GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
A leadless cardiac pacemaker system is a pulse generator with built-in battery and electrode for implantation in a cardiac chamber via a transfemoral catheter approach.

Leadless cardiac pacemakers are designed to achieve the same pacing results as a standard pacemaker, but the process for implanting the leadless pacemaker is different from standard pacemakers. The leadless pacemaker is placed via a catheter into the right ventricle. Unlike a standard pacemaker, a leadless pacemaker does not require creation of a surgical pocket for the pacemaker, and it requires no leads. The pacemaker battery life is equivalent to that of similar standard single chamber pacemakers. The advantage of a leadless pacemaker over a standard pacemaker is avoidance of a surgical scar or lump under the skin where the pacemaker sits. Additional potential advantages include avoidance of problems with lead placement and reduction in risk of infections.

The Micra® (Medtronic) leadless pacemaker is currently FDA approved. The Nanostim™ (St. Jude) leadless cardiac pacemaker is currently not FDA approved. The two pacemakers differ slightly in terms of how they are lodged into the myocardium of the RV apex. Another concept in leadless pacing is a multi-component ultrasound-based LV endocardial pacing system for cardiac resynchronization therapy: the WiCS system (Wireless Cardiac Stimulation, EBR systems, Sunnyvale, CA, USA).

POLICY

<table>
<thead>
<tr>
<th>Leadless cardiac pacemakers (0387T-0391T) are non-covered for HMO, PPO, Individual Marketplace, &amp; Advantage.</th>
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<tbody>
<tr>
<td>Leadless cardiac pacemakers (0387T-0391T) require prior authorization for Elite.</td>
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HMO, PPO, Individual Marketplace, Advantage
Paramount has determined that leadless cardiac pacemakers is experimental and investigational and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of this procedure.

Current Procedural Terminology (CPT), the official CPT codebook with rules and guidelines from the American Medical Association’s CPT editorial panel, includes a section of temporary codes created to identify emerging technology services, and procedures. Category III codes allow data collection for specific emerging technology services. All Category III codes end in a “T” for temporary. The inclusion of a service in the Category III section of CPT neither implies nor endorses clinical efficacy, safety or applicability to clinical practice and may not conform to the usual requirements for CPT Category I codes.

Elite
While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of leadless cardiac pacemakers, per CMS guidelines it may be covered with prior authorization for Elite members.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
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<tr>
<th>CPT CODES</th>
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<tr>
<td>0387T Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular</td>
</tr>
<tr>
<td>0388T Transcatheter removal of permanent leadless pacemaker, ventricular</td>
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<tr>
<td>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</td>
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<tr>
<td>0390T Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery,</td>
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</table>
Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system

**TAWG REVIEW DATES:** 01/27/2017, 02/22/2018

**REVISION HISTORY EXPLANATION**

01/27/17: Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

02/22/18: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.