

Cardio Policy:

Endovascular Tibio-Peroneal Interventions

POLICY NUMBER UM CARDIO_1174	SUBJECT Endovascular Tibio-Peroneal Interventions		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/30/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 10/14/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23	APPROVAL DATE December 20, 2023	EFFECTIVE DATE December 22, 2023	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 08/22/13, 06/30/14, 03/19/15, 08/12/15, 11/28/16, 12/21/16, 10/10/17, 03/08/19, 05/08/19, 12/11/19, 05/13/20, 05/12/21, 10/14/21, 11/09/21, 10/12/22, 02/01/23, 05/10/23, 12/20/23	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Endovascular Tibio-Peroneal Interventions.

II. DEFINITIONS

Endovascular intervention is the treatment of peripheral arterial disease with angioplasty and/or primary stenting. It is performed by opening the blood vessel with a balloon placed on the end of a catheter. A stent is often used with angioplasty to help keep the artery open.

Rutherford Classification (RC) for Peripheral Artery Disease (PAD) or Chronic Limb Ischemia (CLI) is defined as follows:

Classification 0	Asymptomatic
Classification 1	Mild Claudication (calf pain climbing more than two flights of stairs)
Classification 2	Moderate Claudication (calf pain climbing less than two flights of stairs)
Classification 3	Severe Claudication (calf pain climbing less than one flight of stairs)
Classification 4	Ischemic Rest Pain (foot pain due to inadequate perfusion that improves with placing the foot in a dependent position)
Classification 5	Minor Tissue Loss (cutaneous ischemic ulceration)
Classification 6	Major Tissue Loss (skin necrosis and gangrene)

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions^{6,7,8,9,10,11}

III. POLICY

- A. Before a patient with intermittent claudication and or rest pain is offered the option of any invasive revascularization therapy, (endovascular or surgical), the following considerations must be taken into account:
1. Predicted or observed lack of adequate response to exercise therapy and claudication pharmacotherapies (GDMT) ^{5,6,7,8,9,10,11}
 2. Presence of a severe disability, with the patient either being unable to perform normal work or having very serious impairment of other activities important to the patient or having rest pain (RC2-6)
 3. Absence of other disease that would limit exercise even if the claudication was improved (e.g., angina or chronic respiratory disease)
 4. Morphology of the lesion, which must be such that the appropriate intervention would have low risk and a high probability of initial and long-term success.

- B. Prior to considering Infra Popliteal (IP) intervention, all hemodynamically significant inflow disease (aortoiliac and/or Femoral- Popliteal) should be treated to normalize inflow to the IP circulation. Then, if deemed clinically necessary, one may proceed with management of the IP disease.

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

- A. Balloon PTA of infrapopliteal lesions with length less than 100mm is considered appropriate in symptomatic patients (RC 2-6). **(AUC Score 7)**^{1,2,3,4}
- B. Balloon PTA of infrapopliteal lesions with length greater than or equal to 100mm is considered appropriate in symptomatic patients (RC 2-6). **(AUC Score 7)**^{1,2,3,4}
- C. Atherectomy may be appropriate in symptomatic patients (RC2-6) with infrapopliteal heavily calcified lesions that are non-amenable to balloon PTA. **(AUC Score 5)**^{1,2,3,4}

Limitations:

- A. Primary atherectomy and Stenting of IP lesions is not currently recommended due to lack of evidence in improving clinical outcomes.
- B. The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of IP arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well established.
- C. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity peripheral arterial disease.
- D. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.
- E. Before proceeding with endovascular tibioperoneal intervention for a patient with symptomatic PAD the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT^{7,8,9,10,11,12}

IV. PROCEDURE

- A. In order to review a request for medical necessity, the following items must be submitted for review:
 - 1. Progress note that prompted request
 - 2. Angiographic testing pertinent to the request
 - 3. Non-invasive vascular testing
- B. Primary codes appropriate for this service: 37228, 37229, 37230, 37231, 37234, 37235

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

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12. NCQA UM 2023 Standards and Elements.