Decision Memo for Prothrombin Time and Fecal Occult Blood (Revision of ICD-9-CM Codes for Injury to Gastrointestinal Tract) (CAG-00187N)

Decision Summary

CMS has determined that ICD-9-CM codes 863.91 through 863.99 flow from the existing narrative for conditions for which PT and FOBT tests are reasonable and necessary. We intend to modify the NCDs for PT and FOBT testing to include codes 863.91 through 863.99 in the list of ICD-9-CM codes covered by Medicare for these services.

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Decision Memo

To: Administrative File: CAG-00187N Prothrombin Time (PT) and Fecal Occult Blood Test (FOBT) (Revision of International Classification of Diseases-Ninth Revision-Clinical Modificatons (ICD-9-CM) Codes for Injury to Gastrointestinal Tract)

From:

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Re: Decision Memorandum for PT and FOBT for Injury to Gastrointestinal Tract

Date: September 17, 2003

I. Decision

CMS has determined that ICD-9-CM codes 863.91 through 863.99 flow from the existing narrative for conditions for which PT and FOBT tests are reasonable and necessary. We intend to modify the NCDs for PT and FOBT testing to include codes 863.91 through 863.99 in the list of ICD-9-CM codes covered by Medicare for these services.

II. Background

On June 3, 2003 CMS began a national coverage determination process for clarification of ICD-9-CM codes for injury to the gastrointestinal tract with regard to the PT and FOBT NCDs. Basic plasma coagulation function may be assessed using the PT test. Coagulation results from a sequence of reactions involving several coagulation factors. When any of the factors are present in deficient quantity, the PT is prolonged. Deficiencies of coagulation factors may be related to their decreased production or increased consumption. Fecal occult blood tests (FOBT) detect the presence of trace amounts of blood in stool. The range of causes for blood loss includes inflammatory, infectious, vascular, drug, neoplastic diseases, as well as injuries in the gastrointestinal tract.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. Two of these NCDs were for PT and FOBT testing. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that coverage of specific tests was reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test in question is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM codes covered by Medicare” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM codes denied” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM codes that do not support medical necessity” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the PT and FOBT NCDs that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into group three.

IV. Timeline of Recent Activities

As mentioned above, on March 10, 2000 CMS published a Notice of Proposed Rulemaking (NRPM) in the Federal Register (65 FR 13082). As an addendum to this NPRM, we proposed the 23 NCDs as negotiated by the rulemaking committee for public comment. On November 23, 2001, we published a final rule for coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58788). Both the PT and FOBT NCDs included the ICD-9-CM code range 863.0-863.9 in the list of ICD-9-CM codes covered by Medicare, which encompasses injuries to the gastrointestinal tract with or without mention of open wound into cavity affecting the stomach, small intestine, colon, rectum, and other gastrointestinal sites.

On January 1, 2003, CMS introduced a laboratory edit software module to implement the NCDs. As part of the development of the software, we reviewed each ICD-9-CM code included in the NCDs to ensure that they were displayed at their highest level of specificity. During this review, we discovered that ICD-9-CM code 863.9 did not have the required fifth digit. Because the narrative description of the codes in the 863.0 through 863.9 range merely stated injury to the gastrointestinal tract, our contractor subsequently included only the unspecified site code 863.90 in the list of covered diagnoses rather than the full range of codes 863.90 through 863.99 which includes the pancreas, appendix and other sites.

On February 26, 2003, we received an inquiry regarding why the remaining codes in the 863.9 series were not included in the list of covered procedures that prompted us to investigate this issue.

On June 3, 2003 we announced in a tracking sheet posted on the Medicare coverage Internet site (http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=97) that we were considering adding codes 863.91 through 863.99 to the list of covered diagnoses for PT and FOBT and solicited public comments during a 30-day period. At the end of the public comment period, July 3, 2003, we had not received any comments. Since this is an internally generated request and there have been no comments from the public, external meetings have not been necessary.

V. FDA Status

Not Applicable

VI. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage.

We reiterated this position in the November 23, 2001 final rule (66 FR 58795) in responding to public comments requesting the addition of numerous codes to the NCDs. The rule provides that:

“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 code 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.”

Further, in Program Memorandum AB 02-110 we stated:

“The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD. "

Accordingly, in considering whether to add codes 863.91 through 863.99 to the list of Medicare covered diagnoses for PT and FOBT we had to determine whether these codes were an appropriate translation of an existing indication.

VII. CMS Analysis

As noted above, we have steadfastly taken the position that the ICD-9-CM Codes Covered by Medicare list is intended to contain only those codes that flow from the narrative of the indications in the NCD. The PT NCD lists the following indication for PT testing:

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

a. Swollen extremity with or without prior trauma

b. Unexplained bruising
c. Abnormal bleeding, hemorrhage or hematoma
d. Petechiae or other signs of thrombocytopenia that could be due to disseminated intravascular coagulation."

The FOBT indications in the narrative of the NCD include the following:

"To evaluate known or suspected alimentary tract conditions that might cause bleeding into the intestinal tract."

We believe that the ICD-9-CM codes for pancreas (head, body, tail, multiple and unspecified sites), appendix, and other gastrointestinal sites with open wound into cavity represented by codes 863.91 through 863.99 appropriately flow from the indications noted above which are in the existing narrative of the PT and FOBT NCDs. Clearly these gastrointestinal organs with an open wound into cavity could be known or suspected causes of bleeding into the intestinal tract, an existing indication for FOBT testing. Further, we believe that such wounds could produce signs and symptoms of abnormal bleeding which would support the performance of a PT test.

Consequently, we intend to modify the NCDs for both PT and FOBT testing to add the following codes to the list of the ICD-9-CM codes covered for these tests:

863.91, Pancreas head with open wound into cavity
863.92, Pancreas body with open wound into cavity
863.93, Pancreas tail with open wound into cavity
863.94, Pancreas multiple and unspecified sites with open wound into cavity
863.95, Appendix with open wound into cavity
863.99, Other gastrointestinal sites with open wound into cavity
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