Group Builds Consensus on Laboratory Test Policies

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by Sue Prophet, RRA, CCS

The Balanced Budget Act of 1997 (BBA) mandated that the Health Care Financing Administration (HCFA) use a negotiated rulemaking process to develop national administrative and coverage policies for clinical diagnostic laboratory tests under Medicare Part B. The BBA stipulates that the purpose of this negotiated rule is the development of administrative and coverage policies for clinical laboratory services that are designed to promote program integrity and national uniformity. It also intends to simplify administrative requirements, with consideration being given to the following:

- beneficiary information required to be submitted with each claim or order for lab tests
- the medical conditions for which a lab test is reasonable and necessary
- the appropriate use of procedure codes in billing for a lab test, including the unbundling of lab services
- the medical documentation that is required by a Medicare contractor at the time a claim is submitted for a lab test
- record-keeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements
- procedures for filing claims and for providing remittances by electronic media
- limitation on frequency of coverage for the same tests performed on the same individual

This section of the BBA was enacted in response to concerns about significant variations among fiscal intermediaries' and carriers' requirements for Medicare reimbursement for laboratory tests.

The BBA required the secretary of Health and Human Services (HHS) to establish a Negotiated Rulemaking Committee under the terms of the Negotiated Rulemaking Act and the Federal Advisory Committee Act. Negotiated rulemaking is a process by which a committee of representatives of interested parties that will be significantly affected by the rule—together with a representative of the appropriate government agency—attempt to reach consensus on the text or content of a proposed rule with the help of an impartial facilitator. Thus, in 1998, a Negotiated Rulemaking Committee was established to negotiate national coverage and administrative policies for clinical diagnostic laboratory tests.

A convening process was followed to determine the interests likely to be significantly affected by the proposed rule and who should be appointed to the committee to represent those interests. Impartial conveners interviewed potential parties and made recommendations to HCFA regarding committee membership, and members were appointed by the HHS. The committee was chartered under the Federal Advisory Committee Act, and comprised representatives from the following organizations:

- American Association of Bioanalysts
- American Association for Clinical Chemistry
- American Association of Retired Persons
- American Clinical Laboratory Association
- American Health Information Management Association
- American Hospital Association
- American Medical Association
- American Medical Group Association
- American Society for Clinical Laboratory Science
- American Society of Clinical Pathologists
- American Society of Internal Medicine
- American Society for Microbiology
- Clinical Laboratory Management Association
- College of American Pathologists
- Health Care Financing Administration
- Health Industry Manufacturers Association

- Medical Group Management Association
- National Medical Association

The committee met nine times between July 13, 1998, and January 27, 1999. Meetings were open to the public. The committee operated by consensus, defined as unanimous concurrence of committee members (concurrence means that the committee member could live with the decision).

The committee identified and resolved issues regarding administrative policies in the areas of documentation and record keeping, claims processing, procedure codes, and frequency limits and screens. Additionally, the committee developed 23 proposed national coverage policies for specific diagnostic laboratory tests or groups of tests. In order to facilitate the coverage policy development process and procure additional expert input for the development of specific coverage policies, work groups were created to develop the draft coverage policies for specific tests. The draft policies developed by the work groups were submitted to the full committee for approval.

The coverage policies proposed by the committee apply to all Medicare contractors processing Part B laboratory claims (e.g., both carriers and fiscal intermediaries would be required to adhere to the national policies). The policies apply to all laboratories, including independent and hospital-based laboratories, as well as to physicians and nonphysician practitioners qualified to order diagnostic tests.

The following describes the proposed policies in which the committee came to consensus. Please note that this does not mean these policies will automatically become regulations. HCFA will develop a proposed rule based on these concepts, which will be published in the *Federal Register* and will be open to public comment.

Administrative Policies

Documentation and Record Keeping

Section 4554(b)(2) of the BBA provides for uniform national policies for the medical documentation that is required by a Medicare contractor at the time a claim is submitted for a laboratory test and record keeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements. These policies would also cover any information required to be submitted with a claim, including physicians' obligations regarding such requirements. Section 4317 of the BBA states—with respect to diagnostic laboratory and certain other services—that if the secretary of HHS (or fiscal agent of the Secretary) requires the entity furnishing the service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner (ordering the service) shall provide that information to the entity at the time the service is ordered by the physician or practitioner.

The Necessary Information

The committee discussed which information should be furnished on a requisition for a laboratory test and which should be submitted with a claim to support medical necessity. Committee members concurred that the ordering provider must provide diagnostic information with a test requisition in those instances when the laboratory performing the test is required to submit this information on the claim (currently, Medicare does not require diagnostic information for all laboratory tests).

The committee also looked at whether or not diagnostic information should be required for all tests, even those not addressed by a national coverage or local medical review policy. Some committee members (including AHIMA) emphasized that providing information with each test requisition concerning the reason for the patient visit or the test would be useful in evaluating patient outcomes and quality of care and ensure consistency and uniformity. Other committee members expressed concern about the burden physicians would face in providing this information and the burden on laboratories in obtaining this information. However, it was pointed out that once regulations implementing the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) become effective, diagnostic information may be required on every claim. Since the committee did not reach consensus on this issue, no regulatory changes have been proposed as to when diagnostic information would be required.

Responsible Parties

It is important to note that throughout the committee's proposed regulations, diagnostic information was defined as ICD-9-CM code or narrative description. AHIMA felt strongly that the physician should provide the narrative diagnosis, followed by HIM professionals assigning the appropriate ICD-9-CM code to the diagnosis. AHIMA took this position because accurate coding requires specialized knowledge and education. This means that the physician may not possess the necessary knowledge of the coding rules and guidelines to assign the most accurate codes. Other committee members felt that it should be the physician's responsibility to furnish the appropriate diagnosis code(s) to support the ordered laboratory tests. The compliance program elements recommended by the Office of Inspector General (OIG) indicate that the provider submitting a claim is responsible for assuring the accuracy of the information contained on the claim, including the diagnosis and procedure codes. If the coding is performed by an entity outside the control of the provider submitting the claim, there is no way coding accuracy can be assured. Since it became apparent that the committee would be unable to reach unanimous consensus on this issue, the proposed regulatory language will permit diagnostic information furnished by the ordering provider to be in the form of a code or a narrative description. However, AHIMA continues to recommend that providers establish processes whereby the ordering provider submits a narrative diagnosis that is to be coded by a coding expert.

The committee agreed that the ordering provider is responsible for maintaining documentation of medical necessity in the patient's medical record. According to the regulations proposed by the committee, the entity submitting the claim for diagnostic laboratory services would be required to maintain the following information:

- the information that it receives from the ordering provider
- the records documenting that the claim information that it submitted to the Medicare contractor (carrier or fiscal intermediary) accurately reflects the information it received from the ordering provider

The entity submitting the claim may request additional diagnostic and other information to document that the services it bills are reasonable and necessary. When such a request is made, it must be focused on material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations regarding patient confidentiality.

The committee discussed who should be responsible for supplying documentation when a Medicare contractor performs a review of a laboratory claim. There was no dispute that laboratories are required to supply documentation that they must maintain, such as the requisition form. The discussion focused on whether medically necessary documentation maintained by the ordering physician should be supplied directly to the Medicare contractor or to the laboratory (who would then forward it to the contractor). Some committee members (including AHIMA) expressed concerns about protecting beneficiary confidentiality if copies of physicians' office records must be furnished to laboratories. It was noted that this practice could violate some confidentiality laws, unless patient consent was obtained. Some committee members noted that many Medicare contractors currently contact physicians directly in order to obtain medical records, and physicians may be more likely to provide the records to a Medicare contractor than to the laboratory, an approach that reduces the burden on laboratories. Thus, the committee proposed that, upon request by HCFA or a Medicare contractor, the entity submitting the claim would be required to provide the following information:

- documentation of the order for the service billed (including information sufficient to enable HCFA or its contractor to identify and contact the ordering provider)
- documentation showing accurate processing of the order and submission of the claim
- diagnostic or other medical information that supports medical necessity supplied to the laboratory by the ordering provider, including any ICD-9-CM or narrative description supplied

If the documentation provided above does not demonstrate that the service is reasonable and necessary, HCFA or its contractor would take the following actions:

- provide the ordering provider with sufficient information to identify the claim being reviewed
- request from the ordering provider those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed
- informing the entity submitting the claim for laboratory services that the documentation has not been supplied and the claim would be denied if the ordering provider does not supply the documentation requested
- permitting the entity submitting the claim for laboratory services to request additional diagnostic and other medical information from the ordering provider to document that ordered tests are reasonable and necessary. When such a

request is made, it would be required to focus on material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations concerning patient confidentiality

Retention Requirements

The committee discussed current retention requirements and decided not to create any new ones. Documentation of medical necessity shall be retained according to existing applicable requirements for medical record documentation.

Signing Off

The committee recommended that HCFA reiterate in the preamble to the proposed rule that a signature is not required for Medicare purposes on a requisition for laboratory tests, since there are apparently some Medicare contractors that are requiring a physician signature on the requisition.

Matching Up

The committee also recommended that a statement be included in the preamble to the rule explaining that a diagnosis code may in some circumstances appropriately be assigned to a narrative, even if the wording of the narrative does not exactly match the code descriptor. This statement is intended to resolve situations when Medicare contractors have indicated that the ICD-9-CM diagnosis code reported on the laboratory claim did not match the physician's narrative diagnosis, even though the code assigned is the correct code. For example, code 411.1 is the correct code for a diagnosis of unstable angina, even though the code description is for intermediate coronary syndrome.

Claims Processing

The committee discussed the current requirements regarding the beneficiary information to be submitted with each claim, as outlined in the *Medicare Carriers* and *Fiscal Intermediary Manuals*, and agreed not to change these requirements in the proposed regulations. HCFA noted that the current requirements are substantially different from the mandatory claims requirements proposed for the electronic submission of claims under the administrative simplification provisions of HIPAA. HCFA and healthcare providers must comply with all requirements developed pursuant to HIPAA.

Accepting Codes

The committee discussed variation among Medicare contractors in the number of ICD-9-CM codes on a claim form that the Medicare contractors' computer systems will accept. If a contractor's system accepts only a limited number of codes, a claim may be denied even if a code was furnished that supports the medical necessity of the test. When proposed HIPAA standards are implemented, eight ICD-9-CM codes will be permitted on electronic claims. Until these HIPAA standards are implemented, the committee agreed that the interim policy would require Medicare contractors, whose systems accept only a limited number of ICD-9-CM codes in the diagnosis code field, to permit the laboratory to submit additional codes in the narrative field. If this means the Medicare contractor would have to change its claims processing system in order to utilize information in the narrative field, the additional diagnosis codes would only be utilized by the Medicare contractor in processing claims that were suspended for manual review. This interim policy will appear in the preamble to the proposed rule and will be issued as an instruction to the Medicare contractors by HCFA.

The committee discussed the lack of uniformity among Medicare contractors in examination of all submitted diagnosis codes on prepayment review. Committee members reported that some contractors' automated claims processing systems match each submitted ICD-9-CM code with each CPT code submitted on the same claim. Others examine only the ICD-9-CM code placed on the same line as the CPT code or electronically linked to the CPT code. Under current policy, all Medicare contractors process claims using any diagnosis-to-procedure code matching supplied by the laboratory. The committee agreed that it would be most desirable to establish a mechanism whereby the contractors routinely examine all submitted diagnosis codes to establish medical necessity of the laboratory test(s) performed. As a result of committee discussion, HCFA will instruct its contractors that, in the absence of matching ICD-9-CM diagnosis codes with the related CPT procedure codes supplied by the laboratory, the Medicare contractor must examine all submitted codes on prepayment review, taking into account program integrity concerns. Claims will not be denied solely because the laboratory failed to link the diagnosis and procedure codes on the claim form.

Denial of Claims

The committee discussed ways to avoid denial of an entire claim if it is submitted with multiple laboratory tests and one of the diagnosis codes indicates screening or another service that is not covered by Medicare, but the laboratory does not indicate which test(s) was done for screening purposes. HCFA noted that in this circumstance, the contractor might deny all of the claimed services after examining the diagnosis codes if there is no information indicating which test(s) was performed for which purpose. HCFA will instruct the contractors to give laboratories the option of submitting a separate claim for the test that is not covered by Medicare. To ensure that non-covered tests can be identified, the committee concurred that providers who order the tests should supply the necessary information that specifically identifies any non-covered test that was ordered to the laboratory. This could include a test ordered for screening purposes. If this information is supplied to the laboratory by the ordering provider, the laboratory should indicate on the claim form which test is non-covered (by linking the ICD-9-CM code to the appropriate CPT code).

Confirming the Date

The committee discussed the need for a standard definition of the "date of service" on a claim form for a laboratory test. Committee members reported that some laboratory systems are programmed to report the date of acquisition of the specimen by the laboratory as the date of service. HCFA clarified that its interpretation is that date of service is the same as the date of collection of the specimen to be tested. HCFA noted that in some cases, the date of acquisition might occur after the patient has expired. The committee agreed that the preamble of the proposed rule would clarify that the date of service is the date of collection of the specimen, and the ordering provider would be required to furnish the date of collection to the laboratory. Some committee members were concerned about systems changes that may be necessitated by this definition, since some computer systems may not currently allow backdating in the date of service field. In the proposed rule, the public will be invited to comment on this issue and suggest alternative definitions or solutions.

Procedure Codes

Some committee members noted that use of the words "screen" or "screening" in the descriptor of some CPT codes can cause confusion in distinguishing between the process of screening for a disease or disease precursors (which is generally not covered by Medicare) and screening for a specific analyte or group of related analytes (which may be covered by Medicare). The failure to make this distinction can lead to inappropriate denial of claims. To clarify this distinction, the committee recommended that the preamble to the proposed rule explain that the use of the words "screening" or "screening for" in a CPT code description does not automatically mean that the purpose of performing the test is routine screening that is not covered by Medicare. Rather, these words may refer to the methodology of the test.

Committee members also noted potential confusion about multiple claims submissions by a laboratory that uses the same CPT code for the same beneficiary on the same day. Generally, such multiple testing will not be paid for under Medicare. Under certain circumstances, however, claims for multiple services that are assigned the same CPT code may be paid for because the multiple services are medically necessary to diagnose or treat the beneficiary's condition. Modifier -59 (Distinct procedural service) is the appropriate modifier to indicate that a procedure or service is distinct or independent from other services performed on the same day. This may represent a different patient encounter, a specimen from a different anatomic site or the same test performed on a different sample of the same type obtained on the same date of service (e.g., blood cultures or multiple identifications and susceptibilities from the same or different primary culture sources). The committee recommended that the preamble to the proposed rule indicate that multiple occurrences of the same CPT code may be appropriate, and that modifier -59 should be appended to the CPT code to indicate these circumstances.

Frequency Limits and Screens

The committee discussed concerns about the use of frequency screens and the potential for denials based on these screens. This is a problematic issue because frequency screens are not published, leaving no way for the laboratory to know the claim may be denied without additional documentation of medical necessity. HCFA clarified the distinction between frequency screens (utilization parameters used by Medicare contractors to identify claims for closer review to determine whether the tests may not be medically necessary) and frequency limits (limitations on frequency of coverage for the same tests performed on the same individual). Frequency screens are a program integrity tool and are therefore not published, whereas frequency limits are published.

Committee members believe some contractors are using frequency screens as absolute frequency limits on coverage. They also noted that the lack of uniformity among the contractors complicates the issue because providers may be submitting claims to more than one contractor and with no assurance that these claims will be similarly reviewed. A test that may be paid by one contractor may not be paid by another. HCFA agreed that a frequency screen would not result in automatic denial unless information for that test published by HCFA or the contractor includes an indication of the frequency that is generally considered reasonable utilization for Medicare payment purposes.

HCFA will issue instructions to its contractors, via the Medicare Carrier and Fiscal Intermediary Manuals. The instructions state that the contractors may not use a frequency screen that could result in denial unless the contractor has published information about the appropriate frequency for the service or HCFA has published information about the appropriate frequency in a national coverage policy. The information regarding appropriate frequency may either include the frequency with which the service is generally considered reasonable utilization for Medicare purposes or may be an absolute limit on coverage. The information must be published in advance of implementation of a frequency screen in a form—such as a contractor bulletin—that is widely disseminated to affected providers and suppliers. The contractors will consult with appropriate advisors, including medical specialty and other organizations, before developing and publishing local frequency information for a clinical diagnostic laboratory test. Local frequency information for a particular test may not conflict with a national policy that includes frequency information for that test. If a Medicare contractor has been applying a frequency screen in the absence of published information about the appropriate frequency, the contractor must either publish information about the appropriate frequency or stop using the frequency screen. Frequency screens that could result in denial must not be more restrictive than the frequency described in the published information. Contractors may, however, continue to deal with egregious utilization by using Category III edits described in section 7506.2 of the *Medicare Carriers Manual*, which are typically provider-specific.

The committee discussed the impact of frequency screens on laboratories furnishing services to beneficiaries that utilize multiple laboratories. Several committee members suggested proposals for notifying beneficiaries of frequency denials and requesting that they advise their physicians of the denial to encourage the physician to obtain an advance beneficiary notice (ABN). However, such a mechanism would be costly for Medicare, could inaccurately identify potential frequency denial situations due to time lags between encounters, and may be confusing to beneficiaries. The committee did not reach consensus on a solution, but HCFA recognizes the problem and welcomes suggestions outside of the committee's negotiations.

Some committee members expressed concern that HCFA may not be using a consistent denial message to indicate claims that are denied for excessive frequency. HCFA agreed to instruct its contractors to consistently use remittance advice language that identifies the reason for denial as excessive frequency. The language would read as follows: "Claim/Service denied/reduced because the payer deems the information submitted does not support this level of service, this many services, this length of service, or this dosage."

Communication and Implementation

The committee agreed that all administrative and coverage policies will become effective 12 months after publication of the final regulation, with a grace period of no more than 12 months after the effective date of the changes for any changes in systems that may be required. Priority for implementation will be given to the specific coverage policies.

HCFA will instruct its contractors to issue a bulletin to notify affected providers (physicians and laboratories) of policy implementation within 90 days of receiving this instruction from HCFA. The timing of the release of this bulletin will be such that it must be published at least 90 days before the effective date of the policies.

Coverage Policies

A national coverage policy for diagnostic laboratory test(s) is a document stating HCFA's policy regarding coverage of that test—including the circumstances under which the test(s) will be considered reasonable and necessary and covered—for Medicare purposes. This type of policy applies nationwide and is binding on all Medicare carriers, fiscal intermediaries, peer review organizations, HMOs, competitive medical plans, and healthcare prepayment plans, when published in a HCFA program manual or the Federal Register. A Medicare contractor cannot develop a local medical review policy that conflicts with a national coverage policy.

Although it would be desirable to have nationally uniform coverage policies for all laboratory tests, it was simply not possible to accomplish this within the time constraints imposed on the committee. Therefore, the committee focused its efforts on the tests identified as high priorities by committee members. Prioritization was given to a laboratory test if it met at least one of the following criteria:

- test is subject to wide divergence among Medicare contractors
- test is a high-volume test
- medical utility or clinical effectiveness of test is considered controversial

The committee first determined, through consensus, the list of priority tests to be addressed and then negotiated and reached consensus on national coverage policies for these tests, including the medical conditions for which these specific tests will be covered.

Its negotiated process for developing proposed national coverage policies included:

- forming work groups to address laboratory tests in six major clinical categories
- assigning tests (or groups of tests) to the work groups and establishing priorities for addressing those tests
- seeking input from relevant national medical specialty societies and voluntary health agencies
- reviewing relevant scientific literature, practice guidelines, and existing local medical review policies, as well as any relevant templates for local policies developed by a task force of carrier medical directors

The six clinical categories of tests addressed by work groups were endocrinology and metabolism, cardiology and other therapeutic drug monitoring, hematology and coagulation, oncology and anatomic pathology, infectious diseases, and gastrointestinal and renal diseases. Each work group was co-chaired by two committee members, and each committee member was entitled to apoint a designee to each work group. Each work group had at least one Medicare carrier medical director as a nonvoting consultant, and a pathologist, another specialty physician, a primary care physician, a laboratory expert, a coding expert, and a Medicare expert (HCFA staff member). The coding expert on each work group was an HIM professional appointed by AHIMA.

Work group recommendations for specific coverage policies were posted on the HCFA Web site and public comments were solicited. The full committee then considered each work group recommendation, as well as any comments from the public or from committee members, and modified the draft policies as needed. The committee reached consensus on the following tests or groups of tests:

- alpha-fetoprotein
- prostate specific antigen (diagnostic)
- carcinoembryonic antigen
- human chorionic gonadotropin, quantitative
- tumor antigen by immunoassay-CA125
- tumor antigen by immunoassay-CA15-3/CA27.29
- tumor antigen by immunoassay-CA19-9
- glycated hemoglobin/glycated protein
- thyroid testing
- blood glucose testing
- collagen crosslinks
- digoxin therapeutic drug assay
- lipids
- gamma glutamyl transferase
- hepatitis panel
- fecal occult blood
- blood counts
- prothrombin time
- partial thromboplastin time
- serum iron studies
- bacterial urine cultures

- HIV testing (diagnosis)
- HIV testing (prognosis including monitoring)

The policies on tumor antigens and blood glucose testing are contingent upon related changes being made to the CPT codes for these tests. This will enable the procedures discussed in each policy to be the only ones appropriate for the assignment of a particular CPT code.

The committee developed a uniform format, used for all of the proposed coverage policies. This format includes:

- the narrative description of the test, panel of tests, or group of tests addressed in the policy
- the CPT code for the test(s) addressed in the policy
- the clinical indications for Medicare coverage of the test
- limitations on use of the test(s), which include 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)
- the ICD-9-CM diagnosis codes covered by Medicare (this section includes the codes for which there is a presumption of medical necessity for performing the test(s), but the claim is still subject to review to determine whether the test was in fact reasonable and necessary)
- the ICD-9-CM diagnosis codes denied (codes that are never covered—when one of these codes is the reason for performing the test, it may be billed to the beneficiary without first billing Medicare because the test is a service that is never covered under any circumstances, such as a screening test)
- the ICD-9-CM codes that do not support medical necessity (generally non-covered codes for which there are only limited exceptions—diagnosis codes in this section will generally result in denial, but in certain circumstances, additional documentation could support a determination of medical necessity and should be submitted with the claim)
- specific documentation requirements related to the test(s) addressed in the policy
- a list of the sources of information that were used in developing the policy
- applicable coding guidelines

There is also a section in each coverage policy titled "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) addressed in the policy. The section on "reasons for denial" was not negotiated by the committee, but represents HCFA's interpretation of its long-standing policies and is included in the policies for informational purposes.

In each coverage policy, the section on coding guidelines includes some standard guidelines that apply to all tests, as well as any specific guidelines relevant to the specific test or group of tests addressed in the policy. These are the standard coding guidelines that appear in each policy:

- Any claim for a test listed in "HCPCS CODES" in the policy 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 the physician has not established a diagnosis. (Based on *Coding Clinic for ICD-9-CM*, Fourth Quarter 1995, page 43)
- 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 confirm a suspected diagnosis in response to the patient showing a sign and/or symptom is considered to be 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 due to the patient's having contact with, or exposure to, a communicable disease, the appropriate code from category V01, Contact with or exposure to communicable diseases, should be assigned. While this is not a screening code, the test may still be considered screening and may not be 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)
- 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)

- 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)
- 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

In developing national coverage policies for the tests assigned to each work group, the committee agreed to use one of two approaches, inclusionary and exclusionary. Policies using the inclusionary approach list 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. In lieu of listing all of 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." Thus, when the exclusionary approach was used, ICD-9-CM codes that are not listed in the policy are the acceptable codes for which the test or group of tests is covered by Medicare. The proposed coverage policy for blood counts is an example of a policy that was developed using the exclusionary approach.

Related Issues Not Subject to Negotiations

The following issues were areas of concern that were raised during the process of negotiating administrative and coverage policies for laboratory tests, but were determined to be outside the scope of the negotiated rulemaking mandated by Congress. Therefore, the committee did not address them.

Use of Requisition Forms

Some of the representatives of the laboratory industry indicated that they would like a standard requisition form for ordering laboratory services to be developed as a means of standardizing information exchange. HCFA indicated that the Medicare program's interest is limited only to that information necessary to allow a determination regarding Medicare benefits. It does not extend to how information is exchanged among providers, physicians, and suppliers.

Enforcement of Physician Reporting

It was suggested that sanctions or other enforcement mechanisms be established for physicians who do not provide the required documentation to the laboratory. HCFA noted that the BBA requires physicians and other practitioners to include diagnostic information with their laboratory orders when such information is required by HCFA or a contractor in order for the laboratory to get paid. However, the statute does not expressly authorize sanctions for violations of these requirements, and HCFA does not have the resources to monitor and develop the necessary record to pursue sanctions or other disciplinary mechanisms.

Advance Beneficiary Notice

It was suggested that policies related to issuance of the advance beneficiary notice be addressed during the negotiations. It was noted that there is a wide divergence in practices regarding the procurement of an ABN for non-covered laboratory services. Also, since laboratories often have no direct patient contact, they have little or no control over the information that is provided to the beneficiary. However, HCFA did not believe that the policies related to ABNs were written within the scope of negotiations.

Elimination of Local Coverage Policy

It was suggested that local medical review policies should not be permitted, as they are inconsistent with the goal of promoting national uniformity. However, the BBA expressly authorizes local coverage policies as necessary to assure program integrity. The BBA states "After the date the Secretary first implements such national policies, the Secretary shall permit any carrier to develop and implement interim policies ..., in cases in which a uniform national policy has not been established ... and there is a demonstrated need for a policy to respond to aberrant utilization or provision of unnecessary tests."

Screening Tests

Some laboratory provider representatives suggested negotiations on interpretive guidelines for screening tests, since HCFA's policy on what constitutes screening is unclear and misunderstood. However, the issue of interpretive guidelines for screening services involves a broader segment of the medical community than just the interested parties identified for the clinical laboratory negotiated rulemaking process. Therefore, it would not be appropriate for the committee to address this issue.

Note: AHIMA will keep you informed of developments pertaining to implementation of the proposed regulations pertaining to administrative and coverage policies for clinical diagnostic laboratory tests. It is not known when the proposed rule will be published in the Federal Register, but it is anticipated to be in late 1999 or the first part of next year.

For further information concerning the proposed national administrative and coverage policies for clinical diagnostic laboratory tests, contact Sue Prophet at AHIMA.

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