LCD Database ID Number
L33763

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Vascular Stenting of Lower Extremity Arteries

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 11, Section 20.1
Vascular Stenting of Lower Extremity Arteries

CMS Manual System, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Sections 20.7

Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region I

Original Determination Effective Date

10/01/2014

Original Determination Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

Indications and Limitations of Coverage and/or Medical Necessity

Vascular stenting of lower extremity arteries performed for clinically significant occlusive vascular disease will be considered medically reasonable and necessary for a patient under any of the following circumstances:

- Primary therapy for common iliac artery stenosis and occlusions.
- Primary therapy for external iliac artery stenoses and occlusions.
- Primary therapy for femoral/popliteal arterial stenosis and occlusions.
- Salvage therapy for common and external iliac arteries for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50%, or flow-limiting dissection).
- Salvage therapy for femoral/popliteal arteries for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50%, or flow-limiting dissection).
- Salvage therapy for tibial/peroneal arterial lesions for a suboptimal result from balloon dilation.

Limitations

Vascular stenting of lower extremity arteries is considered experimental and investigational for a patient under any of the following circumstances as the effectiveness has not been well established and/or is not recommended, and therefore, will not be considered medically reasonable and necessary:

- Primary therapy for tibial/peroneal arterial stenosis and occlusions.

It is the expectation that for the covered indications of this policy, the utilized stent will have Food and Drug Administration (FDA) approval for that indication. ‘Off-label use’ of drug-eluting stents and polytetrafluoroethylene (PTFE)-covered stents
Vascular Stenting of Lower Extremity Arteries

are non-covered (given the FDA approved use as well as off-label use of such devices is a subject of on-going clinical trials). For the covered indications, a stent approved by the FDA may be covered for off-label use for which efficacy has been supported in peer-reviewed medical literature, given that there are no FDA-contraindications or warnings which have been demonstrated in this regard and given that its use has been a long standing standard of care (this statement is limited to vascular stents for lower extremity arteries as applied to this LCD).

Type of Bill Code

12X Hospital Inpatient (Medicare Part B only)
13X Hospital Outpatient
85X Critical Access Hospital

Revenue Codes

032x Radiology - Diagnostic - General Classification
0320 Radiology - Diagnostic - General Classification
0323 Radiology - Diagnostic - Arteriography
0329 Radiology - Diagnostic - Other Radiology – Diagnostic
0340 Nuclear Medicine - General Classification
0342 Nuclear Medicine – Therapeutic
0349 Nuclear Medicine - Other Nuclear Medicine
035X CT Scan - General Classification
0402 Other Imaging Services – Ultrasound
0404 Other Imaging Services - Positron Emission Tomography
0409 Other Imaging Services - Other Imaging Services
0610 Magnetic Resonance Technology (MRT) – General Classification
0614 Magnetic Resonance Technology (MRT) - MRI – Other
0615 Magnetic Resonance Technology (MRT) - MRA - Head and Neck
0616 Magnetic Resonance Technology (MRT) - MRA - Lower Extremities
0618 Magnetic Resonance Technology (MRT) - MRA – Other
0619 Magnetic Resonance Technology (MRT) – Other MRT

CPT/HCPCS Codes

37221 Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within same vessel, when performed
37223 Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
37226 Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227 Revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37230 Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37231 Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
Vascular Stenting of Lower Extremity Arteries

37235  Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)

ICD-10 Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I70.201-I70.203</td>
<td>Unspecified atherosclerosis of native arteries of extremities</td>
</tr>
<tr>
<td>I70.209</td>
<td>Unspecified atherosclerosis of native arteries of extremities, unspecified extremity</td>
</tr>
<tr>
<td>I70.211-I70.213</td>
<td>Atherosclerosis of native arteries of extremities with intermittent claudication</td>
</tr>
<tr>
<td>I70.219</td>
<td>Atherosclerosis of native arteries of extremities with intermittent claudication, unspecified extremity</td>
</tr>
<tr>
<td>I70.221-I70.223</td>
<td>Atherosclerosis of native arteries of extremities with rest pain, right leg</td>
</tr>
<tr>
<td>I70.229</td>
<td>Atherosclerosis of native arteries of extremities with rest pain, unspecified extremity</td>
</tr>
<tr>
<td>I70.231-I70.249</td>
<td>Atherosclerosis of native arteries of right leg with ulceration of thigh</td>
</tr>
<tr>
<td>I70.261-I70.269</td>
<td>Atherosclerosis of native arteries of extremities with gangrene</td>
</tr>
<tr>
<td>I73.9</td>
<td>Peripheral vascular disease, unspecified</td>
</tr>
<tr>
<td>I74.3</td>
<td>Embolism and thrombosis of arteries of the lower extremities</td>
</tr>
<tr>
<td>I74.5</td>
<td>Embolism and thrombosis of iliac artery</td>
</tr>
<tr>
<td>I74.8</td>
<td>Embolism and thrombosis of other arteries</td>
</tr>
<tr>
<td>I77.1</td>
<td>Stricture of artery</td>
</tr>
<tr>
<td>I77.72</td>
<td>Dissection of iliac artery</td>
</tr>
<tr>
<td>T81.718A-T81.719S</td>
<td>Complication of other artery following a procedure, not elsewhere classified</td>
</tr>
</tbody>
</table>

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation Requirements

Medical record documentation maintained by the performing physician must clearly indicate medical necessity for this service and made available upon request. This documentation should also include, but is not limited, to the following (as applicable to the patient’s episode of care):

- Relevant medical history (e.g., claudication, critical limb ischemia)
- Vascular physical examination (including measurement of the ankle-brachial index)
- Previous noninvasive diagnostic evaluation(s)
- Detailed summary of the angiography report
- Detailed summary of the procedure/operative report
Vascular Stenting of Lower Extremity Arteries

Any procedure has benefit and risk that the treating physician discusses with the patient. To meet the R&N threshold for coverage of a procedure, the physician’s documentation for the case should clearly support both the diagnostic criteria for the indication (standard test results and/or clinical findings as applicable) and the medical need (the procedure does not exceed the medical need and is at least as beneficial as existing alternatives and the procedure is furnished with accepted standards of medical practice in a setting appropriate for the patient’s medical needs and condition).

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Sources of Information and Basis for Decision

- FCSO reference LCD number(s) – L32102


Vascular Stenting of Lower Extremity Arteries


**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A

**Start Date of Notice Period**

04/01/2014

**Revision Number**: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

**Related Documents**

N/A

**LCD Attachments**

N/A