



American
Clinical Laboratory
Association

December 10, 2011

Mr. Marc Hartstein, Acting Director
Hospital and Ambulatory Policy Group
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Mr. Hartstein:

On behalf of the American Clinical Laboratory Association (“ACLA”), I am writing to express our concerns about CMS’s recent actions with respect to HCPCS code G0416, which is used to bill for examination of prostate needle saturation biopsy samples. Recent directives from the National Correct Coding Initiative (“NCCI”), from Medicare contractors, and from CMS itself have been unclear as to how this code is to be billed. We are concerned that CMS is asking laboratories to use this code, originally intended for the far rarer prostate needle saturation biopsy procedure, as a substitute for the code describing the more common prostate needle biopsy procedure. If that is the intent, CMS is instructing laboratories to use incorrect codes for standard prostate needle biopsies, a directive that violates basic tenets of coding in the Medicare program. In addition, it appears that CMS may be using a short-cut to impose a new bundling requirement on prostate biopsies through an improper and unfair process.

ACLA members remain committed to coding and billing correctly for laboratory procedures, and we hope to receive clarification about the proper codes to use when examining prostate needle saturation biopsies and when examining standard prostate needle biopsies. We also will be submitting this letter as a comment on the Medicare Physician Fee Schedule Final Rule with Comment Period, which recently made further changes to CMS’s policy with respect to prostate needle saturation biopsy examination (as described below). We are hopeful that CMS can address these concerns as soon as possible because of the confusion that currently exists in this area.

A. Background

1. Prostate Needle Saturation Biopsy v. Prostate Needle Biopsy

A prostate needle saturation biopsy procedure is not the same as a standard prostate needle biopsy procedure. The objective of a prostate needle saturation biopsy procedure is to sample extensively from the entire prostate using image guidance and to extract the biopsies from precise points within the prostate using a mapping grid or template. With saturation biopsy, it is rare that fewer than 30 individual needle core biopsies are procured during the procedure. Because of the extensive nature of the procedure, a prostate needle saturation biopsy is performed under general anesthesia. This procedure is appropriate when a physician has a high suspicion that a patient has prostate cancer because the patient has an elevated Prostate

Specific Antigen (“PSA”) that is persistently rising, he has had an atypical prior prostate biopsy, or there is evidence of malignancy of the prostate.

A standard prostate needle biopsy procedure, on the other hand, typically involves between two and 12 core needle biopsies taken by the physician from two to five zones within the prostate, and it does not involve grid mapping but may employ ultrasound guidance. This type of biopsy is less comprehensive than a saturation biopsy and is performed under local anesthesia. A decision to perform a prostate needle biopsy takes into account multiple factors, including free and total PSA, patient age, family history, prior biopsy history and comorbidities.

In general, a standard prostate needle biopsy is performed to diagnose cancer, while a prostate needle saturation biopsy is more typical when a physician knows that cancer is present and needs to determine whether a malignancy has grown or spread. As a result, a prostate needle saturation biopsy is a fairly rare procedure that is used only in very specific circumstances. A review of the Medicare claims for 2010 shows that HCPCS code G0416 was submitted on only about 9,000 claims.¹ Prostate needle biopsies, on the other hand, are far more common, and, as we note, they usually require fewer specimens.

2. Implementation of G-Codes for Examination of Saturation Biopsies

CMS implemented HCPCS code G0416 in the Medicare Physician Fee Schedule Final Rule for CY 2009 to be used for “surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens,” and it implemented three other G-codes to be used when the number of specimens is between 21 and 40 (G0417), 41 and 60 (G0418), and greater than 60 (G0419).² When it proposed the codes, CMS explained that saturation biopsy typically entails “40 to 80 core samples taken from the prostate under general anesthesia,” and examination of each core historically had been billed individually using CPT code 88305, “Level IV surgical pathology, gross and microscopic examination.” At the time, CMS stated: “We believe that paying individually for review of each core sample submitted grossly overpays for the pathological interpretation and report for this service,” and it grouped payment for a certain number of core biopsies, instead. *However, CMS also specified that “[u]nder the PFS, CPT code 88305 will continue to be recognized for those surgical pathology services unrelated to prostate needle saturation biopsy sampling.”*³

Thus, it is clear that when the agency established the new G-codes for prostate saturation biopsies, it was concerned with a particular type of collection procedure. Because of the number of biopsies taken during the saturation procedure, the agency was concerned about overpaying if the code for a standard biopsy was used to bill for each saturation sample, instead. However, the agency also distinguished the prostate needle saturation biopsy procedure from the more

¹ 2010 Part B National Data Summary File, *available* at: <http://www.cms.gov/apps/ama/license.asp?file=/NonIdentifiableDatafiles/Downloads/PartBNational2010.zip>. At that time, code G0416 was used to describe examination of prostate needle saturation biopsies with 1-20 specimens.

² Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 73 Fed. Reg. 69,726, 69,751 (Nov. 19, 2008).

³ *Id* (emphasis added).

common standard prostate biopsy, which takes far fewer samples, and it noted that it would continue to pay separately for that service.

3. Recent Prostate Needle Saturation Biopsy Policies Issued by CMS and Medicare Contractors

Notwithstanding the clear statement of policy, recently, Medicare contractors have taken steps that appear to disregard the distinctions between these two types of procedures. First, the NCCI Policy Manual for 2012 established a new edit for prostate saturation biopsies, which was worded ambiguously and seemed to conflate examination of prostate saturation biopsy specimens with examination of prostate needle biopsy specimens. It stated:

HCPCS codes G0416-G0419 describe surgical pathology, including gross and microscopic examination, of prostate needle biopsies from a saturation biopsy sampling procedure. CMS requires that these codes rather than CPT code 88305 be utilized to report surgical pathology on prostate needle biopsy specimens only if the number of separately identified needle biopsy specimens is five or more. Surgical pathology on four or fewer prostate needle biopsy specimens should be reported with CPT code 88305 with the unit of service corresponding to the number of separately identified biopsy specimens.

This policy could be interpreted to state a new position, which had not been stated previously; *i.e.*, that the prostate biopsy codes are to be used where five or more biopsies are taken, and that the standard biopsy codes should be used when four or fewer are involved, regardless of the type of biopsy procedure. It is unclear from the policy's wording whether it is applicable to *any* biopsy of the prostate or only to those taken using the saturation biopsy technique. To our knowledge, however, neither the NCCI contractor nor CMS ever stated publicly that the policy was intended to apply to all types of prostate biopsies.

In August 2012, however, Palmetto GBA, the Medicare contractor for the J1 and J11 regions, issued an article based on the NCCI Policy Manual, applying the edit to *all prostate biopsies*, regardless of whether they are prostate needle saturation biopsies or standard prostate needle biopsies. Palmetto also said that laboratories may be at risk for overpayment collection for dates of service on and after January 1, 2012 for not adhering to its interpretation of this rule.⁴ The Palmetto policy caused great confusion in the laboratory industry because it was not the understanding of laboratories that the NCCI edit was intended to apply to all prostate biopsies. As a result, many laboratories held their claims while they waited for further clarification from CMS.

Most recently, in the Medicare Physician Fee Schedule Final Rule with Comment Period for CY 2013, CMS weighed in with what appears to be an attempt to resolve the issue. However, in fact, the response simply has made the situation more confusing for laboratories.

⁴ Prostate Biopsy Coding/Billing Guidelines (CPT code 88305 and HCPCS code G0416), available at: <http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%2011%20Part%20B~Browse%20by%20Topic~Lab~8WXT7U5536?open&navmenu=Browse^by^Topic|||>.

CMS issued an interim final revision of the descriptor for HCPCS code G0416 to read “surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 10-20 specimens,” (rather than 1 to 20 specimens, as it had been previously). The agency said little more than that it agrees with stakeholders that the description “should be revised to better reflect the interaction of this service, and associated RVUs, with billing for surgical pathology.”⁵ CMS did not address the difference between examination of prostate needle saturation biopsies and prostate needle biopsies. Moreover, CMS changed the definition of a prostate needle saturation biopsy; thus, it did nothing to resolve the confusion about whether the G-code also should be used when billing for a standard prostate needle biopsy that is not collected using the saturation biopsy technique.

The revised edit included in the NCCI Policy Manual for 2013 (reflecting the change in the number of specimens for which code G0416 should be used) does not distinguish between the two types of prostate biopsy procedures, either.⁶ The new edit language reads:

HCPCS codes G0416-G0419 describe surgical pathology, including gross and microscopic examination, of separately identified and submitted prostate needle biopsy specimens from a saturation biopsy sampling procedure. CMS requires that these codes rather than CPT code 88305 be utilized to report surgical pathology on prostate needle biopsy specimens only if the number of separately identified and submitted needle biopsy specimens is ten or more. Surgical pathology on nine or fewer separately identified and submitted prostate needle biopsy specimens should be reported with CPT code 88305 with the unit of service corresponding to the number of separately identified and submitted biopsy specimens.

Thus, the new language simply continues the existing confusion; that is, it does not clarify whether it applies only to prostate needle saturation biopsy procedures or to prostate needle biopsy procedures, as well. As discussed below, it is ACLA’s position that the saturation biopsy and the routine prostate biopsy are distinct procedures and that is inappropriate to extend the limitations on the G-codes to the routine biopsy codes.

B. ACLA’s Concerns with CMS’s Policy on Payment for Examination of Prostate Needle Saturation Biopsies

ACLA is concerned that CMS and some of its contractors have mistakenly and unintentionally conflated prostate needle saturation biopsies with standard prostate needle biopsies. The agency seems to be directing laboratory providers to use a HCPCS code that describes one procedure when billing for an entirely different procedure (although even that is not clear). Furthermore, CMS may have violated the Administrative Procedure Act by changing its payment policies through methods other than notice and comment rulemaking.

⁵ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013, 77 Fed. Reg. 68,892, 69,059 (Nov. 16, 2012). This policy change was not included in the Medicare Physician Fee Schedule Proposed Rule.

⁶ See NCCI Policy Manual for Medicare Services – Effective January 1, 2013, *available at*: <http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html>.

1. CMS and its Contractors Have Conflated Two Distinct Procedures.

We ask that CMS address coding and payment for prostate needle saturation biopsy procedures separately from coding and payment for standard prostate needle biopsy procedures. As we have described above, a prostate needle saturation biopsy procedure is not the same as a standard prostate needle biopsy procedure. CMS seemed to acknowledge this in the Medicare Physician Fee Schedule Final Rule for CY 2009 when it implemented G-codes to be used for prostate needle saturation biopsy and stated flatly: “CPT code 88305 will continue to be recognized for those surgical pathology services unrelated to prostate needle saturation biopsy sampling.” However, the NCCI Policy Manuals for 2012 and 2013, Palmetto’s article based on the manual, and CMS’s recent pronouncement in the Medicare Physician Fee Schedule Final Rule with Comment Period for CY 2013 all include verbiage that has confused the situation. It is not clear whether CMS believes there is any distinction between the two procedures. CMS has not reversed its earlier statement that CPT code 88305 should be used for surgical pathology procedure unrelated to saturation biopsies, and yet its later statements have led to confusion about which codes apply to standard prostate needle biopsy services.

2. Using Codes for Examination of Prostate Needle Saturation Biopsies to Describe Examination of Prostate Needle Biopsies Would Violate Basic Coding Tenets.

If laboratories are supposed to bill using the saturation biopsy code for all procedures involving 10 or more standard prostate biopsies—a position that is far from clear, based on recent CMS actions—it would require laboratories to submit claims using codes that do not accurately reflect the services provided. As you know, a Medicare provider or supplier may be subject to civil monetary penalties for presenting a claim for payment that is for a medical or other item or service that he or she knows or should know was not provided as claimed.⁷ Compliance program guidance issued by the Office of the Inspector General (“OIG”) for laboratories also requires that “all claims for testing services submitted to Medicare or other Federal health care programs correctly identify the services ordered by the physician or other authorized individual and performed by the laboratory...Laboratory compliance policies should ensure that the CPT or HCPCS code that is used to bill accurately describes the service that was ordered and performed.”⁸

Here, CMS and Medicare contractors may be requiring laboratories to use G-codes that describe examination of prostate needle saturation biopsies to bill for examination of standard prostate needle biopsies when the number of specimens crosses a certain threshold. This violates the Civil Monetary Penalties Law and contravenes the OIG’s own compliance program guidance for laboratories. As we stated, the procedures are not distinguished merely by the number of specimens procured—they are different procedures used for different reasons, and laboratories should be billing using codes that reflect the proper procedure. ACLA members remain committed to coding and billing for services properly, and we request that CMS confirm its

⁷ 42 U.S.C. § 1320a-7a(a)(1)(A).

⁸ Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076, 45,080 (Aug. 24, 1998).

earlier statement that the relevant G-codes do not apply to standard surgical pathology procedures unrelated to saturation biopsy.

Application of the prostate needle saturation biopsy examination G-codes to standard prostate needle biopsies also will distort the prevalence of pathology examination of specimens procured through needle saturation biopsy procedures. As we note above, prostate needle saturation biopsy is a fairly rare procedure that is used only in particular circumstances. A requirement to use HCPCS code G0416 for standard biopsies will make it appear that utilization of a relatively rare procedure has suddenly increased exponentially, which is likely to lead to other inappropriate payment policies.

3. CMS's Application of the G-Codes to Examination of Prostate Needle Biopsies Potentially Violates the Administrative Procedure Act.

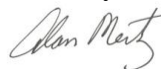
CMS's application of the G-codes to examination of prostate needle biopsies potentially violates the Administrative Procedure Act. CMS implemented the G-codes for prostate needle saturation biopsy in 2008 using a formal rulemaking process: the codes were proposed in a notice of proposed rulemaking, and they were included, with stakeholders' comments and responses, in a final rule. In that rulemaking, CMS did not apply the G-codes to standard prostate biopsies; it carefully excepted examination of standard prostate biopsies from the reach of the G-codes. However, when CMS included the codes in the NCCI manual in January 2012, it appeared to require that the G-codes, rather than CPT code 88305, be utilized to report surgical pathology on standard prostate needle biopsy specimens if the number of separately identified needle biopsy specimens is five or greater.

Although CMS implemented the G-code through rulemaking, it changed the application of the code through subregulatory guidance, the NCCI Policy Manual for 2012. The Administrative Procedure Act requires CMS to give the public advance notice before revising the G-code's descriptor, as it did here. The agency is not required to solicit public comment on interpretive guidance it issues; however, the NCCI Policy Manual descriptor is not merely an interpretation of the 2008 Federal Register notice that finalized the G-codes—it appears to change the G-codes such that they apply to examination of *any* prostate biopsy with more than five specimens, regardless of whether the procedure is a prostate needle saturation biopsy or a prostate needle biopsy.

C. Conclusion

We ask that CMS clarify that HCPCS codes G0416, G0417, G0418, and G0419 should be used only for examination of prostate needle saturation biopsy samples and that CPT code 88305 should continue to be used for examination of standard prostate needle biopsies. Thank you for your consideration of our concerns. We are available to discuss this matter at your convenience.

Sincerely,



Alan Mertz, President