Decision Memo for Codes That Are Not Covered by Medicare (Removal of ICD-9-CM Code V76.44, Prostate Cancer Screening, From the List) (CAG-00297N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code V76.44, Prostate cancer screening, is not appropriately included on the list of ICD-9-CM codes that are not covered by Medicare. We intend to modify the list of “ICD-9-CM Codes Denied” in the Laboratory NCD Coding Manual. This change affects all of the 23 negotiated clinical diagnostic laboratory NCDs. Since removal of V76.44 from the codes denied list would automatically result in inappropriate inclusion on the list of covered diagnoses for blood counts, we have also added V76.44 to the list of codes that do not support medical necessity for blood counts.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Denied that are linked to the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG-00297N Codes That Are Not Covered by Medicare (Removal of ICD-9-CM Code V76.44, Prostate Cancer Screening, From the List)

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RE: Coding Analyses for Codes That Are Not Covered by Medicare

DATE: October 3, 2005

I. Decision

CMS has determined that ICD-9-CM diagnosis code V76.44, Prostate cancer screening, is not appropriately included on the list of ICD-9-CM codes that are not covered by Medicare. We intend to modify the list of "ICD-9-CM Codes Denied" in the Laboratory NCD Coding Manual. This change affects all of the 23 negotiated clinical diagnostic laboratory NCDs. Since removal of V76.44 from the codes denied list would automatically result in inappropriate inclusion on the list of covered diagnoses for blood counts, we have also added V76.44 to the list of codes that do not support medical necessity for blood counts.

II. Background

On August 9, 2005, CMS began a coding analysis for evaluation of the list of ICD-9-CM codes that are not covered by Medicare to consider removal of ICD-9-CM code V76.44, Prostate cancer screening, from the list. The list of codes that are not covered by Medicare is applicable to all 23 of the negotiated clinical diagnostic laboratory NCDs. This list is intended to reflect codes that are never covered by Medicare for reasons other than medical necessity and includes, among other things, diagnoses that would be excluded from coverage under section 1862(a)(7) of the Social Security Act for routine physical exams.

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. 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 specific tests were 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 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 ICD-9-CM Codes Denied are applicable to all 23 of the negotiated clinical diagnostic laboratory NCDs. 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.

IV. Timeline of Recent Activities

On August 9, 2005, CMS opened a coding analysis regarding the inclusion of a diagnosis of prostate cancer screening (V76.44) on the list of IDC-9-CM diagnosis codes that are not covered by Medicare. We posted a tracking sheet to the Internet site (http://cms.hhs.gov/mcd/viewtrackingsheet.asp?id=167), soliciting public comment for 30 days on the appropriateness of removing code V76.44 from the list of codes that are not covered by Medicare. This list (also called ICD-9-CM Codes Denied) is applicable to all 23 of the negotiated clinical diagnostic laboratory NCDs.

At the end of the public comment period, September 9, 2005, we had received 27 comments. Some of the commenters apparently misinterpreted the intent of the proposal and the scope of its applicability, raising questions relative to the billing of screening prostate specific antigen (PSA) tests and/or stating that we should not remove the code from the denied list while arguing that it should be covered. Most other commenters expressed support for the proposal to remove the code from the non-covered list. The comments related personal conclusions and did not provide any scientific literature to support their conclusions.

V. 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. Similarly, the “ICD-9-CM Codes Denied” list was intended to reflect codes that are always denied by Medicare based on a provision of the law other than medical necessity. On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

VI. CMS Analysis

At the time the negotiated rulemaking committee for clinical diagnostic laboratory tests was developing its recommendations for NCDs in 1998, the statutory language governing Medicare in the Social Security Act did not provide for coverage of screening for prostate cancer. We have historically interpreted section 1862(a)(7), the statutory exclusion of routine physicals, to also exclude coverage of routine testing provided during such visits. Further, we have interpreted the exclusion of services that are not reasonable and necessary in section 1862(a)(1)(A) of the Act to exclude tests for which there are no signs, symptoms or personal history of disease, except where specifically noted in the law. Thus, in developing the list of codes for the “ICD-9-CM Codes Denied” list, we included all screening diagnoses other than those specifically covered by statute. This resulted in ICD-9-CM diagnosis code V76.44 being included on the list of ICD-9-CM Codes Denied in the NCD proposals.

Effective January 1, 2000, the Social Security Act was amended to add coverage of prostate cancer screening under section 1861(oo) of the Act. This amendment provides for prostate cancer screening at a frequency of no more often than annually for men over age 50. Although this change in the statute became effective before the negotiated laboratory NCD rule became final in November 2001, it appears that the inclusion of the diagnosis codes for prostate cancer screening on the list of “ICD-9-CM Codes Denied” went unnoticed by both CMS staff and the public commenters on the proposed rule. Consequently, it was incorporated into the final rule and has remained on the denied list without comment for nearly 3 years after implementation.

Given that the statute currently covers prostate cancer screening, it is inappropriate to include this code on the “ICD-9-CM Codes Denied” list. We will remove the code in the January 2006 update of the laboratory edit module and NCD coding manual. We do not believe that this error has resulted in inappropriate payment. This is because the appropriate HCPCS code for billing for screening PSA testing is G0103. G0103 is not included in any of the 23 NCDs and, therefore, is not edited for the codes on the “ICD-9-CM Codes Denied” list. Although CPT code 84153, Prostate specific antigen (PSA), total, is one of the NCDs, this code is not to be used for screening PSA testing.

The blood count NCD was developed on an exclusionary basis. That is, unlike the other 22 negotiated laboratory NCDs that include a specific list of ICD-9-CM codes that are covered, the blood count NCD covers all ICD-9-CM codes that are not listed on the ICD-9-CM Codes Denied list or the ICD-9-CM Codes that Do Not Support Medical Necessity. Thus, removal of code V76.44 from the non-covered list would result in coverage for blood counts if the code is not added to the Does Not Support Medical Necessity list. Given that screening for prostate cancer is not an appropriate medical indication for a blood counts and does not flow from the narrative indications for blood counts, we are will be adding ICD-9-CM code V76.44 to the list of codes that Do Not Support Medical Necessity for the blood count NCD.

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