G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 12, Iss. 16, September 6, 2012

CMS Recommends Fee Crosswalk for New Lab Codes, Gap-Fill Payment for New Molecular Pathology Codes

These initial payment decisions are open to further public comment. Final decisions will be published in November in the Medicare Part B lab fee schedule for 2013.

The Centers for Medicare and Medicaid Services (CMS) has posted its preliminary payment determinations for 16 new Current Procedural Terminology (CPT) lab test codes to be added to the Part B fee schedule, as of Jan. 1, 2013.

In the Aug. 31 posting CMS also presented its initial 2013 pricing determinations for 101 new CPT molecular pathology codes and 10 new CPT codes for multianalyte assays with algorithmic analyses.

New Lab Codes

These include one in chemistry, two in immunology, eight in tissue typing, and five in microbiology (*see table, p. 3*). For 15 of them CMS recommends setting the fees by a crosswalk to a similar code or multiple existing codes and paying at that rate (the lower of the actual charge, the local fee, or the national fee cap; most lab codes are paid at the cap).

For one code in immunology, CMS recommends pricing via the gap-fill method. This alternative is used when there is no comparable existing test. Local contractors set the fees for the first year, based on local pricing patterns, and CMS uses these to establish a national fee cap for the following year.

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ICD-10 Deadline Moved to October 2014

It's official. The compliance date for health care providers, health plans, and clearinghouses to use the International Classification of Diseases, 10th Edition (ICD-10) diagnosis and procedure codes has been extended from Oct. 1, 2013, to Oct. 1, 2014.

The new date was announced by the Centers for Medicare and Medicaid Services (CMS) in a final rule released Aug. 24. The agency had previously proposed the one-year delay to give providers more time to prepare for the transition from the ICD-9 code sets, including thorough testing (*NIR 12, 7/April 12, p. 1*).

In granting the delay, CMS said that "some provider groups have expressed strong concern about their ability to meet the Oct. 1, 2013, compliance date and the serious claims payment issues that might then ensue. Some concerns are based, in part, on difficulties they have had meeting the compliance deadline for adoption of ASC X12 Version 5010 standards for electronic health care transactions."

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CMS Recommends Fee Crosswalk, *from p. 1*

In response to a request to reconsider the crosswalk for CPT 86386, Nuclear Matrix Protein 22 (NMP22), qualitative, CMS says the current crosswalk to 82487, capped at $22.61, is appropriate and will be retained.

New Molecular Pathology (MDx) Codes

CMS recommends using the gap-fill method in 2013 for pricing the MDx codes that the agency decides should be payable under the Part B Clinical Lab Fee Schedule (CLFS).

The new MDx codes were introduced this year by the American Medical Association and are intended to replace the "stacking" codes currently used to bill Medicare for molecular tests. 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).

Because the same molecular test is often billed using different stacks and the stacks may have changed over time, CMS said it does not have enough information to crosswalk the MDx codes and opts for the gap-filling method instead. "This will allow CMS and its contractors the opportunity to gather current information about the manner in which the tests are performed and the resources necessary to provide them so that CMS can set an appropriate payment rate for these tests."

The new CPT Tiers 1 and 2 codes are designed to replace billing for molecular pathology procedures using "stacking codes" (CPT 83890–83914) that focus on methodology rather than analyte. These codes, plus codes for multianalyte assays with algorithmic analyses, can be downloaded at www.cms.gov/ClinicalLabFeeSched/. *Click on "Laboratory Public Meetings," then on "2013 Updates."*

The agency also said that, based on comments received on the proposed 2013 Medicare Physician Fee Schedule (PFS), it may decide that some of the codes on the molecular pathology list are not clinical diagnostic laboratory test codes.

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

Multianalyte Assays With Algorithmic Analyses (MAAAs)

For these 10 new codes (815XX1 through 815XX7 and XXXX1M through XXXX3M), CMS received comments favoring various crosswalks or gap-filling to establish their price. They include tests for ovarian cancer, type 2 diabetes, fetal chromosomal abnormalities, hepatitis C virus, and liver disease.

MAAAs are procedures that utilize multiple results derived from molecular pathology assays, as well as fluorescence in situ hybridization and other non-nucleic-acid based assays, and are then used in proprietary algorithmic analyses to derive a single result, reported typically as a numeric score or probability. Such tools make it possible 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.

However, the agency did not recommend separately pricing these codes, noting that it uses other codes to pay for the underlying clinical lab tests on which the MAAA is done. "A MAAA is a numeric score(s) or a probability (*i.e.*, "p-score") based on the results of laboratory tests and, in some cases, patient information. Medicare does not recognize a calculated or algorithmically derived rate or result as a clinical laboratory test since the calculated or algorithmically derived rate or result alone does not indicate the presence or absence of a substance or organism in the body."

Medicare Lab Fee Schedule for 2013: New CPT Lab Test Codes and CMS Preliminary Payment Determinations

Code/Descriptor	*Preliminary Fee Determinations*	*Current National Fee Cap*
CHEMISTRY		
827XX Galectin-3	Crosswalk to 83520	$18.34
IMMUNOLOGY		
861XX Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);	Gap-fill	N/A
867XX JC (John Cunningham) virus	Crosswalk to 86789	$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	Crosswalk to 86807	$56.05
868XX qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens	Crosswalk to 86808	$42.04
868XX antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I	Crosswalk to 83516 (x7)	$114.38
868XX antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II	Crosswalk to 83516 (x6)	$98.04
868XX high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I	Crosswalk to 83516 (x11)	$179.74
868XX high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II	Crosswalk to 83516 (x10)	$163.40
868XX semi-quantitative panel (eg, titer), HLA Class I	Crosswalk to 83516 (x31)	$506.54
868XX semi-quantitative panel (eg, titer), HLA Class II	Crosswalk to 83516 (x28)	$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	Crosswalk to 87502 + 87503 (x2)	$179.36
876XX 6-11 targets	Crosswalk to 87502 + 87503 (x6)	$297.04
876XX 12-25 targets	Crosswalk to 87502 + 87503 (x16)	$591.24
879XX Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus	Crosswalk to 87902	$364.64
879XX Hepatitis B virus	Crosswalk to 87902	$364.64

CPT codes © American Medical Association. Note: last two digits, XX, to be finalized.

focus on: *CLIA PT Referrals*

Ohio State Lab Challenges Revocation of CLIA Certificate

A clinical laboratory at Ohio State University's (OSU) Wexner Medical Center in Columbus is the latest "poster boy" for the worst that could happen if a lab breaches federal rules on proficiency testing (PT) referrals, even by accident.

The Centers for Medicare and Medicaid Services (CMS) has threatened to revoke its certificate under the Clinical Laboratory Improvement Amendments (CLIA) for violating the prohibition against a lab sending a PT sample to another lab for analysis of a test that it is certified to perform. The center is contesting the decision, putting the sanction on hold for now.

Meanwhile on Capitol Hill, legislation introduced in Congress in July would give CMS leeway in enforcing the PT referral rules short of revoking a lab's CLIA certificate. And markup of the measure in the House is planned for September, industry sources say.

How the Case Developed

Wexner Medical Center laboratories perform approximately 9.6 million patient tests and 9,200 proficiency tests a year and have been fully accredited by the College of American Pathologists since 1969. The lab threatened with certificate revocation performs more than 60 percent of tests ordered for the center's patients.

At issue are six PT referrals that the center self-reported as accidents, noting that corrective action has been taken. This is the "first self-reporting of this nature that the labs at Ohio State's Wexner Medical Center have had to make," the university said in a statement.

Loss of CLIA certification is the most severe sanction that CMS can impose on a clinical lab. It bars the lab from legally performing diagnostic testing on human specimens for at least a year and cancels its approval to receive Medicare and Medicaid payments. It also bars the lab's director and its owner or operator from running another clinical lab for two years

In February of this year the lab sent a PT sample of Lyme disease to Mayo reference lab for Western Blot confirmation. A subsequent review found that five more blood-culture specimens had been improperly referred to another OSU lab with a different CLIA certificate number between November 2009 and November 2011. Staff from the Ohio Department of Health and CMS conducted a complaint survey of the center's lab on March 28, 2012. In a follow-up letter on June 11, CMS told the lab's director that the lab was out of compliance with federal rules on PT referrals. The lab responded with more than 100 pages of documents addressing this conclusion but in a July 12 reply, CMS said this was not enough to change its opinion. Accordingly, it revoked the lab's certificate and Medicare and Medicaid approval, effective Aug. 10, if the lab did not appeal. The lab has notified CMS that it will appeal, putting the sanctions on hold for now.

Problems With Interpretation

Many inadvertent or accidental PT referrals arise from a literal interpretation of the rules—namely, that the PT specimen must be tested in the same manner as specimens of regular patients, said pathologist Thomas Wheeler in an Aug. 15 Medscape blog. "It may be the norm for a positive test on XYZ analyte to be reflexed automatically for confirmation to another CLIA laboratory, a clear but unintentional violation of the statute.

"In another situation, it may be the norm for a pathologist to review an abnormal blood smear flagged by the technologist. On a PT specimen, however, the pathologist must do this review within the same CLIA lab. If the pathologist is in another CLIA lab when he or she makes the review, even within the same hospital, this is considered a PT referral."

The American Clinical Laboratory Association (ACLA) also faults the CMS position. "In several recent cases, CLIA certificates were revoked because the labs referred PT specimens for an HIV test. But for HIV and certain other tests, their standard operating procedure is to refer all samples to another lab. For example, the HIV test involves an initial screening as well as a Western Blot confirmatory test. However, many labs do not offer the latter due to limited resources and, as a result, refer the confirmatory test to a lab that does offer it."

A Legislative Solution

Bills pending in the House and the Senate (the TEST Act, H.R. 6118 and S. 3391) are designed to counter bad things coming out of unintentional referrals, Jason DuBois, ACLA's vice president of government relations, told *NIR*. The bills strike the CLIA statutory language that a lab's certification "*shall* be suspended" and insert the term "*may* be suspended" and 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.

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

The bills, backed by lawmakers from areas where some prominent health care facilities have been affected, are noncontroversial and could pass Congress as stand-alone legislation, industry sources opine—in the House under suspension of the rules (a procedure to move a bill on an expedited vote, with two-thirds voting) and in the Senate by voice vote with unanimous consent.

Tally of Revocations and Appeals

CMS makes public a record of CLIA certificate revocations and appeals under the Laboratory Registry and CLIA-Related Hearing Decisions on the CLIA Web site.

The annual registry has recorded 16 cases from 2009 to 2011 where CMS revoked a lab's certificate for "improper PT referrals." In 2011, three testing facilities were affected in Texas, New Hampshire, and Indiana. In 2010 there were four cases (in California, Florida, Michigan, and Puerto Rico) and in 2009 nine (in California, Minnesota, Texas, and Puerto Rico). Most involved smaller facilities such as physician office labs or medical clinics, while larger health care providers were in the minority.

The list of CLIA-related decisions involving "intentional PT referrals" from 1994 through 2010 (the latest year for which decisions are posted at press time) includes 18 appeals lodged with the Health and Human Services Departmental Appeals Board. In all these cases CMS has prevailed.

Appeals data for 2011 have yet to be posted, but in September of that year one lab is known to have broken the CMS record. In *J.B. and Greeta B. Arthur Comprehensive Cancer Center v. CMS*, the 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*).

ICD-10 Deadline, *from p. 1*

Accordingly, the new ICD-10 compliance date "gives providers and other covered entities more time to prepare and fully test their systems to ensure a smooth and coordinated transition by all industry segments," CMS said.

ICD-10 includes a diagnosis code set (ICD-10-CM) for services in outpatient and office settings and a procedure code set (ICD-10-PCS) for hospital inpatient services only. Implementing ICD-10-CM alone requires physicians and their office staff to contend with 68,000 codes, a fivefold increase from the current 13,000 codes, notes the American Medical Association (AMA). This is a massive administrative and financial undertaking for physicians, AMA said, requiring education, software, coder training, and testing with payers. Depending on the size of a medical practice, the total cost ranges from $83,290 to more than $2.7 million.

CMS Advice on Achieving Compliance

October 2014 sounds like a long way off, but it's closer than it seems and there's a lot to be done before then, CMS said in a recent ICD-10 update to providers.

The size of your organization will determine how much planning and documentation must be necessary, CMS noted, but emphasized that a successful transition depends on you having a communication and awareness plan, "a roadmap to ensure that all employees and other internal departments as well as external partners such as vendors, clearinghouses, and state agencies understand their roles and responsibilities" in the enterprise.

Key elements of the plan include securing a budget that accounts for software upgrades and software license costs, hardware procurement, staff training costs, workflow changes during and after implementation, and contingency planning; preparing and confirming the readiness of all concerned to execute the steps in the transition; and maintaining a timeline for tasks to be completed.

Plan to test your ICD-10 systems early, CMS advises. Beginning steps in this phase of the transition include internal testing, coordination with payers to assess readiness, and a project launch plan by data management and information technology teams.

Divided Appeals Court Upholds Myriad's Gene Patents

In a 2-1 decision, the U.S. Court of Appeals for the Federal Circuit (Washington, D.C.) once again partially reversed a lower court's ruling in a lawsuit challenging patents held by Myriad Genetics on two human genes, BRCA1 and BRCA2, associated with hereditary breast and ovarian cancer.

In its Aug. 16 ruling, the court upheld the Myriad patents as valid because they involve DNA isolates "markedly different" in molecular composition from the DNA that exists in chromosomes in the body. However, the court also ruled that the company cannot patent its method claims for comparing or analyzing the gene sequences.

This is the second time the court has considered this lawsuit, brought by a group of patients and scientists represented by the American Civil Liberties Union (ACLU) and the Public Patent Foundation and including the American Society for Clinical

Pathology, the Association for Molecular Pathology, and the College of American Pathologists.

Earlier this year, the U.S. Supreme Court ordered the appellate judges to rehear the case in light of its ruling in *Mayo v. Prometheus* that patents cannot be issued on natural processes (*NIR 12, 7/April 12, p. 4*). That case involved test process patents held by Prometheus Laboratories, a unit of Switzerland-based Nestle S.A., for a blood test to adjust drug dosage for gastrointestinal and autoimmune disease to a patient's metabolism. In a unanimous decision the high court ruled that the test processes merely describe laws of nature and "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity" (*NIR 12, 6/March 22, p. 1*).

"It is extremely disappointing that despite the Supreme Court's ruling, the appeals court has failed to fully re-consider the facts of this case," said Chris Hansen, a staff attorney with the ACLU Speech, Privacy, and Technology Project, in a statement. "This ruling prevents doctors and scientists from exchanging their ideas and research freely. Human DNA is a natural entity like air or water. It does not belong to any one company."

What happens next? ACLU declined to comment, saying only that its attorneys are considering all legal options and will discuss future strategies with the plaintiffs.

Ups and Downs in the Lawsuit

The lawsuit against Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the BRCA genes, charged that the patents on human genes violate the First Amendment and patent law because genes are products of nature. The suit also charged that the patents give the company a monopoly on BRCA testing, stifling research and curtailing women's access to a lifesaving test. As the patent holder, Myriad has the exclusive right to perform testing on the BRCA genes, license the testing to other users, and threaten litigation against any unlicensed use.

The patentability of human genes is a major issue for the biotechnology and diagnostics industries. Nearly 20 percent of human genes already are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses.

The lawsuit was filed in May 2009, and in March 2010 a U.S. district court ruled in the plaintiffs' favor. But Myriad appealed to the U.S. Court of Appeals for the Federal Circuit, and in July 2011 that court upheld the BRCA gene patents but not Myriad's patent claims on the process of analyzing whether a patient's genes had mutations that raised the risk of cancer, saying this involved only "patent-ineligible abstract mental steps" (*NIR 11, 15/August, pp. 1, 4-5*). In mid-September 2011 the appellate court turned down petitions by both sides to again air arguments in the case, prompting both sides to petition for Supreme Court review (*NIR 11, 18/Oct. 6., p. 5*). The high court, following its March 20, 2012, ruling in *Mayo v. Prometheus*, remanded the *Myriad* case to the appellate court for a rehearing, resulting in the Aug. 16 divided decision favoring Myriad's gene patents but voiding certain test method patents for analyzing gene sequences. GZ

Labs on the Front Line Against West Nile Virus

Outbreaks across 48 states in reported cases of West Nile virus (WNV) have grabbed the headlines (a record-breaking 1,993 cases in people, including 87 deaths, as of Sept. 4, according to the Centers for Disease Control and Prevention). Now, the American Clinical Laboratory Association (ACLA) has put out an alert on a "little recognized but powerful weapon" against the onslaught.

The WNV test is a good example of the kind of innovative tests that clinical laboratories have discovered quickly in response to new and emerging medical crises, such as HIV, herpes meningitis, SARS, H1N1, and Avian flu, said ACLA President Alan Mertz. For more on WNV, go to http://www.cdc.gov/ncidod/dvbid/westnile/index.htm.

The WNV lab test is performed when a person who may have had recent exposure to the virus shows possible signs and symptoms of an infection. The test can confirm whether this exists, allowing doctors to take steps to control its impact. In severe cases, this might include hospital supportive treatment, including intravenous fluids, help with breathing, and nursing care. The test measures antibodies produced by the body's immune system in response to the infection. Most people develop these within eight days. The test also helps distinguish WNV from other infections, such as bacterial meningitis.

A technique called a nucleic acid amplification test (NAAT) is sometimes used. It measures the virus's genetic material and can detect an infection before the antibody test. Routinely used to screen donated blood, tissue, and organs, it also can be used to test birds and mosquito pools for WNV and control its spread.

Upcoming G2 Events

Webinar (2 p.m. - 3:30 p.m. Eastern)

Sept. 20

Built to Last? How to Make Your Lab Outreach Program a Competitive Advantage in the New Health Care Environment

Featured Speaker:
Jane Hermansen, MBA, MT (ASCP)
Outreach Program Director, Mayo Medical Laboratories

Conferences

Sept. 13-14

MDx *NEXT*: Reimbursement Realities, Payment Priorities, and the Future of Genomic Medicine

University Club of Chicago
Chicago
www.mdxconference.com

Oct. 10-12

30th Anniversary Lab Institute *Separating the Best From the Rest*

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www.labinstitute.com

Nov. 14

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 National Intelligence Report (ISSN 0270-6768) 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.

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