G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 32nd Year of Publication

Vol. 11, Iss. 14, July 28, 2011

Pricing Proposed for New 2012 Medicare Lab Codes

CMS also received input on reconsideration requests for five codes on the current lab fee schedule.

Leading scientific societies and national clinical laboratory and pathology groups are among those who responded to the government's call for comment on how to set payment rates for CPT lab test codes to be added to the Part B lab fee schedule, as of Jan. 1, 2012.

The Centers for Medicare and Medicaid Services (CMS) opened the annual comment period at a July 18 public meeting, inviting advice from stakeholders on whether to use the crosswalk method or the gapfill method to price two new CPT codes:

- One in immunology used to detect human bladder cancer.
- One in microbiology used to detect HIV-1 antigen and HIV-1 and HIV-2 antibodies.

The table on page 2 presents pricing recommendations from selected national groups: the American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Society for Clinical Pathology (ASCP), and the College of American Pathologists (CAP). *Continued on p. 2*

CMS Delays Placement, Pricing of New Molecular Pathology Codes

The Centers for Medicare and Medicaid Services (CMS) has officially acknowledged that it will delay implementation of new molecular pathology codes on the Medicare clinical lab fee schedule until 2013.

At a July 18 public forum, CMS officials noted that, by law, since these codes were not discussed at the annual meeting on pricing recommendations for new lab tests, they could not be placed on the lab fee schedule for 2012 (*related story above*).

But officials left the door open to the possibility that some of the codes could be placed on the Medicare physician fee schedule and priced for rollout sometime in 2012. Pricing for this fee schedule follows a separate process from that used for the lab fee schedule.

At issue are 101 new codes approved by the American Medical Association's CPT Editorial Panel for inclusion in the CPT update for 2012. The codes are assigned to one of two categories covering more than 90 percent of the volume of current molecular pathology procedures.

Continued on p. 6

INSIDE *NIR*

www.G2Intelligence.com

Pricing Proposed for New 2012 Lab Codes, *from p. 1*

Two methods are used to set rates on the lab fee schedule: crosswalk or gapfill. Under the crosswalk method, a new test code is matched to a similar code on the fee schedule and paid at that rate. Payment is the lower of the local fee schedule amount or the national fee cap. Most lab codes are paid at the cap.

The gapfill alternative is used when there is no comparable existing test. In this case, local contractors set the fee for the first year, based on local pricing patterns such as charges for the test, routine discounts, resources needed for the test, and what other payers pay. CMS then taps these local amounts to set a fee cap for following years.

CODE/DESCRIPTOR	RECOMMENDED PAYMENT METHOD	CURRENT NATIONAL FEE CAP
IMMUNOLOGY		
863XX Nuclear Matrix Protein 22 (NMP22), qualitative	**AACC:** Crosswalk to 83499, 20-hydroxyprogesterone	$35.48
	ACLA: No comment. **ASCP, CAP:** Crosswalk to 86294, Immunoassay for tumor antigen, qualitative or semiquantitative (e.g., bladder tumor antigen)	$27.61
MICROBIOLOGY		
873XX Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result	**AACC, ACLA, ASCP:** Crosswalk to 87391, HIV-2 antigen assay plus 50 percent of 86703, HIV-1/HIV-2 antibodies, single assay	$34.48
	CAP: Crosswalk to 87390, Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; HIV-1 plus 50 percent of 86703, HIV-1 and HIV-2 antibodies, single assay	$34.48

Recommendations for Reconsidered Codes

In response to reconsideration requests, CMS invited input on appropriate pricing for five codes currently on the Part B lab fee schedule:

G0434, Drug screen, other than chromatographic; any number of drug classes, by CLIA-waived test or moderate-complexity test, per patient encounter. 2011 national fee cap, $20.47.

AACC and ACLA recommended creating a new code to describe instrumented moderate-complexity systems and revising existing code G0434 to clearly describe single-test systems, as follows:

- **G043X**, Drug screen, other than chromatographic; any number of drug classes, by instrumented moderate–complexity test systems intended for repeated use and not capable of being read by direct optical observation (e.g., spectrophotometers, fluorometers, multichannel chemistry analyzers), per patient encounter. Crosswalk new code G043X to 4 x G0434. National fee cap: 4 x $20.47 = $81.88.
- **G0434**, Drug screen, other than chromatographic; any number of drug classes, by CLIA–waived test or non-instrumented moderate–complexity test systems

capable of being read by direct optical observation (e.g., dipsticks, cups, cards), per patient encounter. Crosswalk revised G0434 to existing G0434 payment. National fee cap: $20.47.

G0435, Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening (currently capped at $16.88). AACC, ACLA, ASCP, and CAP had no comment.

83861, Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity (currently capped at $23.58). AACC, ASCP, and CAP had no comment. ACLA said its comments are under consideration.

86481, Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon producing T-cells in cell suspension (current national fee cap, $87.22). AACC recommended a crosswalk to 86480, TB test, cell mediated immunity antigen response measurement; gamma interferon, plus 86332, immune complex assay. Total current cap: $121.15. ACLA has its choice under consideration.

87906, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion) (current national fee cap, $181.14). AACC recommended a crosswalk to 87901, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease. Current cap: $362.28. ACLA said its comments are under consideration.

Next Steps in the Fee-Setting Process

CMS typically makes public its preliminary fee decisions for new lab codes in September, followed by a two-week period for additional comments. Final fee payment decisions will be announced in the 2012 Part B lab fee schedule via a program transmittal to local contractors, typically released in November.

Lab Fees Due for Slight Uptick in 2012

Payment rates under the Medicare lab fee schedule are slated for a slight increase in 2012, according to current projections. The estimated increase is 0.65 percent under the formula established in the health care reform law, the Patient Protection and Affordable Care Act (PPACA), for calculating the annual update to the lab fee schedule.

For 2012, the result is as follows:

Formula Factors	*Percent*
CPI-U	3.60
Productivity adjustment	-1.20
Subtotal	2.40
Additional cut per PPACA	-1.75
Resulting fee update	+0.65

The formula requires setting the update at the consumer price index for all urban consumers (CPI-U), minus a productivity adjustment (though this could never allow the update to fall below zero). In addition, from 2011 to 2015, the PPACA requires a further cut of 1.75 percent.

The official update will be published in the 2012 lab fee schedule later this year. The result could vary from the above by a tenth of 1 percent, depending on the final productivity adjustment. In the proposed Medicare physician fee schedule, the adjustment was minus 1.2 percent. For this year, the lab fee update formula used a minus 1.3 percent.

CMS Urged to Ease Labs' Pain at the Pump

The National Independent Laboratory Association has formally asked the Centers for Medicare and Medicaid Services (CMS) to increase the Medicare travel allowance, based on the decision by the Internal Revenue Service to up the federal mileage rate to 55.5 cents, effective July 1, 2011.

The mileage portion of the travel allowance is currently 51 cents, plus the personnel portion of 45 cents, for a total trip fee of 96 cents.

CMS responded on July 15, NILA head Mark Birenbaum, Ph.D., told G2 Intelligence. The agency said it is working on a change request to let contractors know of the increased federal mileage rate and "to ensure that Medicare is paying updated rates as soon as possible." But the agency did not provide a specific date when this will occur, he said.

NILA also requested that the personnel component of the trip fee be updated, Birenbaum said. But CMS replied that "at this point, we have not seen a problem with access to laboratory services that would suggest the 45 cents per mile travel fee for laboratory technicians is insufficient and in need of being updated."

The codes used to bill for the trip fee, payable only for travel to collect a specimen from a nursing home or homebound beneficiary, are:

- P9603 per mile trip basis
- P9604 per flat rate trip basis.

LabCorp to Pay $49.5 Million to Settle California Lawsuit

Laboratory Corporation of America Holdings (Burlington, N.C.) has agreed to pay the state of California $49.5 million to settle a lawsuit alleging that the company overcharged the state's Medicaid program (Medi-Cal) for clinical laboratory testing.

LabCorp disclosed the settlement in a July 14 filing with the Securities and Exchange Commission (SEC). The company had been scheduled to go to trial in January 2012. LabCorp says it agreed to the settlement to avoid the uncertainty and costs associated with prolonged litigation.

The company recorded a second-quarter pretax charge of $34.5 million (net of a previously recorded reserve of $15 million), $20.7 million after tax. The settlement is subject to a final negotiation and approval.

The lawsuit against LabCorp, Quest Diagnostics, and several other major labs operating in California was filed in 2005 under the state's False Claims Act by a competitor, Chris Riedel, chief executive officer of Hunter Laboratories (Campbell, Calif.). Under the act, the whistleblower can be rewarded with 15 percent to 25 percent of the amount recovered.

In 2009, the state attorney general's office joined the case, noting that under state law, "no provider shall charge [Medi-Cal] for any service . . . more than would have been charged for the same service . . . to other purchasers of comparable services . . . under comparable circumstances" (*NIR 09, 6/March 30, p. 1*). The attorney general's office blasted what it called a pattern of abuse whereby the labs in the case charged Medi-Cal up to six times more for tests than it charged other customers, such as independent practice associations, physician offices, and hospitals.

The LabCorp settlement comes on the heels of a $241 million settlement with Quest Diagnostics (Madison, N.J.), announced in June, of allegations of lab overpricing of Medi-Cal over a 15-year period. Quest also agreed to price-reporting obligations for a limited time and, in lieu of such obligations for a transitional period, to provide Medi-Cal with a discount until the end of July 2012. In reaching a settlement, the company admitted no wrongdoing but sought to avoid the risk, time, and expense of lengthy litigation. As part of the recovery, Riedel reportedly received $70 million.

Seven other labs involved in the California case have either settled or been dropped from settlement discussions. In all, the lawsuit settlements have recovered roughly $300 million.

Riedel and his law firm Cotchett, Pitre & McCarthy have filed "lowest charge" lawsuits in six other states, according to *Laboratory Economics:* Florida, Georgia, Massachusetts, Michigan, Nevada, and Virginia.

Medical Device Makers Urge Repeal of Excise Tax

Medical device makers and medical technology groups have urged House and Senate leaders to repeal the excise tax levied on the device industry by the health care reform law, the Patient Protection and Affordable Care Act.

Starting in 2013, the tax is estimated to cost the industry $2.7 billion annually to help finance broader health care reform, more than 400 industry organizations and companies noted in a July 18 letter to the congressional leadership.

The letter blitz for repeal comes after AdvaMed sent comments to the Internal Revenue Service in March and July, highlighting the complexities of the medical device industry. Also, several lawmakers have proposed repeal bills in both chambers.

Signing on to the Appeal

The 400 entities sending repeal request letters to leaders on Capitol Hill included:

- Medical Device Manufacturers Association
- Advanced Medical Technology Association
- U.S. Chamber of Commerce
- National Association of Manufacturers
- National Federation of Independent Business
- National Venture Capital Association

"If this tax is implemented in 2013, it will undermine our industry's ability to create and maintain good jobs in the United States, and worse, will lead to higher costs for patients, undercutting one of the primary goals of health care reform," said Stephen Ubl, president and CEO of AdvaMed, in a statement.

Citing an April 2010 report by the Office of the Actuary at the Centers for Medicare and Medicaid Services, the groups said in their letter that the tax will have a negative impact on patients through increased costs in health care, with the tax passed through to patients and influencing their access to breakthrough technologies.

Overall, the tax could lead to companies cutting manufacturing operations, research and development, and employment levels to make up for losses from the tax, the letter said, adding that the tax will not be offset by an increase in consumer demand. Although more people may be covered under health insurance, there may not be a "windfall" for device companies.

"The impact will be especially hard on smaller companies whose innovations are not immediately profitable," the letter said. The "threat" of the tax has already led some to halt research and slow hiring, according to a statement from Bruce Josten, executive vice president for government affairs at the U.S. Chamber of Commerce. Discouraging innovation in this industry also will cause the United States to lose its competitive edge in the global marketplace, he said.

New Molecular Pathology Codes, *from p. 1*
One category, Tier 1, includes 92 high-volume tests coded by specific analyte. The other category, Tier 2, includes nine low-volume tests coded by the level of resources required for their performance and interpretation. (The new coding system does not affect molecular microbiology tests or most cytogenetic assays, the AMA said.)

Currently, molecular pathology codes are payable through a system of "stacking codes" (CPT 83890-83914) that are likely to be retired in 2013, though this could happen earlier, depending on provider and payer readiness.

Which Fee Schedule Is the Right Fit?

CMS convened a special information session during the July 18 afternoon forum to obtain input on the key question of where to place and price the new codes for genetic testing.

- On the clinical laboratory fee schedule, where pricing is set using the crosswalk or gapfill method and there is no beneficiary cost sharing for tests; or
- On the physician fee schedule, where pricing is set using relative value units (RVUs) subject to adjustments under the sustainable growth rate (SGR) formula and periodic CMS review of the relative values. Beneficiary cost sharing is required.

CMS is seeking a contractor to help it assess new molecular pathology codes as well as lab testing services on the Medicare lab fee schedule. According to a June 15 solicitation, the agency intends to award a firm fixed-priced purchase order for the period from July 1, 2011, through June 30, 2012. CMS is looking for a contractor with a medical background and requisite expertise, knowledge, experience, and skills.

Representatives from the College of American Pathologists (CAP) and the Association for Molecular Pathology (AMP) supported placing the new codes on the physician fee schedule, arguing that physician interpretation is required for the majority of these tests and the physician fee schedule allows for frequent updating in light of changing technology and greater efficiencies, which is necessary for a fast-moving area like genetic testing.

Speaking for CAP, Jonathan L. Myles, M.D., chair of the society's Economic Affairs Committee, emphasized that there is professional, not just technical, work in providing these services. "Both the professional component and the technical component are resource-based on the physician fee schedule, while the lab fee schedule relies on crosswalking or gapfilling." Myles concluded by noting the role that the AMA/Specialty Society Relative Value Update Committee (RUC) would have in evaluating these codes for Medicare pricing purposes. "Like other codes, the RUC would develop recommendations used to determine the amount of professional work for each code."

For its part, the American Association for Clinical Chemistry (AACC) said, "Most of the genetic testing codes published by CMS for public comment include a professional component that warrants their placement on the physician fee schedule" and suggested that CMS create a mechanism to assess the level of professional input required for each test.

"The remaining genetic tests, whereby the result alone often dictates the diagnosis or treatment, should be placed on the clinical laboratory fee schedule," AACC advised. It further recommended that "CMS retain CPT 83912, molecular diagnostic interpretation and report, until a similar code or mechanism is created that permits

qualified health care providers, such as Ph.D. professional scientists, to continue to bill for the technical interpretation associated with these tests."

The American Clinical Laboratory Association (ACLA) recommended that each new genetic test code be assessed individually to determine how the interpretive function is most commonly performed.

- If the interpretation is most commonly performed by nonphysician doctoral health care professionals, the code should be placed on the lab fee schedule, and CMS should work with stakeholders to develop a new code that will allow these professionals to bill for the interpretive function or continue using CPT code 83912.
- If the interpretation is most commonly performed by pathologists, the code should be placed on the physician fee schedule as a professional component/technical component service, and CMS should develop a policy that would allow suppliers of such services to bill and receive payment for the technical component (notwithstanding that the services were performed and interpreted by qualified Ph.D. health care professionals rather than physicians).
- If the interpretation is most commonly performed by an advanced computer system, the code should be placed on the lab fee schedule and the advanced analysis should be additionally valued as part of the fee schedule payment.

Speaking for Palmetto GBA, a Medicare contractor, medical director Elaine Jeter, M.D., recommended that the new codes be assigned to the lab fee schedule, with a tiered component for professional interpretation. She noted that placing the codes on the physician fee schedule would require a copayment from beneficiaries and this would be burdensome for clinical labs to collect.

The information session also triggered heated discussion concerning what would happen starting January 2012 when the new codes take effect for CPT purposes. While at the national level CMS is not putting these codes on the lab fee schedule, local contractors could make their own pricing decisions about them. However, subsequent back-and-forth between CMS officials and a local contractor did not clarify what this process might entail.

Medicare *Claims Advisory*

Interest Rate Up for Medicare Overpayments, Underpayments

Effective July 18, 2011, the rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has increased to 11.5 percent, up from 11 percent since April 19.

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (1 percent for calendar-year 2011) or the private consumer rate fixed by the Treasury. Upon notification from the Treasury of the new private consumer rate of 11.5 percent, the Centers for Medicare and Medicaid Services announced the new Medicare interest rate in Transmittal 190 (July 12, 2011). The highest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 11 percent and 12 percent.

Coming in August: National Version 5010 Testing Week

The national testing week does not preclude trading partners from testing transactions using Version 5010 immediately with their local Medicare contractor, CMS said. In fact, the agency urges you to do so now if you haven't already. For more on HIPAA Version 5010, go to http://www.CMS.gov/Versions5010andD0.

The Centers for Medicare and Medicaid Services is alerting providers, payers, and clearinghouses to the National Version 5010 Testing Week that the agency has announced for Monday, Aug. 22, through Friday, Aug. 26.

The Version 5010 compliance date—Jan. 1, 2012—is fast approaching, CMS notes. All entities covered under the Health Insurance Portability and Accountability Act (HIPAA) should be taking steps now to get ready for the transition, including external testing to ensure timely compliance. To submit transactions electronically, all covered entities must upgrade from Version 4010/4010A to Version 5010 which, unlike Version 4010, accommodates the new ICD-10 code sets and is a required preliminary step for use of the new ICD-10 medical code sets.

The weeklong event in August is an opportunity for trading partners to come together and test compliance efforts that are already under way with the added benefit of real-time help desk support and direct and immediate access to local Medicare Administrative Contractors (MACs). More details concerning transactions to be tested are forthcoming from your local MAC.

Upcoming Events From G2

Webinar (2 p.m. – 3:30 p.m. Eastern)

Aug. 17
Back to the Future: How the Proposed Lab Copay—and Other Medicare Changes—Could Impact Your Lab's Bottom Line

Conferences

Sept. 23
Molecular Diagnostics—Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Crystal Gateway Marriott
Arlington, Va.

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.

For details and registration information, go to our Web site, *www.G2Intelligence.com*.

NIR Subscription Order or Renewal Form

- ❑ *YES*, enter my one-year (22-issues) subscription to the *National Intelligence Report (NIR)* at the rate of $509/yr. Subscription includes the *NIR* newsletter and electronic access to the current and all back issues. Subscribers outside the U.S. add $100 postal.*
- ❑ AAB & NILA members qualify for special discount of 25% off — or $381.75 (Offer code NIRI1).
- ❑ I would like to save $204 with a 2-year subscription to *NIR* for $814.*

Please Choose One:

- ❑ Check enclosed (payable to G2 Intelligence)
- ❑ American Express ❑ VISA ❑ MasterCard

Card #_____ Exp. Date _____
Cardholder's Signature_____
Name As Appears On Card_____
Name/Title_____
Company/Institution_____
Address_____
City_____State_____ZIP_____
Phone_____Fax_____
e-mail address_____

*Total does not include applicable taxes for MD, NJ, NY, WA and Canada

Mail to: G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Or call 800-401-5937 and order via credit card or fax order to 603-924-4034

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere. For multi-user and firm-wide distribution programs or for copyright permission to republish articles, please contact our licensing department at 973-718-4703 or by email at: jping@G2Intelligence.com.

NIR 7/11B

 G2 Compliance Report (ISSN 1524-0304) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3 , Peterborough, NH 03458-1467 USA. Tel: 800-401-5937 or 973-718-4700. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

Jim Curren, Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO; Doug Anderson, Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 800-401-5937.