

Peripheral Artery Revascularization of the Lower Extremities



INDEPENDENT CARE HEALTH PLAN

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Medical Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

Transcatheter Peripheral Vascular Stents – Chest, Abdomen and Pelvis

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)	20.7		
LCD LCA	Non-Coronary Vascular Stents	L35998 A57590	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE, Part A MAC only for all states except MN and NY IN, MI

Description

Peripheral artery disease (PAD) is a chronic circulation disorder in which the arteries that supply blood to the extremities (arms, legs) are abnormally narrow and cannot keep up with demand. This usually occurs in the lower extremities.

Atherosclerosis, the accumulation of fatty deposits called plaques, is often a cause of PAD. The arteries that may be involved in PAD include the aortoiliac (common iliac, external iliac), infrainguinal (femoral, popliteal or infrapopliteal [tibial, peroneal or pedal]). Affected arteries may become limited in their ability to supply blood to tissues from plaque buildup or completely blocked due to the plaques rupturing or forming clots.

More advanced PAD symptoms in the lower extremities indicating a significant or complete artery blockage include the following:

- **Claudication**, also known as **intermittent claudication**, is characterized by fatigue, discomfort, cramping or pain of vascular origin in the muscles of the lower extremities that is consistently caused by exercise and consistently relieved by rest (within 10 minutes).⁴
- **Critical/chronic limb ischemia (CLI)** characterized by chronic (greater than two weeks) ischemic rest pain, nonhealing wound/ulcers or gangrene in one or both legs attributable to objectively proven arterial occlusive disease by ankle-brachial index (ABI), toe-brachial index (TBI), transcutaneous oximetry or oxygen tension measurement (TcPO₂) or skin perfusion pressure testing.⁴

The management of individuals with lower extremity PAD is aimed at relieving symptoms and lowering the risk of cardiovascular disease progression and complications. Medical management involves cardiovascular risk factor reduction, lifestyle modification and other pharmacologic therapies.

For those with significant or disabling symptoms of claudication unresponsive to lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be reasonable. For individuals with CLI, revascularization is a priority to establish arterial blood flow.²⁰

Endovascular revascularization interventions are surgical procedures in which a catheter containing medications or miniature instruments are inserted through the skin or under direct visualization after open exposure of the artery for the treatment of vascular disease. Most endovascular procedures are performed percutaneously but can be performed via open access if needed. Endovascular treatment options include the following:

- **Angioplasty** involves a catheter with a tiny balloon at the tip is inserted into an artery that has been narrowed by the accumulation of fatty deposits and the balloon is inflated to clear and widen the arterial opening.
- **Atherectomy** involves surgical removal of atherosclerotic plaque from an artery using a catheter fitted with a cutting device.
- **Stents** (mesh or metal) are used to support a cleared vessel and maintain patency.

Peripheral aneurysms located within the popliteal arteries may be asymptomatic or present with ischemic symptoms such as claudication. Repair of popliteal aneurysms may be endovascular stent-grafting or open surgical bypass.¹⁹ During the bypass procedure, blood flow is redirected around the aneurysm with the help of a vein or synthetic graft. The aneurysm is then removed or tied off to prevent blood from refilling the aneurysm.

Surgical bypass procedures for PAD are not discussed in the context of this policy.

The **PQ Bypass DETOUR System** is a fully percutaneous femoral-popliteal bypass system that uses fluoroscopic guidance to move a covered stent graft from the popliteal artery into the femoral vein and from the femoral vein into the superficial femoral artery in an overlapping manner using two independent interconnections or anastomoses. The system purportedly treats large lesions (greater than 15 centimeters) by creating a large lumen stent bypass that allows unobstructed blood flow from the superficial femoral artery to the popliteal artery.

Another surgical technique aimed at providing an option for an individual with chronic limb-threatening ischemia who have limited options, except amputation, is an **endovascular venous arterialization of the tibial or peroneal vein with transcatheter placement of intravascular stent graft(s)**. Catheters are inserted under ultrasound guidance into the tibial vein at the level of the ankle and into the femoral artery at the level of the groin. Both catheters are advanced simultaneously toward each other and ultrasound waves are emitted by the arterial catheter toward the receiving venous catheter to assist the physician in determining the most optimal location for channel creation from the artery to the vein. A device consisting of a small

basket with minute incision hooks is introduced to cut through valves near the bottom of the foot to maximize the arterial flow to the vein into the foot. The severed valves are rendered incompetent, allowing oxygenated blood to flow forward and into the foot. Several self-expanding covered metal stents are then placed to act as permanent conduits for blood flow to the foot.

Intravascular lithotripsy (IVL) combines ultrasound mechanical pulse waves with angioplasty to purportedly treat calcified plaque in stenotic or occluded peripheral arteries. The system consists of a single-use proprietary balloon catheter, a reusable generator, and a reusable connector cable. The balloon catheter has integrated lithotripsy emitters designed to enhance angioplasty by disrupting calcified lesions before balloon revascularization. IVL has also been proposed to treat calcified lesions during transcatheter aortic valve implantation. The Shockwave peripheral intravascular lithotripsy system is an example of such a device.

Coverage Determination

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

Please refer to the above CMS guidance for **percutaneous transluminal angioplasty (PTA)**.

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

Endovascular revascularization procedure of the lower extremities (aorto-iliac and superficial femoral arteries only) will be considered medically reasonable and necessary when the following requirements are met:

- CLI when limb-threatening lower extremity ischemia is present and documented; **OR**
- Claudication when with ALL of the following have been met:
 - Inadequate response to three months of [medical management](#) within the past 12 months¹; **AND**
 - Impairment of activities of daily living and work; **AND**
 - Individual has undergone a home exercise program; **AND**
 - Presence of anatomically suitable lesion for intervention (Noninvasive imaging (computed tomography [CTA], duplex ultrasound or magnetic resonance angiography [MRA]) confirmation of anatomic location and stenosis severity of 70% or greater)

*Medical management includes Class I recommendations for antiplatelet therapy, statins, home exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed

Endovascular revascularization procedure of the lower extremities (*infrapopliteal artery only*) will be considered medically reasonable and necessary when the following requirement is met:

- PTA and stent placement in infrapopliteal vessels is not expected to be often indicated and the rationale for stent placement must be thorough explained in the record (eg, Chronic limb-threatening ischemia)

Non-coronary stents can be approved only if they are US Food & Drug Administration (FDA) approved. Non-coronary vascular stents are covered only after a thorough examination and treatment of symptoms, and when percutaneous transluminal angioplasty (PTA) of the vessel alone has not, or is not expected to, adequately alleviate the symptoms, making surgery the likely alternative.⁵

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](#)

Peripheral revascularization of the lower extremities (*aorto-iliac, infrapopliteal, or superficial femoral arteries*) will not be considered medically reasonable and necessary for the following indications:

- The placement of a stent in a vessel for which there is no objective-related symptom or limitation of function is considered to be preventive, and therefore, not covered by Medicare.⁵
- A non-coronary 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. Payment will cease in the event a manufacturer loses (or violates relevant IDE requirements necessitating FDA's withdrawal of) IDE approval. The FDA issues a special identifier number that corresponds to each device or stent(s) granted an IDE.⁵

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.

Peripheral Artery Revascularization of the Lower Extremities

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	
36248	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)	
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty	
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	
37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	
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)	
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	

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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	
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with 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	
37232	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	
37233	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	
37234	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	
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)	
CPT® Category III Code(s)	Description	Comments

Peripheral Artery Revascularization of the Lower Extremities

0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	
HCPCS Code(s)	Description	Comments
C7531	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal angioplasty with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation	
C7534	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with atherectomy, includes angioplasty within the same vessel, when performed with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation	
C7535	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(ies), unilateral, with transluminal stent placement(s), includes angioplasty within the same vessel, when performed, with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation	
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed	

C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	
C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9767	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed	
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed	

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Change Summary

- 01/01/2024 New Policy.
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