# Laboratory Services Regulations Impact National Coverage Decisions, HIM



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*This is Part 2 of a two-part article on laboratory services regulations. Part 1, which appeared in the September Journal of AHIMA, dealt with the administrative policies contained in these regulations. Part 2 addresses the specific national coverage decisions that were developed as part of this regulatory process. For more information on each coverage policy, review Addendum B of the regulations.*

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Understanding the national coverage policies is extremely important when coding in any setting. Information contained in these policies will assist you in coding, billing, and working with physicians on documentation and coverage issues. Consider creating a task force to communicate these regulations across your organization to ensure that all staff affected by these policies are aware of the changes and can explain them to patients and physicians. The implications these national coverage policies carry for HIM are outlined below.

Coverage and administrative policies for clinical diagnostic laboratory services were developed by a negotiated rulemaking committee and the final regulations regarding these policies were published in the November 23, 2001, *Federal Register*.

## Prioritizing the Tests

Because it was not possible to develop national coverage policies for all diagnostic laboratory tests within the regulatory time constraints, tests were prioritized, resulting in the development of 23 national coverage policies. A test was given prioritization if it met at least one of the following criteria:

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

Work groups were established to develop coverage policies in six major clinical categories. The work groups were comprised of medical experts and professionals with expertise in coding, laboratory testing, clinical research, and Medicare regulation.

One of two approaches was used in the development of the coverage policies: 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. An example of a coverage policy that used the exclusionary approach is the policy for 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**.

## A New Format

A uniform format for national coverage policies was developed and used in their development (see "Sample National Coverage Policy," below ). This format includes the following sections:

**Other Names/Abbreviations**

This section identifies other names for the policy and the actual tests. It generally reflects the more colloquial terminology that is often found in medical record documentation.

**Description**

This section includes a description of the tests addressed by the policy and provides a general description of the appropriate uses of the tests. The description contains very useful information describing when and how the test is used in medical practice.

**HCPCS Codes**

The descriptor used in this section is the CPT or the Centers for Medicare & Medicaid Services' (CMS) Healthcare Common Procedure Coding System (HCPCS). 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 (below).

**Indications**

This section lists detailed clinical indications for Medicare coverage of the tests. The indications section works closely with the actual HCPCS codes and ICD-9-CM diagnostic codes. The negotiated rulemaking committee made every effort possible to ensure that the indications accurately depicted the codes selected. In order for a diagnosis to be added for a clinical laboratory test, information was required to describe the diagnostic indications.

Coding professionals should read the indications section very carefully. If indications are listed for a diagnosis in which no ICD-9-CM code is listed, then the indications and documentation supporting the service should be sent to the local Medicare contractor for further review and request for reimbursement.

**Limitations**

This section lists any national frequency expectations as well as other limitations on Medicare coverage of the specific tests addressed in the policy. For example, it would explain whether 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 in which 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. 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 tests. This section reflects CMS policy and was not negotiated by the committee.

**ICD-9-CM Codes Denied**

This section lists codes that are never covered for the laboratory tests listed. 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. This is because the service is not covered by statute because it is performed for screening purposes and is not within an exception. The beneficiary, however, has a right to have the claim submitted to Medicare, upon request.

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

This section lists and 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, 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, 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. This information is useful if additional research is needed.

**Coding Guidelines**

This section includes coding guidelines that apply generally to all policies, as well as any additional coding instructions appropriate for a specific national coverage policy. The coding guidelines may be from or based on information in Coding Clinic.

**Documentation Requirements**

This section refers to documentation requirements for clinical diagnostic laboratory tests in 42 CFR 410.32(d) and includes any specific documentation requirements related to the tests addressed in the policy. This information is useful in educating physicians on the specific documentation requirement.

**Other Comments**

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

## *Sample National Coverage Policy*

**Culture, Bacterial, Urine, also known as Urine culture**

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.

**CPT Codes**

87086, 87087, 87088, 87184, and 87186

**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**

003.1; 038.0-038.9; 276.2; 276.4; 286.6; 288.0; 288.8; 306.53; 306.59; 518.82; 570; 580.0-580.9; 583.0-583.9; 584.5; 584.9; 585; 586; 590.00-590.9; 592.0-592.9; 593.0-593.9; 594.0-594.9; 595.0-595.9; 597.0; 597.80-597.89; 598.00-598.01; 599.0; 599.7; 600; 601.0-601.9; 602.0-602.9; 604.0-604.99; 608.0-608.9; 614.0-614.9; 615.0-615.9; 616.0; 616.10-616.11; 616.2-616.9; 619.0-619.9; 625.6; 639.0; 639.5; 646.60-.64; 670.00-.04; 672.00-.04; 724.5; 780.2; 780.6; 780.79; 780.9; 785.0; 785.50-.59; 788.0-788; 789.00-789.09; 789.60-789.69; 790.7; 791.0-791.9; 799.3; 939.0; 939.3; V44.50-V44.6; V55.5-V55.6; V58.69; V72.84

**Coding Guidelines Specific to Urine Cultures**
**(as listed in the *Federal Register*)**

A. Use CPT 87086 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 where a commercial kit uses manufacturer-defined media for isolation, presumptive identification, and quantification of morphotypes present. The number of units of service is determined by the number of specimens.

C. Use CPT 87088 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 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. gonorrhea).

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.

I. 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.

J. 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.

## *Understanding the Terms*

Negotiated rulemaking is a process by which a committee of representatives of interested parties that will be significantly affected by the regulation (along with a representative of the appropriate government agency) attempts to reach a consensus on the content of the regulation with the assistance of an impartial facilitator.

A national coverage policy for diagnostic laboratory test(s) is a document stating CMS' policy with respect to the circumstances under which the tests will be considered reasonable and necessary and not screening for Medicare purposes. It is neither a practice parameter nor a statement of the accepted standard of medical practice.

A national coverage policy is considered a national coverage decision. It applies nationwide. A Medicare contractor may not develop a local medical review policy that conflicts with a national coverage policy.

## References

"Medicare Program: Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services." 42 CFR Part 410. *Federal Register* 66, no. 226 (November 23, 2001). Available at http://cms.hhs.gov/regulations/regnotices.asp.

Medicare Transmittal AB-02-030 is available at the CMS Web site at http://cms.hhs.gov/manuals/memos/comm_date_dsc.asp.

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