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Waiting for Medicare's Final Word on Molecular Pathology Codes

CMS said it will release its decisions next month in the final 2013 clinical lab fee schedule at the same time it publishes the final 2013 physician fee schedule rule.

Come November you'll find out how Medicare will cover and pay for 101 new molecular pathology codes up for recognition next year.

That's when the Centers for Medicare and Medicaid Services (CMS) has said it will announce its final decisions on fee schedule placement and pricing of these codes, effective Jan. 1, 2013. While CMS has stated its coverage and payment preferences, it has, in its proposed physician fee schedule rule for 2013, invited comments from provider groups.

Comments reviewed by *NIR* from six pathology and clinical lab groups split along predictable lines, with the former favoring assignment of the new codes to the physician fee schedule and the latter favoring lab fee schedule placement while allowing for physician interpretation services to be paid under the physician fee schedule where required. All of the comments opposed the CMS recommendation to let local Medicare contractors set the pricing for these codes in 2013.

For a gist of CMS proposals and a sampling of comments from lab and pathology groups in response to the proposed 2013 physician fee schedule rule, see the *Focus on Medicare Payment Policy*, pp. 4-6.

INSIDE *NIR*

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Physician Groups Lay Out Path For Medicare Payment Reform

A broad array of national and state physician groups has sent Congress a set of core principles that they urge lawmakers to follow in reforming the way doctors are paid under Medicare.

In an Oct. 15 letter to the Senate Finance Committee, the American Medical Association and more than 100 state and specialty groups, including pathology, said the first step is to eliminate the sustainable growth rate (SGR) formula used to annually update the physician fee schedule.

The SGR has triggered negative updates over the past decade and Congress has stepped in repeatedly, often at the last minute, to block cuts and either freeze fees or grant a modest increase. Under current law the next SGR cut—27 percent—is scheduled for 2013 (along with a 2 percent sequestration cut), though lawmakers are expected to step in with at least another short-term SGR fix.

Scrapping the SGR is only one-half of the equation, the groups said. The other half is to establish new federal policy to shift to a new

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physician reimbursement system. On this point, the groups spelled out "key principles that can provide a foundation for a transition plan that organized medicine can support." These include:

- ❑ Invest in physician infrastructure, the necessary platform for delivery and payment innovations.
- ❑ Update Medicare payments to reflect the costs of providing services as well as efforts and progress in improving quality and managing costs.
- ❑ Reflect the diversity of physician practices with opportunities for doctors to choose payment models that work for their patients, practice, specialty, and region.
- ❑ Encourage incremental changes with positive incentives and rewards during a defined timetable, instead of using penalties to order abrupt changes in care delivery.
- ❑ Tie incentives to physicians' own actions, not the actions of others or factors beyond their influence.
- ❑ Encourage systems of care, regional collaborative efforts, and primary care and specialist cooperation while preserving patient choice.

"Ground-breaking innovations, including many led by physicians, are underway in Medicare and the private sector" that Congress can turn to in the transition, the groups noted in their letter. "These models include patient-centered medical homes, accountable care organizations, an array of approaches to bundled payments and shared savings arrangements as well as new initiatives designed by regional health improvement collaboratives."

Appeals for SGR repeal have fallen on congressional deaf ears for many years. Lawmakers instead have repeatedly fallen back on a series of short-term fixes blocking SGR scheduled cuts. This year, they canceled a 27.4 percent cut due March 1 and froze fees at their current levels through Dec. 31. The key obstacle to having Congress embrace eliminating the SGR is the projected cost of paying for it, currently $300 billion over 10 years.

Two bills to repeal the SGR were introduced in Congress this year. House bill 5707 would pay for it by using unspent funds from the wars in Afghanistan and Iraq. The bill would freeze physician fees in 2013, then increase them over the next four years with an annual 0.5 percent update (2.5 percent for primary care) while Medicare expands coordinated care models as alternatives to fee-for service. Senate bill 3337 would set the update for physician services for 2013 and each subsequent year at the lesser of the annual percentage increase in the consumer price index for urban wage earners and clerical workers or 3 percent.

Health policy experts warn that however appealing SGR repeal may be, if Congress decides to make a fundamental reform in Medicare physician payment policy, this will have to include some mechanism to control the rate of growth in physician spending to keep the program sustainable over the long haul.

Controversy Continues Over Prostate Biopsy Payment Curbs

While the decision by Palmetto GBA, the Medicare contractor for Jurisdictions 1 and 11, to impose payment limits on prostate cancer biopsies is strongly opposed by clinical laboratory and pathology groups, the unanswered question at press time is how the Centers for Medicare and Medicaid Services (CMS) will clarify the issue. Will it apply the policy nationwide or rescind it?

The controversy hinges on Palmetto's interpretation of a National Correct Coding Initiative (NCCI) edit that took effect Jan. 1, 2012, but that Palmetto implemented on Aug. 7.

Palmetto is limiting to four the number of prostate biopsy specimens that can be reported using Current Procedural Terminology (CPT) code 88305. This cuts pathology reimbursement roughly in half. Previously, pathologists and labs could bill up to $1,270 for a 12-core prostate biopsy. Now, the global fee (unadjusted for geographic practice cost variations) will be limited to $671 whenever five or more specimens are billed using code G0416 for one unit of service. Prior to the NCCI edit, Medicare had the G code only for saturation biopsies of the prostate and allowed the standard 12-core biopsy to be billed as 12 x 88305.

NCCI Edit At Issue

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.

Source: National Correct Coding Initiative, Policy Manual Chapter 10, effective Jan. 1, 2012.

Providers that have submitted claims for more than four 88305 services for dates of service on and after Jan. 1, 2012, may be at risk for overpayment collection, Palmetto said.

States in Palmetto's jurisdictions include California, Nevada, Hawaii, West Virginia, Virginia, North Carolina, and South Carolina. In these states Palmetto processes and pays claims for approximately 13.6 million Medicare beneficiaries.

Speaking at this month's Lab Institute 2012 convened by G2 Intelligence, Elaine Jeter, M.D., medical director at Palmetto, confirmed that in accord with the NCCI edit the total number of specimens submitted for pathology evaluation is the determining factor when selecting a code for billing, not the surgical procedure used to obtain the specimen.

Meantime, CMS has been urged, in a Sept. 26 letter from four affected provider groups, to withdraw the Palmetto policy, which they called "inappropriate and ill-advised." The letter was signed by the American Clinical Laboratory Association, California Clinical Laboratory Association, College of American Pathologists, and the Large Urology Group Practice Association.

They contend that the Palmetto policy misinterprets the NCCI edit. It takes guidance intended for post-diagnosis saturation biopsies and applies it to prediagnosis conventional techniques with no regard for the manner in which the samples were collected.

"When CMS established the G codes for saturation biopsies, it specifically noted," the groups said in their letter, "that under the physician fee schedule, CPT 88305

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Lab, Pathology Groups Weigh In on Molecular Pathology

Medicare is set to recognize in 2013 a series of Current Procedural Terminology (CPT) codes for molecular pathology and its preliminary determinations on their fee schedule placement and pricing has drawn fire from national clinical laboratory and pathology advocacy groups in comments they have submitted on the proposed 2013 physician fee schedule (PFS).

The Centers for Medicare and Medicaid Services (CMS) has said it favors using the gap-fill method (where local Medicare contractors set the payment rate based on local pricing patterns) for those codes determined to be clinical lab diagnostic tests payable under the Part B lab fee schedule. The agency also favors letting local contractors set rates for codes determined to be payable under the Part B PFS.

Should a Single Fee Schedule Be Used?

CMS has said it would prefer to assign all the new molecular pathology codes to a single Part B fee schedule using a single payment method—either the clinical lab fee schedule (CLFS) or the PFS.

CMS sees "little variation in the lab methodologies, as all employ gene sequencing processes. Establishing different prices for comparable lab services across two different payment systems would create a financial incentive to choose one test over another simply because of its fee schedule placement." The agency also is concerned that pricing differences would become ever more pronounced over time since the value of PFS services changes based on review while there is no similar process for adjusting values under the CLFS.

The molecular pathology codes at issue include 92 Tier 1 analyte-specific codes for high-volume procedures (CPT 81200-81383) and nine Tier 2 resource-level codes for low-volume procedures (81400-81408). They replace the multiple "stacking" codes (CPT 83890-83914 and 88271) used as the basis of payment for a single genetic test.

Payment rates on the CLFS are set by a crosswalk to an existing codes or codes or by the gap-fill method, with no beneficiary cost sharing for tests. Payment rates under the PFS, where services typically require physician work, are set using relative value units (subject to adjustments for sustainable growth rate and geographic practice differences as well as periodic CMS review). Beneficiary cost sharing of 20 percent generally is required.

While proposing reliance on a single fee schedule and inclining toward the CLFS, CMS has left open the possibility of using both it and the PFS. "We may decide, based on comments received on proposals in the PFS rule for 2013, that some of the codes are not clinical diagnostic laboratory test codes."

Regardless of assignment to either fee schedule, CMS would let local Medicare contractors set the payment rates. The agency said it lacks enough data to arrive at national payment rates under either the CLFS or the PFS. "We need more time to gather current information about how the tests are performed and the resources to provide them. The same molecular test is often billed using different stacking codes and the stacks may have changed over time."

Where Should the New Codes Be Placed?

The American Association for Clinical Chemistry (AACC) opposes placing all the molecular pathology codes on one fee schedule simply for convenience. Rather, each code should be assigned "primarily on the basis of the level of professional expertise required to interpret a test result."

The technology used to perform the molecular tests is increasingly relying on software integrated into automated test systems to generate results that require little or no interpretation. Accordingly, AACC recommends that these tests, and those likely to adopt such technology in the near future, remain on the CLFS. Recent examples include quantitative analysis for viruses, such as HIV-1 and hepatitis B and C. "We anticipate that new analyses, such as copy number variation and next generation sequencing, will follow a similar pattern that gradually replaces professional interpretation."

AACC opposes a blanket placement of the new codes on the PFS. With not enough trained physicians to handle this test volume, this approach "could result in: (1) laboratories being forced to provide interpretative services for free; (2) physicians signing off and labs billing for interpretations conducted by Ph.D.s, which is fraud under Medicare; or (3) a delay in interpretations, which could adversely affect patient care."

The American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) share AACC's concern about a blanket assignment to the PFS. They argue for payment via the CLFS so that interpretation services required for the molecular and genetic tests can be provided by qualified Ph.D. molecular biologists or lab directors trained in this field.

There are many codes under the current CLFS for which Ph.D. molecular biologists already provide extensive consultations (*e.g.*, cytogenetics), AAB and NILA point out, and the Clinical Laboratory Improvement Amendments (CLIA) require that professional interpretation and consultation be provided by a clinical consultant (Ph.D. or M.D.) for all CLIA-covered tests, regardless of the fee schedule they are paid under. AAB and NILA "strongly believe that CMS should compensate labs for CLIA-required consultation services provided for tests, current and future, paid under the CLFS (*i.e.*, a component of the CLFS payment should cover the CLIA-required consultation)."

The American Clinical Laboratory Association (ACLA) supports assigning all molecular pathology codes to the CLFS "because ordinarily they do not require the involvement of physicians and they typically are performed by qualified Ph.D. geneticists. A medical judgment ordinarily is not required for each and every one of the tests represented by the new CPT codes, but when this is required to interpret the results of a specific molecular pathology test, the interpretation service should continue to be reimbursable with a '-26' modifier valued under the PFS as a physician interpretive service and the test itself should continue to be reimbursable under the CLFS."

CMS already allows this approach for 18 clinical lab interpretation services that meet certain criteria for clinical consultations, ACLA notes. These services are reported under the clinical lab code with modifier 26 and are payable under the PFS if furnished to a patient by a hospital pathologist or an independent lab (*Medicare Claims Processing Manual, Pub. 100-04, Ch. 12, Sec. 60.E*).

The College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP) support placing the new codes on the PFS, arguing that physician interpretation is required for the majority of these tests and that the PFS allows for frequent updating to account for changing technology and greater efficiencies.

ASCP acknowledges that this placement poses a problem for scientists with doctoral degrees, a point AACC raised, noting "they currently interpret and report results for molecular tests on the CLFS using stacking code CPT 83912. If the molecular tests are placed on the PFS, they will not be able to provide interpretive services, since they are not on the list of providers able to bill the PFS." ASCP has been lobbying Congress to allow clinical scientists to bill for molecular diagnostics interpretive services under the PFS. "In the interim, we urge CMS to establish a G-code to allow them to do so."

How Should Pricing of the New Codes Be Determined?

All the comments from the six organizations reviewed by *NIR* opposed the CMS recommendation to let local Medicare contractors set the pricing for the codes in 2013. All six contend there are sufficient data to help CMS decide national payment rates.

For tests assigned to the PFS, CAP and ASCP said CMS should rely for pricing on values recommended by the American Medical Association's Relative Value Scale Update Committee (RUC) and CAP.

The RUC provides realistic utilization estimates necessary to establish national values, CAP says, and there is no similar process for updating code valuations on the CLFS. "It is unlikely that individual carriers can duplicate the extensive, detailed, and highly accurate process that the RUC uses to value each molecular pathology code. Moreover, carrier pricing would add unnecessary administrative complexities and unnecessary costs to providers and beneficiaries. Variations in carrier pricing would be disruptive to providers, patients, and health care institutions and could result in movement of sites of testing to the highest paying regions in order to maximize Medicare reimbursement for individual services. In addition, carrier pricing is not necessary as the values for the molecular pathology codes would be interim for 2013 and CMS can revise them prior to finalization."

ACLA says the new molecular pathology codes are good candidates for crosswalking to the CLFS. "These are existing tests that are being described with new codes. They represent tests that, in some cases, have been performed for two decades, and CMS contractors have significant payment and claims history and ample data to use as a guide for applying crosswalking principles."

The crosswalk, ACLA says, should be to fair intermediate price points based on historical pricing. "We believe it is advisable for CMS to select a benchmark among the various data points that are available using the historical billing data for each test, such as the median price," ensuring some consistency in pricing in 2013. The agency has used this methodology in other contexts, ACLA points out, such as when it establishes national limitation amounts for the CLFS.

"The Tier 2 molecular pathology codes (CPT 81400-81408) present a particular challenge," ACLA observes. These include a generic code description followed by a nonexhaustive listing of tests that would meet that description. "For these tests, payment could be based on a median price for all example tests associated with each code. The price may have to be revised in the future as additional example tests are added to each of the generic codes."

Answering the Questions

CMS has said it will post its final payment determinations only for the new test codes "that we determine are clinical diagnostic lab test codes that will be paid under the CLFS. We intend to post these in November (at the same time as the 2013 final PFS rule with comment period is published)." G2

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will continue to be recognized for those surgical pathology services unrelated to prostate needle saturation biopsy sampling. A contractor may not overrule CMS policy established in the *Federal Register* through the issuance of [a policy update]."

The groups said the Palmetto policy "directly contradicts the plain language of the NCCI edit, which provides direction to providers regarding billing for saturation biopsies when there are fewer than 5 samples involved. If implemented, the policy would require providers to bill an inaccurate code for a service, which is flatly inconsistent with all billing and coding requirements and conventions, and establishes a very dangerous precedent."

Lab and pathology representatives have called for clarification on the issue from CMS officials. Industry sources tell *NIR* they "have heard that CMS will address the confusion in the near future" but there is yet no date certain.

G2's 2012 Lab Public Service National Leadership Award

Left to right: Scott Liff, president, business development, Kellison & Co.; Kevin Ellison, president and CEO of Kellison & Co.; and Jonathan Parry and Donald Hitchcock representing OraSure Technologies.

The recipient of this year's award is OraSure Technologies (Bethlehem, Pa.) for its innovative OraQuick In-Home HIV test. The award, presented by G2 Intelligence and sponsored by Kellison & Co., was announced at this year's 30th annual Lab Institute held Oct. 10-12 in Arlington, Va.

This marks the first time an organization, rather than an individual, has received the annual award.

The OraSure test, approved by the Food and Drug Administration (FDA) in July and introduced to the retail market this month, is the first over-the-counter, self-administered HIV test kit to detect the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2). It is an over-the-counter version of OraSure's OraQuick Advance HIV 1/2 Antibody Test, which in 2004 was approved for use by trained technicians in clinical settings.

According to the Centers for Disease Control and Prevention, an estimated 1.2 million people in the United States are infected with HIV. However, about one in five of them is not aware of this. The OraQuick In-Home test has the potential, the FDA said, to identify large numbers of previously undiagnosed HIV infections, especially if used by those unlikely to use standard screening methods.

The award recognizes singular accomplishments that directly enhance patient care and the laboratory profession in one or more specific areas: basic and applied research, business creativity and innovations, public policy, and lifetime achievement.

The test uses an oral fluid sample collected by swabbing the upper and lower gums. The sample is placed into a developer vial, and results are available within 20 to 40 minutes. A positive result indicates that additional testing should be done in a medical setting to confirm the test result.

OraSure recently launched a dedicated Web site for the test as well as a consumer support center available via phone and open 24 hours a day, seven days a week. Clinical studies for self-testing have demonstrated that the OraQuick In-Home HIV Test has an expected performance of 92 percent for test sensitivity (percentage of results that will be positive when HIV is present) and 99.98 percent for test specificity (percentage of results that will be negative when HIV is not present).

Medicare *Claims Advisory*

Interest Rate Drops on Overpayments, Underpayments

The rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has dropped to 10.375 percent, effective Oct. 18, 2012, down from 11 percent since July 18 and 10.875 percent since April 18.

The latest quarterly rate update was announced by the Centers for Medicare and Medicaid Services in Transmittal 213, Change Request 8118 (Oct. 11, 2012).

Medicare Regulation 42 CFR §405.378 provides for the assessment of interest at the higher of the current value of funds rate (1 percent for calendar year 2013) or the private consumer rate as fixed by the Department of the Treasury. The Treasury has notified the U.S. Department of Health and Human Services that the private consumer rate has been changed to 10.375 percent.

The highest interest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 10.50 percent and 12 percent.

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