

**American College of Radiology  
ACR Appropriateness Criteria®  
Management of Iliac Artery Occlusive Disease**

**Variant 1:**                    **Adult. Nonsmoker, sedentary lifestyle. Left lower-extremity claudication on walking, asymmetrically diminished left femoral pulse. No symptoms at rest. Initial management.**

Procedure	Appropriateness Category
Best medical management including supervised exercise program only	Usually Appropriate
Risk factor analysis and lipid profile and ABIs	Usually Appropriate
Antiplatelet adjunctive therapy	Usually Appropriate
US duplex Doppler lower extremity	Usually Appropriate
CTA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	May Be Appropriate
MRA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	May Be Appropriate
Plethysmography and pulse volume recording	May Be Appropriate
Catheter-directed angiography	Usually Not Appropriate
Anticoagulation adjunctive therapy	Usually Not Appropriate

**Variant 2:**                    **Adult. Long history of claudication. Acute-onset left lower-extremity pain. Absent left femoral pulse by palpation, faint audible DP and PT Doppler signals. Initial management.**

Procedure	Appropriateness Category
Anticoagulation adjunctive therapy	Usually Appropriate
CTA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	Usually Appropriate
Catheter-directed angiography	Usually Appropriate
MRA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	Usually Appropriate
US duplex Doppler lower extremity	May Be Appropriate
Ankle brachial index	May Be Appropriate
Risk factor analysis and lipid profile	May Be Appropriate
Plethysmography and pulse volume recording	Usually Not Appropriate

**Variant 3:**

**Adult. Known atrial fibrillation and spine surgery performed within the past month. Sudden-onset right lower-extremity pain. Diminished pulses in right lower-extremity. CTA demonstrates isolated filling defect in right common iliac artery. Initial therapy.**

Procedure	Appropriateness Category
Anticoagulation adjunctive therapy	Usually Appropriate
Catheter-directed mechanical thrombectomy	Usually Appropriate
Surgical revascularization	Usually Appropriate
Antiplatelet adjunctive therapy	May Be Appropriate
Catheter-directed thrombolytic therapy	May Be Appropriate (Disagreement)
Percutaneous transluminal angioplasty iliac artery	Usually Not Appropriate
Primary stent placement iliac artery	Usually Not Appropriate

**Variant 4:**

**Adult. Past medical history of heavy smoking. Severe claudication without rest pain. CTA demonstrates bilateral common iliac artery stenosis at or greater than 90% (TASC A). Initial therapy.**

Procedure	Appropriateness Category
Antiplatelet adjunctive therapy	Usually Appropriate
Best medical management including supervised exercise program	Usually Appropriate
Bilateral primary stent placement iliac artery	May Be Appropriate
Anticoagulation adjunctive therapy	May Be Appropriate
Bilateral percutaneous transluminal angioplasty iliac artery	Usually Not Appropriate
Surgical revascularization	Usually Not Appropriate

**Variant 5:**

**Adult. Past medical history significant for diabetes mellitus, hypertension, and smoking. Increasing claudication of right lower-extremity involving right buttock for the last 3 months. CTA pelvis with runoff reveals short-segment occlusion of the right common iliac artery (TASC B). Initial therapy.**

Procedure	Appropriateness Category
Antiplatelet adjunctive therapy	Usually Appropriate
Best medical management including supervised exercise program	Usually Appropriate
Primary stent placement aortoiliac arterial segment	May Be Appropriate
Anticoagulation adjunctive therapy	May Be Appropriate
Percutaneous transluminal angioplasty aortoiliac arterial segment	Usually Not Appropriate
Surgical revascularization	Usually Not Appropriate

**Variant 6:**

**Adult. Past medical history significant for diabetes mellitus, hypertension, and heavy smoking. Gradually increasing claudication of bilateral lower extremities for at least 2 months. CTA pelvis with runoff reveals bilateral common iliac artery occlusion without any involvement of the external or internal iliac artery (TASC C). Initial therapy.**

Procedure	Appropriateness Category
Antiplatelet adjunctive therapy	Usually Appropriate
Best medical management including supervised exercise program	Usually Appropriate
Anticoagulation adjunctive therapy	May Be Appropriate
Bilateral primary stent placement aortoiliac arterial segment	May Be Appropriate
Bilateral percutaneous transluminal angioplasty aortoiliac arterial segment	Usually Not Appropriate
Surgical revascularization	Usually Not Appropriate

**Variant 7:**

**Adult. Worsening claudication and small ischemic ulcers on digits of both feet. CTA demonstrates diffuse atherosclerosis involving distal aorta and both common and external iliac arteries with multiple stenoses at or greater than 50%, bilateral mid-superficial femoral artery stenoses at or greater than 70% with 2-vessel tibial runoff bilaterally (TASC D). Initial therapy.**

Procedure	Appropriateness Category
Hybrid revascularization with endovascular stenting of aortoiliac disease and infrainguinal bypass	Usually Appropriate
Percutaneous stent placement aortoiliac arterial segment plus superficial femoral	Usually Appropriate
Antiplatelet adjunctive therapy	Usually Appropriate
Surgical revascularization	Usually Appropriate
Percutaneous stent placement aortoiliac arterial segment	May Be Appropriate
Anticoagulation adjunctive therapy	May Be Appropriate
Best medical management including supervised exercise program only	Usually Not Appropriate
Percutaneous transluminal angioplasty aortoiliac arterial segment	Usually Not Appropriate

# MANAGEMENT OF ILIAC ARTERY OCCLUSIVE DISEASE

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## Summary of Literature Review

### Introduction/Background

Management of iliac artery occlusive disease encompasses a review of peripheral artery disease (PAD) as a whole. Several consensus documents provide a comprehensive review of this topic [1-4]. Lower-extremity PAD affects >8 million Americans and >200 million people worldwide [5]. The consensus documents along with more recent literature specific to aortoiliac disease allow for improved medical, endovascular, and surgical approaches in treatment of this disease process.

Aortoiliac occlusive disease can present as a sudden-onset acute thrombotic event or a chronic, progressive atherosclerotic process. History and physical examination rapidly help to establish this distinction and determine the most appropriate application of further clinical and imaging examinations. Chronic limb-threatening ischemia (CLTI) and intermittent claudication (IC) can often be managed on an outpatient basis allowing time to develop an appropriate management decision. Suspected acute limb ischemia (ALI), related to thromboembolic events, often requires rapid evaluation of the patient to determine suitability for possible limb salvage procedures. The management pathway, imaging required, and urgency necessary to obtain this information differ greatly in regard to acute thrombosis versus progressive atherosclerotic disease.

In all cases, initial physical examination by a vascular specialist should include evaluation of extremity pulses; capillary refill; skin quality, color, and qualitative temperature; and evidence of tissue compromise. Lower-extremity noninvasive physiologic studies such as pulse volume recording (PVR) and ankle brachial index (ABI) are simple and valuable tools in the screening and management of patients with chronic limb ischemia. Additional cross-sectional imaging with CT angiography (CTA) or MR angiography (MRA) is often needed to determine anatomic location of disease and for revascularization treatment planning if necessary.

### Initial Therapy Definition

Initial therapy is defined as a first-line treatment option for the medical condition defined by the variant. More than one option can be considered usually appropriate as the initial therapy when:

- There are equivalent alternatives (ie, only one option will be planned to effectively manage the patient's care).

OR

- There are complementary therapies (ie, more than one treatment option is planned to be performed simultaneously or in sequence during the same setting, wherein the therapies provide synergistic or complementary benefits to effectively manage the patient's care).

### Discussion of Procedures by Variant

#### **Variant 1: Adult. Nonsmoker, sedentary lifestyle. Left lower-extremity claudication on walking, asymmetrically diminished left femoral pulse. No symptoms at rest. Initial management.**

Initial management suggests that the procedural option would be considered part of a first-line or initial workup/treatment of the patient based on the clinical variant described.

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### **Anticoagulation Adjunctive Therapy**

There is no relevant literature to support the use of anticoagulation alone as an initial treatment option in this clinical scenario.

### **Antiplatelet Adjunctive Therapy**

Use of acetylsalicylic acid (ASA) alone (range 75-325 mg per day) is recommended in all patients with symptomatic PAD to reduce the risk of major adverse cardiac event (MACE) [3-5]. The use of dual antiplatelet therapy (DAPT) is not well established in patients with IC, but this may be reasonable to reduce limb-related events in patients following revascularization. In addition, there is strong evidence indicating cilostazol as an effective therapy to improve walking distance in patients with IC [5].

### **Best Medical Management Including Supervised Exercise Program Only**

Goals of medical therapy in patients presenting with IC or CLTI can include treatment of underlying diabetes, hypertension (HTN), or hyperlipidemia. Every patient with PAD should receive antiplatelet therapy. Statins and antiplatelet therapy are indicated by the American Heart Association (AHA)/American College of Cardiology (ACC) for all patients with PAD, regardless of lipid profile results [5]. Antihypertensives administered to patients with HTN and PAD can reduce the risk of MACE including stroke, myocardial ischemia (MI), heart failure, or cardiovascular (CV) death. Patients with IC should also be prescribed supervised exercise therapy (SET) if possible. A large, national retrospective review in the Netherlands including 54,504 patients comparing endovascular revascularization (EVR) versus open surgery (OS) versus SET alone in treatment of lower-extremity IC (all anatomic segments included) demonstrated that those undergoing OS or EVR had higher risk of secondary revascularization procedures and overall 5-year mortality [6]. Finally, the 2016 AHA/ACC lower-extremity PAD and 2017 European Society of Cardiology (ESC)/European Society for Vascular Surgery (ESVS) guidelines recommend a trial of cilostazol to improve symptoms and walking distance in patients with IC [1,5].

The Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) study demonstrated superior treadmill walking performance at 6-month follow-up in the SET cohort versus the primary stenting cohort for patients with IC resulting from aortoiliac PAD [7]. The 5-year results from the Invasive Revascularization or Not in Intermittent Claudication (IRONIC) randomized controlled trial, comparing endovascular intervention plus optimal medical therapy (OMT) and SET versus OMT + SET alone, demonstrated that revascularization had lost its early benefit, and there was no long-term improvement in health-related quality of life (QoL) or walking capacity compared with a noninvasive treatment strategy [8].

The Endovascular Revascularization and Supervised Exercise for Peripheral Artery Disease and Intermittent Claudication (ERASE) trial was a multicenter, randomized controlled trial with 212 patients randomized 1:1 to SET versus SET plus EVR. All patients were receiving medical therapy for PAD, and more than half had aortoiliac disease. At 12 months, EVR plus SET (combination therapy) was associated with a significantly greater improvement in maximum walking distance (mean improvement of 1237 m) compared with the SET only group (955 m) (mean difference between groups, 282 m; 99% confidence interval [CI], 60-505 m) and in pain-free walking distance (mean improvement of 1120 m versus 712 m, respectively) (mean difference, 408 m; 99% CI, 195-622 m). In addition, the combination therapy was superior in improvements of disease-specific Vascular Quality of Life Questionnaire and 36-item Short-Form Health Survey physical functioning QoL scores [9].

### **Catheter-Directed Angiography**

Given the invasive nature of catheter-directed digital subtraction angiography (DSA), this may not be useful as an initial diagnostic modality for IC. Additional clinical evaluation and diagnostic imaging would constitute the next initial steps. In most cases, DSA is performed only at the time of endovascular intervention, but in some cases, DSA may augment cross-sectional imaging options before intervention by providing diagnostic information regarding the patency of medium and small runoff arteries. In patients with equivocal imaging and lifestyle-limiting IC, intraarterial pressure measurements may be of value, with systolic gradients >10 mm Hg at rest or after pharmacologic challenge considered significant [2].

### **CTA Abdomen and Pelvis With Bilateral Lower Extremity Runoff With IV Contrast**

If clinical symptoms and initial noninvasive imaging indicate PAD, further confirmation with CTA or MRA can determine the best application of endovascular or surgical intervention. The ACC/AHA practice guidelines give a moderate recommendation for CTA because cross-sectional imaging allows for diagnosis of anatomic disease location and significance of stenosis/occlusion [2]. This in turn leads to improved surgical planning to determine if the patient is best suited for EVR or OS revascularization. CTA increases contrast load to the patient initially, but

the information obtained from CTA imaging can improve preprocedure planning and usually facilitate a marked decrease in contrast dose during the actual EVR interventions.

### **MRA Abdomen and Pelvis With Bilateral Lower Extremity Runoff With IV Contrast**

The most current 2016 AHA/ACC guidelines for lower-extremity PAD management provide a strong recommendation for use of MRA to diagnose anatomic location and severity of disease in patients with symptomatic PAD in whom revascularization is considered (class I recommendation) [5]. Superiority has been demonstrated in the use of 3-D contrast-enhanced MRA compared with 2-D time-of-flight sequences in the evaluation of degree of lesion stenosis and overall correlation with digital subtraction angiography DSA findings [10].

### **Plethysmography and Pulse Volume Recording**

Plethysmography detects the changes in the limb volume by PVR. Over a period of time, the use of plethysmography and PVR has fallen out of favor because of their lack of reliable and reproducible quantitative data [11]. Plethysmography can be used as the initial evaluation in patients with CLTI to establish a diagnosis and for the localization or severity of disease, but accuracy is limited.

### **Risk Factor Analysis and Lipid Profile and ABIs**

In all cases of peripheral arterial disease, risk factor analysis is a key component of treatment and may include risk factor modification such as smoking cessation and control of hyperlipidemia, diabetes, and HTN. A lipid profile can be obtained covering total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglyceride, and (in younger patients) homocysteine levels. ABI can confirm the presence of peripheral vascular disease given that it is noninvasive. The results of ABIs are severely limited in patients with heavily calcified/noncompressible vessels. In that case, toe brachial index can be obtained to evaluate for the presence of distal ischemia. Of note, ABIs may be normal at rest or in patients with isolated iliac occlusive disease [12]. Therefore, exercise/treadmill ABIs should be performed to evaluate objectively for functional limitations in patients suspected of PAD with isolated aortoiliac disease.

### **US Duplex Doppler Lower Extremity**

Noninvasive imaging with ABI can determine if clinical symptoms are concordant with peripheral vascular disease. Additional information can be obtained with duplex ultrasound (DUS), often performed in conjunction with ABIs to help localize anatomic segments of disease. A 2018 retrospective observational study comparing DUS with angiography or CTA demonstrated that overall accuracy of DUS for predicting significant aortoiliac artery lesions was as follows: 92% sensitivity (95% CI, 88%-95%), 96% specificity (95% CI, 95%-97%), 89% positive predictive value (95% CI, 86%-93%), and 97% negative predictive value (95% CI, 96%-98%). Agreement with angiography/CTA had a  $\kappa$  index of 0.81 (95% CI, 0.77-0.84), which reflects a good degree of agreement [13].

Alternatively, a retrospective review comparing DUS with CTA or intraoperative angiography demonstrated a positive predictive value of 60% and negative predictive value of 100% for the iliac artery segment [14].

**Variant 2: Adult. Long history of claudication. Acute-onset left lower-extremity pain. Absent left femoral pulse by palpation, faint audible DP and PT Doppler signals. Initial management.**

### **Ankle Brachial Index**

ALI occurs because of thromboembolism, atheroembolism, in situ thrombosis of the native artery, or thrombosis of a surgical bypass graft. The goal is prompt restoration of flow to the affected limb to preserve function. Given the acute nature of this disease presentation and urgency in prompt initiation of treatment, screening tools such as ABIs are not ideal if there is an anticipated delay in obtaining the necessary information. ABI can be used in conjunction with DUS as an alternative option for CTA. Although ABI can be quick when performed at bedside, it does not provide further detail on the anatomic location of the occlusion.

### **Anticoagulation Adjunctive Therapy**

All patients presenting with ALI should be initiated on anticoagulation therapy immediately, which generally includes a heparin drip. This reduces the risk of thrombus propagation during the inevitable delay as treatment decisions are made.

### **Catheter-Directed Angiography**

The treatment of ALI is prompt restoration of flow to the affected limb. Although there is no convincing evidence for the universal superiority of either endovascular or surgical approaches [15], distinguishing embolic from in situ lesions may help in planning therapy. Furthermore, the severity of ischemia and ability to tolerate surgery are important factors for consideration.

For native-vessel thrombosis, a trial of thrombolytic therapy is helpful for viable limbs. In cases in which a guide wire can be passed across the lesion, catheter-directed thrombolysis may be instituted. If a guide wire cannot be successfully passed, regional thrombolysis can be considered [1,2]. Prospective, randomized trials demonstrated that 1-year limb salvage rates with endovascular techniques are similar to those after surgery, with lower mortality rates but higher rates of recurrent ischemia and amputation [3,14]. The endovascular approach allows treatment of the underlying lesion after thrombolysis, and gradual low-pressure reperfusion may avoid reperfusion injury [15]. The use of mechanical techniques may allow more prompt restoration of flow and expanded use of endovascular techniques in the threatened limb. Surgical approaches should be reserved for patients in whom thrombolysis or endovascular thrombectomy failed, for situations in which an unacceptable delay due to attempted endovascular techniques jeopardizes the viability of a limb, or for nonviable limbs.

### **CTA Abdomen and Pelvis With Bilateral Lower Extremity Runoff With IV Contrast**

CTA is fast and able to reveal the exact nature and level of both thrombosis and underlying atherosclerotic plaque to plan an appropriate treatment strategy, whether endovascular or surgical.

### **MRA Abdomen and Pelvis With Bilateral Lower Extremity Runoff With IV Contrast**

MRA is an alternative if time permits. Intervention for ALI can be emergent depending on clinical examination and Rutherford category at presentation.

### **Plethysmography and Pulse Volume Recording**

Over a period of time, the use of plethysmography and PVR has fallen out of favor because of their lack of reliable and reproducible quantitative data. Plethysmography can be used as the initial evaluation in patients with CLTI to establish diagnosis and for localization or severity of disease, but accuracy is limited [11]. Given urgent/emergent revascularization requirements in patients presenting with ALI, screening tools are not the diagnostic tests of choice.

### **Risk Factor Analysis and Lipid Profile**

Risk factor analysis and evaluating lipid profile are not initial treatment steps in patients with ALI but are important to improve long-term outcomes once the acute presentation has been resolved. Given urgent/emergent revascularization requirements in patients presenting with ALI, screening tools may not be ideal.

### **US Duplex Doppler Lower Extremity**

DUS may present a challenge in patients with ALI because of potential delays in acquisition time. ABI plus DUS may be an alternative in patients who cannot undergo CTA or MRA.

**Variant 3: Adult. Known atrial fibrillation and spine surgery performed within the past month. Sudden-onset right lower-extremity pain. Diminished pulses in right lower-extremity. CTA demonstrates isolated filling defect in right common iliac artery. Initial therapy.**

### **Anticoagulation Adjunctive Therapy**

All patients presenting with ALI can benefit from immediate initiation of anticoagulation therapy, generally a heparin drip. This reduces the risk of thrombus propagation during the inevitable delay as treatment decisions are made. Despite presentation of ALI, anticoagulation in this patient is likely not useful, and potentially detrimental, given recent spine surgery within the past month.

### **Antiplatelet Adjunctive Therapy**

Use of ASA alone (range 75-325 mg per day) is recommended in all patients with symptomatic PAD to reduce the risk of MACE [3-5]. After EVR or OS of an acute thrombotic event, patients may undergo consultation for appropriate medical management of risk factors, determination of SET program, and initiation of antiplatelet therapy.

### **Catheter-Directed Mechanical Thrombectomy**

The 2016 AHA/ACC consensus guidelines indicate that percutaneous catheter-directed thrombectomy can be useful as an adjunctive therapy to thrombolysis [5]. In addition, a retrospective review in which 147 consecutive patients with ALI were treated with EVR were compared with 296 patients treated with OS revascularization. Limb salvage rates were similar between the groups, but overall mortality was significantly higher at 30 days and 1 year in the OS revascularization group [16].

### **Catheter-Directed Thrombolytic Therapy**

Extreme caution should be taken with tPA administration in a patient who has recently undergone spinal surgery.

However, if recent spinal surgery were not a relevant factor in this patient's clinical decision making, a 2018 Cochrane systematic review concluded that there is insufficient evidence to suggest thrombolysis or surgery in the initial treatment of ALI because there was no clear difference in limb salvage, limb amputation, or 30-day mortality rates between patient groups. The quality of the evidence was low, with 5 randomized controlled trials evaluated [15]. Another meta-analysis including 1,773 patients from 6 studies, 5 of which were randomized controlled trials, showed no differences in mortality, amputation rates, or recurrent ischemia at 1, 6, and 12 months between surgical or endovascular treatment for ALI [17].

### **Percutaneous Transluminal Angioplasty Iliac Artery**

There is no evidence to support the treatment of ALI caused by thromboembolic disease with percutaneous transluminal angioplasty (PTA). In fact, this could have a secondary outcome of sending the embolic material downstream leading to even worse ALI symptoms.

### **Primary Stent Placement Iliac Artery**

Although this may treat the thromboembolism and potential underlying iliac lesion if present, this would be considered adjunctive therapy in a patient with ALI. No high-quality evidence exists to determine the appropriate use of primary stenting in this scenario.

### **Surgical Revascularization**

Patients with immediately threatened limbs need early revascularization. Despite systematic reviews demonstrating no significant difference in mortality or amputation rates at 1, 6, and 12 months between endovascular or surgical treatment of ALI [15,17], these studies do not specifically refer to the iliac arteries. Prolonged ischemia of >6 hours is the primary determination of whether a patient will require amputation. Prompt revascularization is prudent to restore flow to the affected limb. The AHA/ACC guidelines state that in patients with ALI due to an embolic event, surgical thromboembolectomy can be effective (Class IIA recommendation) [5]. The 2017 ESC/ESVS guidelines suggest emergent revascularization in patients with ALI and neurologic deficits; however, they do not provide sufficient data to support a distinction between selecting an endovascular versus a surgical approach. Thromboembolic extraction is recommended for those with neurologic deficits and longer duration of symptoms, whereas an endovascular approach may be indicated in less severe cases [1].

**Variant 4: Adult. Past medical history of heavy smoking. Severe claudication without rest pain. CTA demonstrates bilateral common iliac artery stenosis at or greater than 90% (TASC A). Initial therapy.**

### **Anticoagulation Adjunctive Therapy**

The Cardiovascular Outcomes for People Using Anticoagulation StrategieS (COMPASS) trial has shown that patients taking rivaroxaban 2.5 mg 2 times a day and ASA 100 mg daily have reduced CV-related death, MI, or stroke compared with ASA alone or rivaroxaban alone [18]. Heparin can be used as adjunctive therapy during an endovascular intervention if indicated.

### **Antiplatelet Adjunctive Therapy**

Comparative effectiveness review of several randomized controlled trials concluded that there was no significant benefit in reducing CV mortality, MI, or stroke comparing ASA versus placebo in asymptomatic patients with PAD. In addition, the review indicated that clopidogrel monotherapy is more beneficial than ASA alone, and DAPT is not significantly better than ASA alone in reducing CV events including nonfatal MI, stroke, or CV mortality [19]. However, the most recent consensus guidelines recommend ASA alone (range 75-325 mg per day) in all patients with symptomatic PAD/IC to reduce the risk of MACE [3-5]. DAPT may be reasonable to reduce limb-related events in patients following revascularization [3]. In the post hoc analysis of >6,000 patients in the clopidogrel versus aspirin in patients at risk of ischemic events (CAPRIE) trial PAD subgroup, clopidogrel was superior to ASA in the reduction of CV mortality and MACE (hazard ratio, 0.78; 95% CI, 0.65-0.93) [1,20]. Cilostazol is recommended as an effective therapy to improve walking distance in patients with IC [5].

### **Best Medical Management Including Supervised Exercise Program**

Goals of medical therapy for patients presenting with IC or CLTI should include treatment of underlying diabetes, HTN, and/or hyperlipidemia. High-dose statin therapy is indicated if tolerated (class IA) [5,21]. Antihypertensive therapy should be administered to all patients with HTN and PAD to reduce the risk of MACE including stroke, MI, heart failure, or CV death. Patients with IC who are prescribed SET can reduce overall mortality and the need for secondary revascularization procedures [6]. Finally, societal guidelines recommend a trial of cilostazol to improve symptoms and walking distance in patients with IC [1,5].



Several randomized controlled trials mentioned previously including CLEVER, ERASE, and IRONIC have demonstrated significant improvement in disease-specific QoL measurements, as well as walking distance and treadmill walking performance following SET [7,9,22]. A systematic review of SET plus EVR for the treatment of IC versus EVR alone or SET alone demonstrated improvement in the maximum walking distance at 6 months compared with SET or EVR alone, but this difference was no longer present at 12 months [23]. A meta-analysis of 987 patients indicated EVR in combination with SET is associated with significant improvement in total walking distance, ABI, and risk of future revascularization or amputation with to SET alone [24].

A retrospective chart review of 138 patients indicated no significant increase in reintervention, conversion to open surgical bypass, or limb loss in the smoking cohort versus nonsmokers [25]. Despite this, tobacco cessation should be discussed with all patients with IC.

### **Bilateral Percutaneous Transluminal Angioplasty Iliac Artery**

Caution should be practiced when determining invasive treatment for patients with IC because <5% will progress to rest pain, tissue loss, or amputation [12]. Because of this, any invasive treatment for IC should be limited to those patients with lifestyle-limiting claudication. A 2021 retrospective analysis of 16,152 patients who had undergone initial EVR for IC demonstrated only moderate patient compliance with OMT and a treated limb symptomatic recurrence rate of 68%, falling well short of the Society for Vascular Surgery practice guidelines of <50% recurrence at 2 years post-EVR. In subgroup analysis, only 37% of patients with isolated aortoiliac interventions remained free of recurrent IC symptoms at 2 years [26].

A 2015 Cochrane systemic review, updated in 2020, found insufficient evidence to support PTA versus primary stenting for the treatment of severely stenotic or occlusive iliac lesions [27,28].

However, stenting has demonstrated significant benefits over angioplasty alone in TransAtlantic Inter-Society Consensus II (TASC) C and D lesions. A recent large meta-analysis demonstrated significantly higher 12-month primary patency rates for primary stenting (92.1%; 95% CI, 89.0%-94.3%) in comparison with PTA with selective stenting (82.9%; 95% CI, 72.2%-90.0%) for TASC C and D lesions [29]. The Stents versus AnGioplasty (STAG) trial was a multicenter trial randomizing 112 patients to primary stenting versus PTA alone in the treatment of iliac occlusive lesions. The rate of major complication was 5% versus 20%, respectively, mostly related to distal embolization [30]. Therefore, care should be taken when treating iliac artery lesions with PTA alone.

### **Bilateral Primary Stent Placement Iliac Artery**

The patient in this particular variant suffers from severe claudication, not rest pain; therefore, there is insufficient evidence to support stenting as initial therapy. However, it may be considered in certain patients based on the severity of the claudication symptoms and the degree to which it affects the patient's QoL.

Primary stenting for patients with TASC A-D aortoiliac artery lesions can be useful. The MISAGO prospective, nonrandomized trial of 120 patients undergoing primary stenting of TASC A or B iliac lesions found a primary patency rate for the total patient population of 97.4%. The primary patency rates at 12 months for the TASC II class A and TASC II class B(C) lesions were 98.3% and 96.6%, respectively [31]. Other authors have found patency rates for primary stenting of TASC C and D lesions to be similar to those for TASC A and B lesions [32,33]. The 24-month primary patency rate comparing treatment of TASC A-D lesions with primary stenting in the Belgian-Italian Trial Investigating Abbott Vascular Iliac Stents in the Treatment of TASC A, B, C and D Iliac Lesions (BRAVISSIMO) showed no significant difference between TASC group [34]. However, primary stenting has demonstrated significantly higher complication rates in TASC C and D lesions in comparison with TASC A and B lesions, with similar 1-, 3-, 5-, and 10-year primary patencies [35].

An endovascular first approach for treatment of all TASC II iliac lesions, including C and D, has been implemented by multiple societal guidelines including the 2016 AHA/ACC, the 2017 ESC/ESVS, the 2014 Cardiovascular and Interventional Radiological Society of Europe (CIRSE), and the 2017 Society for Cardiovascular Angiography and Interventions (SCAI) update on peripheral arterial interventions. Guidelines indicate that endovascular approaches are an effective treatment option with high success rates and low morbidity and mortality compared with OS revascularization, and they demonstrate relative durability with secondary patency rates similar to OS [1,3-5].

### **Surgical Revascularization**

Surgical revascularization may not be helpful for TASC A aortoiliac lesions given increased morbidity and mortality when compared with an endovascular first approach with similar primary and secondary patencies.

**Variant 5: Adult. Past medical history significant for diabetes mellitus, hypertension, and smoking. Increasing claudication of right lower-extremity involving right buttock for the last 3 months. CTA pelvis with runoff reveals short-segment occlusion of the right common iliac artery (TASC B). Initial therapy.**

### **Anticoagulation Adjunctive Therapy**

A combination of rivaroxaban 2.5 mg twice per day and ASA 100 mg daily was shown to reduce CV-related death, MI, or stroke compared with ASA alone or rivaroxaban alone [18]. Heparin may be used as adjunctive therapy during endovascular intervention if indicated.

### **Antiplatelet Adjunctive Therapy**

Single-agent antiplatelet therapy is recommended in all symptomatic patients with PAD to reduce the risk of MACE and CV mortality [1,3-5,20]. The use of DAPT is not well established in patients with IC, but this may be reasonable to reduce limb-related events in patients following revascularization [3]. In addition, cilostazol is indicated to improve walking distance in patients with IC [5].

### **Best Medical Management Including Supervised Exercise Program**

Goals of medical therapy in patients presenting with IC or CLTI can include SET and treatment of underlying diabetes, HTN, and/or hyperlipidemia. High-dose statin and antiplatelet therapy can be helpful for patients with PAD as tolerated [5,21]. Antihypertensives should be administered to all patients with HTN and PAD to reduce the risk of MACE including stroke, MI, heart failure, or CV death. Patients with IC should receive SET to reduce overall mortality and need for secondary revascularization procedures [6]. Finally, societal guidelines recommend a trial of cilostazol to improve symptoms and walking distance in patients with IC [1,5].

Several randomized controlled trials including CLEVER, ERASE, and IRONIC have demonstrated significant improvement in disease-specific QoL measurements as well as walking distance and treadmill walking performance following SET [7-9]. Two separate recent meta-analyses demonstrated improved maximum walking distance, increased ABI, and decreased risk of future revascularizations in combination of EVR and SET compared with SET or EVR alone [23,24].

A recent retrospective chart review found no significant increase in reintervention, conversion to OS bypass, or limb loss in smoking cohort versus nonsmokers [25]. Despite this, tobacco cessation should be discussed with all patients with IC.

### **Percutaneous Transluminal Angioplasty Aortoiliac Arterial Segment**

A Cochrane systemic review in 2015 and updated in 2020 found insufficient evidence to support PTA versus primary stenting for the treatment of severely stenotic or occlusive iliac lesions [27,28]. PTA may be associated with an increased rate of embolization compared with primary stenting [27,28,30].

### **Primary Stent Placement Aortoiliac Arterial Segment**

The patient in this particular variant suffers from severe claudication, not rest pain; therefore there is insufficient evidence to support stenting as initial therapy. However, it may be considered in certain patients based on the severity of the claudication symptoms and the degree to which it affects the patient's QoL.

The MISAGO trial evaluated 120 patients undergoing primary stenting of TASC A or B iliac lesions and found primary patency rates at 12 months for the TASC II class A and TASC II class B(C) lesions of 98.3% and 96.6%, respectively [31]. Other authors have found patency rates for primary stenting of TASC C and D lesions to be similar to those for TASC A and B lesions [32,33]. The BRAVISSIMO Trial showed that TASC A-D iliac lesions have similar 1-, 3-, 5-, and 10-year primary patencies following primary stenting, however, significantly higher complication rates were noted during treatment of TASC C and D lesions in comparison with TASC A and B lesions [34,35].

An endovascular first approach for treatment of all TASC II iliac lesions is recommended by multiple societal guidelines indicating that endovascular approaches are an effective treatment option with high success rates and low morbidity, and mortality compared with OS revascularization, and they demonstrate relative durability with secondary patency rates similar to OS [1,3-5].

With respect to the role of covered balloon-expandable stents in treating iliac occlusive disease, a systematic review reported primary patency rates of 89.1% to 96.9% and target lesion revascularization of 90% to 100% at 12 months [36]. The 5-year results of the COVERed Balloon-Expandable STents (COBEST) trial indicate a significantly higher patency rate for covered balloon-expandable stents than bare metal stents at 18, 24, 48, and 60 months (95.1%,

82.1%, 79.9%, 74.7% for covered stents versus 73.9%, 70.9%, 63% and 62.5% for bare metal stents; log-rank test,  $P = .01$ ) [37].

### **Surgical Revascularization**

Surgical revascularization may not be helpful for TASC B aortoiliac lesions given increased morbidity and mortality when compared with an endovascular first approach with similar primary and secondary patencies.

**Variant 6: Adult. Past medical history significant for diabetes mellitus, hypertension, and heavy smoking. Gradually increasing claudication of bilateral lower extremities for at least 2 months. CTA pelvis with runoff reveals bilateral common iliac artery occlusion without any involvement of the external or internal iliac artery (TASC C). Initial therapy.**

### **Anticoagulation Adjunctive Therapy**

A combination of rivaroxaban 2.5 mg twice per day and ASA 100 mg daily was shown to reduce CV-related death, MI, or stroke compared with ASA alone or rivaroxaban alone [18]. Heparin is used as adjunctive therapy during endovascular intervention if indicated.

### **Antiplatelet Adjunctive Therapy**

Single-agent antiplatelet therapy is recommended in all symptomatic patients with PAD to reduce the risk of MACE and CV mortality [1,3-5,20]. The use of DAPT is not well established in patients with IC, but this may be reasonable to reduce limb-related events in patients following revascularization [3]. In addition, cilostazol is indicated to improve walking distance in patients with IC [5].

### **Best Medical Management Including Supervised Exercise Program**

Goals of medical therapy in patients presenting with IC or CLTI can include SET and treatment of underlying diabetes, HTN, and/or hyperlipidemia. High-dose statin and antiplatelet therapy can be helpful for patients with PAD as tolerated [5,21]. Antihypertensives should be administered to all patients with HTN and PAD to reduce the risk of MACE. Patients with IC should receive SET to reduce overall mortality and the need for secondary revascularization procedures [6]. Finally, societal guidelines recommend a trial of cilostazol to improve symptoms and walking distance in patients with IC [1,5].

Several randomized controlled trials including CLEVER, ERASE, and IRONIC evaluating SET in patients with IC have demonstrated significant improvement in disease-specific QoL measurements as well as walking distance and treadmill walking performance following SET [7-9]. Two separate recent meta-analyses demonstrated improved maximum walking distance, ABI, and decreased risk of future revascularizations in combination of EVR and SET compared with SET or EVR alone [23,24].

A recent retrospective chart review found no significant increase in reintervention, conversion to OS bypass, or limb loss in smoking cohort versus nonsmokers [25]. Despite this, tobacco cessation should be discussed with all patients with IC.

### **Bilateral Percutaneous Transluminal Angioplasty Aortoiliac Arterial Segment**

A 2015 Cochrane systemic review, updated in 2020, found insufficient evidence to support PTA versus primary stenting for the treatment of severely stenotic or occlusive iliac lesions [27,28]. However, the STAG trial randomized 112 patients to primary stenting versus PTA alone in the treatment of iliac occlusive lesions. The rate of major complication was 5% versus 20%, respectively, mostly related to distal embolization in the PTA group [30]. There are insufficient data to support PTA alone for treatment of TASC C lesions.

### **Bilateral Primary Stent Placement Aortoiliac Arterial Segment**

The MISAGO trial evaluated 120 patients undergoing primary stenting of TASC A or B iliac lesions and found primary patency rates at 12 months for the TASC II class A and TASC II class B(C) lesions of 98.3% and 96.6%, respectively [31]. Other authors have found patency rates for primary stenting of TASC C and D lesions to be similar to those for TASC A and B lesions [32,33]. The BRAVISSIMO Trial showed that TASC A-D iliac lesions have similar 1-, 3-, 5-, and 10-year primary patencies following primary stenting, however, significantly higher complication rates were noted during treatment of TASC C and D lesions in comparison with TASC A and B lesions [34,35].

An endovascular first approach for the treatment of all TASC II iliac lesions is recommended by multiple societal guidelines indicating that endovascular approaches are an effective treatment option with high success rates and

low morbidity, and mortality compared with OS revascularization, and they demonstrate relative durability with secondary patency rates similar to OS [1,3-5].

With respect to the role of covered balloon-expandable stents in treating iliac occlusive disease, a systematic review reported primary patency rates of 89.1% to 96.9% and target lesion revascularization of 90% to 100% at 12 months [36]. The 5-year results of the COBEST trial indicate a significantly higher patency rate for covered balloon-expandable stents than bare metal stents at 18, 24, 48, and 60 months (95.1%, 82.1%, 79.9%, 74.7% for covered stents versus 73.9%, 70.9%, 63% and 62.5% for bare metal stents; log-rank test,  $P = .01$ ) [37].

### **Surgical Revascularization**

For TASC C and D lesions, surgery has historically been recommended, but recent data further support societal guidelines recommending an endovascular first approach [1,3-5]. One study reported similar 1-year survival following aortofemoral bypass regardless of whether prior iliac artery endovascular intervention occurred [38].

Several recent studies have demonstrated no significant differences in short- and long-term primary and secondary patency comparing EVR and OS for treatment of aortoiliac occlusive disease. The EVR approach is associated with increased secondary interventions but decreased length of hospital stay despite similar fewer postoperative complications. EVR is safe, minimally invasive, and durable with similar 5- to 6-year patency rates to OS bypass [39-45].

A recent meta-analysis compared EV revascularization, covered endovascular reconstruction of aortic bifurcation, and OS for treating aortoiliac occlusive disease. OS has improved 3- and 5-year primary patency, but secondary patency is similar between the groups. Also, OS has increased 30-day morbidity and mortality compared with EV or covered endovascular reconstruction of aortic bifurcation [46].

**Variant 7: Adult. Worsening claudication and small ischemic ulcers on digits of both feet. CTA demonstrates diffuse atherosclerosis involving distal aorta and both common and external iliac arteries with multiple stenoses at or greater than 50%, bilateral mid-superficial femoral artery stenoses at or greater than 70% with 2-vessel tibial runoff bilaterally (TASC D). Initial therapy.**

### **Anticoagulation Adjunctive Therapy**

A combination of rivaroxaban 2.5 mg twice per day and ASA 100 mg daily was shown to reduce CV-related death, MI, or stroke compared with ASA alone or rivaroxaban alone [18]. Heparin is used as adjunctive therapy during endovascular intervention if indicated.

### **Antiplatelet Adjunctive Therapy**

Single-agent antiplatelet therapy is recommended in all symptomatic patients with PAD to reduce the risk of MACE and CV mortality [1,3-5,20]. The use of DAPT is not well established in patients with IC, but this may be reasonable to reduce limb-related events in patients following revascularization [3]. In addition, cilostazol is indicated to improve walking distance in patients with IC [5].

### **Best Medical Management Including Supervised Exercise Program Only**

Goals of medical therapy in patients presenting with IC or CLTI can include SET and treatment of underlying diabetes, HTN, and/or hyperlipidemia. High-dose statin and antiplatelet therapy can be helpful for patients with PAD as tolerated [5,21]. Antihypertensives should be administered to all patients with HTN and PAD to reduce the risk of MACE. Patients with IC should receive SET to reduce overall mortality and the need for secondary revascularization procedures [6]. Finally, societal guidelines recommend a trial of cilostazol to improve symptoms and walking distance in patients with IC [1,5].

Several randomized controlled trials including CLEVER, ERASE, and IRONIC evaluating SET in patients with IC have demonstrated significant improvement in disease-specific QoL measurements as well as walking distance and treadmill walking performance following SET [7-9]. Two separate recent meta-analyses demonstrated improved maximum walking distance, ABI, and decreased risk of future revascularizations in combination of EVR and SET compared with SET or EVR alone [23,24].

A recent retrospective chart review found no significant increase in reintervention, conversion to OS bypass, or limb loss in the smoking versus nonsmoker cohort [25]. Despite this, tobacco cessation should be discussed with all patients with IC.

### **Percutaneous Transluminal Angioplasty Aortoiliac Arterial Segment**

A 2015 Cochrane systemic review, updated in 2020, found insufficient evidence to support PTA versus primary stenting for the treatment of severely stenotic or occlusive iliac lesions [27,28]. However, the STAG trial randomized 112 patients to primary stenting versus PTA alone in the treatment of iliac occlusive lesions. The rate of major complication was 5% versus 20%, respectively, mostly related to distal embolization in the PTA group [30]. There are insufficient data to support PTA alone for the treatment of TASC C lesions.

### **Percutaneous Stent Placement Aortoiliac Arterial Segment**

An endovascular first approach for treatment of all TASC II iliac lesions is recommended by multiple societal guidelines indicating that endovascular approaches are an effective treatment option with high success rates and low morbidity and mortality compared with OS revascularization, and they demonstrate relative durability with secondary patency rates similar to OS [1,3-5]. TASC A-D iliac lesions have similar short- and long-term primary patencies following primary stenting with significantly higher complication rates in TASC C and D lesions in comparison with TASC A and B lesions [34,35].

The STAG trial demonstrated improved technical success and decreased major complications related to embolism comparing bare metal stenting to PTA alone of the iliac arteries [29]. With respect to the role of covered balloon-expandable stents in treating iliac occlusive disease, a systematic review reported primary patency rates of 89.1% to 96.9% and target lesion revascularization of 90% to 100% at 12 months [36]. The 5-year results of the COBEST trial indicate a significantly higher patency rate for covered balloon-expandable stents than bare metal stents at 18, 24, 48, and 60 months (95.1%, 82.1%, 79.9%, 74.7% for covered stents versus 73.9%, 70.9%, 63% and 62.5% for bare metal stents; log-rank test,  $P = .01$ ) [37].

Hybrid surgical approaches have demonstrated equivalent patency to OS revascularization for aortoiliac disease, with 1- to 2-year primary assisted patency of 66% to 94% and secondary patencies >90% [47-51]. Additional endovascular therapy following primary stenting of the iliac artery disease may be an adjunct or performed separately to the index procedure. No high-quality evidence was identified evaluating PTA of the common femoral artery during iliac artery revascularization.

### **Percutaneous Stent Placement Aortoiliac Arterial Segment Plus Superficial Femoral Artery**

Patients with nonhealing wounds have progressed from IC to CLTI. The goal of treatment is adequate wound healing to limit the risk of amputation. Improving a single anatomic segment may not be sufficient to treat tissue loss. Evaluation by an interdisciplinary care team should be performed to discuss revascularization options. The 2016 AHA/ACC guidelines recommend EVR to establish in-line blood flow to the foot in patients with nonhealing wounds (class IB) [5]. In addition, CLTI is very rarely related to isolated aortoiliac arterial disease and most often will have additional downstream lesions that should be addressed by means of a multidisciplinary approach either in a 1-step fashion or stepwise based on lesion complexity [1].

An endovascular first approach for treatment of all TASC II iliac lesions is recommended by multiple societal guidelines indicating that endovascular approaches are an effective treatment option with high success rates and low morbidity and mortality compared with OS revascularization, and they demonstrate relative durability with secondary patency rates similar to OS [1,3-5].

The STAG trial demonstrated improved technical success and decreased major complications related to embolism comparing bare metal stenting to PTA alone of the iliac arteries [29]. With respect to the role of covered balloon-expandable stents in treating iliac occlusive disease, a systematic review reported primary patency rates of 89.1% to 96.9% and target lesion revascularization of 90% to 100% at 12 months [36]. The 5-year results of the COBEST trial indicate a significantly higher patency rate for covered balloon-expandable stents than bare metal stents at 18, 24, 48, and 60 months (95.1%, 82.1%, 79.9%, 74.7% for covered stents versus 73.9%, 70.9%, 63% and 62.5% for bare metal stents; log-rank test,  $P = .01$ ) [37].

Additional endovascular therapy following primary stenting of the iliac artery disease may be an adjunct or performed separately to the index procedure. No high-quality evidence was identified evaluating PTA of the common femoral artery during iliac artery revascularization.

### **Hybrid Revascularization with Endovascular Stenting of Aortoiliac Disease and Infrainguinal Bypass**

Hybrid surgical approaches have demonstrated equivalent patency to OS revascularization for aortoiliac disease, with 1- to 2-year primary assisted patency of 66% to 94% and secondary patencies >90% [47-51]. The 5-year primary, primary assisted, and secondary patency rates were 87%, 92%, and 98%, respectively, in 108 patients

undergoing common femoral endarterectomy with iliac artery stenting [50]. It is well established that diffuse, multilevel disease affecting multiple anatomic segments decreases patency of EVR or OS revascularization.

Patients with nonhealing wounds have progressed from IC to CLTI. The goal of treatment is adequate wound healing to limit the risk of amputation. CLTI is very rarely related to isolated aortoiliac arterial disease and most often will have additional downstream lesions that should be addressed by means of a multidisciplinary approach in either a 1-step fashion or a stepwise approach based on lesion complexity [1]. Improving a single anatomic segment may not be sufficient to treat tissue loss. Evaluation by an interdisciplinary care team should be performed to discuss revascularization options. The 2016 AHA/ACC guidelines recommend EVR to establish in-line blood flow to the foot in patients with nonhealing wounds (class IB) [5].

### **Surgical Revascularization**

For TASC C and D lesions, surgery has historically been recommended, but recent data further support societal guidelines recommending an endovascular-first approach [1,3-5]. One study reported similar 1-year survival following aortofemoral bypass regardless of whether prior iliac artery endovascular intervention occurred [38].

Several recent studies comparing EVR and OS for the treatment of aortoiliac occlusive disease have demonstrated similar primary and secondary short- and long-term patencies. The endovascular approach is associated with increased secondary interventions but decreased length of hospital stay and fewer postoperative complications. EVR is safe, minimally invasive, and durable with similar 5- to 6-year patency rates to OS bypass [39-45]. A recent retrospective review comparing EVR or OS bypass for TASC II aortoiliac occlusive disease found equivalent rates of 2-year survival, limb salvage (100% versus 92.3%;  $P = .22$ ), and primary or primary assisted patency (85% versus 85%;  $P = .98$ ) [41]. Aortobifemoral and aortobiiliac bypass procedures maintain a 30-day mortality of 3.6% and stable 30-day major complication rate of 20%, which has remained stable for the past 2 decades. OS bypass is still acceptable when EVR is not feasible [52].

### **Summary of Highlights**

This is a summary of the key recommendations from the variant tables. Refer to the complete narrative document for more information.

- **Variante 1:** For initial management of this patient with mild claudication symptoms and no evidence of CLTI, initiation of antiplatelet therapy, risk factor analysis including ABIs and lipid profile, and optimal medical management of underlying HTN, diabetes, and hyperlipidemia are recommended. To determine concordance between clinical symptoms and PAD, it is recommended that Duplex US imaging of the aortoiliac segment/lower extremity be obtained.
- **Variante 2:** For initial management of this patient presenting with ALI of the left lower extremity, early onset of anticoagulation is recommended to limit thrombus propagation until adjunctive therapies can be employed. Cross-sectional imaging with CTA or MRA is recommended to reveal the exact nature and level of both thrombosis and underlying atherosclerotic plaque to plan the most appropriate treatment strategy. Catheter-directed angiography could also be considered as initial management to both diagnose and promptly restore flow to the affected limb if tissue is threatened.
- **Variante 3:** For initial management of this patient presenting with ALI, early onset of anticoagulation is recommended to limit thrombus propagation until adjunctive therapies can be employed. Options for more-definitive initial therapy include expeditious catheter-directed mechanical thrombectomy or surgical revascularization to restore blood flow to the limb and limit irreversible tissue damage.
- **Variante 4, 5, and 6:** For initial management of any patient without lifestyle-limiting claudication or evidence of rest pain or nonhealing wounds, it is recommended that antiplatelet adjunctive therapy be initiated. This is true for all symptomatic patients with PAD to reduce MACE and CV mortality. Best medical management should also be offered and includes optimizing treatment of underlying HTN, diabetes, and hyperlipidemia. A SET should be initiated in all patients with nonlimb-threatening PAD to improve maximum walking distance.
- **Variante 7:** For initial management of this patient with worsening claudication, but more importantly evidence of nonhealing wounds and critical limb ischemia, antiplatelet therapy should be initiated as an adjunctive treatment. An endovascular approach with percutaneous stent placement and restoration of inline flow to the foot with treatment of the superficial femoral artery disease is appropriate because CLTI is rarely isolated to the aortoiliac segment alone. Restoration of flow to promote healing of the digital wounds is recommended and

can also be achieved by surgical revascularization options such as aortofemoral bypass or hybrid revascularization procedures using a multidisciplinary approach (such as endovascular treatment of the aortoiliac occlusive disease and surgical infrainguinal bypass to address the femoropopliteal segment).

### Supporting Documents

The evidence table, literature search, and appendix for this topic are available at <https://acsearch.acr.org/list>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to [www.acr.org/ac](http://www.acr.org/ac).

### Gender Equality and Inclusivity Clause

The ACR acknowledges the limitations in applying inclusive language when citing research studies that pre-dates the use of the current understanding of language inclusive of diversity in sex, intersex, gender and gender-diverse people. The data variables regarding sex and gender used in the cited literature will not be changed. However, this guideline will use the terminology and definitions as proposed by the National Institutes of Health [53].

### Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel’s recommendation. “May be appropriate” is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.