Heartflow Announces Favorable Coverage Determination for Plaque Analysis by Five Medicare Administrative Contractors

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Coverage policy provides access across the U.S. to artificial intelligence-enabled plaque analysis providing insights to help physicians guide treatment decisions for patients with coronary artery disease.

MOUNTAIN VIEW, Calif. —Oct. 24, 2024 —Heartflow, Inc., the global leader in non-invasive artificial intelligence (AI) heart care solutions, announced Heartflow Plaque Analysis will be covered by five of seven Medicare Administrative Contractors (MAC), with four (WPS, CGS, Palmetto and NGS) beginning November 24, 2024 and Noridian beginning December 8, 2024. This decision will expand patient access across the U.S. to Heartflow Plaque Analysis, which provides highly accurate plaque quantification and characterization to assess the extent of coronary artery disease (CAD) for personalized treatment. Heartflow Plaque Analysis is the only FDA-cleared, AI-enabled plaque quantification tool with a reported 95% agreement with the gold standard, IVUS, in a prospective, international trial using blinded core lab adjudication.[1] It is proven to change medical management in two-thirds of cases, helping physicians to improve outcomes.[2]

“Coronary artery disease is the underlying cause of about 50% of deaths,” said Ron Blankstein, M.D., Director of Cardiac Computed Tomography at Brigham and Women’s Hospital and Professor of Medicine at Harvard Medical School in Boston, Massachusetts. “Medicare coverage of Heartflow Plaque Analysis is a major step forward in improving coronary artery disease management. The earlier we can diagnose and use tools to provide accurate plaque quantification, the earlier we can provide tailored treatments, potentially improving outcomes for patients.”

The coverage of Heartflow Plaque Analysis extends to Medicare beneficiaries with acute or stable chest pain and less than 70% stenosis found on coronary computed tomography angiography (CCTA). Medicare has previously established a national payment of $950 for Heartflow Plaque Analysis in the hospital setting. The remaining MACs will continue to review coverage for Heartflow Plaque Analysis on a case-by-case basis, potentially expanding access even further.

Since its inception, Heartflow has been committed to building a new standard of care for people at risk of heart disease and is now available in more than 1,000 U.S. hospitals and hundreds more outside of the U.S. Medicare coverage for Heartflow Plaque Analysis is yet another milestone on that journey. Heartflow Plaque Analysis is FDA-cleared, backed by robust clinical evidence and guidelines, and is available quickly and reliably. Heartflow continues to rapidly evolve AI-processing and now accepts 96% of computed tomography (CT) scans submitted by customers for analysis with median turnaround time of less than 1.5 hours.[3,4]

“We commend the Medicare Administrative Contractors for recognizing the value and critical role of AI-enabled plaque quantification technologies in cardiovascular disease management,” said John Farquhar, Chief Executive Officer of Heartflow. “Medicare’s coverage of Heartflow Plaque Analysis is a significant step forward for cardiovascular disease diagnosis and treatment, expanding access for patients who will see great benefit from more targeted and effective interventions.”

Medicare’s coverage of Heartflow Plaque Analysis reflects a larger trend towards personalized, data-driven heart care. With broader reimbursement, more physicians can incorporate this technology into everyday clinical practice, improving outcomes for a growing number of heart disease patients.

Heartflow is dedicated to reshaping cardiovascular care and ensuring that physicians and patients have access to comprehensive, accurate, and efficient solutions in precision coronary care. Heartflow’s suite of non-invasive technologies helps clinicians characterize and quantify coronary atherosclerosis (Plaque Analysis), identify stenoses in the coronary arteries (Roadmap™ Analysis), and assess coronary blood flow (FFR_{CT} Analysis).

About Heartflow, Inc.

Heartflow is transforming precision coronary care with the only AI-powered non-invasive integrated heart care solution across the CCTA pathway. As the pioneer of FFR_{CT}, which is now supported by the ACC/AHA Chest Pain Guideline, Heartflow continues to advance the diagnosis and management of CAD. Heartflow’s suite of non-invasive technologies includes its FFR_{CT} Analysis, Roadmap™ Analysis and Plaque Analysis. More than 500 peer-reviewed publications have validated our approach and more importantly, our technologies have helped clinicians diagnose and manage over 250,000 patients. For more information, visit www.Heartflow.com.

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References

1. Narula et al. Prospective Deep Learning-based Quantitative Assessment of Coronary Plaque by CT Angiography Compared with Intravascular Ultrasound EHJ 2024
2. Rinehart, Sarah et al. JSCAI March 26, 2024: https://www.jscai.org/article/S2772-9303(24)00003-6/fulltext?dgcid=raven_jbs_etoc_email
3. Acceptance rate is defined as analysis completed out of eligible CCTAs submitted by customers. Data on file.
4. Turnaround time is defined as the time it takes from customer CCTA submission for Heartflow to deliver back the Analysis. US median turnaround time. Data on file.