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CMS Gets Pricing Advice for New 2013 CPT Lab Codes

After considering input received, CMS will release preliminary fee determinations in early September for additional comment. Final fee decisions will be unveiled in November, the agency said, in the 2013 Part B lab fee schedule.

Leading scientific societies and national clinical laboratory and pathology groups recommend that the Centers for Medicare and Medicaid Services (CMS) use the crosswalk method to set payment rates for virtually all of the 16 new Current Procedural Terminology (CPT) test codes to be added to the Part B lab fee schedule, as of Jan. 1, 2013.

Under this method, a new test code is matched to a similar code, multiple existing codes, or a portion of an existing code on the fee schedule and is paid at that rate (the lower of the actual charge, the local fee, or the national fee cap). The gap-fill alternative is used when there is no comparable existing test. Local contractors set the fee for the first year, based on local pricing patterns.

Recommendations from four organizations shown in the table on pages 2-3 were submitted to CMS at its July 16-17 public meeting, which kicked off the annual process to get pricing input from industry stakeholders. Input from these groups includes 15 code crosswalks and one gap-fill alternative in chemistry, immunology, tissue typing, and microbiology.

INSIDE NIR

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Medicare Lab Fees Due for 4.95% Cut

Under current law Medicare payment rates for clinical laboratory tests on the Part B lab fee schedule are slated for a cut of 4.95 percent, starting Jan. 1, 2013.

The fee update formula, revised by the health care reform law, includes the consumer price index (1.7 percent) minus a productivity adjustment (currently estimated at 0.9 percent) plus an additional cut of 1.75 percent.

The 0.9 percent productivity adjustment, the Centers for Medicare and Medicaid Services cautions, is subject to change with more recent data, and the final figure will be announced in a program instruction implementing the 2013 lab fee update.

On top of the update formula cuts, lab fees are due for a 2 percent cut enacted to help pay for this year's Medicare physician fee fix and another 2 percent sequestration cut required by the deficit-reduction deal reached in 2011 which called for automatic across-the-board cuts of at least $1.2 trillion over 10 years, starting in 2013, and split equally between defense and nondefense spending.

Continued on p. 6

Medicare Lab Fee Schedule for 2013: New CPT Codes and Payment Method Recommendations*

Code/Descriptor	Code Crosswalk or Gap-Fill	Current National Fee Cap
CHEMISTRY		
827XX Galectin-3	**AACC:** Crosswalk to 83880 **ACLA:** Crosswalk to 82652 **ASCP:** Crosswalk to 82652 **CAP:** Crosswalk to 83880	$48.08 $54.53 $54.53 $48.08
IMMUNOLOGY		
861XX Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);	**AACC:** Crosswalk to 88239 + 88283 + 88249 **ACLA:** Crosswalk to 88239 + 88283 + 88249 **ASCP:** Crosswalk to 88239 + 88283 + 88249 **CAP:** Gap-fill, based on manufacturer's microcosting analysis	$551.39 $551.39 $551.39
867XX JC (John Cunningham) virus	**AACC:** Crosswalk to 86790 **ACLA:** Crosswalk to 84446 **ASCP:** Crosswalk to 84446 **CAP:** Crosswalk to 86789	$18.25 $20.08 $20.08 $20.39
TISSUE TYPING		
868XX 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	**AACC:** Crosswalk to 86807 **ACLA:** Crosswalk to 86806 **ASCP:** Crosswalk to 86806 **CAP:** Crosswalk to 86807	$56.05 $67.41 $67.41 $56.05
868XX qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens	**AACC:** Crosswalk to 86808 **ACLA:** Crosswalk to 75 percent of 86806 **ASCP:** Crosswalk to 86808 x (0.75) **CAP:** Crosswalk to 86808	$42.04 $50.56 $50.56 $42.04
868XX antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I	**AACC:** Crosswalk to 83516 (x7) **ACLA:** Crosswalk to 86806 (x2) **ASCP:** Crosswalk to 86806 (x2) **CAP:** Crosswalk to 83516 (x7)	$114.38 $134.82 $134.82 $114.38
868XX antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II	**AACC:** Crosswalk to 83516 (x6) **ACLA:** Crosswalk to 86806 (x2) **ASCP:** Crosswalk to 86806 (x2) **CAP:** Crosswalk to 83516 (x6)	$98.04 $134.82 $134.82 $98.04
868XX high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I	**AACC:** Crosswalk to 83516 (x11) **ACLA:** Crosswalk to 86806 (x3) **ASCP:** Crosswalk to 86806 (x3) **CAP:** Crosswalk to 83516 (x11)	$179.74 $202.23 $202.23 $179.74

Code/Descriptor	*Code Crosswalk or Gap-Fill*	*Current National Fee Cap*
TISSUE TYPING		
868XX high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II	**AACC:** Crosswalk to 83516 (x10) **ACLA:** Crosswalk to 86806 (x3) **ASCP:** Crosswalk to 86806 (x3) **CAP:** Crosswalk to 83516 (x10)	$163.40 $202.23 $202.23 $163.40
868XX semi-quantitative panel (eg, titer), HLA Class I	**AACC:** Crosswalk to 83516 (x31) **ACLA:** Crosswalk to 86806 (x7.5) **ASCP:** Crosswalk to 86806 (x7.5) **CAP:** Crosswalk to 83516 (x31)	$506.54 $505.58 $505.58 $506.54
868XX semi-quantitative panel (eg, titer), HLA Class II	**AACC:** Crosswalk to 83516 (x28) **ACLA:** Crosswalk to 86806 (x7.5) **ASCP:** Crosswalk to 86806 (x7.5) **CAP:** Crosswalk to 83516 (x28)	$457.52 $505.58 $505.58 $457.52
MICROBIOLOGY		
876XX 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	**AACC:** Crosswalk to 87502 + 87503 **ACLA:** Crosswalk to 87502 + 87503 **ASCP:** Crosswalk to 87502 + 87503 **CAP:** Crosswalk to 87502 + 87503	$149.94 $149.94 $149.94 $149.94
876XX 6-11 targets	**AACC:** Crosswalk to 87502 + 5 x 87503 **ACLA:** Crosswalk to 87502 + 87503 (x6) **ASCP:** Crosswalk to 87502 + 87503 (x6) **CAP:** Crosswalk to 87502 + 87503 (x6)	$265.85 $297.04 $297.04 $297.04
876XX 12-25 targets	**AACC:** Crosswalk to 87502 + 16 x 87503 **ACLA:** Crosswalk to 87502 + 87503 (x15) **ASCP:** Crosswalk to 87502 + 87503 (x15) **CAP:** Crosswalk to 87502 + 87503 (x15)	$587.27 $561.82 $561.82 $561.82
879XX Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus	**AACC:** Crosswalk to 87901 **ACLA:** Crosswalk to 87902 **ASCP:** Crosswalk to 87902 **CAP:** Crosswalk to 87901	$364.64 $364.64 $364.64 $364.64
879XX Hepatitis B virus	**AACC:** Crosswalk to 87901 **ACLA:** Crosswalk to 87902 **ASCP:** Crosswalk to 87902 **CAP:** Crosswalk to 87901	$364.64 $364.64 $364.64 $364.64

**Acronyms:* AACC, American Association for Clinical Chemistry; ACLA, American Clinical Laboratory Association; ASCP, American Society for Clinical Pathology; and CAP, College of American Pathologists.

 Note: last two digits, XX, to be finalized.

CMS: 'How Should We Price New Molecular Pathology Codes?'

That's what the Centers for Medicare and Medicaid Services (CMS) asked clinical laboratory, pathology, and other industry stakeholders as it put on display July 6 its proposed Medicare physician fee schedule rule for calendar year 2013.

The agency got a preview of what to expect in industry comments at the July 16-17 annual public forum on pricing new test codes to be added to the Part B lab fee schedule in 2013 (*related story, p. 1*).

At issue are 101 Current Procedural Terminology (CPT) codes for molecular pathology tests that the American Medical Association (AMA) introduced this year but Medicare does not yet recognize. They 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 are intended to replace the "stacking" codes used to bill Medicare, that is, multiple generic molecular diagnostic codes (CPT 83890–83914 and 88271) to form the basis of payment for a single genetic test.

CMS Proposals

In the proposed rule, CMS seeks advice on whether to place the new codes:

- On the clinical laboratory fee schedule (CLFS) which sets payment rates using the crosswalk or gap-fill method, with no beneficiary cost sharing for tests; or
- On the physician fee schedule (PFS), whose services typically require physician work and fees are set using relative value units subject to adjustments for the sustainable growth rate and geographic practice differences as well as periodic CMS review. Beneficiary cost sharing of 20 percent generally is required.

CMS said it 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. We are also concerned that the differences in prices would become more pronounced over time as the PFS continues to review physician work values and practice expense inputs relative to established CLFS prices."

Accordingly, the agency has proposed assigning the codes to one single fee schedule using one payment method and, if that schedule is determined to be the PFS, to let local contractors set the payment rate.

Which Fee Schedule Is the Right Fit?

Industry groups urge CMS to establish payment rates via the crosswalk method (matching the new code to an existing one) and by referring to historical reimbursement levels.

The College of American Pathologists, the American Society for Clinical Pathology, and the Association for Molecular Pathology support assigning the new codes to the PFS, arguing that physician interpretation is required for the majority of these tests and that the PFS allows for frequent updating in light of changing technology and greater efficiencies.

The American Clinical Laboratory Association (ACLA) and the American Association for Clinical Chemistry (AACC) believe each code should be assessed individually to determine if it requires interpretation by a pathologist (PFS) or by a nonphysician or computer (CLFS). It should be placed on the appropriate fee schedule based on how the interpretive function is most commonly performed.

Speaking for ACLA at the lab public forum, attorney Peter Kazon, of Alston & Bird (Washington, D.C.), said CMS "should not engage in a wholesale re-examination of the pricing of the existing MDx tests being issued new codes. . . . The well-defined principles used in crosswalking should be applied here."

Pricing should also reflect historical reimbursement levels, ACLA commented, noting that under current law, clinical labs "face a 'tsunami'" of fee cuts, which could ultimately limit patients' access to vital services (*related story, p. 1*).

AACC registered strong opposition to the proposal to place all the codes on one fee schedule, saying a "blanket" assignment based on convenience rather than established criteria is a bad idea: "We recommend that CMS review and assign the codes based on the level of professional interpretation required, not simplicity of implementation and oversight."

AACC further noted that doctoral scientists 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 on that fee schedule." If CMS decides this requires a legislative correction, AACC urges it to "contact the appropriate congressional committees" to press the need for timely action.

The Coalition for 21st Century Medicine said CMS should crosswalk the analyte-specific Tier 1 codes to the relevant combination of molecular pathology codes reported for these tests prior to 2012. If there is no established set of molecular method codes, CMS should resort to gap-filling. For Tier 2 codes, CMS and the AMA should look at additional options "to identify tests billed to payers, e.g., Palmetto's MolDx program, which uses unique test identifiers" (*NIR 12, 10/May 24, p. 1*).

At the lab public forum Glenn McGuirk of CMS's hospital and ambulatory policy group said stakeholders should have an answer to the placement question by the end of August when preliminary fee determinations are released for new codes on the CLFS. If the molecular pathology codes are not on that list, it would be safe to assume they would be placed on the PFS, he said.

At the same forum, industry representatives commented on Multianalyte Assays with Algorithmic Analyses (MAAAs), a new group of 10 tests assigned CPT codes for 2013 (*NIR 12, 11/June 7, p. 6*). These procedures use multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays. Algorithmic analysis, tapping these results as well as other patient information, is then performed and reported typically as a numeric score or as a probability.

While presenters gave pricing recommendations on individual MAAA tests, in general they urged CMS to reimburse for the algorithm component and to examine each MAAA individually to decide whether to apply crosswalking or gap-filling to determine payment.

Medicare Lab Fees Due for 4.95% Cut, *from p. 1*

Along with the fee cuts, clinical laboratories face the prospect of future price increases for medical devices, supplies, kits, and reagents due to the 2.3 percent excise tax that the health care reform law imposed on medical device manufacturers, starting in 2013, and applicable to gross sales receipts in excess of $5 million. The House has voted to repeal the tax, but it is not clear whether the Senate will go along, though several Democrats there have come out for repeal.

OIG Finds Wide Swings in Genetic Test Pricing

Nearly all state Medicaid programs and three Federal Employee Health Benefits (FEHB) plans cover genetic tests in a way similar to Medicare, though payment rates for the tests vary widely, according to a recent report from the Health and Human Services Office of Inspector General (OIG) to the Centers for Medicare and Medicaid Services (CMS).

As examples of the pricing variations versus Medicare lab fee schedule rates, the OIG noted, "Among state Medicaid programs, the payment rate for a BRCA1 gene analysis ranged from $1,000 in Pennsylvania to nearly $4,500 in Iowa. Among FEHB plans the AlloMap test ranged from $2 to $3,658. Other tests had less variation, such as the Pathwork Tissue of Origin, which ranged from $5 to $38. One plan official said the variation in payment rates is likely due to low test volume and services provided by nonpreferred provider organizations."

CMS requested the report to assist it in establishing coverage and payment policies for 101 new genetic test codes in molecular pathology approved by the American Medical Association in 2012 but not yet recognized by Medicare (*related story, pp. 4-5*).

The OIG report presents the findings from surveys of 50 state Medicaid programs and three national FEHB plans but makes no recommendations. The surveys examined payment rates in effect from Jan. 1 through March 31, 2011, for 16 genetic tests by name and by CPT stacking codes. Stacking is the use of multiple generic molecular diagnostic codes (CPT 83890–83914 and 88271) to form the basis of reimbursement for a single genetic test, and the 101 new molecular diagnostic codes are intended to replace this payment method.

The OIG report, Coverage and Payment for Genetic Laboratory Tests *(OEI-07-11-00011), is available at* http://go.usa.gov/dJF.

Medicare rules do not address the quantity or configuration of stacking codes for genetic tests, the OIG stated. Reliance on stacking codes also does not provide specificity to the payer as to what was tested because the same set of codes is used in a variety of genetic test types, the OIG noted. "Different laboratories may use differing procedures to perform the same lab test; therefore, they use differing quantities of CPT codes to file claims for the tests. For example, a cystic fibrosis profile at one lab might be coded with a total of 29 units of 5 different CPT codes, while the same test from another lab might be coded with a total of 89 units of 6 different CPT codes."

As the largest health insurer in the United States, Medicare has "great influence on the actions of other health care insurers," the OIG said. Medicare uses a combination of national and local coverage determinations for genetic tests to diagnose and guide treatment and therapy.

National coverage determinations (NCDs) are made at the federal level and apply to all Medicare beneficiaries and Medicare administrative contractors (MACs). Currently, there are two NCDs related to genetic tests: (1) testing to predict patient responsiveness to the drug warfarin sodium and (2) cytogenetic studies.

MACs make local coverage determinations (LCDs), which apply only to beneficiaries in the contractor's jurisdiction. Of the nearly 9,000 LCDs, only 11 are related to genetic tests. For example, one MAC covers BRCA1 and BRCA2 genetic testing for breast or ovarian cancer for beneficiaries who meet certain criteria.

All but one of the state Medicaid programs and each of the three FEHB plans surveyed by the OIG had some level of coverage for genetic tests, according to the OIG report.

Thirty-nine Medicaid programs paid for genetic tests using only the stacking method, and eight states used a combination of stacking and paying by test name.

Of the 47 state Medicaid programs paid via the stacking method, only Iowa set a maximum quantity and combination of stacked codes that it would reimburse for a given test.

Bills Give CLIA Leeway in Enforcing PT Referral Rules

Bipartisan legislation introduced in the House and the Senate this month would give the Centers for Medicare and Medicaid Services (CMS) regulatory flexibility in enforcing the prohibition against referral of proficiency testing (PT) samples from one clinical laboratory to another for analysis of a test which it is certified to perform in its own facility.

The purpose of the ban under the Clinical Laboratory Improvement Amendments (CLIA) is to prevent a lab from substituting another lab's work to satisfy its PT testing and reporting requirements for regulated nonwaived analytes.

CMS has held that the CLIA statute does not give it discretion in strictly enforcing the ban on improper PT referrals, even when a referral is made for reflex or confirmatory testing or is made inadvertently. Accordingly, it is required to take action to revoke the lab's CLIA certificate for one year and to bar the lab's director and owner or operator from running a lab for two years.

The House and Senate legislation would change that by striking the CLIA statutory language that a lab's certification "*shall* be suspended" and inserting the term "*may* be suspended." It would allow CMS to substitute intermediate sanctions where warranted, including a directed plan of correction, civil money penalties, and costs for on-site monitoring or any combination of these.

The House bill, H.R. 6118, was introduced July 12 by Rep. Michael Grimm (R-N.Y.), with three co-sponsors: Rep. Peter Roskam (R-Ill.), Mike Ross (D-Ark.), and Steve Womack (R-Ark.). It has been referred to the House Committee on Energy and Commerce.

The Senate bill, S. 3391, was introduced July 17 by Sen. Amy Klobuchar (D-Minn.) with co-sponsors John Boozman (R-Ark.) and Jeanne Shasheen (D-N.H.). It has been referred to the Committee on Health, Education, Labor, and Pensions.

Bills Give CLIA Leeway in Enforcing PT Referral Rules, *from p. 7*

The American Clinical Laboratory Association said in a statement that it gives "strong and full support" to "this much-needed discretion so that laboratories of all types, including hospital and independent labs, would not have their CLIA certificates revoked for the unintentional referral of PT samples . . . for either a test that it does not perform or for confirmatory testing. "

Though not commenting on specific legislation, CLIA officials recognize that there are instances when PT referrals are made by accident and would welcome more enforcement flexibility.

To date, CMS has been upheld in almost all administrative appeals involving PT referrals, but not in one decision handed down in September 2011. In that case, *J.B. and Greeta B. Arthur Comprehensive Cancer Center v. CMS*, the Health and Human Services Departmental Appeals Board ruled that CMS could not revoke the center's CLIA lab certificate based on its having sent unused portions of its PT samples to the lab of an affiliated medical center for storage and disposal, even though the latter decided on its own initiative to test the samples before the cancer center lab had reported its PT results (*NIR 12, 1/Jan. 12, p. 3*).

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