Clover

Clover Health Leadless Cardiac Pacemakers Reimbursement Policy

Policy # RP-021

Policy Title	Leadless Cardiac Pacemakers Reimbursement Policy
Policy Department	Payment Strategy and Operations
Effective Date	1/1/2022
Revision Date(s)	3/1/2022
Next Review Date	

Disclaimer:
Clover Health applies The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), Local Coverage Determinations (LCD), Clover Policies, and MCG for determining medical necessity. Clover Policies are intended to provide a standard guideline but are not used to preempt providers' judgment in rendering services. Providers are expected to provide care based on best practices and use their medical judgment for appropriate care.

Description:

The leadless pacemaker eliminates the need for a device pocket and insertion of a pacing lead which are integral elements of traditional pacing systems. The removal of these elements eliminate an important source of complications associated with traditional pacing systems while providing similar benefits. Leadless pacemakers are delivered via catheter to the heart, and function similarly to other transvenous single-chamber ventricular pacemakers.

Definitions:

- **National Coverage Determination (NCD)**
  - National level coverage determinations (NCDs) are made through an evidence-based process, these are done at the Federal level
- **Coverage with Evidence Development (CED)**
  - A part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study.
- **Clinical Trial**
  - A research study which studies new tests and treatments and evaluates their effects on human health outcomes.

Policy:

Effective January 18, 2017, the Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development (CED). CMS covers leadless pacemakers when procedures are performed in Food and Drug Administration (FDA) approved studies. CMS also covers, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either:

- an associated ongoing FDA approved post-approval study; or
- completed an FDA post-approval study.

Leadless Cardiac Pacemakers are not covered by CMS or Clover Health when furnished outside of an approved FDA Clinical Trial.

When billing a Clinical Trial to Clover Health, all required CMS indicators must be present on the claim: Condition Code, Diagnosis Code, Procedure Code (if applicable) and the Clinical Trial Study Number (NCT). If a claim is submitted to Clover for a Leadless Cardiac Pacemaker, but is missing one of the required claim fields, the claim will be denied.

Claim Codes (if applicable)	HCPCS Codes ● **0387T -** Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular ● **0389T -** Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report, leadless pacemaker system. ● **0390T -** Peri-procedural device evaluation (in person) and programming of device system parameters before or after surgery, procedure or test with analysis, review and report, leadless pacemaker system. ● **0391T -** Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system. Diagnosis Code ● **Z00.6** – Encounter for examination for normal comparison and control in clinical research program Condition Code ● **30 -** Qualified Clinical Trial

References
NCD 20.8.4 Leadless Pacemakers
Coverage with Evidence Development
National Coverage Determination (NCD20.8.4): Leadless Pacemakers
Medicare Claims Processing Manual, Chapter 32