



Heartflow Announces FDA 510(k) Clearance and Launch of Next Generation Heartflow Plaque Analysis Platform

September 22, 2025

AI-Powered Heartflow Plaque Analysis to be Covered by Cigna Health Plans Nationwide

MOUNTAIN VIEW, Calif., Sept. 22, 2025 (GLOBE NEWSWIRE) -- [Heartflow, Inc.](#) (Heartflow) (Nasdaq: HTFL), the leader in AI technology for coronary artery disease (CAD), today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Next Gen [Heartflow Plaque Analysis](#) algorithm and the platform is now available. The technology features an updated algorithm, vastly expanded nomogram, and advanced 3D color-coded visualization of plaque type, volume, and distribution, empowering clinicians with the insights needed to make confident care decisions with ease. Heartflow also announced that Heartflow Plaque Analysis will be covered by Cigna across all of its lines of business, including Commercial and Medicare Advantage plans, beginning in October.

Advanced Heartflow Plaque Analysis Platform Provides Clarity in 3D

Heartflow Plaque Analysis is the only FDA-cleared, AI-powered plaque quantification tool with a reported 95% agreement with the gold standard, IVUS, using blinded core lab adjudication.¹ The latest algorithm advancement shows 21% improvement in plaque detection compared to the first-generation algorithm, so clinicians can be confident in their diagnosis and management of CAD.²

“Understanding not only how much plaque is present, but also plaque type and distribution, is critical in predicting patient risk and guiding personalized treatment,” said Matthew Budoff, M.D., Professor of Medicine at the David Geffen School of Medicine at the University of California Los Angeles (UCLA) Medical Center. “With these enhanced capabilities, Heartflow Plaque Analysis provides clinicians with the clarity we need to move from detection to decision with speed and confidence.”

Leveraging enhanced AI, this new Plaque Analysis update marks the most sophisticated iteration of Heartflow’s technology. It provides clinicians with an intuitive visual representation of plaque types, enabling rapid assessment of CAD location and severity. Heartflow’s enhanced nomogram is powered by data from ~273,000 patients—a dataset 9x larger than any current plaque quantification study.³

Cigna Adds Nationwide Coverage for Heartflow Plaque Analysis

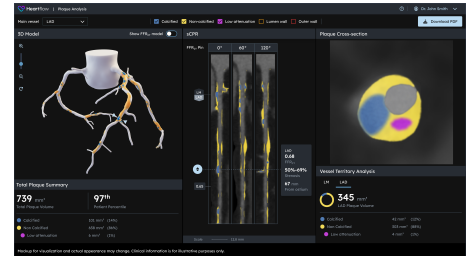
Cigna is the second national insurer to update its policies to cover Heartflow Plaque Analysis to fully align with the guidelines issued by radiology benefit manager EviCore, following a similar decision by [UnitedHealthcare](#). The updated coverage will become effective on October 1, 2025 for Cigna patients with acute or stable chest pain and mild-to-moderate narrowing of coronary arteries (1-69% stenosis) identified on coronary CTA.

“Heartflow is proud to lead the way in coronary plaque analysis with our Next Gen platform, delivering the most representative visualization and context available for assessing patients’ disease and risk. Cigna’s decision to cover Heartflow Plaque Analysis is a testament to the power of our technology to positively impact care for its members across the United States,” said John Farquhar, President and CEO of Heartflow. “Heartflow Analyses give clinicians a view of coronary plaque by type and impact on blood flow with FFR_{CT} that’s key to informing management strategies. These latest advancements build on Heartflow’s record of proven innovation, leveraging clinical rigor and the world’s largest dataset of coronary CTA images to continually improve our technology for clinicians and patients.”

Heartflow’s continued advancement of plaque analysis technology follows the company’s recent unveiling of the landmark [DECIDE Registry data](#), which showed Heartflow Plaque Analysis led to medical management change in over 50% of patients beyond coronary CTA alone, resulting in an expected ~15% event reduction.^{4,5} Heartflow is dedicated to reshaping cardiovascular care and ensuring that physicians and patients have access to comprehensive, accurate, and efficient solutions for precision coronary care.

About Heartflow, Inc.

Next Generation Heartflow Plaque Analysis



Our Next Generation Plaque Analysis platform harnesses an FDA-cleared updated algorithm, vastly expanded nomogram, and advanced 3D color-coded visualization to deliver unprecedented insight into plaque type, volume, and distribution. This update marks the most sophisticated iteration of Heartflow’s technology – empowering clinicians to make confident care decisions with ease.

Heartflow is transforming coronary artery disease from the world's leading cause of death into a condition that can be detected early, diagnosed accurately, and managed for life. The [Heartflow One](#) platform uses AI to turn coronary CTA images into personalized 3D models of the heart, providing clinicians with actionable insights into plaque volume and composition and its impact on blood flow – without the need for invasive procedures. Supported by ACC/AHA guidelines and more than 600 peer-reviewed publications, Heartflow has helped clinicians manage nearly 500,000 patients worldwide. Discover how we're shaping the future of cardiovascular care at heartflow.com.

¹ Ihdahid A, et al. Radiol Cardiothorac Imaging. 2024. doi: 10.1148/ryct.230312 and internal bridging study with ICC correlation between first generation and second generation Plaque Analysis algorithm.

² U.S. Food and Drug Administration. 510(k) Premarket Notification: K250902. https://www.accessdata.fda.gov/cdrh_docs/pdf25/K250902.pdf

³ Tzimas, et al., Presentation SCCT July 2025.

⁴ DECIDE Registry. Rinehart, et al., Presented at SCCT July 2025.

⁵ Collins et al. Lancet 2016. DOI: 10.1016/S0140-6736(16)31357-5

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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/5f268838-f806-4612-995b-af3aa4676cc0>