New Medicare Local Coverage Determinations Published for the Heartflow Analysis

April 6, 2021

Patients with stable chest pain in 38 states now have formal Medicare coverage for the Heartflow Analysis

REDWOOD CITY, Calif. – April 6, 2021 — Heartflow, Inc., a leader in revolutionizing precision heartcare, announced today that three more Medicare Administrative Contractors (MACs) have published final Local Coverage Determinations (LCDs) providing coverage for the Heartflow FFR_{CT} Analysis. With the publication of these policies, patients with coronary artery disease (CAD) in 38 states now have formal Medicare coverage for the AI-powered Heartflow Analysis.

The LCDs were published by CGS Administrators, LLC (effective April 25, 2021); WPS Government Health Administrators (effective April 25, 2021) and Noridian Healthcare Solutions (effective April 26, 2021). The published policies were finalized based on the body of clinical evidence for the Heartflow Analysis and are consistent with policies previously published by two other MACs, Palmetto GBA and National Government Services, Inc. (NGS).

The publication of the LCDs creates a clear pathway for coverage of the Heartflow Analysis for Medicare beneficiaries with symptomatic, stable CAD. The criteria in the coverage policies are closely aligned with the indication statement for the Heartflow Analysis cleared by the Food and Drug Administration (FDA). The Heartflow Analysis is a non-invasive, personalized cardiac test for stable symptomatic patients with CAD, the leading cause of death worldwide.

“The publication of the LCDs is validation of the clinical value of the Heartflow Analysis and the important role it plays in helping physicians accurately and efficiently diagnose CAD,” said Campbell Rogers, MD, FACC, Chief Medical Officer, Heartflow. “As a leader in providing precision diagnostics and optimization of therapy, we welcome the opportunity to continue to make the Heartflow Analysis available to all Medicare beneficiaries covered by these LCDs.”

The remaining MACs, Novitas Solutions and First Coast Service Options, are providing coverage for Medicare patients on a case-by-case basis.

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About the Heartflow FFR_{CT} Analysis

Starting with a standard coronary CTA, the Heartflow Analysis leverages deep learning and highly trained analysts to create a digital, personalized 3D model of the heart. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and provides FFR_{CT} values along the coronary arteries. This information helps physicians evaluate the impact a blockage may be having on blood flow and determine the optimal course of treatment for each patient. A positive FFR_{CT} value (≤0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle to a degree which may warrant invasive management.

Data demonstrating the safety, efficacy and cost-effectiveness of the Heartflow Analysis have been published in more than 400 peer-reviewed publications, including long-term data out to five years. The Heartflow Analysis offers the highest diagnostic performance available from a non-invasive test.[1] To date, clinicians around the world have used the Heartflow Analysis for more than 75,000 patients to aid in the diagnosis of heart disease.

About Heartflow, Inc.

Heartflow, Inc. is a leader in revolutionizing precision heartcare, uniquely combining human ingenuity with advanced technology. Our non-invasive Heartflow FFR_{CT} Analysis leverages artificial intelligence to create a personalized 3D model of the heart. By using this model, clinicians can better evaluate the impact a blockage has on blood flow and determine the best treatment for patients. Our technology is reflective of our Silicon Valley roots and incorporates decades of scientific evidence with the latest advances in artificial intelligence. The Heartflow FFR_{CT} Analysis is commercially available in the United States, Canada, Europe and Japan. For more information, visit www.Heartflow.com.

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1. Driessen, R., et al. Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis. J Am Coll Cardiol. 2019;73(2),161-73.