

Press release

Epigenomics AG announces recent payment decision by CMS

Berlin (Germany) and Germantown, MD (U.S.A.), November 21, 2017 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY) announced the Centers of Medicare & Medicaid Services (CMS) has changed their pricing determination for Epi proColon[®], the first and only FDA-approved blood-based test for colorectal cancer (CRC) screening.

In its recently published final payment determination for the Clinical Lab Fee Schedule, CMS agreed that the original “crosswalk” determination was not appropriate and that reimbursement for Epi proColon should be determined by “gapfilling”. Gapfilling is used when a test is deemed “novel” or unique and no comparator test is available. The process requires each of the Medicare Administrative Contractors (MAC’s) to determine and publish a preliminary rate in the spring (typically April) and CMS will then issue a final determination in November based upon the MAC’s rate recommendations.

“While the determination of final pricing is prolonged, we are still pleased that CMS has finally agreed that the crosswalk to code 81287 was not appropriate as we believe it undervalues the test. The Gapfill process now gives us the opportunity to work with the MAC’s to set an appropriate price that reflects the novel nature of the first FDA approved blood test for CRC screening,” said Greg Hamilton, CEO of Epigenomics AG.

While the new payment determination process is being initiated by CMS, Epigenomics will continue its efforts to gain coverage for Epi proColon through multiple mechanisms.

About Epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon, is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, and China and selected other countries. Epigenomics' second product, Epi proLung[®], is in development as a blood-based test for lung cancer detection.

For more information, visit www.epigenomics.com.

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