



Personal Genome Diagnostics Announces Medicare Coverage of PGDx elio™ tissue complete Assay for Patients with Advanced Cancer

Reimbursement Now Available for Comprehensive Test that can be Performed in Labs Across the Country, Expanding Local Access to Personalized Cancer Care

BALTIMORE, MD, Sept. 9, 2020 – Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics, announced today that the CMS Molecular Diagnostics Program (MoIDX) has issued a local coverage determination (LCD) for the FDA-cleared PGDx elio™ tissue complete assay. The MoIDX coverage determination establishes reimbursement for laboratory facilities across the 28-state MoIDX jurisdiction, extending Medicare benefits for this comprehensive genomic test to patients living with advanced cancers.

“The MoIDX coverage decision is a major milestone toward enabling broader access to comprehensive genomic profiling for cancer patients,” said Megan Bailey, Chief Executive Officer of PGDx. “Despite the well-understood and widely accepted benefits of tumor profiling in guiding optimal care, testing unfortunately remains low – less than 20% for some cancers – and this is especially true in the community setting. By establishing reimbursement at reasonable levels, MoIDX’s decision will increase access to precision medicine for more cancer patients and eliminate a barrier to adoption by physicians across the country.”

Cancer guidelines increasingly call for comprehensive molecular profiling to optimize treatment planning and inform care. PGDx elio tissue complete, the first FDA-cleared comprehensive genomic profiling kit, is used to identify alterations in the tumor and inform treatment decisions for patients with advanced solid tumors. The kitted system allows molecular laboratories anywhere to perform this advanced genomic testing of cancer in a more efficient, standardized, and accurate manner. By providing tests that can be run locally and automating the data analysis process, PGDx is enabling the adoption of precision medicine in healthcare systems across the country, no matter where a patient seeks treatment.

PGDx elio™ tissue complete

PGDx elio™ tissue complete is an FDA-cleared diagnostic kit and accompanying software for molecular labs that provides comprehensive genomic profiles of all solid tumors. PGDx elio tissue complete detects single nucleotide variants (SNVs) and small insertions and deletions (indels) in 500+ genes, select amplifications and translocations, and genomic signatures including microsatellite instability (MSI), and tumor mutation burden (TMB). Designed to be used locally at any laboratory across the country, PGDx elio testing and automated bioinformatics ensures both consistency and quality of results regardless of location.

About Personal Genome Diagnostics

Personal Genome Diagnostics (PGDx) empowers the fight against cancer by unlocking actionable information from the genome. We are committed to improving clinical insight, speed of results, and healthcare economics by delivering a portfolio of regulated tissue-based and liquid biopsy genomic products for health systems worldwide. PGDx was established by researchers from Johns Hopkins University who are pioneers in cancer genome sequencing and liquid biopsy technologies. For additional information, visit

www.PersonalGenome.com.

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