

Leadless Cardiac Pacemaker, Surgical 126

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<u>Effective Date</u>	9/2021
<u>Next Review Date</u>	7/2025
<u>Coverage Policy</u>	Surgical 126
<u>Version</u>	4

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual’s benefit plan for details [*](#).

Purpose:

This policy addresses the medical necessity of Leadless Cardiac Pacemakers.

Description & Definitions:

Leadless Cardiac Pacemaker may be a single or dual-chamber device. It is an ultrasound-guided access directly through the femoral vein and attached the small capsule to the heart. This device does not require a chest incision or a subcutaneous generator chest pocket.

Criteria:

Leadless pacemakers are considered medically necessary when individual requires pacing but lacks venous access that precludes a transvenous approach when **all of the following** criteria are met:

- Individual requires a leadless approach as indicated by **one or more of the following**:
 - Individual has congenital heart disease with right to left shunting
 - Individual has limited access to the right ventricle
 - Individual has inadequate vascular access to allow for placement of an implantable device
 - Individual has no conventional pocket site due to previous device related infections or other chronic indwelling catheters preventing access to a potential pocket site.
- No contraindications for leadless pacemaker as indicated by **all of the following**:
 - Individual does not have an implanted inferior vena cava filter
 - Individual does not have a mechanical tricuspid valve
- Individual meets **one or more of the following** clinical indications for permanent pacer placement:
 - Individual requires a **single chamber leadless right ventricular (RV) pacemaker** when **one or more of the following** clinical indications are met:
 - Individual has symptomatic paroxysmal AV Block
 - Individual has permanent high-grade AV block in the presence of Atrial Fibrillation (AF)
 - As an alternative to dual chamber pacing when atrial lead placement is considered difficult, high risk, or considered not necessary for appropriate therapy in an individual with symptomatic paroxysmal or permanent high-grade AV block in the absence of AF
 - As an alternative to atrial or dual chamber pacing when atrial lead placement is considered difficult, high risk, or not considered necessary for effective therapy in an individual with

- symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses),
- Individual requires a **single chamber leadless right atrial pacemaker** and has a diagnosis of sinus node dysfunction with normal AV and intraventricular conduction systems
- Individual requires a **dual chamber leadless pacemaker** when **one or more of the following** clinical indications are met:
 - Individual has chronic, symptomatic second or third-degree AV block
 - Individual has recurrent Adams-Stokes syndrome
 - Individual has sick sinus syndrome
 - Individual has symptomatic bilateral bundle branch block when other causes have been ruled out

There is insufficient scientific evidence to support the medical necessity for any other reason than those represented in the Clinical Indications for Procedure section.

Coding:

Medically necessary with criteria:

Coding	Description
33274	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
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component

0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0823T	Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed
0824T	Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed
0826T	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 by a physician or other qualified health care professional, leadless pacemaker system in single-cardiac chamber

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2024: July – Annual review completed. Expanded criteria to provide coverage. Updated references. Added codes 0795T-0803T.

Reviewed Dates:

- 2023: July
- 2022: July

Effective Date:

- September 2021

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

Leadless Cardiac Pacemaker, SHP Surgical 126, LCP, leadless pacemaker, LP, Micra, Nanostim, Leadless intracardiac pacemakers, Transcatheter Pacing System