
PRESS RELEASE

GENFIT Announces U.S. Medicare Coverage and Future Reimbursement for NASHnext®, a Non-Invasive Diagnostic Technology to Identify Patients with At-Risk MASH

- Coverage and future reimbursement (effective August 10, 2026) secured for NASHnext®, Labcorp’s non-invasive blood-based diagnostic test powered by GENFIT’s proprietary NIS4® technology
- Focuses on patients at highest risk, including those with prediabetes, type 2 diabetes, obesity and dyslipidemia
- A technology positioned for scale at a key inflection point in the U.S. MASH market, with the first therapy already achieving near-blockbuster status in its first year and additional agents from leading pharma players approaching launch
- Licensing agreement with Labcorp positions GENFIT to establish a second revenue stream, with further guidance expected in the fall

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), July 2, 2026 - GENFIT (Euronext: GNFT), a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced the coverage and future reimbursement by U.S. Medicare for NASHnext®, a non-invasive blood test available through Labcorp, a global leader of innovative and comprehensive laboratory services. This will support large-scale adoption and additional revenue for GENFIT.

NASHnext® is a diagnostic test developed and commercialized by Labcorp as a laboratory developed test (LDT) under license from GENFIT. Built on GENFIT’s technology, the test uniquely captures both disease activity and fibrotic burden, including F2 (stage 2 fibrosis), delivering clinically meaningful insights to support earlier identification of at-risk patients and allow for more informed clinical decision-making across care settings.

NASHnext® will be reimbursed by Medicare under the Clinical Laboratory Fee Schedule at approximately \$252 per test.¹ Reimbursement to Medicare patients that meet coverage criteria² will become effective beginning August 10, 2026. This major milestone supports broader adoption and future coverage by private insurers.

¹ CMS Clinical Laboratory Fee Schedule (CLFS) – CPT 0468U: \$251.70; Labcorp NASHnext® test listing – CPT 0468U

² LCD - MoIDX: Biomarker Testing in Metabolic Dysfunction-Associated Steatotic Liver Disease and Metabolic Dysfunction-Associated Steatohepatitis

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In the U.S., projections point to a substantial and expanding population with a high metabolic burden over the coming years, with approximately 260 million adults expected to present risk factors for metabolic disease, around 170 million expected to be diagnosed with metabolic disease (prediabetes, type 2 diabetes, obesity, hypertension, hyperlipidemia, etc.), and nearly 90 million expected to exhibit elevated liver enzymes and/or steatosis.³ Together, these figures underscore the scale of the diagnostic gap and the need for earlier, non-invasive identification of patients already within the MASH spectrum and at risk of progression.

Naim Alkhouri, MD, FAASLD, Chief Medical Officer at Summit Clinical Research, Director of the Steatotic Liver Program at North Shore Gastroenterology, and member of the American Association for the Study of Liver Diseases (AASLD) MASLD Special Interest Group, commented: *“Securing Medicare coverage is a critical step toward integrating non-invasive blood-based testing into routine clinical practice. In MASH, many patients already within the disease spectrum remain unidentified until they have progressed to more advanced stages. As MASH therapies begin to expand rapidly, tools such as NIS4, now combined with appropriate reimbursement and clinical pathways, enable clinicians to identify patients with at-risk MASH earlier and to make more informed, timely treatment decisions. Ensuring that these tests are both accessible and embedded within a structured clinical framework is key to translating diagnostic advances into meaningful patient outcomes.”*

Kenneth Cusi, Professor of Medicine at the Division of Endocrinology, Diabetes & Metabolism in the Department of Medicine at the University of Florida (USA), added: *“In a prevalent metabolic disease like MASH, which can progress to advanced liver damage without clear symptoms or early clinical signals, enabling convenient and scalable testing pathways is critical to support earlier identification of patients in routine care. With therapies becoming increasingly available, patient-centric models that allow patients to initiate testing, combined with rapid turnaround of results, were an important first step in facilitating earlier engagement and intervention. Now, with a Medicare reimbursement framework in place, access to testing becomes more straightforward and practical for patients.”*

GENFIT plans to host an analyst and investor event focused on MASH diagnostics this fall. Additional details to follow.

³ Source: Iqvia 2026

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ABOUT GENFIT

GENFIT is a biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades. Today, GENFIT focuses on Acute on-chronic Liver Failure (ACLF) and associated conditions such as acute decompensation (AD) and hepatic encephalopathy (HE). It develops therapeutic assets which have complementary mechanisms of action, selected to address key pathophysiological pathways. GENFIT also targets other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorders (UCD) and organic acidemia (OA). Its R&D portfolio, covering several stages of development, ensures a constant news flow. GENFIT's expertise in developing high-potential molecules – from early to advanced pre-commercialization stages – culminated in 2024 with the accelerated approval of Iqirvo® (elafibranor) by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom for second-line treatment of Primary Biliary Cholangitis (PBC). Iqirvo® is now marketed in several countries.⁴ Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® for the detection of Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis). GENFIT, a BCorp™ certified company since 2025, is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Euronext regulated market in Paris, Compartment B (Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including, but not limited to, statements regarding the target population eligible for Medicare coverage of the NASHnext® test, the extent of its rollout and adoption, its reimbursement by private payers, and the Company's ability to generate significant and recurring revenues from its commercialization by Labcorp. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current

⁴ Elafibranor is marketed and commercialized, notably in the U.S and Europe, by Ipsen under the trademark Iqirvo®

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expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among others, the uncertainties inherent in research and development, including in relation to non-clinical and pre-clinical programs, reproducibility of preclinical results, the translation of animal model data to human biology, in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, patient recruitment, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, pricing, approval and commercial success of elafibranor in the relevant jurisdictions, exchange rate fluctuations, and our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Risk Factors and Internal Control" of the Company's 2025 Universal Registration Document filed on April 3, 2026 (no. 26-0221) with the Autorité des marchés financiers ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in reports filed with the AMF or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this press release. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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