



IMMUNOVIA SUBMITS FORMAL REQUEST FOR MEDICARE COVERAGE OF PANCREASURE

Immunovia AB (IMMNOV: Nasdaq Stockholm), a pancreatic cancer diagnostics company, today announced that it has submitted a request for a new Local Coverage Determination (LCD) for PancreaSure, the company's blood test for early detection of pancreatic cancer in high-risk individuals. The submission is Immunovia's formal request for Medicare coverage of the test.

"Submitting the LCD request is an important milestone for Immunovia. Pancreatic cancer is largely a disease of older adults; people aged 65 and older account for roughly three out of four pancreatic cancer deaths in the United States. Coverage would provide eligible Medicare beneficiaries access to a blood test designed to detect the disease at an earlier stage, when curative surgery is possible. For the company, Medicare represents an important source of future revenue," says Jeff Borcharding, CEO and President, Immunovia.

Medicare covers a significant share of the pancreatic cancer population

Pancreatic cancer is the third leading cause of cancer death in the United States, and incidence is rising. The disease burden falls largely on the Medicare population: 70% of new diagnoses and 76% of deaths occur at age 65 or older, with the median age at death at 73. Age is the most significant non-genetic risk factor for pancreatic ductal adenocarcinoma (PDAC), the predominant form of the disease.

Most pancreatic surveillance guidelines for high-risk individuals recommend regular screening beginning at age 50. As a result, Medicare beneficiaries represent a substantial proportion of the population eligible for high-risk surveillance.

The process ahead

An LCD is a decision by a Medicare Administrative Contractor on whether Medicare covers a service. The contractor determines whether the service is considered "reasonable and necessary" under Medicare's coverage requirements. Medicare is the U.S. federal health insurance program primarily for people aged 65 and older.

The formal request is the first of a multi-step process that, if successful, culminates in a positive coverage decision. The LCD development process may include consultation with subject matter experts and, if appropriate, an optional Contractor Advisory Committee meeting, followed by publication of a proposed LCD. The proposed LCD is then subject to a public comment period and an open meeting, at which the Medicare Administrative Contractor discusses the proposed policy and supporting evidence with the public. Following consideration of the public comments and other input, the contractor will publish the final LCD.

The LCD request is supported by the clinical evidence generated for PancreaSure to date, including biomarker discovery¹; model development²; analytical validation³; independent clinical validations CLARITI⁴, VERIFI⁵, and AFFIRM⁶; pooled analysis of high-risk individuals⁷, and pooled analysis of high-risk individuals with clinical abnormalities⁸; an analysis of early real-world use of the test⁹; and patient opinions about biomarker testing from ADHERE¹⁰. Collectively, the company deems the scientific evidence well aligned with the evidence standards applied to laboratory-developed tests under the MoIDX program. Immunovia also plans to further supplement the clinical evidence by submitting results from additional studies as they are completed in coming months.

References

1. Athanasiou A, Kureshi N, Wittig A, et al. J Proteome Res. 2025;24(1):315–322. doi:10.1021/acs.jproteome.4c00752
2. Palma NA, Lucas AL, Katona BW, et al. Cancers. 2025;17(11):1866. doi:10.3390/cancers17111866
3. Pescatore R, Milliken N, King T, et al. Diagnostics. 2025;15(24):3177. doi:10.3390/diagnostics15243177
4. Lucas AL, Simeone DM, Katona BW, et al. Gastroenterology. 2026;170(2):375–384. doi:10.1053/j.gastro.2025.08.034
5. Polanco PM, Gonda T, Borazanci E, et al. Curr Oncol. 2025;32(11):638. doi:10.3390/curroncol32110638
6. Borazanci E, Persson J, Pilarsky C, et al. JCO Oncol Adv. 2026;3:e2500225. doi:10.1200/OA-25-00225
7. Immunovia AB. PancreaSure clinical validation data to be presented at the American Gastroenterology Annual Scientific Meeting. Press release, 27 October 2025. <https://investors.immunovia.com/en/press-releases/artikel?slug=pancreasure-clinical-validation-data-to-be-presented-at-the-american-gastroenterology-annual-scientific-meeting>
8. Immunovia AB. Immunovia announces new performance data for PancreaSure ahead of upcoming application for Medicare coverage. Press release, 15 June 2026. <https://investors.immunovia.com/en/press-releases/artikel?slug=immunovia-announces-new-performance-data-for-pancreasure-ahead-of-upcoming-application-for-medicare-coverage>
9. Early-use clinical utility study. Polanco PM, et al. Immunovia AB, data on file, 2026.
10. Immunovia AB. Immunovia presents survey data showing strong patient support for blood-based tests to detect pancreatic cancer at an earlier stage. Press release, 13 August 2026. <https://investors.immunovia.com/en/press-releases/artikel?slug=immunovia-presents-survey-data-showing-strong-patient-support-for-blood-based-tests-to-detect-pancreatic-cancer-at-an-earlier-stage>

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Immunovia in brief

Immunovia AB is a diagnostic company whose mission is to increase survival rates for patients with pancreatic cancer through early detection. Immunovia is focused on the development and commercialization of simple blood-based testing to detect proteins and antibodies that indicate a high-risk individual has developed pancreatic cancer. Immunovia collaborates and engages with healthcare providers, leading experts and patient advocacy groups to make its test available to individuals at increased risk for pancreatic cancer.

USA is the world's largest market for detection of pancreatic cancer. The Company estimates that in the USA, 1.8 million individuals are at high-risk for pancreatic cancer and could benefit from annual surveillance testing.

Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit www.immunovia.com.

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