SVS | Society for Vascular Surgery

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May 13, 2020

Sam Marchio
Anthem, Inc
225 North Michigan Ave
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Sent via: Samuel.Marchio@anthem.com

Re: Anthem Endovascular Techniques (Percutaneous or Open Exposure) for Arterial Revascularization of the Lower Extremities - CG-SURG-49

Dear Mr. Marchio:

The Society for Vascular Surgery (SVS) is a professional medical specialty society, composed primarily of vascular surgeons, that seek to advance excellence and innovation in vascular health through education, advocacy, research and public awareness. SVS, on behalf of its 5,900 members, appreciates the opportunity to comment on one of Anthem's Medical Policies and Clinical UM Guidelines. SVS has particular concerns with policy CG-SURG-49 Endovascular Techniques (Percutaneous or Open Exposure) for Arterial Revascularization of the Lower Extremities policy. Those concerns are outlined below.

Section A. Treatment of Claudication

Regarding the treatment of patients with claudication, the main area of concern is the requirement for at least 6 months of conservative management prior to endovascular treatment. The supervised exercise therapy (SET) program while beneficial for some patients, does not cure claudication but rather improves walking distance and symptoms. Therefore, given the limited benefit, inability for all claudicants to participate and duration of treatment, we need to provide for exceptions to this requirement based on clinical assessment and judgment. The first exception are patients whose claudication is so severe that being able to double their walking distance after 6 months of therapy would still leave the patient severely debilitated and adversely affect their quality of life including activities of daily living. Other patients are risking their jobs and health care benefits if they are not treated in a timely fashion and cannot afford to embark upon such a lengthy trial of walking. In the SVS Guidelines that is referenced in your document, Conte *et al* stated that the 6 month trial of smoking cessation, risk factor modification, exercise, cilostazol, or a combination should be initiated before any invasive therapy in "most claudicant patients".[1] This implies that there are patients that do have medical necessity requiring more timely invasive procedures and should not be subjected to a 6 month course if clinically deemed not warranted or in the best care of the patient.

The second exceptions are patients that cannot meet all the criteria in your guidelines for medical necessity. While SVS Guideline 5.1 recommends invasive therapy for those "when pharmacologic or exercise therapy, or both, have failed", not all patients are candidates for this non-operative regimen. Patients may not be able to participate in a SET program because of availability, transportation, therefore leaving medical management as the only alternative. Further, cilostazol, which is the only medical pharmacologic treatment mentioned in the 6-month conservative management, is contraindicated in patients with congestive heart failure or poor ejection fractions due to serious adverse outcomes. Studies have shown that PAD and CAD are commonly found together and more than 25% of patients with PAD also have CHF.[2] Thus for those patients with socioeconomic limitations or comorbidities that limit optimal medical management,

endovascular and open therapy are their only options.

When determining the optimal of invasive therapy for the treatment of patients with claudication, SVS Guideline 5.2 recommends "an individualized approach to select an invasive treatment." Your guidelines for medical necessity for the treatment of claudication is clearly supported by TASC II and the American College of Cardiology Appropriate Use Criteria Task Force for treatment of lesions shorter than 15cm.[3-4] Unfortunately, your guidelines do not allow for endovascular treatment of lesions longer than 15cm in any scenario. This is presumably due to the TASC II Recommendation 37, that states "endovascular treatment is preferred for TASC B lesions and surgery is preferred for good risk TASC C patients".[3] The carrier guidelines prohibiting endovascular therapy of lesion lengths greater than 15cm is restrictive and fails to address the potential risk of surgical therapy in high risk patients. The lesion length should not be the sole characteristic to guide optimal medical therapy, but rather an individualized approach with sound decision making and communication between the patient and the physician. Please be reminded that recommendation 37 goes on to state that a fully informed patient and the operator's long-term success rate must be considered when making treatment recommendations for TASC B and C lesions. Therefore, a standardized treatment does not apply for a maximum lesion length as the approach must be truly individualized and clinical decision making between clinician and patient is imperative for optimal patient care.

Section B. Salvage (Provisional) Therapy for Claudication

This section references the bailout therapy necessary when treatment in the first section, "Treatment of Claudication", has demonstrated lack of optimal target vessel revascularization. Within this section there were outlined several patient populations that would benefit from primary stenting for claudication. When dealing with salvage therapy for claudication, the policy in the first section does not include treatment with atherectomy in any anatomic location or in the SFA for lesion lengths <5cm. Stenting and atherectomy are certainly recommended for salvage therapy for the conditions mentioned- residual diameter stenosis greater than 50% or persistent translesional pressure gradient or flow limiting dissection. This policy does not take into account other important anatomic factors such of the quality and number of runoff vessels. This policy seems to apply to the TASC A criteria in that a single stenosis of less than or equal to 10 cm in length or a single occlusion less than or equal to 5 cm in length when applying the criteria in the claudication section.[5,6] This policy applies data derived in 2006 and 2007 and fails to match existing technology and evidence-based medicine. Even data published by the same author the same year as the landmark TASC criteria showed claudicants having a lower restenosis rate (49.2% versus 74.3%; P=0.028) and a trend toward a better clinical outcome. Other studies followed demonstrating primary stenting, when used primarily rather than as salvage therapy, had significantly improved physical function, lower bodily pain, and better overall general health.[7,8] Overall, the application of TASC criteria for therapy is limited and outdated. Since the publication of the original TASC recommendations, there has been an explosion of technological advances and applications of atherectomy and drug eluting platforms. These tools have resulted in improvements in both short-term technical results and long-term patency. This policy does not consider the improved patency and exercise tolerance when stenting is performed as a primary therapy and not as a salvage procedure.

In regard to the residual stenosis treatment with bailout stenting of 50% or greater within the SFA or other vessel, this policy correctly addresses a key goal in the treatment utilizing atherectomy and stenting to ensure optimal target vessel revascularization- vessel preparation. In this policy, the proceduralist is permitted to use stenting or atherectomy as salvage therapy and not utilize atherectomy for target vessel preparation prior to stenting. Lesions treated with atherectomy and angioplasty have been demonstrated to have fewer occurrences of need for salvage stenting.[9] Further, atherectomy may have benefits in heavily calcified lesions, high flexion locations where stents may not be optimal, and longer lesions.[10] This policy statement appreciates the importance of target vessel preparation in the treatment of atherosclerotic vascular lesions and that by appropriately preparing the vessel, short- and long-term patency rates will be improved. The

treatment of flow limiting dissections utilizing provisional atherectomy or stenting is appropriate.

Not Medically Necessary

While we agree with this policies limitation of treatment as not medically necessary in some instances, we argue that some of the policies stances as "not medically necessary" are outdated. The carrier policy references and utilizes the SVS practice guidelines for atherosclerotic occlusive disease of the lower extremities for asymptomatic disease and claudication. Unfortunately, several of the premises of the guidelines are outdated or simply unproven. For example, profunda femoris artery disease is cited as not clinically significant in this publication but there is extensive literature to demonstrate the contrary. Treatment of the PFA in isolation and with CFA disease is beneficial in providing augmented inflow to the limb and treating limb ischemia as initially documented Brewster and Darling publication.[11],[12] As endovascular treatments continues to evolve so have our treatment options leading to Soares et al recommendation in favor of concomitant endovascular PFA treatment at the time of additional interventions while a more comprehensive pooled analysis of endovascular common femoral and profunda femoral artery interventions demonstrated >95% technical success with very low limb loss and major adverse cardiovascular events.[13,14] In addition, the updated 2019 Supplement to the Journal of Vascular Surgery guidelines discuss the importance of PFA patency and endovascular therapy of this vessel particularly in a hostile groin.[15] While the SVS agrees that treatment for asymptomatic PAD is not warranted in general, there are instances when it is valid. Patients with previous interventions such as stent placement or bypass procedures, irrespective of the conduit, who present with severe or critical stenosis would absolutely warrant intervention despite the lack of clinical symptoms. Treatment of these lesions have been proven to maintain patency and reduce acute limb ischemia and limb loss.[16,17] Therefore, asymptomatic PAD patients with previous interventions may benefit from interventions and this decision making should be based on the clinical scenario.

The SVS appreciates the opportunity to provide feedback on the Anthem Medical Policies and Clinical UM Guidelines. We look forward to hearing from you on this issue. We can be reached at trishacrishock@gmail.com.

Sincerely,

Matthew Sideman, MD
SVS Coding Committee Chair

Sunita Srivastava, MD
SVS Coding Committee Vice Chair

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References:

1. Conte MS, Pomposelli FB, Clair DG *et al*. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. *J Vasc Surg* 2015;61(3Suppl)2S-41S.
2. Keswani AN, White CJ. The impact of peripheral arterial disease on patients with congestive heart failure. Heart Fail Clin. 2014 Apr;10(2):327-38.
3. TASC Steering Committee, Jaff MR, White CJ *et al*. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: A supplement to the inter-society consensus for the management of peripheral arterial disease (TASC II). J Endovasc Ther 2015 Oct;22(5):663-77.
4. 4Bailey SR, Beckman JA, Misra S *et al*. ACC/AHA/SCAI/SIR/SVM 2018 appropriate use criteria for peripheral artery intervention: A report of the American College of Cardiology appropriate use task force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. J Am Coll Cardiol 2019 Jan;73(2):214-37.
5. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, Rutherford RB: Inter-society consensus for the management of peripheral arterial disease. *Int Angiol* 2007, 26(2):81-157.
6. Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, Schlager O, Cejna M, Lammer J, Minar E: Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med* 2006, 354(18):1879-1888.
7. Schillinger M, Sabeti S, Dick P, Amighi J, Mlekusch W, Schlager O, Loewe C, Cejna M, Lammer J, Minar E: Sustained benefit at 2 years of primary femoropopliteal stenting compared with balloon angioplasty with optional stenting. *Circulation* 2007, 115(21):2745-2749.
8. Lindgren HIV, Qvarfordt P, Bergman S, Gottsater A: Primary Stenting of the Superficial Femoral Artery in Patients with Intermittent Claudication Has Durable Effects on Health-Related Quality of Life at 24 Months: Results of a Randomized Controlled Trial. *Cardiovasc Intervent Radiol* 2018, 41(6):872-881.
9. Foley TR, Cotter RP, Kokkinidis DG, Nguyen DD, Waldo SW, Armstrong EJ: Mid-term outcomes of orbital atherectomy combined with drug-coated balloon angioplasty for treatment of femoropopliteal disease. *Catheter Cardiovasc Interv* 2017, 89(6):1078-1085.
10. Katsanos K, Spiliopoulos S, Reppas L, Karnabatidis D. Debulking Atherectomy in the Peripheral Arteries: Is There a Role and What is the Evidence? Cardiovasc Intervent Radiol. 2017 Jul;40(7):964-977
11. Brewer, DC and RC Darling. "Optimal methods for aortoiliac reconstruction." Surgery. 1978 Dec;84(6):739-48.
12. Kashyap, V et al. "The management of severe aortoiliac occlusive disease: Endovascular therapy rivals open reconstruction." J Vasc Surg. 2008 Volume 48, Issue 6, Pages 1451–1457.e3.
13. Soares et al. "The importance of the superficial and profunda femoris arteries in limb salvage following endovascular treatment of chronic aortoiliac occlusive disease." J Vasc Surg. 2018 Vol 68, Issue 5, p1422-1429.
14. Bath J, Avgerinos E. A pooled analysis of common femoral and profunda femoris endovascular interventions. Vascular. 2016 Aug;24(4):404-13.
15. Conte et al. "Global vascular guidelines on the management of chronic limb-threatening ischemia." J Vasc Surg. 2019 Volume 69, Issue 6, Supplement, Pages 3S–125S.e40: p66S.

16. Diamantopoulos A. Peripheral Stent Thrombosis Leading to Acute Limb Ischemia and Major Amputation: Incidence and Risk Factors in the Aortoiliac and Femoropopliteal Arteries. Cardiovasc Intervent Radiol. 2017 Mar;40(3):351-359.
17. Smith AD, Hawkins AT, Schaumeier MJ, de Vos MS, Conte MS, Nguyen LL. Predictors of major amputation despite patent bypass grafts. J Vasc Surg. 2016 May;63(5):1279-88.