Leadless Cardiac Pacemaker

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary leadless cardiac pacemaker.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Health Children (DHCP) and Diamond State Health Plan Plus members.

Leadless pacemakers – Single-unit devices that are implanted in the heart via femoral access, thereby eliminating the potential for complications as a result of leads and surgical pocket. The Micra transcatheter pacing system is the only commercially available leadless pacemaker in the United States (U. S.) approved by the Food and Drug Administration (FDA).

PROCEDURES

A prior authorization is not required.

Pacemakers are intended to be used as a substitute for the heart's intrinsic pacing system to correct cardiac rhythm disorders. Conventional pacemakers consist of two components: a pulse generator and

electrodes (or leads). Pacemakers are considered life-sustaining, life-supporting class III devices for individuals with a variety of brady-arrhythmias. Even though the efficacy and safety profile of conventional pacemakers are excellent, in a small proportion of individuals, they may result in lead complications and the requirement for a surgical pocket. Further, some individuals are medically ineligible for conventional pacemakers due to lack of venous access and recurrent infection.

The Micra transcatheter pacing system may be considered medically necessary in individuals when BOTH conditions below are met:

- The individual has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses); and
- The individual has a 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; or
  - Limited access for transvenous pacing given venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an AV fistula for hemodialysis; or
  - Presence of a bio-prosthetic tricuspid valve

The Micra transcatheter pacing system not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Contraindications

As per the U.S. FDA label, the Micra transcatheter pacing system is contraindicated for individuals who have the following types of devices implanted:

- An implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician; or
- An implanted inferior vena cava filter; or
- A mechanical tricuspid valve; or
- An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra device

As per the FDA label, the Micra transcatheter pacing system is also contraindicated for individuals who have the following conditions:

- Femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity); or
- Morbid obesity that prevents the implanted device to obtain telemetry communication within <12.5 cm (4.9 in); or
- Known intolerance to titanium, titanium nitride, parylene C, primer for parylene C, polyether ether ketone, siloxane, nitinol, platinum, iridium, liquid silicone rubber, silicone medical adhesive, and heparin or sensitivity to contrast medical which cannot be adequately pre-medicated.

As per the FDA label, the Micra transcatheter pacing system should not be used in individuals for whom a single dose of 1.0 mg dexamethasone acetate cannot be tolerated because the device contains a molded and cured mixture of dexamethasone acetate with the target dosage of 272 µg dexamethasone acetate. It is intended to deliver the steroid to reduce inflammation and fibrosis.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service: Inpatient/Outpatient

Experimental/investigational (E/I) services are not covered regardless of place of service.

The Micra transcatheter pacing system is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed.
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed.

Covered Diagnosis Codes

G90.01	I44.1	I44.2	I45.2	I45.3	I45.5	I47.2
R00.1	I48.0	I48.11	I48.19	I48.20	I48.21	I48.3
I48.4	I48.91	I48.92	I49.3	I49.5		

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

<Date>	<Event>