

LEADLESS PACEMAKER
Medicare National Coverage Determination (NCD) 20.8.4 Checklist

NCD 20.8.4	Patient Name:	MR#
Effective Date: For services performed on or after 01/18/2017		
<p>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.</p>		
GENERAL REQUIREMENTS		
CODING – Leadless pacemakers through CED are billed with the following:		
<p style="text-align: center;">CPT Codes/Modifier</p> <ul style="list-style-type: none"> • 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 • Modifier: Q0 (zero) - Investigational clinical service provided in an approved clinical research study 	<p style="text-align: center;">ICD-10 Diagnosis Code</p> <ul style="list-style-type: none"> • Z00.6 – Encounter for examination for normal comparison and control in clinical research program 	<p style="text-align: center;">Additional Claim Billing Information:</p> <ul style="list-style-type: none"> • The National Clinical Trial (NCT) 8-digit identifier number is required on all claims • Condition Code 30
COVERAGE INDICATIONS		
<p>Leadless Pacemakers are covered when the implantation procedure is performed in a CMS-approved Coverage with Evidence Development (CED) study for certain clinical indications.</p>		
<input type="checkbox"/> Clinical indications described in the NCD	<input type="checkbox"/> CMS approved studies are posted on the CMS CED website	CMS CED Website
<p><i>Note: As of 9/24/18 UF Health Shands participates in the Micra Study (NCT03039712). Please contact the Research Billing Office (link below) for current approved study participation.</i></p>		
NON-COVERED INDICATIONS		
<p>Leadless pacemakers are non-covered when furnished outside of a CMS approved Coverage with Evidence Development (CED) study.</p>		
DOCUMENTATION REQUIREMENTS		
<input type="checkbox"/> The medical record must include documentation to support the medical necessity of the procedure and the diagnosis and procedure codes selected to report the service.		
QUESTIONS		
<input type="checkbox"/> Contact the Research Billing Office (RBO)		Research Billing Office
Checklist completed by:		Date:
<p>Disclaimer: The content of the checklists were created as an educational tool. Use of these documents are not intended as a replacement for the documentation requirements published in National or Local Coverage Determinations, or the CMS's documentation guidelines, written law or regulations. Medicare policy changes frequently; Providers/Departments are reminded to review current National and Local Coverage Determination and Policy Articles for specific documentation and coding guidelines.</p>		