



Personalis Announces Medicare Coverage for NeXT Dx(R) Comprehensive Genomic Tumor Profiling Assay

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NeXT Dx helps clinicians make informed, personalized cancer treatment selections and match patients with clinical trials

Access to NeXT Dx expands to the 66 million Medicare and Medicare Advantage beneficiaries

FREMONT, Calif.--(BUSINESS WIRE)--Jan. 16, 2024--(Nasdaq: PSNL), a leader in advanced genomics for precision oncology, today announced it has received a final Medicare coverage determination for its [NeXT Dx ultra-comprehensive tumor genomic profiling assay](#), providing access for the nation's 66 million Medicare and Medicare Advantage beneficiaries.

Matching patients to their optimal cancer therapy requires a testing platform that can accurately report a broader range of clinically actionable genomic alterations. NeXT Dx analyzes a tumor's entire exome (DNA) and transcriptome (RNA) to uncover deeper insights into therapy selection, including RNA-based fusions and advanced biomarkers that smaller panels might miss, such as tumor mutational burden (TMB) and microsatellite instability (MSI). In addition, NeXT Dx utilizes paired tumor and non-tumor samples to report more accurate results.

Coverage for NeXT DX was extended effective August 29, 2023, under the Palmetto GBA MolDx program foundational Local Coverage Determination (LCD) L38119 ("Next-Generation Sequencing for Solid Tumors"). Personalis estimates that approximately half of new solid tumor cancer cases will be diagnosed in patients covered by Medicare.

"We are thrilled to receive our first coverage determination with our ultra-comprehensive NeXT Dx test, which offers treating physicians a better chance of finding an FDA-approved therapy or clinical trial for patients with advanced cancer," said Chris Hall, President and Chief Executive Officer at Personalis. "With our recent early access launch of the ultra-sensitive NeXT Personal Dx test, which is designed to detect molecular residual disease and cancer recurrence, we continue our momentum in offering products that provide deep genomic insights throughout a cancer patient's entire journey."

About Personalis

At Personalis, we are transforming the active management of cancer through breakthrough personalized testing. We aim to drive a new paradigm for cancer management, guiding care from biopsy through the life of the patient. Our highly sensitive assays combine tumor-and-normal profiling with proprietary algorithms to deliver advanced insights even as cancer evolves over time. Our products are designed to detect MRD and recurrence at the earliest timepoints, enable selection of targeted therapies based on ultra-comprehensive genomic profiling, and enhance biomarker strategy for drug development. Personalis is based in Fremont, California. To learn more, visit www.personalis.com and connect with us on [LinkedIn](#) and X ([Twitter](#)).

Forward-Looking Statements

All statements in this press release that are not historical are "forward-looking statements" within the meaning of U.S. securities laws, including statements relating to attributes or advantages of the NeXT Dx or NeXT Personal assays, the expected benefits of the Medicare coverage determination for NeXT Dx, the expected launch of NeXT Personal Dx into the clinical market, or other future events. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from any anticipated results or expectations expressed or implied by such statements. Factors that could materially affect actual results can be found in Personalis' filings with the U.S. Securities and Exchange Commission, including Personalis' most recent reports on Forms 8-K, 10-K and 10-Q, and include those listed under the caption "Risk Factors." Personalis disclaims any obligation to update such forward-looking statements.

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