G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

DIAGNOSTIC TESTING & Emerging Technologies

New Trends, Applications, and IVD Industry Analysis

October 2017

INSIDE THIS ISSUE

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2017 Looking Good for Health Care Investment; Diagnostic Industry Poised for Large, Future Exits

So far, 2017 is proving to be a good year for fundraising and investment in the broad health care industry, according to report by Silicon Valley Bank (SVB). There have been some big bets placed in the diagnostics and tools (DX/Tools) sector, particularly in companies that use artificial intelligence- and machine learning-based technology.

Fundraising

The report, *Trends in Healthcare Investments and Exits: Mid-Year 2017*, says that in the first half of 2017 $5 billion was raised in health care venture fundraising and the industry may be on pace to be a record-setting year, passing the $7.5 billion raised in 2015. Venture fund investments have been primarily focused in biopharma and the DX/Tools sectors, with traditional investors having "lost interest" in the device area, writes Jonathan Norris, managing director of SVB, in the report. He notes, though, that nontraditional venture investors, such as private equity, family offices, angel groups, and corporate funds are still investing in devices.

Continued on page 2

Payers Turning to Automated Pre-Approval Systems for Genetic Tests

Payers are turning to automated systems for pre-approval of genetic tests as a way to contain costs and ensure proper utilization in the face of a dizzying number of news tests. UnitedHealthcare released a network bulletin in August 2017 announcing it will be implementing a national online prior authorization program for genetic and molecular testing performed in an outpatient setting effective Oct. 1 for its fully insured commercial members. Anthem Blue Cross implemented AIM Specialty Health's Genetic Testing Solution July 1 for fully-insured and self-insured members, and will add national account members in 2018.

Continued on page 11

2017 Looking Good for Health Care Investment, *from page 1*

In the DX/Tools sector the most active investors are tech-focused firms, including AME Cloud Ventures, Data Collective, Innovation Endeavors, Felicis Ventures and Khosla Ventures. There has also been significant investment from a wide range of corporate investors, including biotech (Lilly Ventures), tools (Illumina), general health care (GE Ventures), and tech (Google's venture arm, GV). These tech investors are seeking Dx/Tools companies involved in artificial intelligence- and machine learning-based technology. SVB predicts that this focused area will continue to see "aggressive fundraising" in the second half of 2017 and into 2018.

Early-stage, Series A investments across all sectors are on pace to exceed the 2016 record, SVB found. For the first half of 2017, Series A investment has been "strong" in the Dx/Tools sector. Norris says that almost 40 percent of these deals did not disclose investors, which suggests "significant angel investment."

Exits

There were no Dx/Tools exits (mergers and acquisitions [M&A]or initial public offerings) in the first half of 2017, which Norris calls "troubling," but he sees future opportunities due to the "significant" Dx/Tools investments, including "big bets" that have been placed on next-generation sequencing, liquid biopsy, artificial intelligence- and machine learning-based technology activities.

"We expect to see some exceptional exit opportunities in the next two to five years, and possibly a $1 billion-plus M&A exit in 2017," writes Norris, who expects the acquirers will more likely will be large pharmaceutical and tech companies.

Since 2015, PMA/de novo 510(k) device acquisitions have generated larger upfront multiples and a quicker time to exit than iterative 510(k) pathway exits; these returns now are approaching what we see from biopharma M&A. This makes a case for more investment in innovative early-stage device companies, and potentially a reallocation by traditional venture funds to device.

What is driving this trend: Iterative 510(k) pathway companies.

Trends to Watch

SVB identified several trends to keep an eye on.

- Innovative PMA/de novo 510(k) device acquisitions have shown larger returns and a quicker time to exit than iterative 510(k) pathway exits. Norris notes these returns now are approaching what is typically seen from biopharma M&A. This trend is being driven, he says because companies pursuing iterative 510(k) pathways often require regulatory clearance, followed by an equity raise for commercialization and revenue ramp prior to generating acquirer interest. However, "nearly all" innovative PMA/de novo 510(k) acquisitions occur pre-approval.
- As previously mentioned, tech-focused investment firms are "aggressively" investing in health care companies developing artificial intelligence

DTET

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Diagnostic Testing and Emerging Technologies (ISSN 2330-5177) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

and machine learning technologies designed for biopharma and Dx/Tools applications. Since 2015, $2.2 billion has been invested in 44 deals involving Dx/Tools companies that artificial intelligence- and machine learning-based technologies. While the median deal size in this area was $12 million, companies like Grail, Guardant Health, and Human Longevity have raised multiple $100 million rounds, and 11 other companies have each raised more than $30M, since 2015. Norris expects this "aggressive fundraising" to continue.

Takeaway: The broad health care industry is poised for a strong 2017 in terms of investment. Look for large, future exits in the Dx/Tools sector.

Attitude Toward Inpatient Testing Frequency Varies By Provider Type

While clinicians and several professional recognize that routine laboratory testing is overused in the inpatient setting, attitudes towards testing necessity differ by health care provider type, according to a research note published in the August issue of *JAMA Internal Medicine*.

> *"RNs are important care team members despite not placing orders. Little evidence describes their influence on the ordering process. We found that RNs generally favored more testing than other health care providers [but] the impact on test ordering is unclear."*
>
> — Benjamin Roman, M.D.

In the study, physicians (residents, fellows, and attending physicians) and nonphysician health care providers (nurse practitioners [NPs], physician assistants [PAs], and registered nurses [RNs]) with inpatient duties were electronically surveyed to assess attitudes towards inpatient laboratory testing. Among the 1,580 participants receiving an invitation to participate, 53 percent completed the survey (41 percent RNs, 197 attending physicians, 139 trainee physicians, and 154 APPs). Nearly three-quarters of respondents were female.

The researchers found that 60 percent of participants reported unnecessary laboratory testing on their unit, but only 37 percent reported requesting unnecessary laboratory testing themselves over the last six months. Differences by health care provider type were seen among those reporting requesting unnecessary testing themselves: trainees, 62 percent; APPs, 59 percent; attendings, 43 percent; RNs, 14 percent.

"RNs are important care team members despite not placing orders," write the authors led by Benjamin Roman, M.D., from Memorial Sloan Kettering Cancer Center in New York. "Little evidence describes their influence on the ordering process. We found that RNs generally favored more testing than other health care providers [but] the impact on test ordering is unclear."

An interesting contradiction appeared in the results with nonattendings believing that attendings would be uncomfortable with less testing, but attendings overwhelmingly endorsing less testing. Misperceptions of attendings' beliefs may drive unnecessary testing, the authors say.

Takeaway: Improved communication among care team members could align clinicians' attitudes towards unnecessary inpatient laboratory testing.

Annual TB Testing of Health Care Workers Not Cost Effective

Routine annual tuberculosis (TB) screening of health care workers is no longer cost effective, according to a study published May 17 in *BMC Medicine*. The incidence of TB is at an all-time low in the United States and previous studies have shown that health care workers' rates of active TB is the same as the general population. The results of the new modeling study led the authors to say that annual screening needs to be reconsidered.

The authors created a decision analysis model to simulate a hypothetical group of 1,000 workers with negative baseline tests. The model considered their duties, tuberculosis exposure, testing scenarios, and treatment. The model used two tests—the tuberculin skin test (TST) and QuantiFERON-TB-Gold In-Tube (QFT; Qiagen). Three screening strategies were compared, including annual screening, targeted screening, where workers with high-risk duties (e.g., respiratory therapy) were tested yearly and other workers only after exposure, and post exposure-only screening only. Patient care duties were characterized as high-risk (1 percent annual risk of infection) or standard patient care duties (0.3 percent). An alternate higher-risk scenario was created with annual risks of infection of 3 percent and 1 percent, respectively. Costs, morbidity, quality-adjusted survival, and mortality were modeled over 20 years.

"Annual worker screening may no longer be appropriate in most settings, and reconsideration of this longstanding recommendation may be warranted. The resources currently allocated to routine TB testing for HCWs may be more productively used for other TB prevention activities"

— Guillaume Mullie

Over the modeling period, annual screening with TST yielded an expected 2.68 active tuberculosis cases per 1,000 workers, versus 2.83 for targeted screening, and 3.03 for post-exposure screening only. As might be expected, the least costly screening strategy was post-exposure screening only with the TST, while annual screening with the QFT was the most costly.

Annual TST screening had an incremental cost of $1,717,539 per additional case prevented versus targeted TST screening, which cost an incremental $426,678 per additional case prevented, versus post-exposure TST screening only. In the higher-risk scenario, annual TST cost $426,678 per additional case prevented versus the targeted TST strategy, which cost an estimated $52,552 per additional case prevented, versus post-exposure TST screening only. In all cases, QFT had no or limited added benefit, but was more expensive than TST.

"Annual worker screening may no longer be appropriate in most settings, and reconsideration of this longstanding recommendation may be warranted," write the authors led by Guillaume Mullie, from McGill University in Canada. "The resources currently allocated to routine TB testing for HCWs may be more productively used for other TB prevention activities."

Takeaway: Given that health care workers in the United States are exposed to fewer patients with tuberculosis, annual screening is no longer cost effective.

INSIDE THE DIAGNOSTICS INDUSTRY

Diagnostics Industry Responding to Opioid Epidemic

Prescription opioids are among the most common drugs prescribed and are the most effective treating for pain, whether it is debilitating, chronic pain or temporary pain, such as after surgery.

While effective at pain relief, opioids can cause severe complications, are highly addictive, and are frequently misused. The numbers behind the opioid epidemic are staggering. The Substance Abuse and Mental Health Services Administration says that in 2014, almost 2 million Americans abused or were dependent on prescription opioids. The U.S. Centers for Disease Control and Prevention found that 91 Americans die every day from an opioid overdose and since 1999, the number of overdose deaths involving opioids (both prescription opioids and heroin) quadrupled.

Clinicians must finely balance between working to control rising rates of opioid abuse, while adequately managing patients' pain. Clinical laboratory tests have an important role in helping to support efforts aimed at curbing abuse and the diagnostics industry is responding to an eager market with new tests. It is estimated that there are 116 million people with chronic pain worldwide. But pain management specialists are only a fraction of the whole opioid-related testing market. Worker's compensation programs, oncologists, rheumatologists, orthopedists, and sports medicine providers are all opioid prescribers and potential users of screening or risk assessment tests.

DTET examined a sampling of tests aimed at opioid surveillance, screening at the point-of-care, and assessing risk of addiction using genetic factors.

Testing for Surveillance

Quest Diagnostics' (Madison, N.J.) 2017 analysis of its annual workplace drug testing shows that drug use in the American workforce, fueled by illicit drugs, reached the highest positivity rate in 12 years. The annual analysis of the Quest Diagnostics Drug Testing Index examines more than 10 million workforce drug test results across three categories of workers: federally-mandated, safety-sensitive workers; the general workforce; and the combined U.S. workforce.

The annual analysis breaks down positivity rate by drug category, including opioids. In 2016, following four years of increases, urine-testing positivity for heroin, remained steady in the general U.S. workforce and declined slightly among federally-mandated, safety-sensitive workers. Prescription opiate positivity declined in urine testing among the general U.S. workforce, indicating that state and federal efforts to more tightly control opiate prescribing may be having an impact. Continued surveillance and screening testing will be necessary to assess the impact of opioid policy on use and misuse.

Point-of-Care Testing

While workforce drug testing is important to ensuring safe, accident-free environments, point-of-care testing is important to clinicians prescribing opioids to enable early detection of misuse and ensure patient compliance with prescribed therapies.

INSIDE THE DIAGNOSTICS INDUSTRY

> *"Frequent in-office monitoring is an essential strategy to address opioid abuse, a threat which has become a menacing epidemic."*
>
> — Robert DuPont, M.D.

This summer Alere (Waltham, Mass.) released two new FDA-cleared point-of care tests. The iCUP Rx Drug Screen, is a lateral flow chromatographic immunoassay that tests for five of the most commonly abused opioid-derived drugs — benzodiazepines, buprenorphine, methadone, opiates, and oxycodone. The iCup test builds the five assays into a single, self-contained urine collection cup and results are available in less than five minutes. iCup results are considered preliminary, and the company says they must be confirmed with more laboratory-based methods such as gas chromatography-mass spectrometry or liquid chromatography-tandem mass spectrometry.

"Frequent in-office monitoring is an essential strategy to address opioid abuse, a threat which has become a menacing epidemic," said Robert DuPont, M.D., director of the National Institute on Drug Abuse, in a statement on behalf of Alere. "An easy-to-use test that provides actionable results during a patient visit is a valuable first-line tool to detect potential opioid abuse and, when it occurs, to get these patients the specific addiction treatment they need."

The second new test, the Sefria Drug Screening Kit, is the first in-office product capable of screening for fentanyl; a super-powerful opioid that is 50- to 100-times more potent than morphine. The company says that the test was previously available for forensic use, but this clearance enables it to be used in clinical settings.

Multi-Drug Testing

A new biochip array can simultaneously screen for 20 drugs of abuse in urine, according to a study presented by Randox Toxicology (United Kingdom) at the American Association for Clinical Chemistry (AACC) Annual Scientific Meeting & Clinical Lab Expo (San Diego, July 30 to Aug. 3).

Biochip array technology enables maximal output through the detection of multiple analytes from a single sample. The company's DOA Ultra Urine biochip array is run on the Evidence Evolution analyzer, which is a fully automated, high-throughput system. Additionally, the platform offers random access with STAT capability.

The assay is based upon competitive semi-quantitative chemiluminescent technology, with signal output inversely proportional to the concentration of drug in the sample. Cutoff values and limits of detection were determined for each of the 20 analytes. The cutoff values were further validated by assessing inter-assay precision.

The company says that time to first result is 36 minutes, and that 60 samples can be loaded per hour. No sample preparation is required and toxicology tests can be run alongside other clinical tests making, making "this system a new reliable multi-analytical tool for test consolidation," the company says.

INSIDE THE DIAGNOSTICS INDUSTRY

Assessing Genetics of Addiction

It is suspected that genetic factors play a role in addiction, but they are currently not widely evaluated in clinical practice. Researchers believe that identifying these genetic factors can enable improved opioid management and tailored prescribing to better prevent abuse and addiction.

> *"Right now we need to make better use of tools to address opioid management. It is very clear that genetics is a very good tool, but it is not the only tool."*
>
> — Fareed Kureshy, CEO, AutoGenomics

Autogenomics (Carlsbad, Calif.) has a commercially available multivariant genetic panel and prediction algorithm that it says can distinguish diagnosed addicts from those with lower risk of addiction. The company made two presentations at the AACC annual meeting.

AutoGenomics researchers compared the frequency of 16 single nucleotide polymorphisms involved in the brain reward pathways in 37 patients with and 30 matched controls without opioid addiction. Results were used to design the predictive model scored one to 100. Any score over 52 represents an elevated risk of addiction.

Use of the Addiction Risk Assessment Panel and prediction score algorithm was then validated on an additional 138 patient samples—70 patients diagnosed with prescription opioid and/or heroin addiction and 68 non-affected individuals. Of the 70 addicts tested, 53 had an addiction risk score greater than 52, while 49 of the 68 healthy controls scored under 52, yielding a 76 percent sensitivity and 72 percent specificity. Both the positive and negative predictive values of this model were 74 percent.

Despite the desire for a sure-fire solution to guide opioid prescribing decisions, Autogenomics is realistic about the capabilities of a test to predict the genetic risk of addiction.

"Right now we need to make better use of tools to address opioid management. It is very clear that genetics is a very good tool, but it is not the only tool," Fareed Kureshy, the CEO of AutoGenomics tells *DTET*. "It depends on one's genetic makeup to determine how the body will respond to and metabolize the drug. But, a physician is in charge and they cannot strictly use genetics to reach a conclusion. When starting opioids they can look at a panel to advise them on dosage and if a patient shows addictive tendencies. But, they have to use their judgment, too."

Caution Urged for Tests of Addiction Risk Prediction

Despite urgent need for opioid-related testing products and industry's desire to capitalize on ripe market conditions, some experts are questioning the quality of evidence surrounding these emerging tests, particularly in the realm of risk prediction, The diagnostics industry has been cautioned to maintain its high standards in test development and validation, including the need for validation of laboratory-developed tests in large studies.

One company receiving intense scrutiny is Proove Biosciences (Irvine, Calif.). This summer the Stat News late last year and early this year that questioned the

INSIDE THE DIAGNOSTICS INDUSTRY

Federal Bureau of Investigations raided the company's office in a health care fraud investigation, centered around the company's practice of allegedly providing kickbacks to doctors for enrolling patients in its research studies.

While the investigation is focused on fraud, addiction experts have raised concerns regarding emerging tests' abilities to predict opioid addiction risk. Joel Gelertner, M.D., from Yale University, has publicly raised concerns that both Proove's and Autogenomics' tests' accuracy claims are based upon small studies. He additionally raised concerns that the genetic markers included in the panels were derived from literature searches, rather than more comprehensive genome-wide association studies.

Takeaway: The diagnostics industry is taking an active role in helping to curb the opioid epidemic. However, the industry has been cautioned to maintain its high standards in test development and validation, despite the overwhelming need for new products.

Future of Traditional Rapid Flu Tests in Doubt as New Review Highlights Improved Performance of New Testing Technologies

With the start of the 2017-2018 flu season approaching, and the upcoming deadline for the U.S. Food and Drug Administration's (FDA's) new minimum performance requirements, there is renewed interest in understanding the performance characteristics of different flu testing methods.

A newly published review in the Annals of Internal Medicine shows that newer-generation influenza tests—including digital immunoassays (DIAs) and rapid nucleic acid amplification tests (NAATs)—perform better than traditional rapid influenza diagnostic tests (RIDTs).

"The results … suggest that traditional RIDTs are likely to be phased out by regulatory agencies like the FDA because of their poor sensitivity, especially in adults," write the authors led by Joanna Merckx, M.D., from McGill University in Canada. "Understanding the performance characteristics of different test methods across different patient populations is important for laboratory directors who must decide on their implementation and clinicians who must interpret their results for patient management."

Rapid diagnosis of flu infection is important to prompt initiate antiviral therapy, limit ancillary diagnostic tests, reduce hospitalizations, institute prompt hospital infection control measures, and cut unnecessary antibiotic use.

"Despite guidance that antivirals should be prescribed for high-risk patients and those hospitalized with clinically suspected influenza before confirmation by diagnostic testing, clinical practice falls far short of the guidelines," writes Michael G. Ison, M.D., from Northwestern University Feinberg School of Medicine in Chicago, Ill. in an accompanying editorial. "The newer DIAs and

especially rapid NAATs have the appropriate characteristics and sensitivity to provide actionable results. Increased availability and use of such assays likely will drive more appropriate early use of antivirals, may decrease unnecessary antibacterial therapy, and may improve patient outcomes."

Reverse transcriptase polymerase chain reaction (RT-PCR) is the gold standard for flu diagnosis, but batch testing in specialized laboratories leads to delays in time to results that hamper its clinical usefulness, despite the test's superior sensitivity. Traditional RIDTs that rely on immunoassay to detect viral antigens remain in use, despite concerns over their sensitivity because they can deliver results at the point of care (POC) within 30 minutes. More recently, though, two novel classes of rapid flu assays (automated immunochromatographic antigen detection tests [DIAs] and

NAATs) have entered the commercial market with claims of improved sensitivity. The performance of these tests will be scrutinized with the December 2018 implementation of the FDA's new minimum performance standards for rapid flu tests of at least 80 percent sensitivity (with a 95% confidence interval lower bound of 70 percent against an RT-PCR comparator).

The recently published systematic literature review identified published papers comparing commercialized rapid tests to RT-PCR (162 studies, including 130 of RIDTs, 19 of DIAs, and 13 of NAATs). Among the tests evaluated were the BD Veritor System for Flu A+B (BD Diagnostic Systems), the Sofia Influenza A+B Fluorescent Immunoassay (Quidel), the Alere i Influenza A & B (Alere), and the cobas Liat Influenza A/B assay (Roche Diagnostics). Studies covered pediatric and adult populations, as well as POC and hospital testing. Nasopharyngeal swabs were the most commonly used specimens.

The review and meta-analysis found that pooled sensitivities for detecting influenza A were 54.4 percent for RIDTs (below the new FDA minimum performance standards), 80.0 percent for DIAs, and 91.6 percent for NAATs. For influenza B, the pooled sensitivities were 53.2 percent, 76.8 percent, and 95.4 percent, respectively. Pooled specificities were uniformly high at above 98 percent.

"The improved sensitivity of DIAs is likely due to proprietary chemistry innovations and to automated readers that eliminate the subjectivity of an operator visualizing and interpreting test results," the authors note.

Other key clinical takeaways are that:

- Newer-generation tests are acceptable for use in the pediatric populations
- There is a possibility of DIA false negative results in adults and clinicians should consider retesting by RT-PCR if the result could influence patient management
- NAAT testing may be the preferred rapid test for adults.

"Physicians can therefore diagnose influenza with confidence on the basis of a positive RIDT, DIA, or rapid NAAT result," write the authors. "However, the cost of DIAs ($15 to $20 per test) is similar to that of RIDTs, whereas rapid NAATs may cost two- to five-times that amount. Whether the incremental gains in sensitivity of rapid NAATs versus DIAs are worth their added costs

will likely depend on the patient populations and clinical contexts in which they are used."

The authors note that industry sponsorship was common in DIA studies evaluated (68.4 percent) and rapid NAAT studies (61.5 percent). Additionally, several review authors reported financial ties to the diagnostics industry.

Takeaway: With improved performance of novel rapid flu tests and the upcoming implementation of the FDA's new minimum performance standards, there are some questions about the long-term commercial viability of traditional immunoassay RIDTs.

Eliminating Creatine Kinase–Myocardial Band Testing Saves Money, Improves Quality

Creatine kinase–myocardial band (CK-MB) testing provides no incremental value to patient care, and if hospitals and emergency rooms would eliminate its use for evaluating suspected acute coronary syndrome, it could lead to millions of health care dollars saved without adversely affecting patient care, according to a special communication published online Aug. 14 in *JAMA Internal Medicine*.

Since 2000, the American College of Cardiology and the European Society of Cardiology have recognized cardiac troponin (cTn) as the preferred biomarker for assessing myocardial infarctions due to its "nearly absolute" specificity for myocardial tissue and high sensitivity for myocardial injury. CK-MB has higher rates of false positives because, as it can be elevated with skeletal muscle damage.

Despite considerable evidence supporting cTn use over CK-MB and institutional efforts to improve testing orders (e.g., institutional guidelines, clinician education efforts, removal of CK-MB from routine order sets, and alerts within the computerized provider order entry system), CK-MB has not yet been eliminated from clinical practice. The College of American Pathologists' 2013 proficiency survey found that more than three-quarters of U.S. laboratories still use CK-MB. A 2010 study that used National Hospital Ambulatory Medical Care Survey data found that cardiac biomarker testing (both cTn and CK-MB) occurred in nearly 17 percent of all emergency department visits, translating to an estimated 28.6 million visits nationwide annually.

Its high use also makes cardiac biomarker testing costly. Based upon Medicare's 2016 Clinical Diagnostic Laboratory Fee Schedule national payment for cTn testing was $13.40 and CK-MB was $15.73, accounting for approximately $416 million in spending annually.

"Eliminating a simple laboratory test that provides no incremental value to patient care can lead to millions of health care dollars saved without adversely affecting patient care quality, and in this case potentially improving patient care," write the authors led by Matthew D. Alvin, M.D., from Johns Hopkins in Baltimore, Md., and colleagues from the High Value Practice Academic Alliance. "Successful deimplementation of CK-MB requires leadership support, education, and reassurance that diagnostic efficacy will not be compromised."

Takeaway: Laboratories have an opportunity to work with clinicians to improve test ordering, save unnecessary spending, and improve patient care through the elimination of CK-MB testing in cases of suspected acute coronary syndrome.

■ Payers Turning to Automated Pre-Approval Systems for Genetic Tests, *from page 1*

The payers say that these automated processes can streamline prior authorization for providers, while laboratories are hopeful that automating the approval process can bring more transparency and predictability to coverage and reimbursement decisions, and potentially, can reduce the number of appeals for notoriously frustrating struggles for payment for molecular tests.

> *"Through our newest solution for genetic testing management, we are offering the market a unique approach and highly automated system that incorporates a requirement for genetic counseling into the clinical review process."*
>
> — Brandon Cady, president and CEO, AIM

While new for the diagnostics industry, the use of automated pre-approval systems or benefits management is not new for payers. The systems for genetic test management are analogous to efforts to rein in overuse of expensive imaging or prescription drugs. Payers say this solution is needed for molecular testing because managing costs and utilization is nearly impossible in the face of the rapid pace of development and the sheer number of new, complex commercially available tests.

Anthem Blue Cross

Anthem's online platform is being administered by national specialty benefits manager AIM Specialty Health (AIM, a wholly-owned subsidiary of Anthem, Inc.) and was developed in partnership with InformedDNA, a genetic testing clinical decision support and genetic counseling services company.

"While the use of genetic testing has become more common, its complexity has often left both consumers and physicians without the expert guidance they need to decide which tests are most appropriate, what their test results mean—or whether they should have genetic testing at all," said Brandon Cady, president and CEO of AIM, in a statement. "Through our newest solution for genetic testing management, we are offering the market a unique approach and highly automated system that incorporates a requirement for genetic counseling into the clinical review process."

AIM says its Genetic Testing Solution improves efficiency for laboratories, doctors' offices, and insurers by shifting practice away from "a manual, labor-intensive and post-service process" to a real-time automated system. The company says the average time for submitting and processing an insurance claim can be cut from days to minutes because the prior authorization review provides specific CPT code information to the insurer to facilitate the claim processing.

AIM customizes the tool for each of its clients according to its unique genetic testing medical policies, which in the case of Anthem is 47. Within the Anthem program, the company says, that after the provider inputs information about the gene they want to test and the test they want to order, the platform generates the CPT code. This is a core benefit of the system for the insurer, as CPT

Continued on page 12

codes are not unique to a specific test. Experts estimate that there are fewer than 200 billing codes for approximately 70,000 commercially available genetic tests. One CTP code can be applied to multiple tests that may differ in terms of number of genes assessed and test performance. While payers are seeking clarity on what they are paying for, laboratories are concerned that the automated systems will negatively impact coverage decisions.

UnitedHealthcare

UnitedHealthcare released a network bulletin in August announcing it will be implementing a national online prior authorization program for outpatient genetic and molecular testing (including Tier 1 and 2 molecular pathology procedures, genomic sequencing procedures, multivariate assays with algorithmic analyses) effective Oct. 1 for fully insured Commercial members.

United Healthcare will only authorize payment for those CPT codes that have been registered with the Genetic and Molecular Testing Prior Authorization Program for each specified genetic test. According to Xifin consulting firm, it is the laboratory's responsibility to determine if an authorization has been received as services rendered without an authorization will be denied and the member cannot be balance billed.

Takeaway: Payers hope that automated prior authorization will improve their efforts to manage utilization of genetic tests. However, laboratories remain wary that such systems will expedite their reimbursement.