

# Transcatheter Peripheral Vascular Stents – Chest, Abdomen and Pelvis



INDEPENDENT CARE HEALTH PLAN

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## Medical Coverage Policy

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**Disclaimer** The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## Related Medical/Pharmacy Coverage Policies

Percutaneous Coronary Intervention Medical Coverage Policy HUM-1063

Peripheral Artery Revascularization of the Lower Extremities Medical Coverage Policy HUM-1182

## Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

| Type                    | Title                                       | ID Number  | Jurisdiction Medicare Administrative Contractors (MACs)  | Applicable States/Territories                   |
|-------------------------|---|--|--|---|
| NCD                     | Percutaneous Transluminal Angioplasty (PTA) | <a href="#">20.7</a>                             |  |   |
| LCD (and pertinent LCA) | Non-Coronary Vascular Stents                | <a href="#">L35998</a><br><a href="#">A57590</a> | J5 - Wisconsin Physicians Service Insurance Corporation<br><br>J8 - Wisconsin Physicians Service Insurance Corporation | IA, KS, MO, NE<br><br>IN, MI                    |
| LCD (and pertinent LCA) | Dialysis Access Maintenance                 | <a href="#">L34062</a><br><a href="#">A56460</a> | J15 - CGS Administrators, LLC (Part A/B MAC)   | KY, OH  |
| LCD (and pertinent LCA) | Endovenous Stenting                         | <a href="#">L37893</a><br><a href="#">A56414</a> | JH - Novitas Solutions, Inc. (Part A/B MAC)  | AR, CO, D.C, DE, NM, MD, OK, PA, NJ, TX, LA, MS |
| LCD (and pertinent LCA) | Endovenous Stenting                         | <a href="#">L38231</a><br><a href="#">A56644</a> | JN - First Coast Service Options, Inc. (Part A/B MAC)  | FL, PR, U.S. VI                                 |

## Description

**Transcatheter peripheral vascular stent placement** is a minimally invasive procedure used to improve blood flow in obstructed (blocked) or stenosed (narrowed) arteries and veins in the abdomen, extremities or organs as an alternative to open vascular surgery. A stent (small wire mesh tube) is used in cases where percutaneous transluminal angioplasty (PTA) alone is not expected to provide a durable result or as an adjunct to suboptimal PTA. To place the stent with PTA, a catheter (thin, hollow tube) with a balloon at the tip is inserted through a vessel in the arm, groin or neck and guided to the location of the obstruction or stenosis. The balloon is inflated to expand the artery or vein and improve blood flow. Guided to the affected area, a delivery catheter places the stent to keep the vessel open.

Angiography or intravascular ultrasound (IVUS) is used during the PTA to produce images of the vascular lumen (interior of the vessel) and guide the stent placement procedure. Angiography uses an injection of radiopaque contrast dye to obtain x-ray images of the blood vessels to detect abnormalities. IVUS uses high-frequency sound waves to provide images of the blood vessel lumen to delineate plaque and lesion characteristics and distribution. Both techniques are used to evaluate blood vessel characteristics to guide treatment decisions including stent size and positioning.

A variety of conditions may be treated with transcatheter peripheral vascular stent placement, including but not limited to:

- **Brachiocephalic or subclavian artery stenosis** – Reduced blood flow through the brachiocephalic or subclavian arteries may occur with a number of conditions including, but not limited to, atherosclerosis (plaque buildup), external compression, radiation-induced arteriopathy, subclavian steal syndrome (SSS), Takayasu arteritis or thromboembolism. Exercise-induced arm pain, fatigue, numbness or upper extremity pain at rest may occur with subclavian steal syndrome when a subclavian artery occlusion or stenosis creates a flow reversal away from the arm on the same side of the body. Other symptoms include, but may not be limited to, dizziness, syncope or vertigo with upper-extremity exertion.
- **Celiac artery compression syndrome** (eg, celiac axis syndrome, Dunbar syndrome, median arcuate ligament syndrome [MALS]) – Compression of the celiac artery by the median arcuate ligament can cause chronic recurrent abdominal pain. Symptoms including, but not limited to, abdominal bruit, postprandial (after a meal) pain and unintentional weight loss may occur with reduced blood flow in the celiac artery. Treatment of symptomatic celiac artery compression aims to restore celiac blood flow by laparoscopic decompression of the celiac artery. For persistent or recurring symptoms, angioplasty and stent placement may be performed.
- **Chronic mesenteric ischemia** – Occlusions of the celiac, superior mesenteric or inferior mesenteric arteries can lead to mesenteric ischemia due to inadequate blood flow to the intestines. Mesenteric artery stenosis is most often caused by atherosclerosis and can cause chronic symptoms of diarrhea, food fear, postprandial pain and weight loss.
- **Hemodialysis (HD) arteriovenous (AV) fistula or graft stenosis or thrombosis** – A stenotic lesion can develop and cause narrowing at any point in the HD access circuit where there is turbulent blood flow. As the lesion progresses, it decreases blood flow and can lead to failure of the AV fistula or graft and inability to successfully manage hemodialysis.
- **Hepatic venous outflow tract obstruction** (eg, Budd-Chiari syndrome) – Primary Budd-Chiari syndrome is caused by obstruction due to a predominantly venous process (eg, phlebitis, thrombosis), whereas secondary Budd-Chiari syndrome occurs with compression of the hepatic veins and/or the inferior vena cava by a lesion outside the vein (eg, malignancy, tumor). Left untreated, Budd-Chiari syndrome can cause ascites, hepatic necrosis and liver failure.
- **Iliac vein compression syndrome** (eg, May-Thurner syndrome, also known as ilio caval venous outflow tract obstruction or Cockett's syndrome) – Extrinsic compression of the left iliac vein by the arterial system against bony structures in the ilio caval territory results in interrupted blood flow through the legs back to the heart. This may cause pooling of blood in the legs and lead to deep vein thrombosis (DVT) with associated pain, swelling and/or ulcers (open sores).
- **Iliocaval and iliofemoral venous obstruction** – Venous obstruction in the systemic veins of the abdomen and pelvis can be due to one of several etiologies including, but not limited to, an endoluminal obstruction related to an endoluminal device, thrombosis or vein wall injury. Most etiologies are predominantly thrombotic or nonthrombotic but may lead to thrombosis depending on the severity of

the obstruction. Obstruction of the iliac veins and/or vena cava may result in severe lower extremity symptoms including, but not limited to, chronic pain, edema and nonhealing ulcerations.

- **Peripheral vascular disease** – Stenosis or obstruction occurs when blood flow is restricted in vessels that lead to the upper extremities and internal organs (eg, kidneys, stomach). Venous stenosis in the upper extremities most commonly affects the axillary, brachial, cephalic or brachiocephalic veins, or the superior vena cava, but can also affect the central veins in the abdomen.<sup>19</sup> Common causes include, but may not be limited to, embolism, extrinsic compression, thrombosis or stenosis from placement of central venous catheters, hemodialysis catheters and pacemaker leads.
- **Renal artery stenosis (RAS)** – A progressive narrowing of the renal artery, most commonly due to atherosclerosis, is a cause of hypertension, ischemic nephropathy and destabilizing cardiac syndromes. RAS is often asymptomatic, although resistant hypertension may be evidenced by a lack of blood pressure control on optimal guideline-directed medical therapy including 3 maximally dosed antihypertensives, one of which is a diuretic. Fibromuscular dysplasia is a less common cause of RAS with anatomy that may be unfavorable to stent placement and is typically treated with medication, angioplasty or surgical revascularization.
- **Suboptimal or failed PTA** – A suboptimal or failed PTA may occur when the vascular dilation is unsuccessful. This may be due to the presence of unfavorable lesion morphology (structure) including, but not limited to, residual stenosis of more than 30% for a vein measured at the narrowest point of the vascular lumen at the site of the angioplasty or more than 50% reduction of lumen diameter; a tear in the intima (inner lining) or vascular lumen; or persistent occlusion or dissection at the angioplasty site, elastic recoil occlusion or refractory spasm.
- **Superior vena cava syndrome** – Blood flow is reduced or blocked by either the direct invasion or external compression of the vessel by a benign or malignant tumor, stenosis caused by post-radiation vasculopathy (radiation-induced vascular stenosis) or thrombosis.

### Coverage Determination

*iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:*

**Transcatheter intravascular stent placement for cervical/intrathoracic carotid, coronary, extracranial vertebral, intracranial, or lower extremity (for occlusive disease) arteries and femoral-popliteal or tibial-peroneal venous segments are not addressed in this medical coverage policy.**

### Transcatheter Peripheral Arterial Stent Placement

**Transcatheter peripheral (noncoronary) ARTERIAL stent placement** with an FDA-approved stent will be considered medically reasonable and necessary when the following requirements are met:

- Individual has had a thorough evaluation and treatment of symptoms and when PTA of the vessel alone has not, or is not expected to sufficiently resolve the symptoms making surgery the likely alternative<sup>20</sup>;

**AND one or more** of the following indications:

- A noncoronary intravascular stent(s) that carries an Investigational Device Exemption (IDE) may be covered under Medicare. Medicare coverage of IDE devices is predicated, in part, upon their status with the FDA. The FDA issues a special identifier number that corresponds to each device or stent(s) granted an IDE<sup>20</sup>; **OR**
- Brachiocephalic or subclavian artery stenosis (eg, atherosclerosis, external compression, radiation-induced arteriopathy, subclavian steal syndrome, Takayasu arteritis, thrombo-embolism); **AND**
  - Diagnosis confirmed by computed tomography angiography (CTA);

**AND EITHER** of the following:

- Symptoms with upper-extremity exertion such as dizziness, and/or lightheadedness, and/or syncope and/or vertigo; **OR**
- Upper extremity ischemia (eg, arm and/or hand claudication, and/or paresthesia and/or rest pain and/or non-healing tissue ulceration or focal gangrene); **OR**
- Pulmonary artery PTA and stenting may be indicated for certain people with congenital pulmonary artery stenosis<sup>20</sup>; **OR**
- Renal artery and **one or more** of the following:
  - Anatomically challenging or high-risk lesion (early bifurcation, small vessel, severe concentric calcification and/or severe aortic atheroma or mural thrombus)<sup>20</sup>; **OR**
  - Aneurysm<sup>20</sup>; **OR**
  - Atherosclerosis greater than 50% in a transplanted kidney<sup>20</sup>; **OR**
  - Dissection<sup>20</sup>; **OR**
  - Flash pulmonary edema or acute coronary syndrome (ACS) with severe hypertension<sup>20</sup>; **OR**
  - Ischemic neuropathy with chronic kidney disease with estimated glomerular filtration rate (eGFR) less than 45 cc/min and global renal ischemia (unilateral significant renal artery stenosis with a solitary kidney or bilateral significant renal artery stenosis) without other explanation<sup>20</sup>; **OR**

- Resistant hypertension (uncontrolled hypertension with failure of maximally tolerated doses of at least three antihypertensive agents, one of which is a diuretic, or intolerance [hemodynamic instability] to medications)<sup>20</sup>; **OR**
- Unilateral renal artery stenosis with chronic kidney disease (eGFR less than 45 cc/min)<sup>20</sup>; **OR**
- Unilateral renal artery stenosis with prior episodes of congestive heart failure ([Stage C](#))<sup>20</sup>; **OR**
- Salvage of thrombosed or stenotic arteriovenous dialysis access fistula or graft with compromised arterial inflow or venous outflow (narrowing of the vascular lumen greater than or equal to 50%) confirmed by imaging for **one or more** of the following indications<sup>19</sup>:
  - Aneurysm or pseudoaneurysm present<sup>19</sup>; **OR**
  - Central venous stenosis or occlusion<sup>19</sup>; **OR**
  - Graft salvage (eg, PTA is unsuccessful due to elastic recoil or stenosis has recurred at less than 3 months)<sup>19</sup>; **OR**
  - Percutaneous transluminal angioplasty (PTA) induced rupture<sup>19</sup>; **OR**
- Suboptimal or failed percutaneous transluminal angioplasty (PTA) due to the presence at the angioplasty site of **one or more** of the following:
  - Acute vessel occlusion immediately post-PTA; **OR**
  - Flow-limiting dissection; **OR**
  - Occlusion elastic recoil or refractory spasm<sup>19</sup>; **OR**
  - Recurrence of lesion with a greater than or equal to 50% reduction of lumen diameter within 12 months post-PTA; **OR**
  - Residual stenosis greater than or equal to 30% at the narrowest point of the vascular lumen or resulting in greater than or equal to 50% reduction in vessel diameter<sup>19</sup>; **OR**
  - Tear that interrupts the integrity of the intima or lumen causing hemorrhage<sup>19</sup>; **OR**
  - Trans-stenotic pressure gradient greater than or equal to 5 mmHg; **OR**
- Treatment of mesenteric arteries for acute mesenteric ischemia, chronic mesenteric ischemia, mesenteric thrombosis, dissection or other vascular insufficiency:

**AND ALL** the following:

- Angioplasty of the vessels alone would not suffice<sup>20</sup>; **AND**
- A thorough medical evaluation and treatment plan has been completed<sup>20</sup>; **AND**
- Chronic mesenteric ischemia with stenosis is defined as greater than 70% within the celiac axis and/or superior mesenteric artery (SMA) and confirmed by CTA, duplex Doppler ultrasound or MRA; **AND**
- Gastrointestinal symptoms (eg, diarrhea, and/or food fear, and/or postprandial pain and/or weight loss); **AND**
- Surgery is the likely alternative to this procedure<sup>20</sup>

### **Transcatheter Peripheral Venous Stent Placement**

**Transcatheter peripheral VENOUS stent placement** with an FDA-approved stent will be considered medically reasonable and necessary when the following requirements are met:

- Individual has had a thorough evaluation and treatment of symptoms and when PTA of the vessel alone has not, or is not expected to sufficiently resolve the symptoms making surgery the likely alternative<sup>20</sup>;  
**AND one or more** of the following indications:
  - Adjunct to catheter-directed thrombolysis for acute femoroiliocaval deep vein thrombosis when post thrombolysis imaging identifies symptomatic residual stenosis<sup>20</sup>; **OR**
  - A noncoronary intravascular stent(s) that carries an Investigational Device Exemption (IDE) may be covered under Medicare. Medicare coverage of IDE devices is predicated, in part, upon their status with the FDA. The FDA issues a special identifier number that corresponds to each device or stent(s) granted an IDE<sup>20</sup>; **OR**
  - Hepatic venous outflow obstruction (eg, Budd-Chiari syndrome) and **BOTH** of the following:
    - Diagnosis confirmed by computed tomography (CT), Doppler ultrasound or magnetic resonance imaging (MRI); **AND**
    - Symptoms such as abdominal pain, and/or distension and/or hepatomegaly<sup>19</sup>; **OR**
  - Iliac vein compression syndrome (eg, ilio caval venous outflow tract obstruction, May-Thurner or Cockett syndrome) and **BOTH** of the following:
    - Diagnosis confirmed by CTA or MRA with venography (greater than 50% luminal stenosis of the iliac vein and loss of contrast density at the point the iliac artery crosses the vein)<sup>16,47</sup>; **AND**
    - Moderate to severe symptoms (limb swelling, and/or pain and/or Clinical, Etiologic, Anatomic, Pathophysiologic [CEAP] clinical [classes 4 to 6](#) hyperpigmentation and/or ulceration<sup>47</sup>; **OR**

- Iliocaval venous occlusion with **BOTH** of the following:
  - Diagnosis confirmed by venous duplex ultrasound; **AND**
  - Moderate to severe symptoms (pain, and/or swelling and/or CEAP clinical [classes 3 to 6](#) hyperpigmentation and/or ulceration)<sup>49</sup>; **OR**
- Iliofemoral venous obstruction confirmed by Doppler ultrasound, CT or magnetic resonance venography (MRV);  
  
AND **one or more** of the following:
  - Symptoms (eg, edema and/or pain that limits daily functioning) not relieved by conservative therapies (eg, compression and/or medication); **OR**
  - Venous lower extremity ulceration; **OR**
- Post-operative stenosis or venous narrowing due to repair of congenital cardiac disease (eg, sinus venosus Atrial Septal Defect (ASD), discordant atrioventricular connection status post Mustard or Senning repair of transposition of the great arteries [TGA])<sup>19</sup>; **OR**
- Post radiation venous stenosis<sup>19</sup>; **OR**
- Post-thrombotic syndrome (PTS)<sup>19</sup>; **OR**
- Pulmonary vein stenosis greater than or equal to 60% stenosis and **BOTH** of the following:
  - Diagnosis confirmed by echocardiography and/or CTA; **AND**
  - Stenosis resulting from congenital malformation, extrinsic compression, sequelae of radiofrequency ablation (RFA), lung transplantation or post repair of total anomalous pulmonary vein return (TAPVR)<sup>19</sup>; **OR**
- Suboptimal or failed percutaneous transluminal angioplasty (PTA) due to the presence at the angioplasty site of **ANY** of the following:
  - Acute vessel occlusion immediately post-PTA; **OR**
  - Flow-limiting dissection; **OR**
  - Occlusion elastic recoil or refractory spasm; **OR**
  - Recurrence of lesion with a greater than or equal to 50% reduction of lumen diameter within 12 months post-PTA; **OR**



- Residual stenosis greater than or equal to 30% at the narrowest point of the vascular lumen or resulting in greater than or equal to 50% reduction in vessel diameter; **OR**
- Tear that interrupts the integrity of the intima or lumen causing hemorrhage<sup>19</sup>; **OR**
- Trans-stenotic pressure gradient greater than or equal to 5 mmHg; **OR**
- Superior vena cava and subclavian/innominate veins stents to treat congenital stenosis and/or thrombosis and/or embolism, including acute thrombophlebitis<sup>20</sup>; **OR**
- Superior vena cava syndrome and **BOTH** of the following:
  - Diagnosis confirmed by CT, duplex Doppler ultrasound or MRI; **AND**
  - Source of obstruction is malignant compression, and/or post radiation stenosis and/or thrombosis); **OR**
- Symptomatic post-traumatic venous stenosis including those resulting from central venous catheters or transvenous device (eg, defibrillators, pacemakers), pacemaker leads or a history of abdominal and/or pelvic surgery<sup>19</sup>; **OR**
- Thrombosis and embolism<sup>20</sup>; **OR**
- Transvenous decompression of portosystemic shunts<sup>19</sup>

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following **transcatheter intravascular stent** placements will not be considered medically reasonable and necessary:

- A noncoronary intravascular stent(s) that has had a withdrawal of FDA Investigational Device Exemption (IDE) approval<sup>20</sup>; **OR**
- Placement of a stent in a vessel for which there is no objective-related symptom or limitation of function that is considered to be preventive<sup>20</sup>

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description   | Comments |
|--------------|---|----------|
| 36245        | Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family   |          |
| 36246        | Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family   |          |
| 36247        | Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family  |          |
| 37221        | Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed  |          |
| 37236        | Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery   |          |
| 37237        | Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure) |          |
| 37238        | Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein  |          |

| 37239                           | Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (List separately in addition to code for primary procedure) |          |
|---------------------------------|--|----------|
| 37252                           | Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)                            |          |
| 37253                           | Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)                    |          |
| CPT®<br>Category III<br>Code(s) | Description  | Comments |
| No code(s) identified           |  |          |
| HCPCS<br>Code(s)                | Description  | Comments |
| No code(s) identified           |  |          |

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## Appendix

### Appendix A

#### CEAP Classification for Chronic Venous Disorders<sup>49</sup>

| Clinical Classification | Description   |
|-------------------------|---|
| C0                      | No visible or palpable signs of venous disease                              |
| C1                      | Telangiectasias, reticular veins  |
| C2                      | Varicose veins  |
| C2r                     | Recurrent varicose veins  |
| C3                      | Edema   |
| C4                      | Changes in skin and subcutaneous tissue secondary to chronic venous disease |
| C4a                     | Pigmentation or eczema  |
| C4b                     | Lipodermatosclerosis or atrophie blanche                                    |
| C4c                     | Corona phlebectatica  |
| C5                      | Healed venous ulcer   |
| C6                      | Active venous ulcer   |
| C6r                     | Recurrent active venous ulcer   |

### Appendix B

#### Stages in the Development of Heart Failure (HF)<sup>42</sup>

| Stage | Description  |
|-------|--|
| A     | At high risk for HF but without structural heart disease or symptoms of HF.  |
| B     | Structural heart disease but without signs or symptoms of HF. This stage includes the individual in New York Heart Association (NYHA) functional class I with no prior or current symptoms or signs of HF. |
| C     | Structural heart disease with prior or current symptoms of HF. This stage includes the individual with any NYHA functional class (including class I with prior symptoms).                                  |
| D     | Refractory HF requiring specialized interventions. This stage includes the individual in NYHA functional class IV with refractory HF.  |

## Change Summary

- 01/01/2024 New Policy.

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