Veracyte Sees Clinical Evidence, Medicare Coverage as Major MDx Success Factors

Sep 09, 2016 | Leo O'Connor

NEW YORK (GenomeWeb) – Medicare coverage of Veracyte's lung cancer test is an important part of CEO Bonnie Anderson's disciplined approach to achieving long-term, sustainable growth.

The company received notice of a draft local coverage determination late Wednesday from Medicare contractor Noridian that would allow broad coverage of tests done with Veracyte's Percepta Bronchial Genomic Classifier.

Veracyte expects to receive similar determinations soon from the three other Medicare contractors — Palmetto GBA, CGS, and WPS — that are part of the national Molecular Diagnostic Services program.

"We will begin to ramp our sales and marketing efforts in the regions closely aligned with the four [Medicare contractors], and we will continue to pursue expanded Medicare coverage," Anderson told GenomeWeb. "We would love to get to 100 percent Medicare coverage, and we will become more aggressive in our pursuit of commercial payors as well."

Getting coverage requires patience and endurance along the path to revenues for companies doing diagnostic tests in CLIA-certified laboratories. Coverage represents a key milestone for Anderson and her colleagues not just for Percepta, but for each of the products developed by Veracyte for use in its laboratory in San Francisco, where the firm performs and bills for molecular tests. An important focus of its plans is to show payors evidence of the analytical and clinical proficiency of its diagnostic test products through clinical trials and publication of results in peer-reviewed journals.

"The one thing we know about diagnostics is that it's a journey," Anderson said. "Certainly, the first step in broad access is getting a coverage decision from key players. Because lung cancer tends to be in the older population, we estimate that over half of the patients that are eligible for Percepta will be covered by Medicare."

Anderson said that the company also carefully pursued a strategy of showing analytical and clinical evidence for the firm's Afirma Gene Expression Classifier, its first commercial product launched in 2011, which is a thyroid nodule analyzer that helps physicians reduce the number of avoidable surgeries by identifying benign nodules among those that were originally classified by cytopathology as indeterminate.

"We followed the same focus with Afirma," Anderson said. "We built a significant library of evidence for that test … and we've performed over 60,000 tests to date. Over 25,000

thyroidectomies have been saved, yielding approximately a half a billion dollars in cost savings to the healthcare system."

It can often take years to get major coverage decisions so Veracyte's coverage for Percepta, when it clears, represents rapid progress, Anderson added.

The company will follow a similar evidence-based path upon launch of its next product Envisia, which it's developing to improve the diagnostic clarity of patients with idiopathic pulmonary fibrosis.

"We anticipate that Envisia will be commercialized by the end of this year," Anderson said. "We will then continue to build out the body of clinical evidence similar to what we have done with Percepta and Afirma, with the plan of getting Envisia covered and receiving expanded access to patients and reimbursement in 2018."

The Envisia test is based on a deep RNA sequencing technology. "This one happens to be launching on a sequencing platform," Anderson said. "That by itself is not as important as our capability to merge rich RNA expression with very sophisticated machine learning algorithms to develop classifiers that inform on a better classification of the patient's diagnostic status."

The Percepta test is run following an inconclusive result from bronchoscopy — a minimally invasive procedure that is commonly used to evaluate suspicious lung nodules and lesions found on CT. Percepta analyzes a brushing of epithelial cells lining the bronchial airway, eliminating the need for obtaining an invasive tissue sample and presenting a diagnostic option to physicians when a bronchoscope is unable to obtain access to a suspicious nodule.

Clinical validation data from two prospective, multicenter studies were published in July 2015 in The New England Journal of Medicine and, according to Veracyte, the studies demonstrated that the Percepta test identified patients at low risk of cancer with a high degree of accuracy, including a negative predictive value of 91 percent.

The test also increased the accuracy of bronchoscopy — 97 percent combined sensitivity for cancer versus 75 percent using bronchoscopy alone, the firm said. Published clinical utility data suggest that use of the Percepta test could reduce unnecessary surgeries and other invasive procedures by 50 percent, according to Veracyte.

"When we launch Envisia at the end of this year, we will be one of the first genomic testing specialty lab companies to launch three significant clinical products inside of eight years, and that is really significant," Anderson said.

On the back of that success, she said, the company is well prepared to continue to build out and grow the business by itself, and it has invested in the infrastructure and capability to do that. “We are building the company for long-term, sustainable growth,” Anderson said. “The positioning of our test to improve what is today a very ambiguous diagnostic pathway is a unique and important way to have a real impact both for patients and for cost."

"[We founded] the company on a mission of helping to improve the early diagnosis of disease when early indications for patients are often ambiguous, and they end up in a diagnostic odyssey that often requires invasive surgeries that ultimately prove to be unnecessary," Anderson said. "We decided that if we could pick the spot in the pathway of care that significantly improved the outcome for patients and also brought with it a significant cost reduction, we would be at the intersection for the deployment of genomics."formatics.