



Cardio Policy:

Endovascular Femoropopliteal Interventions

POLICY NUMBER UM CARDIO_1173	SUBJECT Endovascular Femoropopliteal Interventions	DEPT/PROGRAM UM Dept	PAGE 1 OF 6
DATES COMMITTEE REVIEWED 09/09/11, 01/09/13, 08/22/13, 06/28/14, 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, 09/08/21, 11/09/21, 09/14/22	APPROVAL DATE September 14, 2022	EFFECTIVE DATE September 30, 2022	COMMITTEE APPROVAL DATES 09/09/11, 01/09/13, 08/22/13, 06/28/14, 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, 09/08/21, 11/09/21, 09/14/22
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 Femoropopliteal Interventions.

II. DEFINITIONS

Endovascular intervention is the treatment of peripheral arterial disease with angioplasty and/or primary stenting. It is performed by opening up 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)

TASC II Classifications of Femoral and Popliteal Lesions amenable for endovascular intervention:

A. Type A lesion:

1. Single stenosis \leq 10cm
2. Single occlusion \leq 5cm

B. Type B lesion:

1. Multiple lesions, each \leq 5cm
2. Single stenosis or occlusion \leq 15cm not involving infrageniculate popliteal artery
3. Single Popliteal stenosis
4. Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for distal bypass.

C. Type C lesion:

1. Multiple stenosis or occlusion $>$ 15cm with or without heavy calcification

Lesion length is categorized into *focal* ($<$ 10 cm), *intermediate* (10-20 cm), and *diffuse* ($>$ 20 cm), which is consistent with the definitions used for the SCAI peripheral vascular interventions AUC document.³

For the purpose of this document, *intended definitive therapy* is defined as what is known to be medically appropriate at the time of the initiation of the service. *Adjunctive therapy* is defined as a service that becomes necessary during the intended definitive therapy, e.g., as a bailout/salvage procedure.

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

III. POLICY

Indications for approving a request for medical necessity are:

- 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 must be considered:
1. When applicable, optimal GDMT for PAD (*as outlined in UM CARDIO_1432 Guidelines for Medical Management of Peripheral Artery Disease*) must have been implemented, with a focus on therapies with Class I recommendations that have demonstrated reductions in the risk of MI, stroke, heart failure, and cardiovascular deaths.
 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 (RC 2-6).
 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. (See TASC Classification)
- B. The approval criteria for requests will be based upon updated clinical scenarios from reference (2) as indicated in tables A and B below.

Table A. AUC score for device selection as the Intended Definitive Therapy in the femoral-popliteal arterial interventions:

	PTA	Specialty balloon	BMS (Self-expanding)	DES	DCB	Laser Atherectomy	Orbital/ Directional/ Excisional / Aspiration Atherectomy
CFA bifurcation lesion	4	4	5	4	4	1	1
Above knee popliteal lesion	1	1	6	8	9	1	1
Ostial SFA lesion	4	4	6	8	9	1	1
Focal SFA lesion	4	1	6	8	9	1	1
Intermediate SFA lesion	1	4	6	8	9	1	1
Diffuse SFA lesion	1	1	5	8	8	1	1
Mod to severe calcified, focal lesion	4	4	4	7	7	1	1
Mod to severe calcified, intermediate lesion	1	1	4	7	7	1	1
Mod to severe calcified, diffuse lesion	1	1	4	7	7	1	1
CTO, focal lesion	4	1	5	8	8	1	1

CTO, intermediate lesion	1	1	5	8	8	1	1
CTO, diffuse lesion	1	1	4	8	8	1	1
ISR, focal lesion	4	1	1	4	8	5	1
ISR, intermediate lesion	1	1	1	4	8	5	1
ISR, diffuse lesion	1	1	1	4	8	5	1

Abbreviations: PTA, percutaneous transluminal angioplasty; BMS, bare metal stent; DES, drug eluting stent; DCB, drug coated balloon CFA, common femoral artery; SFA superficial femoral artery; CTO, Chronic Total Occlusion; ISR, in-stent restenosis.

Table B. AUC score for device selection as the *Adjunctive Therapy* in the femoral-popliteal arterial interventions:

	Specialty balloons	Laser Atherectomy	Directional Atherectomy	Orbital/ Rotational Atherectomy	Excisional / Aspiration Atherectomy
CFA bifurcation lesion	4	1	4	4	1
Above knee popliteal lesion	1	1	1	1	1
Ostial SFA lesion	4	1	4	4	1
Focal SFA lesion	1	1	1	1	1
Intermediate SFA lesion	1	1	1	1	1
Diffuse SFA lesion	1	1	1	1	1
Mod to severe calcified, Undilatable focal lesion	4	4	1	4	4
Mod to severe calcified, Undilatable intermediate lesion	4	4	1	4	4
Mod to severe calcified, Undilatable diffuse lesion	4	4	1	4	4
Mod to severe calcified, dilatable focal lesion	4	1	1	4	1

Mod to severe calcified, dilatable intermediate lesion	4	1	1	4	1
Mod to severe calcified, dilatable diffuse lesion	4	1	1	4	1
CTO, focal lesion	1	5	1	1	1
CTO, intermediate lesion	1	1	1	1	1
CTO, diffuse lesion	1	1	1	1	1
ISR, focal lesion	1	5	1	1	1
ISR, intermediate lesion	1	5	1	1	1
ISR, diffuse lesion	1	5	1	1	1

Abbreviations: CFA, common femoral artery; ISR, in-stent restenosis; SFA, superficial femoral artery.

Limitations:

- A. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity peripheral arterial disease.
- B. With few exceptions, laser, directional, orbital/rotational, and excisional/aspiration atherectomy procedures are Class III LOR. Such cases involve laser atherectomy (approvable only for in-stent restenosis (ISR)), and moderate to severe lesions that are documented to be heavily calcified and undilatable.
- C. 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.

IV. PROCEDURE

- A. 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: 37224(PTA), 37225 (PTA with Atherectomy), 37226 (PTA with Stent), 37227 (PTA with Atherectomy and Stent), Ultrasound guided vascular access- 76937.

V. APPROVAL AUTHORITY

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

VI. ATTACHMENTS

None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. Florida. Local Coverage Determination (LCD) (L33763). Vascular Stenting of Lower Extremity Arteries. Retrieved from <https://www.cms.gov> April 24th, 2019.
2. Feldman, DM et al. SCAI Consensus Guidelines for Device Selection in Femoral-popliteal Arterial Interventions. *Catheter Cardiovasc Interv*. 2018; 92:124-140. <https://doi.org/10.1002/ccd.27635>
3. Klein, Andrew, et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. May 2017. Oct 2017. Volume 90, Issue 4, Pages E90-E110.
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. NCQA UM 2022 Standards and Elements.