

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality
Coverage and Analysis Group

Conformal Medical, Inc.
William A. Gray, MD
System Chief, Division of Cardiovascular Disease,
Main Line Health and President, Lankenau Heart Institute
Lankenau Medical Center
100 East Lancaster Avenue
Suite 356 MOB East
Wynnewood, PA 19096 USA

March 23, 2022

Shephal Doshi, MD
Providence St. John's Health Center / Pacific Heart Institute
2001 Santa Monica Blvd., #280W
Santa Monica, CA 90404

Dear Dr. Gray & Dr. Doshi,

Thank you for your study protocol submission and request for coverage under Coverage with Evidence Development (CED) for Percutaneous Left Atrial Appendage Closure (LAAC) Therapy. After careful review by our multidisciplinary team of your proposed CED study, "An Evaluation of the Safety and Effectiveness of the Conformal CLAAS System for Left Atrial Appendage Occlusion", NCT # 05147792 the Centers for Medicare & Medicaid Services (CMS) has determined that it fulfills the requirements of the National Coverage Determination (NCD) 20.34 for LAAC.

You must notify us of any substantial changes to the protocol, such as sample size revisions. The ClinicalTrials.gov website must be kept up to date. Please remember that the results of your research should be published in peer-reviewed journals. We may use these results in future coverage decisions.

To facilitate the Medicare payment process, you should provide your study sites with appropriate billing instructions. These include entering the National Clinical Trial (NCT) identifier from the ClinicalTrials.gov website on Medicare claims along with the other codes and modifiers provided in the NCD claims processing instructions.

We appreciate your commitment to research and evidentiary development to improve care for Medicare beneficiaries. Please direct any questions to Melissa Evans at melissa.evans@cms.hhs.gov.

Sincerely,

X

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group