G2 INTELLIGENCE

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Direct Access Genetic Tests Under More FDA Scrutiny

A major concern is how consumers on their own can correctly interpret the test results, understand the limitations of a particular test, and make lifestyle choices based on what the results may or may not mean.

Genetic tests marketed directly to consumers are back in the federal crosshairs again. A federal panel has advised the Food and Drug Administration (FDA) that consumers should access certain clinical genetic tests only through their doctor or a qualified health care professional.

That was the general accord reached by the 21-member Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee at its March 8-9 public meeting to examine scientific issues concerning direct-to-consumers (DTC) genetic tests that make medical claims.

A majority on the panel said they were concerned that without the involvement of a medical professional, consumers may misunderstand the test results or not know when the results are "meaningful," requiring further attention.

Issues Aired Before the Panel

(1) The risks and benefits of making clinical genetic tests available to consumers without the involvement of a clinician (that is, without a prescription). Do risks and benefits for different tests or categories of tests support a difference in the regulatory approach? Tests under scrutiny include:

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Preempting Problems for Labs With the New Medical Device ExciseTax

To forestall any misunderstandings down the road, the American Clinical Laboratory Association (ACLA) has asked the government to clarify in future guidance that laboratory-developed tests (LDTs) are not subject to the new medical device excise tax.

ACLA made the request in a Feb. 28 letter to the Internal Revenue Service as the agency considers draft guidance on how the tax would apply. The tax was approved in last year's health care reform law to help pay for the overhaul of the nation's health care system and the expansion of coverage to millions of uninsured Americans.

Effective Jan. 1, 2013, the tax is to be imposed on "the sale of any 'taxable medical device' by the manufacturer, producer, or importer" and is "equal to 2.3 percent of the price for which so sold." With certain exceptions, the term "taxable medical device" is defined as "any device (as defined in the federal Food and Drug Act) intended for humans."

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Preempting Problems With New Medical Device Tax, *from p. 1*

AdvaMed, which lobbies for medical device manufacturers, advocates congressional repeal of the excise tax. The group also has petitioned the FDA to require that LDTs meet the same standards as test kits subject to premarket review.

ACLA does agree that reagents, equipment, and other inputs used to perform an LDT should be subject to the excise tax to the extent that these inputs constitute "taxable medical devices."

Imposing traditional excise tax rules in the context of medical devices in general, and LDTs in particular, raises new issues, ACLA noted. "The medical device industry is diverse and innovative and includes a wide array of products and technologies, each of which may present unique issues under the excise tax. Clear guidance will be needed so that those affected will understand their responsibilities."

ACLA has met with officials as well as sending the letter to explain its position on medical devices and LDTs in light of what the FDA is preparing in its draft regulatory framework for LDTs based on their level of risk. Currently, the agency's oversight of LDTs is limited to analyte-specific reagents used in performing a test and to In Vitro Diagnostic Multivariate Index Assays (IVDMIAs) that use a proprietary algorithm to generate patient-specific results.

ACLA is concerned that the forthcoming IRS and Treasury guidance could inadvertently sweep LDTs in as medical devices due to the FDA's plans to expand oversight of these categories of tests, Alan Mertz, ACLA president, told *NIR*. Further, in meetings with House and Senate Committee staff, ACLA has been assured that no one considered LDTs in connection with device tax requirements.

In making its case, ACLA argues that clinical labs performing LDTs are providing a service, not selling a product. The LDT is performed only within the CLIA-certified lab that develops it. Although the lab makes the results available to ordering physicians, it does not sell the actual LDT in the same way that a manufacturer sells a test kit.

During the health care reform debate in the Senate, clinical labs escaped having a tax imposed on their receipts. That proposal was deleted when the Senate legislation instead made cuts in Medicare Part B lab reimbursement rates, beginning with a cut of 1.75 percent this year and totaling $10 billion over 10 years.

Why Do Labs Decide to Develop In-House Tests?

- To fill gaps in tests. There may not be a commercial test kit for a particular use available. Sometimes, rare diseases affect such a small population subset that there are few incentives for manufacturers to develop a commercial test.
- To develop a superior version of a test. A lab may have specific or proprietary clinical information that it can use to obtain clearer results.
- To modify existing technology so the test can be performed more efficiently, with clearer results, and targeted to a specific subset of the population. Any FDA-approved commercial kit that a lab modifies in any way is considered an LDT under CLIA rules as a high-complexity test subject to the most stringent performance standards.

Thousands of LDTs are performed in stand-alone clinical reference labs, or labs in hospitals, pathology practices, and university medical centers. Both large and small labs develop some tests for their own use, in addition to purchasing test kits and equipment from medical device makers.

LDTs include genetic tests and others used to prevent, diagnose, and treat patients with a wide range of cancers, cardiovascular and neurological disease, Alzheimer's, HIV, and many other serious health conditions.

Medicare *Preventive Service Benefits*

CMS Considers Coverage of More Screening Services

The Centers for Medicare and Medicaid Services (CMS) has begun a national coverage analysis on adding screening for sexually transmitted infections, alcohol misuse, and depression to the list of Part B-covered services for Medicare beneficiaries.

For each of these screenings, CMS has opened a 30-day public comment period from the date the coverage analysis was initiated. The agency is inviting recommendations on the appropriate frequency of the various screenings and those qualified to provide them based on documentation from the medical literature, current clinical practice guidelines, or recommendations of the U.S. Preventive Services Task Force (USPSTF).

Since Jan. 1, 2009, CMS has had authority from Congress to expand the list of Medicare preventive services using its national coverage decision process for services that the USPSTF has rated A (strongly recommended) or B (recommended), among other requirements (Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275). The agency thus far has exercised this authority twice, in December 2009 when it added voluntary HIV screening and in August 2010 when it added counseling for smoking and tobacco use cessation.

Coverage of Sexual Infection Screenings

This potential benefit would cover:

- ❏ Screening for chlamydial infection for all sexually active nonpregnant young women ages 24 and younger and for older nonpregnant women who are at increased risk;
- ❏ Screening for gonorrhea infection in all sexually active women, including those who are pregnant, if they are at increased risk;
- ❏ Screening for hepatitis B virus infection in pregnant women at their first prenatal visit;
- ❏ Screening for those at increased risk for syphilis infection; and
- ❏ High-intensity behavioral counseling for the prevention of sexually transmitted infections for all sexually active adolescents and for adults at increased risk.

Approximately 8 million individuals are covered by Medicare due to a disability, rather than age. Adults 18 and older with a disability may qualify. This benefit does not include voluntary HIV screening, which is already covered.

Formal review initiated: Feb. 24. Public comment period ends March 25. Proposed decision memo due date: Aug. 24. Expected review completion date: Nov. 22, 2011.

Alcohol Misuse

This potential benefit would cover screening and behavioral counseling interventions in primary care to reduce misuse of alcohol by adults, including pregnant women. This service has a grade B rating by the USPSTF. Formal review initiated: Feb. 18. Public comment period ends March 20. Proposed decision memo due date: Aug. 18. Expected completion date: Nov. 26, 2011.

Depression

This potential benefit, which is rated grade B by the USPSTF, would be targeted at identifying depressed nonpregnant adults, including older adults,

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Part B Lab, Pathology Spending by the Numbers

The data below are derived from the list of top 100 clinical laboratory and pathology codes analyzed in the forthcoming updated *Medicare Reimbursement Manual for Laboratory and Pathology Services 2011* from G2 Intelligence.

The analysis is based on the annual BESS file (Part B Extract and Summary System) for CPT codes in the 80000 series paid by Medicare Part B during calendar year 2009, the latest available payment information from the Centers for Medicare and Medicaid Services.

Medicare Part B spending on clinical laboratory services continued to increase in 2009, reaching $8 billion, an increase of 11 percent over the 2008 total of $7.2 billion, according to CMS data published in the 2010 Medicare Trustees Report.

As a percentage of total Medicare spending, Part B spending on lab services remained constant at 1.6 percent.

Total Medicare program expenditures in 2009 were $509 billion, an increase of 8.8 percent over 2008.

The criterion for identifying the top 100 lab and pathology procedures from a total of more than 1,000 active procedure codes in 2009 was the number of total Medicare-allowed services. The BESS data reflect only Part B lab and pathology services; they do not include these services processed under Part A for hospitals, skilled nursing facilities, and home health agencies.

Clinical Laboratory Tests

How many clinical lab tests ranked in the top 100 list?

A total of 88. Not surprisingly, they accounted for a significant majority of Medicare-allowed services ($289.96 million or 88 percent). However, they constituted only 62 percent ($3.52 billion) of the total allowed charges, making for an average allowed charge per procedure of $12.11. This represents an increase of 75 cents per lab procedure compared to the $11.36 per-test average allowed charge in 2008.

Which test ranked No. 1 on the list?

Consistent with previous years, CPT 85025—Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC, and platelet count) and automated differential WBC count––held the top spot in 2009, with 31.9 million allowed services. This code generated $357.33 million in allowed charges, up 6 percent from 2008, and had an average allowed charge per test of $11.21, an increase of 4.4 percent over the previous year.

Coming in second with the highest overall payment was CPT 84443, Thyroid stimulating hormone (TSH), at $348.63 million.

In addition to the CBC and TSH, which other laboratory tests generated the highest volume in annual Medicare-allowed charges?

	ALLOWED SERVICES	ALLOWED CHARGES	AVERAGE ALLOWED CHARGE
Comprehensive metabolic panel (80053)	26.45M	$317.38M	$12.00
Lipid panel (80061)	20.90M	$314.75M	$15.06
Parathormone (83970)	3.37M	$203.01M	$60.21
Glycosylated hemoglobin test (83036)	11.96M	$168.86M	$14.12
Vitamin D, 25 hydroxy (82306)	3.68M	$156.85M	$42.61

Which tests had the highest and the lowest average allowed charge?

Parathormone (83970) had the highest at $60.21. The high-volume lab tests with the lowest per procedure were Urea nitrogen, quantitative (84520) at $2.35 and Bilirubin, direct (82248) at $2.26.

Which of the highest-volume tests showed an increase in 2009 in average allowed charges over 2008?

Seven in all, as follow:

- ❏ CBC (47 cents)
- ❏ TSH ($1.04)
- ❏ Comprehensive metabolic panel (43 cents)
- ❏ Lipid panel (67 cents)
- ❏ Parathormone ($2.60)
- ❏ Glycosylated hemoglobin test (60 cents)
- ❏ Vitamin D, 25 hydroxy ($1.73).

Pathology Procedures

How many pathology procedures made the top 100 list?

Twelve. They accounted for about 40 million allowed services (12 percent). More importantly, they accounted for a robust 38.22 percent ($2.17 billion) of total allowed charges in 2009, for an average allowed charge of $54.80. This actually is a decline of $4.88 per procedure when compared to the average allowed charge in 2008 of $59.68. As a result, the average allowed charge for the 12 leading pathology procedures was about 4.5 times the average amount paid by Medicare for the top 88 laboratory tests.

Which pathology procedure ranked No. 1?

CPT 88305, Level IV-Surgical pathology, gross and microscopic examination, continues to rank as the highest-volume pathology code paid under Medicare Part B. It remains the first and only CPT code to top the $1 billion mark in allowed Medicare charges for a single year.

CPT 88305 had about 18.3 million allowed services and $1.24 billion in allowed charges in 2009, well over three times more than any other single procedure on the top 100 list. The average allowed charge for 88305 was $67.46, a 2.8 percent increase over 2008.

Which pathology procedures continued to have the highest average allowed charges?

- ❏ Level V – Surgical pathology, gross and microscopic examination (88307). The average allowed charge was $90.25, up from the 2008 average of $88.40 but still below the 2005 average of $95.72.
- ❏ Cytopathology, cervical or vaginal, requiring interpretation by physician (88112). The average allowed charge was $69.62, down from $72.23 in 2008 and significantly below its 2005 average of $80.97. G2

Top 100 Part B Outpatient Laboratory, Pathology Procedures for 2009

DESCRIPTION	ALLOWED SERVICES	ALLOWED CHARGES	AVERAGE ALLOWED CHARGE
Top 88 lab and 12 pathology tests	329.61M	$5.68B	$17.25
Top 88 lab tests	289.96M	$3.51B	$12.11
Top 12 pathology tests	39.65M	$2.17B	$54.80
% of pathology services/charges included in totals		12.03%	38.22%

Direct Access Genetic Tests, *from p. 1*

❏ Genetic carrier screening for hereditary diseases (*e.g.*, cystic fibrosis);

❏ Genetic tests to predict risk for future development of disease in currently healthy persons (*e.g.*, tests to predict the risk of developing breast or ovarian cancer); and

❏ Genetic tests for treatment response prediction (*e.g.*, tests to predict whether an individual will respond to a specific drug).

(2) The risks of and possible mitigations for incorrect, miscommunicated, or misunderstood test results for clinical genetic tests that might be beneficial if offered through direct access testing.

(3) The level and type of scientific evidence appropriate for supporting DTC genetic testing claims, including whether it should be different from that required for prescription-use clinical genetic tests.

The FDA weighed in forcefully on DTC testing last year when it squelched a plan by San Diego-based Pathway Genomics to sell its genetic test kit over the counter at Walgreens drugstores nationwide, starting in mid-May. The company said its CLIA-certified lab would generate personalized reports for drug response, pregnancy planning, and other conditions. The FDA said the product appeared to meet the definition of a medical device subject to premarket review (*NIR 10, 10/May 25, p. 1*). The agency subsequently sent warning letters to other companies marketing DTC genetic tests online that their products also appeared to require FDA approval.

The agency reiterated its stance at a July 2010 public meeting to discuss its plan to develop a risk-based regulatory framework for laboratory-developed tests (LDTs). FDA officials said the agency would rein in LDT genetic tests offered directly to consumers because of concerns about the risks of such testing.

A top FDA official repeated this message at the advisory panel meeting. While certain LDTs have not been regulated under the agency's enforcement discretion, DTC genetic test marketers will come under FDA oversight. "It's not a question that [they] will be regulated," said Alberto Gutierrez, director of the Office of In Vitro Diagnostics in FDA's Center for Devices and Radiological Health. "They will be." Elizabeth Mansfield, director for personalized medicine at the office, said that the agency and DTC genomics firms are working out how these companies can comply with FDA's medical device regulations.

Arguments for and Against

In remarks prepared for the panel meeting, the American Medical Association said DTC genetic tests should be allowed without the supervision of a physician or qualified health care professional only "under the most limited circumstances."

"DTC genetic tests may offer some benefits to consumers, such as promoting awareness of the genetic bases of disease and increasing attention to healthy behaviors that prevent the onset of disease," the AMA said. But "without the guidance of a physician, genetic counselor, or other genetics specialist, test results could be misinterpreted, risks miscalculated, and incorrect health and lifestyle changes pursued."

The American Clinical Laboratory Association (ACLA) said it shared concerns about the false sense of security or false apprehensions that consumers could experience "without important input before and after testing from a qualified health care provider or genetic counselor."

Noting that some DTC entities appear to be making claims that may be misleading, ACLA "supports state and federal investigations by the appropriate authorities to determine whether DTC entities are in full compliance with all applicable regulatory requirements and that the test claims can be substantiated and are not misleading."

The Federal Trade Commission has the authority to investigate any advertising claims and take action should it find they are false or misleading, ACLA noted. "DTC advertising should include all relevant information regarding capabilities and limitations of the tests and contain a statement referring patients to qualified health care providers or genetic counselors to obtain further information."

DTC proponents say they are responding to growing interest by the public in learning more about their genetic profile and what it means for their health or disease prospects. In its presentation to the panel, 23andMe, a DTC genetic test marketer and one of the companies to receive a warning letter from the FDA, said its tests offer important benefits to consumers and sought to allay critics' concerns over perceived risks.

The risk of incorrect data generated can be mitigated by a risk-based approach to analytical performance standards and ongoing clinical research, 23andMe said. It supports a defined regulatory framework and education. The risk of misunderstood test results can be mitigated by "robust labeling, a trained customer service point of contact, and having a genetic counseling service available." Consumers also should be advised that they may choose to share the test results with their physician for guidance on any follow-up needed.

CMS Sets July Date for Lab Test Pricing Forum

The annual public meeting on proposed pricing of new CPT codes to be added to the Medicare clinical lab fee schedule for the coming year will be held July 18, the Centers for Medicare and Medicaid Services (CMS) has announced.

The forum kicks off the public comment period on the appropriate basis for establishing Part B payment amounts for new codes to be added to the fee schedule for calendar year 2012. Two methods are used: (1) crosswalk a new code to an existing code and pay at that rate or (2) gap-fill by letting the payment be set based on local pricing patterns.

The new codes, developed by the CPT Editorial Panel, will be posted prior to the meeting at *cms.hhs.gov/ClinicalLabFeeSched* under Laboratory Public Meetings. The forum will convene in the main auditorium of the central building of CMS, 7500 Security Blvd., Baltimore. Interested parties may register to participate in the forum beginning June 20, at *cms.hhs.gov/ClinicalLabFeeSched*.

Medicare Preventive Service Benefits, *from p. 3*

in primary care settings that have "staff-assisted depression care supports." This term refers to clinical staff who assist the primary care clinician by providing some direct depression care, such as care support or coordination, case management, or mental health treatment.

Formal review initiated: March 2. Public comment period ends April 1. Proposed decision memo due: Sept. 2. Expected review completion date: Dec. 1, 2011.

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March 24

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