble.)
- Clarification that Medicare contractors will 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. (See section III.F.1 of the preamble.)
- Codification of the existing policy that Medicare will not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation submitted with the claim. (See section III.F.2 of the preamble and §410.32(d)(4) contained in this final rule.) Remaining provision of the rule, which are primarily provisions that are likely to involve system changes and require educational efforts to avoid erroneous denial of claims, will become effective November 25, 2002. These provisions include:
- Date of service (section III.A.3 of the preamble).
- Use of consistent remittance message (section III.F.4 of the preamble.
- National coverage decisions (addendum).
- Maintenance and submission of documentation (section III.D.1 and 2 of the preamble and §410.32(d)(2) and (d)(3)).

The effective dates for changes made to the CFR as described in this rule are as follows:

- Sections 410.28 (f) and section 410.32(e), which provide for equal application of the rules relating to laboratory service to hospital and CAHs, are effective February 21, 2002.
- The redesignation of paragraphs in §410.32(d) is effective February 21, 2002.
- Section 410.32(d)(2) and (d)(3), which specifies documentation and recordkeeping requirements and claims review procedures, are effective November 25, 2002.
- Section 410.32(d)(4), which provides for review of information submitted with a claim before denial for utilization parameters unless a national of local policy on the service exists, is effective February 21, 2002.

IV. Summary of Changes to the Proposed Rule

The proposed rule stated that the policies would be applicable to all laboratory tests ''billed under Medicare Part B, regardless of the location * * * (Physicians' office laboratories, hospital laboratories, independent laboratories, etc., or of the type of Medicare contractor processing the claims (carriers or fiscal intermediaries).'' 65 FR 13084. In order to make the policies applicable to all settings, Centers for Medicare & Medicaid Services is revising § 410.28 and § 410.32 to clarify the applicability of the provisions of this rule to hospitals and CAHs providing tests covered under Part B to outpatients.

1. We are adding the following codes to the list of codes covered by Medicare in the various policies:

Blood glucose: 780.31, 781.0, 783.6
Digoxin: 429.2, 972.0
Fecal Occult Blood Test: 003.0, 003.1, 095.2, 095.3, 098.0, 098.7, 098.84, 139.8, 159.0–159.9, 569.82, 569.83, 596.1, 751.1
Gamma Glutamyl Transferase: 230.7, 230.9, 642.5, 782.4, 789.1, 790.4, 790.5, V42.7
Lipids: 278.00, 401.0–401.9, 402.00–402.91, 403.00–403.91, 404.00–404.93, 405.01–405.99, V42.7
Prostate Specific Antigen: 236.5, 599.6, 788.30, 788.41, 788.43, 788.62
Human immunodeficiency virus testing (Diagnosis): 263.0, 263.1, 263.9, 486
Partial thromboplastin time: 362.30, 362.31, 362.32, 362.33, 362.34, 362.35, 362.36, 362.37, 410.0–.9, 456.8, 530.82,
Prothrombin time: 786.50, V12.51–V12.59
Iron Studies: 579.8, 579.9, 713.0, 716.4–716.9, V56.0, V56.8
Thyroid: 290.3, 297.1, 333.99, 358.1, 359.5, 376.21, 376.22, 425.7

2. We are removing the paragraph regarding denial of claims for services using devices that require, but do not have, FDA approval from the reasons for denial section of all 23 policies. Under the national coverage decision regarding clinical trials, certain items that require but do not have FDA approval may be covered.

3. We are amending the NCD on collagen crosslinks by adding a clarification that both men and women may receive the test. We are also deleting codes 203.00 and 203.01 from the list of ICD–9–CM codes that are covered by Medicare, as this diagnosis is not included in the indication section of the policy.

4. We are modifying the policy for Gonodotropin, chorionic (HCG); quantitative to clarify that the test is not useful for diagnosing pregnancy.

5. We are deleting the language proposed for inclusion in § 410.32(d)(4) on automatic denial and manual review that relates to egregious overutilization.

6. We are changing the effective date for certain provisions of the rule from that proposed. The following provisions are effective February 21, 2002, and we will issue the program instructions within 90 days of publication of the final rule. We believe that this includes the provisions related to the following:

• Clarification that laboratory policies apply equally to all laboratories (hospital and nonhospital) as contained in section III of the proposed rule, and §§ 410.28(f) and 410.32(e) of this final rule.

• Clarification of codes that use the word ''screening'' in the descriptor as contained in section III.C.1 of the proposed rule.

• Clarification of coding of multiple tests as contained in section III.C.2 of the proposed rule.

• Clarification the signature is not required on requisition as contained in section III.D.3 of the proposed rule.

• Clarification of coding narrative diagnoses as contained in section III.E.1 of the proposed rule,

• Clarification on the number of diagnoses on a claim as contained in section III.E.2 of the proposed rule.

• Clarification on diagnosis and procedure code matching as contained in section III.E.3 of the proposed rule.

• Publishing frequency guidance before implementing screens as contained in section III.F.1 of the proposed rule.

• Reminder of auto denial policies as contained in section III.F.2 of the proposed rule, and § 410.32(d)(4).

• Consistency in remittance messages as contained in section III.F.4. of the proposed rule.

Provisions that will become effective November 25, 2002 include the following:

• Date of service as described in section III.A.3. of the proposed rule.

• Use of consistent remittance message as described in section III.F.4 of the preamble.

• National coverage decisions as described in the addendum.

• Requesting documentation directly from ordering practitioner as described in section III.D.2 of the proposed rule and §§ 410.32(d)(2) and (d)(3) of this final rule.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) 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 PRA 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.

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 Centers for Medicare & Medicaid Services upon request; (1) documentation of the physician's order for the service billed (including information sufficient to enable Centers for Medicare & Medicaid Services 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 under 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 three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group, Division of Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850l. Attn: John Burke 3250–F; and Office of Information and

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

VI. Regulatory Impact Analysis

We have examined the impacts of this final 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 604 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 100 beds.

A. Executive Order 12866

The intent of this final 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 final rule to have a significant cost effect upon providers or suppliers. The provisions of the final 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 final 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. 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 will result in cost savings to the Medicare program. If an LMRP was more restrictive than a national coverage decision, it will 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 national coverage decisions will 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 $110 million. As noted above, we do not anticipate that this final rule will have a significant cost impact. Thus, we certify that this final rule will not result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector of $110 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 to $25 million or less annually (see 65 FR 69432). Intermediaries and carriers, physicians, and many laboratories are considered small entities.

This final rule will 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 final rule on these entities, for the most part, will be positive.

As stated above, this final rule will, for the most part, explicitly state and codify existing policies. Having a clear statement of policies will 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 will reduce the burden of recordkeeping and reporting on laboratories without increasing the burden on physicians. Publication of clear and consistent national coverage decisions will assist physicians and laboratories in knowing in advance situations in which 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 will 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 will result in denial of payment in situations in which payment is presently made. We

believe that the 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 will 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 will be covered by Medicare.

For these reasons, the Secretary certifies that this rule will 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, the Office of Management and Budget reviewed this regulation.

We have reviewed this 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 42 CFR Part 410

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

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services amends, 42 CFR chapter IV 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. A new paragraph (f) is added to § 410.28 to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

3. In § 410.32:

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

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

C. Paragraphs (d)(2) through (e) 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 or nonphysician practitioner.

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

(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 CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(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 or nonphysician practitioner, 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, CMS takes the following actions:

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

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

(C) If the ordering physician or nonphysician practitioner 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 or nonphysician practitioner 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, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if 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 law.

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital

Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 11, 2001.

Thomas A. Scully,

Administrator, Health Care Financing Administration.

Dated: October 9, 2001.

Tommy G. Thompson,

Secretary.

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. CMS 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 CMS'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.

Medicare National Coverage Decision

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).

HCPCS Codes

The descriptor(s) used in this section is (are) the Current Procedural Terminology (CPT) or other CMS 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

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 CMS policy.

ICD–9–CM Codes Denied

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

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 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
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)

Code	Descriptor
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 notreasonable 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 Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

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

Code	Descriptor
V82.0–V82.9	Special screening for other conditions

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

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
7536	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 anti-retroviral 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 anti-retroviral 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 Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

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

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 semi-quantitative, multiple step; HIV–1
87391	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, 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 that 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

Code	Description
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
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
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.9	Unspecified protein-calorie malnutrition
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
481.0–482.9.1	Pneumococcal pneumonia

Code	Description
484.1	Pneumonia in cytomegalic inclusion disease
486	Pneumonia, organism unspecified
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
647.60–647.64	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
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 Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

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–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

Any ICD–9–CM code not listed in either 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)
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

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 Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

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
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
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

Code	Description
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
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

Code	Description
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

Sources of Information

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Cancer: Principals & Practice of Oncology, DeVita, et al., 5th edition, Philadelphia: Lippincott-Raven, 1997.

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

Williams Hematology, Beutler, et al., 5th edition, 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
02.0–002.9	Typhoid and paratyphoid
03.0–003.9	Other Salmonella infections
038.9	Unspecified Septicemia
042	Human immunodeficiency virus (HIV) disease
060.0–060.9	Yellow fever
065.0–065.9	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
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

Code	Description
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
286.8–286.9	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
362.30–362.37	Retinal vasclar occlusion
362.34	Amaurosis fugax
362.43	Hemorrhagic detachmentof 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
410.0–410.9	Acute myocardial infarction
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
456.8	Varices of other sites
459.89	Ecchymosis
530.7	Gastroesophageal laceration—hemorrhage syndrome
530.82	Esophgael hemorrhage
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)
719.10–719.19	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
772.0–772.9	Fetal and neonatal hemorrhage
774.0–772.7	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
786.50	Chest pain, unspecified
786.59	Chest pain
789.00–789.09	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
803.00–803.99	Other fracture, skull
804.00–804.99	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
808.8–808.9	Fracture of pelvis
809.0–809.1	Fracture of trunk
810.00–810.13	Fracture of clavicle
811.00–811.19	Fracture of scapula

Code	Description
812.00–812.59	Fracture of humerus
813.10–813.18	Fracture of radius and ulna, upper end, open
813.30–813.38	Fracture of radius and ulna, shaft, open
813.50–813.58	Fracture of radius and ulna, lower end, open
813.90–813.98	Fracture of radius and ulna, unspecified part, open
819.0–819.1	Multiple fractures
820.00–821.39	Femur
823.00–823.92	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
861.00–861.32	Injury to heart and lung
862.0–862.9	Injury to other and unspecified intrathoracic organs
863.0–863.9	Injury to gastrointestinal tract
864.00–863.19	Injury to liver
865.00–863.19	Injury to spleen
866.00–866.13	Injury to kidney
867.0–867.9	Injury to pelvic organs
868.00–868.19	Injury to other intra-abdominal organs
869.0–869.1	Internal injury to unspecified or ill defined organs
900.00–900.9	Injury to blood vessels of head and neck
901.0–901.9	Injury to blood vessels of the thorax
902.0–902.9	Injury to blood vessels of the abdomen and pelvis
903.00–903.9	Injury to blood vessels of upper extremity
904.0–904.9	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 Amendment of 1988 (CLIA) certificate for the testing performed will result in denial of claims.

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 eoplasms
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

Any ICD–9–CM 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.

Wintrobe's Clinical Hematology; 9th Ed, 1993, Lea and Febiger.

Harrison's *Principles of Internal Medicine, 14th Ed., McGraw Hill, 1997.*

Disorders of Hemostasis, Ratnoff, Oscar D. and Forbes, Charles D., W.B. Saunders Company, 1996.

Hemostasis and Thrombosis: Basic Principles and Clinical Practice. *Colman,* et al editors, J.B. Lippincott, 3rd Edition, 1994, pp 896–898 and 1045–1046.

''College of American Pathologists Conference XXXI on Laboratory Monitoring of Anticoagulant Therapy,'' Arch Pathol Lab Med, Vol 122, Sep 1998, pp 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
084.8	Blackwater fever
120.0	Schistosomiasis
121.1	Clonorchiasos
121.3	Fascioliasis
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
342.90–342.92	Hemiplegia NOS
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

Code	Description
374.81	Hemorrhage of eyelid
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
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
1428.0–428.9	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

Code	Description
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 with 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
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 pelvic region and thigh
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

Code	Description
780.2	Syncope and 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
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
813.10–813.18	Fracture of radius and ulna, upper end, open
813.30–813.38	Shaft, open
813.50–813.58	Lower end, open
813.90–813.98	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
861.00–861.32	Injury to heart and lung
862.0–862.9	Injury to other and unspecified intrathoracic organs
863.0–863.9	Injury to gastrointestinal tract
864.00–864.19	Injury to liver
865.00–865.19	Injury to spleen
866.00–866.13	Injury to kidney
867.0–867.9	Injury to pelvic organs
868.00–868.19	Injury to other intra-abdominal organs
869.0–869.1	Internal injury to unspecified or ill defined organs
900.00–900.9	Injury to blood vessels of head and neck
901.0–901.9	Injury to blood vessels of the thorax
902.0–902.9	Injury to blood vessels of the abdomen and pelvis
903.00–903.9	Injury to blood vessels of upper extremity
904.0–904.9	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