CMS Finalizes Medicare Lab Fee Schedule Update for 2013

The 2013 update, effective Jan. 1, to the Medicare Part B clinical laboratory fee schedule will trigger a 2.95 cut in payment rates for covered services, the Centers for Medicare and Medicaid Services (CMS) announced in a Nov. 30 transmittal.

This marks the third time in four years that the lab fee update has fallen into negative territory (see table, p. 2). The only increase over that time was 0.65 percent this year.

The 2013 update is determined by a multipart statutory formula: the consumer price index for urban areas (CPI-U), 1.7 percent, minus a productivity adjustment of 0.9 percentage points, minus a 1.75 percentage point reduction required by the Patient Protection and Affordable Care Act, and a 2 percent cut to help pay for this year’s Medicare physician fee fix.

Payment for a clinical lab test is the lesser of the actual charge billed for the test, the local fee schedule payment, or the national limitation amount (NLA). The Part B deductible and coinsurance do not apply.

The 2.95 percent update cut to the lab fee schedule also reduces the national minimum payment for Pap smears, reducing it in 2013 to $14.53 from $14.97 this year. The national minimum payment in 2011 was $14.97.

Supreme Court to Hear Human DNA Patents Case

The U.S. Supreme Court said Nov. 30 that it will hear arguments in a case seeking to invalidate patents for two genes associated with hereditary breast and ovarian cancer.

The court certified only the following question for deliberation, one that would have major consequences for gene-based medicine: Are human genes patentable? A decision is expected in the court’s current term that runs to the end of June.

The patents on the BRCA1 and BRCA2 genes are held by Myriad Genetics (Salt Lake City), which has the exclusive right to perform testing on these genes, license the testing to other users, and threaten litigation against any unlicensed use.

The challenge to the patents is being pursued by the American Civil Liberties Union (ACLU) and the Public Patent Foundation on behalf of women who are at risk of inheriting these genes.

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was $14.87. It was $15.13 in 2010 and $15.42 in 2009. From 2004 through 2008 it was frozen at $14.76.

Medicare pays for Pap smears at the lesser of the local fee or the NLA, but never below the national payment floor and never more than the actual charge. The affected codes are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

The 2013 update for laboratory costs subject to reasonable charge payment, including blood products, transfusion medicine, and reproductive medicine procedures, is 1.7 percent, based solely on the CPI-U for the 12-month period ending June 30 of each year. The reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the CPI-U.

<table>
<thead>
<tr>
<th>YEAR</th>
<th>PERCENT</th>
<th>YEAR</th>
<th>PERCENT</th>
</tr>
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<tbody>
<tr>
<td>1990</td>
<td>4.7</td>
<td>1998-2002</td>
<td>0.0</td>
</tr>
<tr>
<td>1991</td>
<td>2.0</td>
<td>2003</td>
<td>1.1</td>
</tr>
<tr>
<td>1992</td>
<td>2.0</td>
<td>2004-2008</td>
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</tr>
<tr>
<td>1993</td>
<td>2.0</td>
<td>2009</td>
<td>4.5</td>
</tr>
<tr>
<td>1994</td>
<td>0.0</td>
<td>2010</td>
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<tr>
<td>1995</td>
<td>0.0</td>
<td>2011</td>
<td>-1.75</td>
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<tr>
<td>1996</td>
<td>2.8</td>
<td>2012</td>
<td>0.65</td>
</tr>
<tr>
<td>1997</td>
<td>2.7</td>
<td>2013</td>
<td>-2.95</td>
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</table>

Gearing Up to Gap-Fill Molecular Pathology Codes

With gap-filling to be used to set payment rates for 114 molecular pathology codes new to the 2013 Part B clinical lab fee schedule, effective Jan. 1, local Medicare Administrative Contractors (MACs) have little lead time to calculate what the rates should be based on pricing practices in their jurisdiction.

The new codes are arranged in two tiers: Tier 1, CPT 81200-81383, for analyte-specific, high-volume tests, and Tier 2, CPT 81400-81479, for resource-based, low-volume procedures. They replace the stacking codes, CPT 83890-83914, that have been used to bill for molecular pathology tests are eliminated in 2013.

Can MACs complete the gap-fill process for the new codes in time to avoid disruption to reimbursement for these codes? “Until MACs complete the gap-filling process, clinical labs may not be paid for molecular pathology tests with the new CPT codes,” the American Clinical Laboratory Association (ACLA) noted in a Nov. 30 letter to the Centers for Medicare and Medicaid Services (CMS). ACLA said it has not yet heard of any guidance from CMS to local contractors on handling this process.

In the interim, ACLA proposed that CMS set temporary rates based on crosswalking or, as an alternative, establish G-codes to replace the stacking codes and price them at the same level as the stacking codes. However, CMS reportedly is not likely to choose the G-code option.

Gap-filling is one of two approved methods that CMS uses to establish payment rates for tests covered under the Medicare lab fee schedule. It is used when there

Continued on p. 4
# Medicare Lab Fee Schedule for 2013: New CPT Codes and Final Payment Determinations

<table>
<thead>
<tr>
<th>CODE/_DESCRIPTOR</th>
<th>FINAL FEE DETERMINATIONS</th>
<th>NATL. FEE CAP, 2012/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHEMISTRY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>82777 Galectin-3</td>
<td>Crosswalk to 83520</td>
<td>$18.34/$17.80</td>
</tr>
<tr>
<td><strong>IMMUNOLOGY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>86152 Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)</td>
<td>Gap-fill</td>
<td>N/A</td>
</tr>
<tr>
<td>86711 JC (John Cunningham) virus</td>
<td>Crosswalk to 86789</td>
<td>$20.39/$19.79</td>
</tr>
<tr>
<td><strong>TISSUE TYPING</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Crosswalk to 86807</td>
<td>$56.05/$54.40</td>
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<tr>
<td>86829 qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens</td>
<td>Crosswalk to 86808</td>
<td>$42.04/$40.80</td>
</tr>
<tr>
<td>86830 antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I</td>
<td>Crosswalk to 83516 (x7)</td>
<td>$114.38/$110.99</td>
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<tr>
<td>86831 antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II</td>
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<td>$98.04/$95.13</td>
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<tr>
<td>86832 high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I</td>
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<td>$179.74/$174.40</td>
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<tr>
<td>86833 high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II</td>
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<td>$163.40/$158.55</td>
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<td>86834 semi-quantitative panel (eg, titer), HLA Class I</td>
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<tr>
<td><strong>MICROBIOLOGY</strong></td>
<td></td>
<td></td>
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<tr>
<td>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</td>
<td>Crosswalk to 87502 + 87503 (x2)</td>
<td>$179.36/$176.34</td>
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<tr>
<td>87632 6-11 targets</td>
<td>Crosswalk to 87502 + 87503 (x6)</td>
<td>$297.04/$293.37</td>
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<tr>
<td>87633 12-25 targets</td>
<td>Crosswalk to 87502 + 87503 (x16)</td>
<td>$591.24/$572.91</td>
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<tr>
<td>87910 Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus</td>
<td>Crosswalk to 87902</td>
<td>$364.64/$353.88</td>
</tr>
<tr>
<td>87912 Hepatitis B virus</td>
<td>Crosswalk to 87902</td>
<td>$364.64/$353.88</td>
</tr>
</tbody>
</table>

CPT codes © American Medical Association.
Gearing Up to Gap-Fill Molecular Pathology Codes, from p. 2

is no comparable crosswalk to an existing code or set of codes. It is rarely used and only for new tests with low volume initially and that have not been covered by Medicare in the past. The impact has been smaller in the past, ACLA said, “because new tests typically have low claim volumes. In contrast, here, gap-filling would be used for well-established and frequently ordered tests.”

Gap-filling requires MACs to set their Medicare rates based on several factors in their jurisdictions, such as the cost of the testing, charges for it after discounts, and reimbursement rates set by other payers.

In the case of the new molecular pathology codes, CMS said it decided to adopt the gap-fill method because it did not have sufficient information to set national payment caps for 2013. But the agency said it would tap pricing data from MACs to establish national median levels, or fee caps, for these codes in 2014.

Meantime, one MAC, Palmetto GBA, which handles Jurisdiction 1, has announced that for services performed on or after Jan. 1, 2013, it will include the Tier 1 and Tier 2 codes in its MolDx program, requiring labs to register each assay and, if applicable, be assigned a unique McKesson Z-Code identifier in order to bill and be paid for these codes. The MolDx program affects all labs that perform molecular diagnostic testing and bill in California, Nevada, Hawaii, and the Pacific territories of American Samoa, Guam, and the Northern Marianas.

Lab Coalition to Congress: ‘Protect Medicare Lab Services’

The Clinical Laboratory Coalition has urged House and Senate leaders in both parties to not consider as part of any deficit-reduction deal or any fix to the scheduled 26.5 percent cut in Medicare physician fees any further cuts to the lab fee schedule and any new requirement for cost sharing by beneficiaries for covered lab services.

The coalition made the plea in a Nov. 29 letter with 50 signatories, including clinical lab and pathology associations, scientific societies, independent lab companies, and medical device makers. Among those signing were the American Society for Clinical Pathology, American Clinical Laboratory Association, American Association for Clinical Chemistry, American Association of Bioanalysts, American Medical Technologists, Clinical Laboratory Management Association, and the National Independent Laboratory Association.

“Further reductions to the fee schedule—whether through a direct cut or the imposition of new laboratory cost sharing requirements—gravely threaten laboratory providers’ ability to serve their communities and specifically meet the needs of the Medicare population,” the groups said in the letter.

“Clinical laboratory testing represents approximately 1.6 percent of all Medicare spending, yet it has been subject to significant payment freezes and cuts over the last two decades—especially in the past three years. These include a cumulative 20 percent reduction under the health care reform law; another 2 percent cut under the short-term physician fee fix passed in February of this year (representing 15 percent of the offset to pay for the SGR deal); and another 2 percent through sequestration.”

Any additional fee cuts would especially harm small and midsized clinical labs serving rural communities as well as nursing home and homebound patients. “For some labs, 60 percent or more of their patient base consists of Medicare beneficiaries.”
Lab Competitive Bidding: An Idea That Won’t Die

Competitive bidding for clinical laboratory services is again being touted as a cost-cutting change to the Medicare program, with the potential to save an estimated $4.2 billion. Its latest advocate is the Center for American Progress, an independent nonpartisan think tank with headquarters in Washington, D.C.

The lab competitive bidding proposal is contained in the center’s Senior Protection Plan and is one of a series of proposals that overall would “save an estimated $385 billion in health care costs without harming beneficiaries.”

In the section on “enhancing competition based on price and quality,” the plan proposes extending Medicare competitive bidding by 2015 to laboratory tests, medical devices, advanced imaging services, and all other health care products. It also calls for creating a panel of business and academic experts to govern the process. Further, the plan proposes extending competitively bid pricing to Medicaid and all other government health programs.

The center’s proposal for lab competitive bidding marks the third time this year that this option has been brought to the fore as a Medicare cost-saver. Two other reports have urged the same: one published in the Aug. 1 *New England Journal of Medicine* and authored by health policy veterans from academic and political circles, and the other from RTI International and posted on the online peer-reviewed research journal *Medicare and Medicaid Research Review*.

The last effort by Medicare to introduce a lab competitive bidding demonstration, designed by RTI International, was squelched in 2008 when Congress repealed the authority it had previously granted for a pilot program.

OIG Repeats Call for Major Medicare Lab Pay Changes

The Health and Human Services Office of Inspector General (OIG) is again encouraging the Centers for Medicare and Medicaid Services (CMS) to seek legislative authority to introduce beneficiary cost sharing for Part B covered clinical laboratory services. And while the OIG urges CMS to periodically evaluate the Part B lab fee schedule to align payment rates with the prices that physicians pay for lab tests, it also reiterates its recommendation that CMS establish a new process for setting accurate and reasonable rates for Part B lab tests.

The proposals were aired in the December 2012 edition of the OIG’s compendium of unimplemented recommendations. Imposing a deductible and a 20 percent copayment for Medicare lab services would provide more controls over utilization and billing, the OIG asserted, citing a Congressional Budget Office estimate in December 2008 that the savings over 10 years would amount to $23.8 billion, with annual savings of $2.4 billion kicking in by 2014.

With regard to Medicare reimbursement, the OIG said the data used to establish and update the Part B lab fee schedule do not reflect the actual costs of performing lab tests as well as the differences in cost from one geographic area to another. To correct this, the OIG recommends that CMS seek legislative authority for a new fee-setting process that accounts for costs, adjusted for geographic variations. CMS has told the OIG that it would consider this approach as it monitors the effects of current lab payment policies. Medicare contractors now reimburse labs at the lower of the actual charge for the test, the fee schedule amount for their jurisdictions, or the national fee cap set by CMS.
Supreme Court to Hear Human DNA Patents Case, from p. 1

of researchers, genetic counselors, patients, breast cancer and women’s health groups, and medical professional associations representing 150,000 geneticists, pathologists, and laboratory professionals.

The ACLU, which asked for the high court review Sept. 25, contends that BRCA1 and BRCA2 and their mutations are products of nature and thus ineligible for patent protection under current law. Further, the patents give Myriad a monopoly over crucial genetic information used to make important medical decisions, restricting both scientific research and patients’ access to a lifesaving test and to a second opinion when called for.

Myriad counters that the U.S. Court of Appeals for the Federal Circuit has twice declared the patents valid under Section 101 of the U.S. Patent Act, ruling that they involve DNA isolates “markedly different” in molecular composition from the DNA that naturally exists in chromosomes in the body.

The patentability of the BRACAnalysis® test “has helped close to 1 million people learn about their hereditary cancer risk,” said Peter Meldrum, president and CEO of Myriad Genetics. “Myriad devoted more than 17 years and $500 million to develop the test. The discovery and development of pioneering diagnostics and therapeutics require a huge investment and our U.S. patent system is the engine that drives this innovation.”

The BRACAnalysis test detects the presence of the BRCA1 and BRCA2 genetic mutations that can help determine a patient’s risk of breast and ovarian cancer and inform treatment options. According to Myriad, women who test positive have an 82 percent higher risk of developing breast cancer and a 44 percent higher risk of ovarian cancer in their lifetimes.

Chronology of the Case

May 2009 ACLU files lawsuit, Association for Molecular Pathology et al. v. Myriad Genetics et al.


July 2011 In a split decision, 2-1, the appeals court upholds the BRCA gene patents but not Myriad’s claims on analyzing whether a patient’s genes had mutations that raised the risk of cancer, saying this involved only “patent-ineligible abstract mental steps.”

September 2011 The appeals court turns down petitions by both sides to again air arguments in the case. Both sides petition for Supreme Court review.

March 2012 The Supreme Court, following its March 20 ruling in Mayo v. Prometheus, remands the case to the appellate court for a rehearing.

August 2012 The appeals court again splits, 2-1, upholding Myriad’s gene patents but voiding certain test method patents for analyzing gene sequences.

September 2012 The ACLU petitions the Supreme Court to review the case.

October 2012 Myriad files an opposing brief with the high court.

November 2012 The Supreme Court accepts the ACLU request, limiting its review to one question: Are human genes patentable? 

The case has major implications for biotechnology and diagnostics industries and for personalized medicine. More than 4,000 of the roughly 22,000 genes in the human genome have U.S. patents, the ACLU says, covering genes associated with Alzheimer’s disease, muscular dystrophy, colon cancer, asthma, and many other illnesses.
Final Rule Issued on Medical Device Excise Tax

The Internal Revenue Service (IRS) has published in the Dec. 7 Federal Register a final rule implementing the 2.3 percent excise tax to be levied on medical devices, as required under the health care reform law of 2010. Also released was Notice 2012-77, offering interim guidance on the tax along with a request for comments.

The rule, which affects manufacturers, importers, and producers of such devices, took effect Dec. 7 and applies to medical device sales as of Jan. 1, 2013, with the first semimonthly deposit of tax due Jan. 29. However, the IRS will not impose penalties for the first three calendar quarters of 2013 on taxpayers who make a good-faith attempt to comply with tax filing requirements.

Which Devices Are Taxable?
The definition of a taxable medical device is the same as previously proposed last February. It is a device that is listed with the Food and Drug Administration (FDA) under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 Code of Federal Regulations Part 807. This, the IRS said, provides greater certainty regarding which devices are subject to taxation.

To the relief of pathology and clinical laboratory groups, this would exclude laboratory-developed tests since these are not listed with FDA as medical devices.

Exemptions
In addition to reiterating the statutory exemption for eyeglasses, contact lenses, and hearing aids, the final rule clarifies the retail exemption, adding a safe harbor for other devices that are typically purchased at retail by the general public for individual use. These include:

- Devices described as “OTC” or “over the counter” in the relevant FDA classification regulation heading.
- Devices described as “OTC” or “over the counter” devices in the FDA’s product code name, the FDA’s device classification name, or the “classification name” field in the FDA’s device registration and listing database (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm).
- Devices that qualify as parenteral and enteral nutrients, equipment, and supplies or as durable medical equipment or prosthetic and orthotic devices (not implanted or inserted by medical professionals) for which payment is available on a purchase basis under Medicare Part B payment rules.

Custom procedure kits that hospitals assemble for use in their own facility will not be subject to the tax, the IRS clarified, noting that these “self-kitters are exempt from the FDA’s registration and listing requirements.”

Device industry groups have faulted the IRS for not allowing enough time to meet the new requirements. The Medical Imaging and Technology Alliance wants Congress to delay the effective date for a year if the tax is to remain law. The Advanced Medical Technology Association urges Congress to repeal the tax. The House voted in June for repeal, but the Senate shows no sign of going along.
President Signs CLIA PT Referral Legislation

President Obama on Dec. 4 signed into law (Pub. L. 112-202) legislation that gives the Centers for Medicare and Medicaid Services (CMS) discretion in enforcing sanctions on clinical laboratories for violating proficiency testing (PT) referral rules. The measure cleared the Senate Nov. 14 and the House Sept. 19.

Key provisions of H.R. 6118, the Taking Essential Steps for Testing (TEST) Act, amend the Clinical Laboratory Improvement Amendments (CLIA) to revise sanctions for labs that unintentionally refer PT samples to other labs. CMS now has enforcement discretion to make the one-year CLIA certificate revocation optional rather than mandatory and levy intermediate sanctions instead of the two-year prohibition against common lab ownership or operation that would otherwise apply.

Being able to consider PT referral sanctions on a case-by-case basis is a change that CLIA officials welcome. Under previous policy, CMS maintained that the CLIA statute gave it no choice but to impose the most severe sanctions, even for unintentional violations.

Reminder: December is a one-issue month for NIR.