MDxHealth

NEWS RELEASE

Medicare Establishes Final Positive Local Coverage Determination for Use of ConfirmMDx for Prostate Cancer

Providing Nationwide Coverage for Medicare Patients

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CEST, July 23, 2018 – MDxHealth SA (Euronext: MDXH.BR), today announced that Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies, has issued a positive final Local Coverage Determination (LCD) to expand Medicare coverage of the ConfirmMDx for Prostate Cancer test.

The final LCD, which expands Medicare coverage to all providers, becomes effective on September 3, 2018. The prior LCD, first established in 2014, limited coverage to only those providers enrolled in a certification and training registry program (CTR). In addition, the new LCD removes other conditions to continuing Medicare coverage by deleting references to the Pascual clinical study, removing patient number limitations, and eliminating certain other conditions associated with the former MolDX coverage with data development (CDD) program.

“The expanded Medicare coverage of ConfirmMDx demonstrates the clinical value of our test to reduce unnecessary invasive clinical procedures,” said Dr. Jan Groen, CEO of MDxHealth. “With this streamlined LCD, we can now broaden the impact of ConfirmMDx, facilitating access for all men covered by Medicare.”

Details on the LCD are posted to the Medicare Coverage Database on the Centers for Medicare and Medicaid Services (CMS) website (ConfirmMDx L35632). LCDs are subject to annual review by MACs. MDxHealth will continue to generate scientific data and publications to demonstrate enhanced clinical utility of the ConfirmMDx test.

About ConfirmMDx for Prostate Cancer

ConfirmMDx for Prostate Cancer is the first epigenetic, and only tissue-based test in the 2018 NCCN and EAU guidelines for early detection of prostate cancer which addresses false negative biopsy concerns. It is the only molecular diagnostic test that provides a very high negative predictive value (NPV) of 96% for clinically significant prostate cancers, and 90% NPV for all prostate cancers, as well as prostate mapping of the test results to help guide repeat biopsies. Each year, more than 1 million American men undergo an invasive prostate biopsy with a negative result, however approximately 30% of those men have prostate cancer. The current standard of care for prostate biopsy procedures samples less than 1% of the prostate, leaving men at risk for undetected cancer and leading to a high rate of repeat biopsies, even on cancer-free men. ConfirmMDx for Prostate Cancer helps urologists identify low-risk men who may forego an unnecessary repeat biopsy and high-risk men who may benefit from intervention. ConfirmMDx has qualified for Medicare reimbursement and covered by numerous private health insurance plans.

About MDxHealth

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. For more information, visit mdxhealth.com and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.
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