Lower Extremity Endovascular Procedures (for Kansas Only)

Policy Number: CS166KS.01
Effective Date: June 1, 2025

➲ Instructions for Use

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Related Policies

- Pneumatic Compression Devices (for Kansas Only)
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Kansas Only)

Application

This Medical Policy only applies to the state of Kansas.

Coverage Rationale

Note: This policy does not apply to upper extremities.

Endovascular revascularization procedures (e.g., stents, angioplasty, and/or atherectomy) for treating lower extremity ischemia are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Endovascular Intervention, Peripheral Artery.

Click here to view the InterQual® criteria.

Transluminal peripheral atherectomy of the iliac artery is unproven and not medically necessary due to insufficient evidence of efficacy.

Endovenous femoropopliteal bypass using a stent graft is unproven and not medically necessary for treating peripheral artery disease due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel

CPT Code	Description
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
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
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)

Description of Services

Peripheral artery disease (PAD) is a narrowing of vessels due to atherosclerosis that limits blood flow to the limbs. PAD most commonly affects arteries in the legs. While many people with PAD do not have any symptoms, some will have leg pain, numbness, or cramping during exercise that is relieved by rest (Claudication). Risk factors include age, smoking, diabetes, obesity, high blood pressure, and high cholesterol.

PAD is associated with an increased risk of heart attack, stroke, and, when left untreated, can lead to CLTI. Treatment options include lifestyle changes, medications, endovascular techniques, and surgery. Endovascular techniques to treat Claudication and Chronic Limb Threatening Ischemia (CLTI) include balloon dilation (angioplasty), stents, endovenous stent grafts, and atherectomy. The technique chosen for endovascular treatment depends on many factors including lesion characteristics such as anatomic location, lesion length, and degree of calcification (Gornik et al., 2024; National Heart, Lung, and Blood Institute website).

Clinical Evidence

The Best Endovascular Versus Best Surgical Therapy for Patients With Critical Limb Ischemia (BEST-CLI) Trial was a prospective, open label, multicenter, randomized controlled, multidisciplinary, superiority trial comparing treatment efficacy, functional outcomes, and quality of life in patients undergoing endovascular or open surgical revascularization. Clinical sites in the United States and internationally enrolled 1830 patients with chronic limb-threatening ischemia (CLTI) and infrainguinal PAD who were candidates for both treatment options. Patients were enrolled into one of two parallel trial cohorts. Patients with suitable single segment of great saphenous vein available for potential bypass were randomized within Cohort 1 (n = 1620), while patients without were randomized within Cohort 2 (n = 480). The primary outcome was a composite of a major adverse limb event (amputation above the ankle or a major limb reintervention) or death from any cause. In Cohort 1, after a median follow-up of 2.7 years, the incidence of a major adverse limb event or death was significantly lower in the surgical group than in the endovascular group. In Cohort 2, after a median follow-up of 1.6 years, the outcomes in the two groups were similar. The incidence of adverse events was similar in the two groups. Because investigators were allowed to use their preferred techniques, there was a potential for selection and operator bias. Also, due to funding issues, the follow-up was longer in Cohort 1 than Cohort 2 (Farber et al., 2022). The study was funded by the National Heart, Lung and Blood Institute.

A Cochrane systematic review by Fakhry et al. (2018) assessed the effectiveness of endovascular revascularization compared with no specific therapy for intermittent claudication or compared with a conservative therapy option such as supervised exercise or drug therapy. The review included ten studies with a total of 1,087 participants. The results showed that endovascular revascularization and supervised exercise are comparable treatment options in improving walking distances and quality of life in individuals with intermittent claudication. Combination therapy (endovascular revascularization with either supervised exercise or drug therapy) seemed to result in greater improvements than those seen with supervised exercise or drug therapy alone. (The ERASE trial by Fakhry et al., 2015 and the CLEVER trial by Murphy et al., 2015, which were previously cited in this policy, are included in this systematic review)
Malgor et al. (2015) conducted a systematic review to evaluate the efficacy of three treatment strategies for individuals with claudication. Primary outcome measures included mortality, amputation, walking distance, quality of life, patency, and measures of blood flow (ABI). The review included eight systematic reviews and 12 trials enrolling 1,548 patients. Compared with medical management, each of the three treatments (surgery, endovascular therapy, and exercise therapy) was associated with improved walking distance, claudication symptoms and quality of life. Evidence supporting superiority of one of the three approaches was limited. However, blood flow parameters improved faster and better with both forms of revascularization compared with exercise or medical management. Compared with endovascular therapy, open surgery may be associated with longer length of hospital stay and higher complication rates but resulted in more durable patency (moderate-quality evidence). (The CLEVER trial by Murphy et al., 2012, which was previously cited in this policy, is included in this systematic review).

Vemulapalli et al. (2015) conducted a systematic review and a network meta-analysis to evaluate the comparative effectiveness of medical therapy, supervised exercise training, endovascular intervention and surgical revascularization in patients with claudication. Outcomes assessed included walking distance, claudication distance, all-cause mortality and quality of life. Thirty-five studies (n = 7,475) were included in the analysis. A meta-analysis of 16 studies suggested that, compared with usual care, maximal walking measures were improved to a greater extent with supervised exercise than with medical therapy or endovascular intervention. A meta-analysis of 12 studies demonstrated that exercise training and endovascular intervention, but not cilostazol, improved initial claudication measures compared with usual care. A meta-analysis of 13 studies suggested that although all treatment modalities were superior to usual care, there was no significant difference between modalities in respect to quality of life. The authors noted that heterogeneity in functional endpoints, single-arm observational study design and poor subgroup reporting significantly limit comparative effectiveness analysis in PAD. Further studies with attention to study design, standardized efficacy and safety endpoints, and appropriate subgroup reporting are needed. (The multicenter CLEVER trial by Murphy et al., 2012, which was previously cited in this policy, is included in this systematic review)

Iliac Artery Atherectomy

Insufficient quality evidence exists to support the efficacy and safety of iliac artery atherectomy.

Atherectomy of the iliac artery is uncommon due to the risk of life-threatening perforation. Lee et al. (2018) assessed the feasibility and safety of orbital atherectomy for the treatment of iliac artery disease using retrospective data from the CONFIRM registries. Patients with at least one iliac artery lesion treated with orbital atherectomy (n = 62 patients; n = 68 lesions) were compared to patients with at least one superficial femoral artery lesion treated with orbital atherectomy (n = 1570 patients; n = 1809 lesions). Both groups had similar baseline demographics; however, the iliac artery group had a lower prevalence of diabetes. For lesion characteristics, the iliac artery group had shorter lesions and a higher percentage of severely calcified lesions. Procedural complication rate was defined as the composite of flow limiting dissection, perforation, slow flow, vessel closure, spasm, embolism, or thrombosis. The iliac group had one reported perforation and one reported vessel closure. The procedural complication rate was low in both groups; however, it was significantly lower in the iliac artery group. The authors note that a randomized trial with long-term follow-up is needed to determine the ideal revascularization strategy for patients with calcified iliac artery disease. The study is limited by the possible bias associated with the observational design.

Endovenous Femoropopliteal Bypass

The DETOUR system utilizes a novel endovenous femoropopliteal bypass procedure for treating patients with moderate to severe PAD who have long occlusive lesions of the superficial femoral artery. The system uses stents routed through the femoral vein to restore blood flow to the leg. Clinical trials are ongoing. Larger high-quality studies evaluating the safety and efficacy of the procedure and comparing the DETOUR system with open surgical bypass are needed.

An ECRI Clinical Evidence Assessment stated that the DETOUR stent graft system appears to be safe and provides a less invasive treatment option for patients who may otherwise require open bypass surgery. Two available single-arm clinical trials reported participants experienced functional improvements one to three years after treatment with the DETOUR system, with relatively high primary patency and freedom from adverse events despite their lesion's large size and severity. However, available studies provide very-low-quality evidence that does not enable firm conclusions, and no studies compared the DETOUR system with other treatments for long-segment femoropopliteal occlusions and their effect on patient-oriented outcomes including adverse events, revascularization, and functional status (ECRI, 2023).

In an Emerging Technology Report, Hayes found that published evidence supporting the DETOUR system is limited to the results of the DETOUR I study, which has up to 3-year follow-up data for a subset of trial participants. Technical and procedural success was reported to be high. The DETOUR system appears to be a promising alternative to surgical bypass in patients with long occlusions in the superficial femoral artery. However, published results from the pivotal trial and additional studies comparing the DETOUR system with open surgical bypass are needed to better characterize the effectiveness and safety of the system and procedure (Hayes, 2022; updated 2023).

The DETOUR 2 investigational device exemption study is an ongoing prospective, single-arm, multicenter non-randomized study to evaluate the safety and effectiveness of the DETOUR system for percutaneous femoropopliteal bypass. A total of 202 participants in the United States and Europe with severe femoropopliteal artery disease were enrolled, with 200 treated with the DETOUR system. Prespecified end points included primary safety (composite of major adverse events) at 30 days, and effectiveness (primary patency defined as freedom from restenosis or clinically driven target lesion revascularization) at one year. The mean lesion length was 32.7 cm, of which 96% were chronic total occlusions and 70% were severely calcified. Technical success was achieved in 100% of treated patients. The primary safety end point was met with a 30-day freedom from major adverse event rate of 93.0%. The 1-year primary effectiveness end point was met with 72.1% primary patency at 12 months. Primary-assisted and secondary patency were 77.7% and 89.0%, respectively, at 12 months. The 12 month deep venous thrombosis incidence was 4.1% with no pulmonary emboli reported. Venous quality-of-life scores showed no significant changes from baseline. There was a Rutherford improvement of at least one class through 12 months in 97.2% of patients. The mean ankle-brachial index (ABI) also improved from 0.61 to 0.95 during this period. The authors also noted marked improvements in quality of life and functional status measures. This study is limited by lack of randomization, long-term follow-up and comparison to open surgical bypass (Lyden et al., 2024).

DETOUR I was a prospective, single-arm, multicenter non-randomized study with 78 participants. Technical and procedural success during the index procedure were both 96%. Primary stent graft patency rates were 81% at year one and 79% at year two. The authors concluded the DETOUR system was a safe and effective percutaneous alternative to open surgical bypass (Krievins et al., 2020; Halena et al, 2022). Due to the novel transvenous approach of the DETOUR system and risk of thromboembolic complications, venous outcomes were also evaluated in the DETOUR I study. At one year, Schneider et al. (2021) reported a low rate of deep venous thrombotic and obstructive complications. Cross-sectional femoral vein luminal area was preserved, and in some participants, the compensatory vein diameter increased over time. After evaluating a subset of patients enrolled at one study site, Rumba et al. (2022) reported three-year results. (This study is included in the ECRI 2023 report). The femoral and popliteal vein remained patent with no compensatory

enlargement, and there were no significant changes in venous symptom scores or physiologic function. The study is limited by the single-arm study design.

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Interventional Radiology (SIR)/Society for Vascular Medicine (SVM)

In a multi-society report, Bailey et al. (2019) published appropriate use criteria for peripheral artery interventions. The panel recommends that patients with PAD and intermittent claudication should first be treated with guideline-directed medical therapy and structured exercise. Revascularization should be considered only in patients who continue to have lifestyle-limiting claudication despite these noninvasive approaches. In situations where medical therapy is insufficient, the selection of surgical or endovascular revascularization depends on several factors including patient risk level and lesion characteristics, such as anatomic location, length and presence of stenosis or occlusion. The criteria indicate that atherectomy of the iliac artery is rarely appropriate in all clinical scenarios. This rating is due to an absence of data supporting the use of this technology compared with balloon angioplasty and stenting. For patients with CLTI, both endovascular or surgical revascularization procedures are considered appropriate and critical for the reduction of high morbidity and mortality rates associated with limb loss and cardiovascular events.

American Heart Association (AHA)/American College of Cardiology (ACC)

AHA/ACC guidelines for the management of lower extremity PAD address revascularization procedures for atherosclerotic and thrombotic disease and include diseases of the aortoiliac, femoropopliteal, and infrapopliteal arterial segments. The guidelines were developed in collaboration with the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American Podiatric Medical Association (APMA), Association of Black Cardiologists (ABC), Society for Cardiovascular Angiography and Interventions (SCAI), Society for Vascular Medicine (SVM), Society for Vascular Nursing (SVN), Society for Vascular Surgery (SVS), Society of Interventional Radiology (SIR), and Vascular & Endovascular Surgery Society (VESS) (Gornik et al., 2024).

International Working Group on the Diabetic Foot (IWGDF)

IWGDF guidelines on the prevention and management of diabetes-related foot disease state that in patients with either an ankle pressure < 50mm Hg or an ABI < 0.4, consider urgent vascular imaging, always with detailed visualization of below-the-knee and pedal arteries, and revascularization. Also consider urgent assessment for revascularization if the toe pressure is < 30 mmHg or $TcPO_2$ is < 25 mmHg. Clinicians might also consider revascularization at higher pressure levels in patients with extensive tissue loss or infection (Schaper et al., 2024).

National Institute for Health and Care Excellence (NICE)

A National Institute for Health and Care Excellence (NICE) clinical guideline offers recommendations on the management of PAD (NICE, 2012; updated 2020).

Society for Vascular Surgery (SVS)

SVS guidelines provide a comprehensive set of recommendations for the evaluation and management of CLTI. Vein bypass may be preferred for average-risk patients with advanced limb threat and high complexity disease, while those with less complex anatomy, intermediate severity limb threat or high patient risk may be favored for endovascular intervention. All patients with CLTI should be afforded best medical therapy including the use of antithrombotic, lipid-lowering, antihypertensive and glycemic control agents, as well as counseling on smoking cessation, diet, exercise and preventive foot care (Conte et al., 2019).

Separate SVS guidelines provide a comprehensive set of recommendations for the evaluation and management of asymptomatic disease and intermittent claudication. Emphasis is placed on risk factor modification, medical therapies, and broader use of exercise programs to improve cardiovascular health and functional performance. Revascularization for intermittent claudication is an appropriate therapy for selected patients with disabling symptoms, after a careful risk-benefit analysis. Treatment should be individualized based on comorbid conditions, degree of functional impairment and anatomic factors. Invasive treatments for intermittent claudication should provide predictable functional improvements with reasonable durability. A minimum threshold of a > 50% likelihood of sustained efficacy for at least 2 years is suggested as a benchmark. Endovascular approaches are favored for most candidates with aortoiliac disease and for selected patients with femoropopliteal disease in whom anatomic durability is expected to meet this minimum threshold. Conversely, caution is warranted in the use of interventions for intermittent claudication in anatomic settings where durability is limited (extensive calcification, small-caliber arteries, diffuse infrainguinal disease, poor runoff). Surgical bypass may be a preferred strategy in good-risk patients with these disease patterns or in those with prior endovascular failures. Common

femoral artery disease should be treated surgically, and the saphenous vein is the preferred conduit for infrainguinal bypass grafting. Patients who undergo invasive treatments for intermittent claudication should be monitored regularly in a surveillance program to record subjective improvements, assess risk factors, optimize compliance with cardioprotective medications and monitor hemodynamic and patency status (Conte et al., 2015).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved several stents and stent systems for the treatment of PAD of the lower extremities. Refer to the following website (use product codes NIO and NIP) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed July 23, 2024)

The FDA has approved several catheter systems used for the treatment of PAD of the lower extremities. Refer to the following website (use product code DQY) for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 23, 2024)

In June 2020, the DETOUR system (Endologix) received FDA designation as a Breakthrough Device. The system consists of the TORUS stent graft and the ENDOCROSS™ Device. On June 7, 2023, the FDA granted full premarket approval of the DETOUR System for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis > 70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR System, or any of its components, is not for use in the coronary and cerebral vasculature. Refer to the following website for more information. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P220021. (Accessed July 23, 2024)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) criteria for substance use disorder (SUD) services, in administering health benefits. If InterQual® does

not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies that have been approved by the Kansas Department of Health and Environment. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.