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HIGHLIGHTS

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MolecularHealth Adds Insurance Coding Service to Assays

In a bid to better mitigate the high costs of treating cancer, MolecularHealth has introduced a product to help patients and providers better navigate through the maze of payer possibilities.

Known as RxAssistance, the product is integrated into MolecularHealth's TreatmentMAP service, which recommends specific drugs and other treatment regimens as the result of molecular testing.

The patient's test results, recommendations, and insurance coverage are examined by a professional medical coder, who then makes specific suggestions about courses of care and how much they may cost the patient out of pocket. The service is currently available for all patients with commercial coverage, and MolecularHealth officials say it is in the process of doing the same for Medicare enrollees.

MolecularHealth officials say the service is intended to optimize the treatment patients are receiving by helping to ensure it remains affordable. Both pharmaceutical manufacturers and hospitals have been marking up cancer drugs precipitously in recent years. For ex-

Continued on page 2

Getting a Better Grip on Reference Testing Costs

Reference testing is a nagging issue with most laboratories—it is often a necessary fact of doing business, and the expense in sending out testing seems to hover between minor and large enough to have some impact on the bottom line. Is getting it under better control worth the time and effort?

The answer is a definite yes, according to a webinar conducted by Michigan-based consulting firm Chi Solutions in late July.

To start with, reference testing is often not a negligible expense. A 2011 G2 Intelligence study indicated that labs spent an average of $1.6 million a year on reference testing, and a poll during the webinar indicated that about half of the attendees' labs spend between $500,000 and $2 million a year on reference testing.

While Chi's own research indicated that the average lab spends 11 percent of its spending on reference testing, Wake Forest Baptist

Continued on page 7

MolecularHealth Adds Insurance Coding Service to Assays, *from page 1*

ample, Carolinas HealthCare's Levine Cancer Institute charges $4,500 for a dose of irinotecan, a colon cancer drug that typically retails for $60. Memorial Sloan-Kettering Hospital in 2012 refused to continue providing the drug Zaltrap, which costs $11,000 a month.

Partly as a result of the high price of drugs, the cost of treating some cancer patients can run more than $100,000 a year in the first year of treatment, according to data from the National Cancer Institute.

"In general, oncologists are seeing more expensive and targeted treatment options than ever before. Payers and [pharmaceutical benefit managers] are wrestling with the same," said Laura Housman, MolecularHealth's chief commercial officer. "This leads to a heightened and more frequent level of discussion between oncologists and payers, increasing the time and effort on the part of the oncologist and [their] staff. We aim to provide some level of added support and value to ensure patients will ultimately have access to needed therapies."

In one specific case, TreatmentMAP recommended an off-label treatment for the patient—a drug not approved by federal regulators for that specific use but permitted if the physician approves. RxAssistance was able to confirm to the patient's oncologist that insurance would cover the treatment before it commenced.

Takeaway: MolecularHealth is attempting to add value to its TreatmentMAP service by providing patient-specific payer data to providers ordering its tests. G2

XIFIN Acquired by Private Equity Firm

XIFIN, the San Diego-based laboratory finance, billing, and consulting company, has been purchased by a private equity firm that will likely underwrite its continued expansion.

Chicago-based GTCR purchased XIFIN in late July for an undisclosed sum, and the other terms of the deal were not disclosed. GTCR owns or has invested heavily in several health care firms, including regional hospital chain Capella Healthcare and Maravai Life Sciences, which develops in vitro diagnostics testing.

"We believe XIFIN's leading position, market expertise, and best-in-class technology provide a unique value proposition to laboratories as they navigate a complex reimbursement and regulatory environment," said Dean Mihas, a GTCR managing director.

XIFIN Chief Executive Officer Lâle White said the deal was a private equity recapitalization—a deal that allows prior investors in the company to be paid off. XIFIN's early investors included Southern California firms Windward Ventures and Enterprise Partners.

XIFIN remains heavily invested in the laboratory sector, providing cloud-based billing and management platforms. Last year it acquired PathCentral, an Irvine, Calif.-based firm with a proprietary cloud-based laboratory and anatomic pathology information system, and last spring it appointed an eight-member medical advisory board comprised of pathologists to help it with future product development and corporate strategy.

However, White indicated that the company is now expanding beyond laboratories into other facets of health care delivery. "We are already focused beyond the lab/payer market and have radiology and device manufacturer clients," she said.

Both White and GTCR officials indicate that the latter company intends to invest heavily in continuing to expand XIFIN.

"GTCR is a great partner for XIFIN," White said. "They have tremendous capital resources and a proven history of building market-leading companies."

The deal was financed from GTCR's Fund XI, a private equity fund seeded earlier this year with $3.85 billion of limited partner equity capital. GE Capital and CapitalSource funded this particular transaction.

Takeaway: GTCR's acquisition of XIFIN is expected to play into the latter company's plans to expand beyond the laboratory sector. G2

Illumina Enters Pact With Three Major Drugmakers on Test Development

Illumina has entered into a strategic alliance with three major pharmaceutical makers in the hopes of further fine-tuning molecular companion diagnostics for oncology care.

The San Diego-based Illumina will work with Sanofi, AstraZeneca, and Janssen Biotech in order to create a multigene testing panel for determining the best drug regimen for treating a specific cancer patient. The companies will collaborate on future clinical trials for targeted cancer therapies.

The intent, officials said, is to expand the current genetic pathways for optimizing courses of treatment. To date, only 125 cancer-related genes and 12 growth-related pathways have been discovered, and there are presumably hundreds of more that are extant. Meanwhile, some 800 oncology drugs are currently in some stage of development and require more data to fine-tune dosages and targeting.

"This partnership has the potential to deliver an unprecedented amount of clinical information from a single test," said Ruth March, AstraZeneca's vice president of personalized health care. "Our aim is that doctors can use these tests to prescribe the right drugs to the right patients."

The discoveries would allow the three pharma firms to more easily obtain regulatory approval and market the dozens of oncology drugs that are in their product pipeline, while helping Illumina develop a more accurate and broad next-generation sequencing platform.

The financial terms of the collaboration were not disclosed.

Illumina, which focuses on companion diagnostics and sequencing platforms, has been growing dramatically. Its revenue through the first half of 2013 was up nearly 30 percent. It has recently inked business agreements to help it expand its business in both Europe and China. The company's stock is up more than 140 percent over the past year.

Takeaway: Illumina will work closely with pharmaceutical manufacturers to help fine-tune its next-generation sequencing test platform for oncology patients. G2

Toxicology Niche Shows Both Promise and Headwinds

Precision Toxicology has only been operating since 2011, yet it has managed to accomplish a great deal in just three years.

The San Diego-based lab grew rapidly after launch, with its payroll reaching some 80 employees. Its annual test volumes swiftly reached the six figures. It recently moved into a new 10,000-square-foot lab. Business is diverse, with orders coming in from all quarters of the country, particularly the Southwest and Midwest.

Earlier this year, Precision had a bull's-eye on its back—the right kind of target at a time when many labs are struggling to grow. It was acquired by BelHealth Investment Partners, a New York-based private equity firm that focuses on small to midsize companies. BelHealth wants to turn Precision into a household name in toxicology testing.

"I am excited to have the resources and experience of BelHealth to help us accelerate our growth," said Jason Hansen, Precision Toxicology's chief executive officer and co-founder. "We . . . look forward to leveraging the vast resources and experience of BelHealth to build Precision into a leading national toxicology lab."

Although the terms of the transaction were not disclosed, it is clear that BelHealth has great hopes for Precision's future. Within a few weeks of the deal being announced, it had installed Ken Whitfield as chief financial officer at the company. His last job was as comptroller for the city of San Diego.

"The goal is to grow [Precision] as quickly as we can," said Dave Sturek, a BelHealth managing director.

Sturek noted that toxicology seemed an area where quick growth could be realized. "The segment has been very interesting to us. There's been a lot of growth in the sector. We also thought there would be a lot of synergies given our current portfolio," he said.

"The goal is to grow [Precision] as quickly as we can."
— Dave Sturek, Managing Director, BelHealth Investment Partners

Another of BelHealth's holdings is General Genetics Corp., a New Mexico-based firm that conducts genetic and forensic lab testing. It is expected that both labs could eventually share customers, Sturek suggested. Another of its holdings, Linden Care, is the largest mail-order pharmacy in the U.S. that is focused on pain management.

Sturek said BelHealth vetted about a half-dozen labs before making its decision. It was particularly interested in the efficiency of existing staff and scalability of operations, along with the fact that company was very focused on compliance.

"We believe that Precision could double or even triple throughput without adding any more employees," he said.

The Precision deal is the second significant deal involving a toxicology lab and private equity firm this year. Aegis Sciences Corp. was acquired by Boston-based ABRY partners earlier this year.

Headwinds Still Formidable

But whether mergers and acquisitions in the toxicology testing niche is heating up remains to be seen. Industry observers say toxicology labs are facing a lot of headwinds, including increasing scrutiny from public and private payers for potential overtesting and consolidation among pain-management practices.

In a recent report, the ratings service Standard & Poor's said what it called "drugs-of-abuse testing" would experience above-average growth this year and in 2015. But IBISWorld, a Los Angeles-based research firm, estimated that the toxicology testing business grew by about 1.2 percent last year. That's somewhat higher than the 1 percent annual growth in prior years but not exactly a stirring clip.

"The [workplace testing] volume is picking back up."
—Nina French, Partner, Current Consulting Group

"I don't think the segment is as hot as it once was," said Christopher Jahnle, a managing director at Haverford Healthcare Advisors in Paoli, Pa. He noted that Medicare fiscal intermediaries and even private insurance companies are beginning to eye testing volumes more closely. While deals are being consummated, they tend to be at lower valuations than a few years ago.

Sturek acknowledged that there has been increased scrutiny on test volumes. "It's a concern, but we felt [Precision] could grow through that," he said.

Yet for better or for worse, the United States is currently in a quasi-legal drug epidemic. That stems in part from the aging of the population, which has led to the prescription of more oral painkillers such as oxycodone. But such medication can be addictive, both from a physiological and financial point of view. Users often get hooked, while others sell prescription painkillers on the black market for $10 or more a tablet.

That has made toxicology testing a two-pronged diagnostic: Many patients are being tested to ensure not only that they are not abusing such drugs but also that they are taking them as originally prescribed. It may be the only form of lab testing where a negative result can have potential ramifications as serious as a positive one.

Workplace Testing on the Rise Again

The prescription drug concerns, plus a growing push to legalize marijuana for both medical and recreational use, is also leading more employers to embrace drug testing for workers, both as a condition of an offer of employment and post-hiring.

A white paper prepared by Alere Toxicology, one of the larger labs that focuses specifically on such testing, noted that 8.7 percent of Americans were illicit drug users in 2011. That's up from 8 percent in 2008. And 47 percent of companies now conduct random testing, up from 39 percent in 2006.

Nina French, a partner with Current Consulting Group in Philadelphia—which prepared the white paper for Alere—noted that while workplace

testing began to "hit its stride" in the 1990s, price cutting among fierce competition became rampant. Oftentimes testing was tucked into a standard background check package, eroding margins. The huge job cuts and corporate belt-tightening during and after the Great Recession damaged the business further.

French said the typical workplace toxicology test retails for between $9 and $25. That's a fraction of the price for a prescription adherence test, which Jahnle said can retail for between $50 and $100.

But French believes workplace toxicology testing is making a comeback. "The volume is picking back up," she said, although it remains short of prerecession levels. Among the drivers: news and social media reports of adults and even adolescents misusing painkillers and stimulants such as Ritalin, which is usually used to treat attention deficit hyperactivity disorder, and the wider use of medical marijuana (which remains legal grounds for disciplinary action). Employers are under more pressure to ramp up productivity, which means they must ensure that workers are not impaired.

However, the testing in both the workplace and pain management realms is becoming more sophisticated. French noted that workplace managers have to make decisions whether to test for drugs such as synthetic marijuana or bath salts—which can drive up prices—or to exclude conventional marijuana completely.

And toxicology labs are also branching out into more sophisticated assays in the realm of environmental testing. For example, there are a variety of tests to determine human exposure to certain toxins that might be at or near a work site or other area containing hazardous materials. And toxicology labs are also conducting tests for drug manufacturers to determine whether certain compounds they are using to create new products have more of a potential to harm their customers than cure them.

Some toxicology labs are going even further. San Diego-based Millennium Health (formerly Millennium Laboratories), for example, provides advanced analytics that can predict whether a patient will adhere to their prescribed medications. It also offers tests to better determine how individual patients will react to specific painkillers and other drugs.

And despite his concerns about the future of the niche, Jahnle does believe there is potential for testing growth at clinics that provide behavioral health services for patients trying to recover from substance abuse. Although payments are typically set at Medicaid rates, that's still better than the prices for workplace testing. And given the rise in both prescription and illicit drug use in the United States, demand is growing.

"Toxicology labs might consider hedging their bets a bit and focus on those facilities," Jahnle said.

Takeaway: Toxicology testing is the one facet of lab operations that appears to have a bright future for many of the players. G2

■ Getting a Better Grip on Reference Testing Costs, *from page 1*

Medical Center reported at a conference earlier this year that reference testing comprised as much as 16 percent of its annual budget.

"No one has yet to tell me that reference testing costs are going downward," said Anne Daley, a Chi senior consultant, who advises laboratory management to look at two components in order to control reference testing: cost and utilization.

Although there are a variety of ways to control both cost and utilization, one way is to update your contracts with reference labs. "If you have not negotiated a [request for proposal] within the past two to three years, there are some cost opportunities," she said.

Renegotiating with your reference labs gives you an opportunity to "slice and dice" key bits of information, said Daley. Vendors should be asked to submit tests and their fees in a spreadsheet format so you can determine what tests they provide, which ones they do not, and what every single test costs.

That test list should be divided into the top 100 tests that the primary lab sends out for reference. Daley noted that it in many instances, 20 of those tests account for 80 percent of the reference costs and make a good point for negotiating prices. "Some hospitals have good pricing for the top 100, but they're getting killed with the others," she said, such as pricey molecular tests.

Along with the test list, reference labs should also be asked to present accompanying Current Procedural Terminology codes, said Daley, who admitted this can be a struggle. "They don't want to be locked in, but it gives a glimpse of their methodology," she said. "And if there are multiple codes, it's important to find out what they are."

Reference labs should also be asked if the testing is being performed at their primary lab or another facility. In the latter instance, they may be tacking on an additional handling fee that can be reduced or avoided through negotiation.

It is also important to try to consolidate the number of reference labs that are used. Daley noted that some hospitals use as many as 40 different reference labs. Although this diversity of reference labs may be in part to please the hospital's clinical staff (which might have their own favorites), it can make it virtually impossible to keep a handle on costs. She suggested that hospitals keep their lists down to five clinical labs and a handful of anatomic pathology labs, while continually monitoring utilization and costs. Physicians—particularly newer staff—can be trained on the utilization and cost issues to make them more pragmatic as to how they handle reference testing, Daley suggested.

There are also more radical ways to cut costs, such as the use of online reverse auctions for testing, although the logistics of using those can be more complicated than having a contract with a lab, Daley suggested.

Takeaway: Controlling reference testing costs is achievable if close attention is paid to the data and operations of the contracting labs. G2

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INDUSTRY BUZZ

Mayo Clinic First Major Provider to Adopt Cologuard Test

Less than two weeks after Madison, Wis.-based Exact Sciences Corp. received federal approval of its molecular test to detect colon cancer, the first major health care provider moved to include it in its coverage.

The Rochester, Minn.-based Mayo Clinic, which operates hospitals and outpatient care centers in Minnesota, Arizona, and Florida, said on Aug. 25 it would make the Cologuard assay available via its network of primary care physicians.

"Cologuard represents a significant advancement in identifying colorectal cancer at its most treatable stage. We believe offering this new tool will promote patient and community public health and may move more patients to get screened earlier," said Vijay Shah, M.D., chair of Mayo Clinic's gastroenterology and hepatology departments.

The approval by Mayo came just 13 days after the Food and Drug Administration and the Centers for Medicare and Medicaid Services approved the test for use and for coverage as part of a pilot program to conduct parallel reviews of some laboratory tests.

The stool-based test kit is able to detect DNA abnormalities and biomarkers in trace amounts of blood that may be shed by precancerous intestinal polyps. Exact Sciences claims the test can detect more than 90 percent of colon cancers and nearly 70 percent of advanced precancerous polyps in patients who are considered to be at average risk of contracting the disease.

Exact Sciences has positioned the assay—which retails for $599—as a less expensive and far less invasive alternative to a colonoscopy, which can cost $2,000 or more. As a result, company officials expect the estimated 23 million Americans over the age of 50 who haven't been screened for colon cancer will shrink. While the five-year survival rate in the earliest stages of the disease is nearly 75 percent, only about 40 percent of the cases are diagnosed in the earliest stages. The survival rates among those with the more advanced form of the disease are below 30 percent.

Takeaway: A protracted approval process for the Cologuard test is apparently no impediment for its swift adoption by major health care providers.

References

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