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Molecular Pathology Codes to Go on Lab Fee Schedule

For final 2013 Medicare payment determinations for 16 new lab codes and nine new algorithmic analyses codes, see story and table on pages 4 and 5.

Medicare will pay for new molecular pathology services—the next innovation of clinical laboratory tests that will foster the development of personalized medicine—under the Part B clinical lab fee schedule (CLFS) with 2013 payment set by the gap-filling method.

The Centers for Medicare and Medicaid Services (CMS) announced this decision in the final rule for the 2013 Part B physician fee schedule, released Nov. 1 and effective Jan. 1. The rule will be published in the Nov. 16 *Federal Register*, with a comment period closing on Dec. 31.

The agency explained its position by saying that after reviewing comments received, it believes "that the molecular pathology CPT codes describe clinical diagnostic lab tests that should be paid under the CLFS because these services do not ordinarily require interpretation by a physician to produce a meaningful result."

But acknowledging that for some tests a pathologist's interpretation may be medically necessary, CMS said this would be paid under the physician fee schedule on an interim basis for calendar year 2013, using a new HCPCS code, G0452, to replace CPT 83912-36 which will be deleted in 2013.

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Medicare Update Formulas Trigger Physician, Lab Fee Cuts

Medicare payments to pathologists and other physicians are scheduled for a cut of 26.5 percent, starting Jan. 1, 2013, while payments to clinical laboratories are due for a 3 percent cut.

The cuts are required under the update formula, required by law, for the Part B physician fee schedule (PFS) and the Part B clinical laboratory fee schedule (CLFS).

The Centers for Medicare and Medicaid Services (CMS) announced the negative updates in the final 2013 PFS rule with comment period, released Nov. 1.

The physician fee cut is required under the sustainable growth rate formula that updates the PFS. The 26.5 percent cut translates to a conversion factor (CF) of $25.0008 for calendar year 2013. The CF is

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Molecular Pathology Codes, *from p. 1*

For G0452—Molecular pathology procedure; physician interpretation and report—CMS is assigning a work relative value of 0.37 and five minutes of preservice time, 10 minutes of intraservice time, and five minutes of postservice time.

Physicians can continue to receive payment for the current clinical pathology consultation codes (CPT 80500 and 80502) if the consultation relating to a molecular pathology test meets four coverage requirements. These codes are payable only if the consultation is requested by the patient's attending physician, relates to a test result that lies outside the clinically significant normal or expected range in view of the condition of the patient, results in a written narrative report in the patient's medical record, and requires the exercise of medical judgment by the consultant physician. Payment for CPT 80500 and 80502 is for only professional component services; there is no technical component.

The new molecular pathology codes replace the multiple "stacking" codes (CPT 83890-83914 and 88271) used as the basis of payment for a single genetic test.

Routine conversations between a laboratory director and an attending physician about test orders or results do not qualify as consultations unless all of the above four requirements are met. Lab personnel, including the director, may from time to time contact attending physicians to report test results or to suggest additional testing or be contacted by attending physicians on similar matters. These contacts do not constitute clinical consultations under CMS rules.

The CMS decision on coverage and payment for Tier 1 and Tier 2 molecular pathology codes (CPT 81200-81408) can be found in two online postings: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*and *www.cms.gov/ClinicalLabFeeSched/*. Click on *Laboratory Meetings*.

CMS Slashes TC Payment for Pathology Code 88305

In the final 2013 physician fee schedule rule, released Nov. 1, the Centers for Medicare and Medicaid Services (CMS) announced that it was cutting the technical component (TC) payment for surgical pathology code 88305 by 52 percent, although it raised the professional component by 2 percent. This results in a reduction of 33 percent in the global payment for this code.

The cut is expected to hit pathology practices and labs hard as 88305 ranks as the highest-volume pathology procedure paid under Medicare Part B. CPT 88305 remains as the first and only CPT code to top the $1 billion mark in allowed charges for a single year. In 2010 Medicare spent $1.3 billion for 88305.

Currently, the national Part B payment for 88305-TC (unadjusted for geographic practice variations) is $70, with reimbursement ranging from as much as $95 in northern California to as little as $58 in West Virginia, notes *Laboratory Economics*.

The reduction in payment for 88305-TC results from a CMS initiative, as directed by the health care reform law, to scrutinize high-volume codes from all specialties as potentially overvalued services so that the agency can redirect resources to primary care. The TC for 88305 is not only high-volume, but it has not been reviewed since initially valued in 2000.

The American Clinical Laboratory Association (ACLA) has expressed "great concern" over the TC decision. "CMS' decision to make this drastic cut, amounting to hundreds of millions of dollars, appears to be based on a report of a single stakeholder who recommended reviewing the code's pricing, claiming that $18 was the appropriate amount. That report based its analysis on one clinical application of the tissue biopsy services included in code 88305."

Medicare reimbursement to hospitals for 88305-TC under the DRG inpatient payment will not be affected, nor will the APC outpatient rate.

ACLA disputes the assertion that there exists a "typical" or "atypical" clinical case for CPT 88305 on which to base pricing, since wide variations exist among patients and among laboratories in the types of tissue being biopsied *(e.g.*, breast or prostate) and the way specimens are handled (*e.g.*, numbers of microscope slides created per biopsy).

Protests Block Medicare Contract Award to Noridian

Work has stopped on the previously announced award to Noridian Administrative Services (Fargo, N.D.) of the contract for Medicare Parts A and B claims processing and payment for West Coast Jurisdiction E.

The stoppage comes after protests were filed in October with the Centers for Medicare and Medicaid Services (CMS) over its decision to switch from the current contractor, Palmetto GBA (Columbia, S.C.) to Noridian. Palmetto is among those challenging the contract award.

As a result of the protests, CMS said, the Government Accountability Office will review the procurement record and is expected to complete this process by the end of January 2013.

"Because of the stop work order Noridian may not do any work related to the award," CMS said. "Implementation activity may not take place until the stop work order is revoked." The agency had planned to phase in the workload transition over the next six months.

Accordingly, clinical labs, pathologists, and other Medicare providers in Jurisdiction E will continue to file their claims with Palmetto.

This jurisdiction (formerly known as Jurisdiction 1) covers California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands. It includes more than 3.5 million Medicare fee-for-service beneficiaries and serves approximately 500 Medicare hospitals and 86,500 physicians. The workload comprises approximately 8.9 percent of the national Medicare A and B fee-for-service claims volume.

The contract has an estimated value of $345.2 million and a maximum duration of five years.

If the award to Noridian is upheld, the company will have a lock on Medicare A and B business on the West Coast and in key states along the Rocky Mountains. Since 2011, Noridian has handled the A/B workload for 10 states consolidated in Jurisdiction F: Alaska, Washington, Oregon, Idaho, Montana, Wyoming, Utah, Arizona, North Dakota, and South Dakota.

CMS Releases Final Fee Decisions for New Lab Codes

Final payment rates for 16 new CPT codes to be added to the Medicare Part B 2013 clinical laboratory fee schedule have just been released by the Centers for Medicare and Medicaid Services (CMS), and they represent no change from the preliminary fee determinations the agency posted Aug. 31.

CMS used the crosswalk method to set final 2013 fees for these 16 codes in all cases but one where gap-filling was approved (*see table, p. 5*).

Payment Method Differences

The crosswalk method involves matching a new code with an existing one or set of codes and paying at the rate of the actual charge, the local fee schedule amount, or the national fee cap. The gap-fill method allows local contractors to set the payment rate for a year based on local pricing patterns and related resources, and CMS uses these data to set a nationwide rate the following year.

Molecular pathology codes (Tiers 1 and 2, CPT 81200-81408) are assigned to the clinical lab fee schedule and are to be gap-filled in 2013 (*related story, p. 1*).

No to Algorithmic Analyses Codes

CMS declined to recognize nine new codes for Multivariate Assays with Algorithmic Analyses (MAAAs) in 2013. The codes are CPT 81500-81599 and include tests for ovarian cancer, type 2 diabetes, fetal chromosomal abnormalities, hepatitis C virus, and liver disease.

The agency said that most comments received were not specific to these codes and further study is needed before Medicare pays for them. Accordingly, in 2013, clinical laboratories should continue using the existing codes for the component tests.

MAAAs utilize multiple results from molecular pathology assays, as well as fluorescence in situ hybridization and other non-nucleic-acid based assays, and then use proprietary algorithmic analyses to derive a single result, reported typically as a numeric score or probability. They enable clinicians to screen thousands of potential biomarkers that can predict a disease state, determine the likelihood of disease progression, or calculate the probability of responding to a therapy or other medical information.

No to Reconsideration Request

CMS declined a request to reconsider what it currently pays for CPT 86386, Nuclear matrix protein 22 (NMP22), qualitative. The agency retained the current crosswalk to 82487, Chromatography, qualitative; paper, 1-dimensional, analyte not elsewhere specified (currently capped at $22.61).

"Like lateral flow immunochromatography performed for 86386, 82487 uses a one dimensional flow chromatography," the agency said. "For code 82487, a chemical reaction is utilized to characterize results while code 86386 utilizes an immune reaction. Therefore, we believe the crosswalk is appropriate and should not be changed."

The agency's final payment determinations and the rationale for them are posted at *www.cms.gov/ClinicalLabFeeSched*. Click on *Laboratory Meetings*.

MEDICARE LAB FEE SCHEDULE FOR 2013: NEW CPT CODES AND FINAL PAYMENT DETERMINATIONS		
CODE/DESCRIPTOR	***FINAL FEE DETERMINATIONS***	***CURRENT NATL. FEE CAP***
CHEMISTRY		
82777 Galectin-3	Crosswalk to 83520	$18.34
IMMUNOLOGY		
86152 Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);	Gap-fill	N/A
86711 JC (John Cunningham) virus	Crosswalk to 86789	$20.39
TISSUE TYPING		
86828 Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens	Crosswalk to 86807	$56.05
86829 qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens	Crosswalk to 86808	$42.04
86830 antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I	Crosswalk to 83516 (x7)	$114.38
86831 antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II	Crosswalk to 83516 (x6)	$98.04
86832 high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I	Crosswalk to 83516 (x11)	$179.74
86833 high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II	Crosswalk to 83516 (x10)	$163.40
86834 semi-quantitative panel (eg, titer), HLA Class I	Crosswalk to 83516 (x31)	$506.54
86835 semi-quantitative panel (eg, titer), HLA Class II	Crosswalk to 83516 (x28)	$457.52
MICROBIOLOGY		
87631 Infectious agent detection by nucleic acid (DNA or RNA); *Bartonella henselae and Bartonella quintana, direct probe technique*; respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets	Crosswalk to 87502 + 87503 (x2)	$179.36
87632 6-11 targets	Crosswalk to 87502 + 87503 (x6)	$297.04
87633 12-25 targets	Crosswalk to 87502 + 87503 (x16)	$591.24
87910 Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus	Crosswalk to 87902	$364.64
87912 Hepatitis B virus	Crosswalk to 87902	$364.64
CPT codes © American Medical Association.		

Medicare Update Formulas, *from p. 1*
used to calculate the fee for a physician's service based on relative value units for work, practice expense, and malpractice expense. In 2012, it is $34.0376. Had not Congress stepped in and approved statutory increases, it would have fallen to $24.6712.

The lab fee cut is required by a multipart formula that updates the 2013 CLFS. It includes the consumer price index for urban areas (1.7 percent), a productivity adjustment (-0.9 percent), a percentage adjustment through 2015 (-1.75 percent), and an additional cut (-2 percent) specified in the Middle Class Tax Relief and Job Creation Act to help pay for the short-term physician fee fix that blocked a 27 percent cut in 2012 and froze the update at zero through Dec. 31. This results, CMS said, in a total cut of -3 percent (rounded).

In addition to spending reductions required by their update formulas in 2013, Medicare physician and lab fees are slated for a 2 percent sequestration cut as part of automatic across-the-board federal spending cuts scheduled for next year under the Budget Control Act of 2011. The law limits the sequestration for Medicare providers to a maximum of 2 percent.

Most Medical Devices to Carry Unique Device Identifier

Most medical devices purchased by your clinical laboratory or pathology practice, such as analyzers and reagents, will carry a unique device identifier (UDI) under a rulemaking by the Food and Drug Administration (FDA).

A UDI system, similar to the Unique Product Code (UPC) familiar in retail stores, will enable tracking and identification of medical devices across their life cycle—from production through use in clinical practice. This, the FDA said, will help identify adverse events and other product problems more quickly, better target recalls, and improve patient safety.

A further aim of the system, the agency said, is to "provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies."

A UDI is a numeric or alphanumeric code that acts as a key to certain basic identifying information about a device, such as the name of the manufacturer and the type of device, and may represent certain other information about the device, such as its expiration date and batch or lot number.

FDA launched the UDI rulemaking in response to a mandate in the FDA Amendments Act of 2007 and the FDA Safety and Innovation Act of 2012 that passed Congress with broad bipartisan support. The agency released its draft rule in July 2012 and the comment period closed Nov. 7, 2012.

In a free webinar on Nov. 5, FDA touted the value of the UDI system, pointing out that it will help health care systems and providers to streamline internal supply chains, manage recalls more effectively, and provide more device information to inform point-of-care decisions.

Further, the agency noted that though the mandate requires manufacturers to label devices on a predetermined timeline, it does not extend to the use of the UDI in electronic health records, payment systems, or incident reporting systems.

The FDA intends to take a risk-based, phased-in approach to implementation over 10 years, focusing on the highest-risk medical devices first (Class III) and exempt-

ing low-risk devices from some or all of the requirements. Over-the-counter devices sold at retail would be exempt since these generally have UPCs in place. The highest-risk devices will carry a UDI within a year after the final rule is published. The cost for implementing the system is estimated at more than $500 million over the next decade.

With certain exceptions, a UDI would include:

- ❑ A device identifier, which is a unique numeric or alphanumeric code specific to the version or model of a device; and
- ❑ A production identifier, which includes the current production information for a device.

The UDI will be presented on the label of a device in some form of automatic identification and data capture technology, such as a barcode or radiofrequency identification tag. This information will be contained in a publicly available UDI database, and no identifying patient information will be stored there.

Labs Play Critical Role Against Chronic Kidney Disease

Low-cost clinical laboratory tests have a big payoff in both lives and money saved in the fight to control chronic kidney disease (CDK), notes a recent alert from Results for Life.

"That's especially true if you have diabetes or high blood pressure, which puts you at high risk for CKD. Clinical lab tests to detect CKD cost less than $15 and could help you take steps to prevent kidney damage—and the $82,000 annual cost of dialysis if your kidneys fail."

Results for Life is an educational campaign sponsored by the American Clinical Laboratory Association (ACLA) to raise awareness among policymakers and the public of the value of laboratory medicine (*www.labresultsforlife.org*).

"More than 20 million Americans have CKD, and many of them don't know it. We want to especially remind those at increased risk for this disease that inexpensive lab tests can help protect and save lives, as well as dollars," said Alan Mertz, ACLA president.

About 40 percent of people with diabetes will develop CKD. High blood pressure also is a leading cause of the disease. CKD, which often goes undetected because there are few symptoms, can lead to serious kidney damage and even complete kidney failure and a life on kidney dialysis. Other complications include anemia and cardiovascular disease.

The prevalence of diabetes and high blood pressure is growing rapidly, putting ever more Americans at risk for CKD in particular populations at higher risk, including African American and Hispanic groups. The hemoglobin A1C test, which measures blood glucose and does not require fasting, can be used to detect diabetes. Medicare pays about $13.75 for this test.

Key Low-Cost Tests to Detect CKD

- **Urine Albumin**, which measures excessive protein in urine. Medicare pays about $7.33 for this test.
- **Estimated Glomerular Filtration Rate**, or eGFR, which assesses how well kidneys are removing waste from the patient's blood. For that test on its own, Medicare pays about $7.28.

Surveying Lab, Physician E-Health Data Exchange

How well clinical laboratories exchange health information electronically with test ordering physicians is the subject of a survey that the Office of the National Coordinator for Health Information Technology is planning.

The study will sample 2,729 hospital-based labs and 1,963 independent labs. It will concentrate on two measures: the percentage of laboratory facilities that are able to send structured lab results electronically to ordering physicians and the percentage of lab results now being sent electronically to ordering physicians.

The data will be used to support the work of the State Health Information Exchange Cooperative Agreement Program by providing a baseline of information exchange required and targeted help to those behind the nationwide average. For labs in the study, the survey is expected to take no more than 20 minutes to complete.

Notice of the planned *National Survey on Health Information Exchange in Clinical Laboratories* was printed in the Oct. 19 *Federal Register*. The comment period closes Nov. 19.

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