



March 5, 2024

Jason Bennett
Director, Technology, Coding, and Pricing Group
Center for Medicare
Center for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted via e-mail at DevicePTapplications@cms.hhs.gov

**RE: Request for Preliminary Approval of Transitional Pass Through (TPT) Payment:
Dual-Chamber Leadless Pacemaker**

Dear Director Bennett:

On behalf of the Heart Rhythm Society (HRS), we are writing to request your consideration of dual-chamber leadless pacemakers for transitional pass-through payment status under the Hospital Outpatient Prospective Payment System (OPPS).

HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. HRS represents more than 8,200 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists, and allied health care professionals. Electrophysiology is a distinct specialty of cardiology, with board certification in both cardiology and clinical cardiac electrophysiology through the American Board of Internal Medicine. Cardiac electrophysiologists determine the need for pacing and optimal modality (conventional intracardiac lead vs. leadless, single vs. dual chamber) for each patient.

Dual chamber leadless pacemakers represent a clinical breakthrough compared to existing transvenous technology. The Food and Drug Administration (FDA) granted a Breakthrough Device designation, and CMS has recognized the value of this new technology in its payment policies in the inpatient setting. The device subsequently received approval as the first dual-chamber leadless pacemaker in 2023, allowing providers to reach different patients.

In the CY 2024 IPPS final rule, CMS granted New Technology Add-on Payment (NTAP) status to the device, permitting additional payment under the inpatient reimbursement methodology for dual-chamber leadless pacemakers (until a bundled payment methodology is developed that recognizes the incremental costs associated with this novel device).

A similar reimbursement mechanism, transitional pass-through payment, unfortunately has yet to be approved in the outpatient setting for this novel device. Having a similar reimbursement mechanism in the outpatient setting would: 1) improve patient access to this device, and 2) result in a significant cost savings to the healthcare system (versus the alternative of having ALL implants performed and billed only in the inpatient setting).



The dual-chamber leadless pacemaker is the optimal and only safe option for a subset of patients (i.e. challenges with vascular access, high infection risk, etc.). It is important to allow the physicians to determine the appropriate setting of care. A payment disparity between inpatient and outpatient may impede physician decision-making regarding the most appropriate setting of care based on specific patient needs and characteristics. Therefore, bringing balance to the inpatient and outpatient policies as soon as possible will limit bias in site of service before it becomes a significant issue.

For the sake of patient access and safety, HRS kindly requests that CMS consider pass-through status for dual-chamber leadless pacemakers under the OPPS until permanent pricing and policies are developed. Moreover, such a mechanism could result in cost-savings to the healthcare system.

We thank you in advanced for your consideration, and please do not hesitate to reach out to Lisa Miller at lmiller@hrsonline.org if HRS can be of any additional assistance.

Sincerely,

A handwritten signature in black ink that reads "C. F. Liu". The signature is stylized with a large, looped "C" and "L".

Christopher F. Liu, MD, FHRS
Chair, HRS Health Policy and Regulatory Affairs Committee

cc: Amanda Rhee
Allison Pompey
Amit Shanker, MD
Lisa Miller, MS
Anne Marie Smith, MBA