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 small, are implanted in the right ventricle and are a single-chamber intracardiac device. 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. Leadless pacemakers may also be a better option than surgical endocardial pacemakers for patients with no vascular access due to renal failure or congenital heart disease.

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>HMO, PPO, and Individual Marketplace.</th>
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<tbody>
<tr>
<td>Leadless cardiac pacemakers (33274 and 33275) are non-covered.</td>
</tr>
</tbody>
</table>

**Advantage - Effective 12/1/2019**

| Leadless cardiac pacemakers (33274 and 33275) require prior authorization. |

**Elite**

| Leadless cardiac pacemakers (33274 and 33275) does not require prior authorization when the definition/criteria of medical necessity documented below is met. |

**HMO, PPO, Individual Marketplace**
Paramount has determined that leadless cardiac pacemakers is experimental and investigational for arrhythmias and all other indications and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness and/or safety of this procedure.

**Advantage, 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 Advantage and Elite members.

**Coverage Criteria**
The Micra transcatheter pacing system may be considered medically necessary in patients when ALL conditions below are met:

1. The patient has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses).
2. The patient has no significant contraindication precluding placement of conventional single chamber ventricular pacemaker leads such as any of the following:

- History of an endovascular or cardiovascular implantable electronic device (CIED)
- Infection or who are at high risk for infection
- Limited access for transvenous pacing given venous anomaly, occlusion of axillary, subclavian or innominate veins, congenital venous anomaly, or planned use of such veins for a semi-permanent catheter or current or planned use of an AV fistula for hemodialysis
- Presence of a bioprosthetic tricuspid valve

3. There are no contraindications per the device FDA label.

The Micra transcatheter pacing system is considered investigational in all other situations in which the above criteria are not met.

**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>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>33274</td>
<td>Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed</td>
</tr>
<tr>
<td>33275</td>
<td>Transcatheter removal of permanent leadless pacemaker, right ventricular.</td>
</tr>
<tr>
<td>0387T</td>
<td>Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular endated 1/1/2019</td>
</tr>
<tr>
<td>0388T</td>
<td>Transcatheter removal of permanent leadless pacemaker, ventricular endated 1/1/2019</td>
</tr>
<tr>
<td>0389T</td>
<td>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 endated 1/1/2019</td>
</tr>
<tr>
<td>0390T</td>
<td>Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure or test with analysis, review and report, leadless pacemaker system endated 1/1/2019</td>
</tr>
<tr>
<td>0391T</td>
<td>Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system endated 1/1/2019</td>
</tr>
</tbody>
</table>

**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).
- **10/24/19**: Policy updated to the 2019 CPT codes, 33274 and 33275. CMS and the Ohio Department of Medicaid (ODM) indicate coverage. Coverage criteria indicated for the Advantage and Elite product lines only. Prior Authorization required effective 12/1/2019 for the Advantage product line. Policy reviewed and updated to reflect most current clinical evidence.

**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.