Flexible ordering may unravel pay snags for respiratory panels

Kevin B. O'Reilly

October 2015—The advantages of molecular respiratory viral panels are accompanied by a challenge for laboratories that find it difficult to secure payment for testing that can cost hundreds of dollars, depending on the number of pathogens involved.

These respiratory panels can create complications for laboratories that must juggle several platforms to meet clinician needs, spare patients from unnecessary out-of-pocket costs, and responsibly use lab resources. A newly cleared flexible respiratory testing panel could offer laboratories another approach.

Dr. Root

"With traditional culture methods—and this is what payers are used to, as well as clinicians—you generally tested a small number of pathogens and then reflexed to more specific organisms when it was necessary," Charles Root, PhD, said during a CAP TODAY webinar presented in cooperation with Nanosphere. "We're now in a much different situation where we can test a lot of pathogens almost instantly in large screening panels. . . . But now the payers are saying, 'Well, do I really need all that, or do I want to pay for it?'"

GenMark Diagnostics' eSensor Respiratory Viral Panel, for example, can detect 14 respiratory virus types and subtypes. CPT code 87633 is used to report infectious agent detection by nucleic acid (DNA or RNA) for between 12 and 25 targets, said Dr. Root, CEO of Schaumburg, Ill.-based CodeMap, a firm that offers advice on coding, payment, and coverage for laboratory tests. Medicare will pay $567.18 for an RVP with that many targets.

That sort of eye-popping figure "sets the stage for some of the pushback that we're beginning to see from payers," Dr. Root said. "A $567 payment from Medicare or other payers tends to get their attention much more than one down in the $100 or $100-or-less range."

While Medicare, he added, largely takes a pay-and-chase approach to reimbursement, pursuing testing alleged to be medically unnecessary after the fact through its audit process, private insurers "tend to be a little smarter than that and they react a little quicker."

"The commercial payers are paying attention, especially to the six-to-11 and 12-to-25 target codes saying, 'Well, these are not medically necessary. You don't need all of those [targets], especially for low-risk populations,'" he said. "They want to see small, targeted panels that are the most likely to [find] the causative agent. And then reflexing to a larger panel only when it's necessary, when you still have symptoms, but you've got a negative result."

And that can mean a greater financial burden for patients, said Nathan Ledeboer, PhD, medical director of microbiology and molecular pathology at Wisconsin Diagnostic Laboratories, which is owned by Froedtert Health in Milwaukee.

Dr. Ledeboer

“Patients, in many cases, are paying for laboratory-based diagnostics rather than insurance companies. And it means that patients have become much more cost-sensitive when insurance isn’t paying the overall bill. So clinicians are now also looking increasingly at cost to the patients, as well as patients looking at their own cost and whether testing should be done. And, again, the laboratory needs to be aware of this,” said Dr. Ledeboer, who spoke along with Dr. Root during the CAP TODAY webinar, which is available for viewing on demand at http://www.captodayonline.com/cap-today-hosted-webinars/#nanosphere.

RVPs also have added another layer of complexity and cost for laboratories, Dr. Ledeboer said.

“If you look at our laboratory just as one example, in order to meet the demands of all of our clinicians and to have all of our different panels that are available, we have to go to multiple vendors, which represents a challenge,” he said. “We use things from Alere, we use things from Cepheid, we use things from Quidel, from Nanosphere, from BioFire, from GenMark. We use a variety of different tests, and we assemble that into a broader array of different respiratory panels in order to make the optimum platforms or the optimal panels available to meet our clinicians’ needs.”

The laboratory also uses a lab-developed test for its Bordetella testing. That approach to respiratory testing offers flexibility for clinicians, but this versatility comes with its own set of headaches.

“If you break apart our current algorithm, the benefit is that we’re able to offer four orderable respiratory virus panels to our clinicians, giving them a great degree of flexibility in giving the patient the right diagnosis with the right number of tests being ordered,” said Dr. Ledeboer, associate professor of pathology at the Medical College of Wisconsin. “The limitation of our algorithm is that it complicates ordering. It requires multiple entries into our information systems. It’s costly because we have to have multiple reagents from multiple vendors. We have to maintain proficiency on all these systems. We have to show comparability between these systems. And they require space.”

New NGS SPEC

The CAP has made available a new short presentation on emerging concepts, or SPEC, on next-generation sequencing and cancer genomics.

Pathology SPECs are created for pathologists and focused on diseases for which molecular tests play a key role in managing patients. They are a resource for discussions at tumor boards or with colleagues.

Also new is a book of the nine molecular SPECs that have been made available to date, on HER2 testing and prenatal screening and other topics ($49 for members). Call 800-323-4040 (or 847-832-7000) option 1, or log on to www.cap.org (Resources and Publications).

Laboratory leaders familiar with these problems may want to learn more about a newly available commercial test that Dr. Ledeboer and his colleagues in Wisconsin helped evaluate. The Verigene Respiratory Pathogens Flex Nucleic Acid Test is called the RP Flex for short by its manufacturer, Northbrook, Ill.-based Nanosphere. The test, granted 510(k) clearance in September by the FDA, operates on the automated sample-to-result Verigene System and allows for flexible ordering of testing for 16 target respiratory pathogens.

"In this product, we can break apart individual panels, including influenza A, adenovirus, and human metapneumovirus into a panel, the parainfluenza viruses and rhinovirus in a panel, RSV in its own reportable group, and *Bordetella* in its own reportable group. And we only pay based upon the results that we generate," explained Dr. Ledeboer. (He disclosed that he owns Nanosphere stock options and was paid for his participation in the CAP TODAY webinar.)

So, for example, if a physician orders a flu A/B PCR at first for a patient, it could be performed and resulted using the RP Flex. While tests for the other pathogens covered by the test are performed simultaneously, those results are blinded from view by clinicians and laboratory professionals until orders for those tests are entered.

"Instead of having to run each individual panel . . . we now only have to run and report out those additional results that we haven't already done," Dr. Ledeboer explained. "Or in other words, we only report out what they've now requested."

Dr. Root explained how this would work on the billing side.

"For example, if a physician orders a flu A and B test, he would then order a reflex to RSV A and B if it's negative. And if, as a result of that order, the initial results are negative and then the test gets reflexed immediately to RSV A and B and one of those turns out positive, you would bill all four targets," he said. "Even if the RSV A and B turned out negative, you'd still bill for the four targets because you performed the four tests. And the criteria for payment, remember, is always what is ordered, what is performed, and what is reported back to the physician. That's what constitutes a legitimate billable action."

In the clinical trial for RP Flex, the test was compared with the BioFire for targets that overlapped, and with bidirectional sequencing for targets that were discrepant between the two tests or not included on the BioFire panel, Dr. Ledeboer tells CAP TODAY.

At Wisconsin Diagnostics Laboratory, the RP Flex achieved "excellent sensitivity," or positive agreement, for influenza, parainfluenzas 1–3, and respiratory syncytial viruses A and B. For rhinovirus, on the other hand, the positive agreement between the RP Flex and the gold standard was 80.6 percent, "not all that great," Dr. Ledeboer says.

"It's really on the low side of where we'd want to be," he says, but adds that "it doesn't really bother me a great deal as no diagnostic test is 100 percent."

There are two potential upsides to integrating RP Flex into a laboratory's testing algorithm, Dr. Ledeboer says.

"One is being able to offer a highly customized menu to meet different patient populations' needs. This meets the immunocompromised patient's needs versus the immunocompetent patient's. Second, this type of technology allows us to do that in a manner that's also respectful of the patient's ultimate finances," he says. "We have to be able to deliver high-quality care that's customized to the patient's needs but also respectful of their limited health care dollars."

During the webinar, Dr. Ledeboer said he and his colleagues created a model for a year's worth of respiratory testing at Wisconsin Diagnostics Laboratory. For more than 5,000-plus respiratory test orders, they estimated that using a flexible RVP test could have saved about $280,000 compared with using only a broad respiratory panel. The downside to pursuing the more circumspect approach to respiratory testing made possible by the RP Flex is that there will be some cases when the right diagnosis is delayed, Dr. Ledeboer says.

“The disadvantage of this kind of panel, as compared with a broad panel, is that if you’re not thinking about it [the pathogen] or looking for it, you’ll miss it. That being said, the counterargument is that—to practice cost-effective medicine—when you hear hoofbeats, think horsies, not zebras,” he says. “If we ran every test on every patient, would we pick up other things? Yes. But would our health care system be bankrupt? Yes.”

Both of the CAP TODAY webinar speakers addressed an important ethical and legal concern potentially raised by this kind of test. What if, for example, a physician orders a smaller panel of testing for flu but there is a positive result for RSV that wasn’t actually ordered? Is the laboratory obligated to report the finding?

Dr. Ledeboer said that concern is one important reason why the RP Flex, like other flexible-reporting systems outside respiratory testing, would keep the hypothetical RSV result “blinded to the laboratory so that if the test isn’t ordered, we don’t know it.”

In an interview, he explains that it is impossible to accidentally view results for RP Flex testing that was not ordered.

“The software is designed to the point where I can’t just push a couple of buttons and get those results—wink-wink, nod-nod. It has to be blinded unless that test is ordered,” he says. “It’s truly like you never ran the test until you order it.”

At the same time, Dr. Ledeboer says, laboratory professionals who opt for a flexible-reporting system should inform clinicians that if the first round of testing comes up empty, additional testing can be ordered and the results made available immediately.

“They would have to be educated that if they need additional information, it’s as simple as calling the lab and doing an add-on for it,” he says. “We don’t need another sample.”

The rising use of flexible-reporting tests is “the first indication of a much broader issue out there” that extends beyond respiratory panels, Dr. Root tells CAP TODAY.

“Many of the instruments allow you to more economically do a whole bunch of tests at one time, even though they aren’t ordered. This is an issue payers are going to have to deal with in terms of coverage and how they want those tests submitted. I don’t think anybody’s really thought about that too much except in this area of infectious agents,” he says. “If you look at the whole area of mass spectrometry, you can run set panels for all kinds of stuff. And payers will say, ‘You don’t’ need all that. Why are you running it?’ It makes more sense, from an operational and economical point of view, to run it [the test] and retrieve the results later, if needed.”

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