



NEWS RELEASE

# Natera's Prospera™ Lung Transplant Assessment Test Granted Medicare Coverage

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Represents third covered indication for Prospera

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA (cfDNA) testing, today announced that it has received confirmation that its Prospera Lung donor-derived cfDNA (dd-cfDNA) transplant assessment test has met coverage requirements from the Centers for Medicare & Medicaid Services' (CMS) Molecular Diagnostics Services Program (MoIDX).

The MoIDX technology assessment program has determined that Prospera Lung will be covered under the existing Medicare Local Coverage Determination for Molecular Testing for Solid Organ Allograft Rejection for use in the surveillance setting in lung transplant patients.

Lung transplantation has a five-year survival rate of 59%, the lowest rate of all transplanted organs. Moreover, in the last 20 years, there has been limited improvement in recipient survival.<sup>1</sup> This is primarily driven by acute rejection (AR) and chronic lung allograft dysfunction (CLAD), which is the leading cause of mortality among lung transplant recipients.<sup>2</sup>

"The current standard of using transbronchial biopsy for monitoring lung transplant rejection is associated with significant procedural risks and complications and is a physical and emotional burden on the patient," said Howard J. Huang, M.D., associate professor of clinical medicine, division of pulmonary, critical care, and sleep medicine at Houston Methodist Hospital. "Prospera Lung fulfills a critical unmet need for a less invasive method of detecting acute rejection to help guide biopsy decision-making and inform treatment."



The Prospera Lung clinical validation, the VALID study,<sup>3</sup> was published in 2022 and highlighted performance from 195 biopsy-matched samples from 103 patients. This blinded, prospective study analyzed Prospera Lung in connection with various complications from lung transplantation, including AR, CLAD and allograft infection. The study demonstrated outstanding performance, with an area under the curve of .91 when analyzing AR versus stable patients.

“Medicare’s decision enables broad access to the Prospera Lung test and represents a significant win for lung transplant patients and the field of transplant monitoring,” said Bernie Tobin, general manager of organ health at Natera. “Prior to this decision, nearly 50 percent of the top 50 transplant centers have used Prospera Lung. We are encouraged by this momentum and gratified by the ongoing support from members of the transplant community who understand the clinical utility of dd-cfDNA testing and the critical benefits it can bring to patients.”

## About the Prospera test

The **Prospera**<sup>TM</sup> test leverages Natera’s core single-nucleotide (SNP)-based massively multiplexed PCR (mmPCR) technology to identify allograft rejection non-invasively and with high precision and accuracy, without the need for prior donor or recipient genotyping. The test works by measuring the fraction of donor-derived cell-free DNA (dd-cfDNA) in the recipient’s blood. It may be used by physicians considering the diagnosis of active rejection, helping to rule in or out this condition when evaluating the need for diagnostic testing or the results of an invasive biopsy. The Prospera test has been clinically and analytically validated for performance regardless of donor relatedness, rejection type, and clinical presentation. It has been developed and its performance characteristics determined by Natera, the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). CAP accredited, ISO 13485 certified, and CLIA certified.

## About Natera

Natera<sup>TM</sup> is a global leader in cell-free DNA testing, dedicated to oncology, women’s health, and organ health. We aim to make personalized genetic testing and diagnostics part of the standard of care to protect health, and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera’s tests are validated by more than 150 peer-reviewed publications that demonstrate high accuracy. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas and San Carlos, California. For more information, visit [www.natera.com](http://www.natera.com).

## Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera’s plans, estimates, or expectations will be achieved. These

forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, or our expectations of the benefits of our tests and product offerings to patients, providers and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q and in other filings Natera makes with the SEC from time to time. These documents are available at [www.natera.com/investors](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

## References

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2. Bedair B and Hachem RR. Management of chronic rejection after lung transplantation. *J Thorac Dis*. 2021;13(11):6645-6653.
3. Rosenheck JP, Ross DJ, Botros M, et al. Clinical Validation of a Plasma Donor-derived Cell-free DNA Assay to Detect Allograft Rejection and Injury in Lung Transplant. *Transplant Direct*. 2022;8(4):e1317.

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