

DRAFT Medical Coverage Policy | Peripheral Artery Disease (PAD) Rehabilitation



EFFECTIVE DATE: 02/01/2023

POLICY LAST UPDATED: 10/19|2022

OVERVIEW

Peripheral arterial disease (PAD) is a common chronic cardiovascular condition that affects the lower extremities and can substantially limit daily activities and quality of life. Lifestyle interventions, including smoking cessation, diet modification, regular physical activity, and pharmacotherapy, are often prescribed to treat patients with PAD.

MEDICAL CRITERIA

Commercial Products

SET for symptomatic noncritical PAD is considered medically necessary when ALL of the following criteria are met:

- Presence of non-critical limb ischemia claudication characterized by fatigue, discomfort, cramping or pain of vascular origin in the muscles of the lower extremities that is consistently caused by exercise and consistently relieved by rest (within 10 minutes); and,
- Requires a face-to-face visit with the physician responsible for PAD treatment for referral to SET program and, at this visit, individual must receive information regarding cardiovascular disease, PAD risk factor reduction (ie, education, counseling, behavioral interventions and outcome assessments); and,
- Must be provided in a hospital outpatient setting or physician's office, under direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist trained in both basic and advanced life support; and,
- Must be delivered by qualified auxiliary personnel to ensure benefits exceeds harms and who are trained in exercise therapy for PAD; and,
- The program consists of 36 sessions over a 12-week period, with sessions lasting 30-60 minutes and comprised of therapeutic exercise training; and,
- Verifiable smoking cessation counseling.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Effective for services performed on or after May 25, 2017, the Center for Medicare and Medicaid Services (CMS) has determined that the evidence is sufficient to cover supervised exercise therapy (SET) for members with intermittent claudication (IC) for the treatment of symptomatic peripheral artery disease (PAD). Therefore, these services will be covered when rendered as part of a supervised exercise therapy (SET) program.

Commercial Products

SET is considered medically necessary when the medical criteria above are met.

SET beyond 36 sessions is typically not medically necessary as the individual is expected to have been taught the appropriate self-care.

SET is considered not medically necessary for the following:

- Critical/chronic limb ischemia (CLI) characterized by chronic (greater than two weeks) ischemic rest pain, nonhealing wound/ulcers or gangrene in one or both legs attributable to objectively proven arterial occlusive disease.
- Individuals with absolute contraindications to exercise as determined by their primary physician.

SET is considered not medically necessary for all other indications as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Peripheral vascular rehabilitative physical exercise consists of a series of sessions, lasting 45 to 60 minutes per session, involving use of either a motorized treadmill or a track to permit the patient to achieve symptom-limited claudication. Each session is supervised on a one-on-one basis by an exercise physiologist, physical therapist, or nurse. The supervising provider monitors the individual patient's claudication threshold and other cardiovascular limitations for adjustment of workload. During this supervised rehabilitation program, the development of new arrhythmias, symptoms that might suggest angina, or the continued inability of the patient to progress to an adequate level of exercise may require physician review and examination of the patient.

Both physical activity and medications are used to treat peripheral vascular disease. Vascular specialists agree that long daily walks are the best treatment for people with intermittent claudication, thereby increasing the distance of pain-free walking through the development of collateral circulation. Patients whose legs hurt during physical activity often find it hard to follow a walking program. For this reason, the cardiac rehabilitation departments of some hospitals have created supervised exercise programs that offer support and encouragement. These peripheral vascular rehabilitation programs are geared to patients with various peripheral vascular disorders, including post-surgical patients (e.g., peripheral angioplasty, peripheral arterial bypass, stent) and patients with peripheral arterial disease who are not candidates for surgery. Services are provided by a multi-disciplinary team, which includes nurses, physical therapists and physicians. The usual duration of the program is 3 times a week for 12 weeks (36 visits). The goal of treatment is to improve endurance and decrease symptoms.

Research has shown supervised exercise therapy to be an effective, minimally invasive method to alleviate the most common symptom associated with PAD (IC). SET has been shown to be significantly more effective than unsupervised exercise, and could prevent the progression of PAD and lower the risk of cardiovascular events that are prevalent in these patients. SET has also been shown to perform at least as well as more invasive revascularization treatment.

Medicare Advantage Plans

Research has shown Supervised Exercise Therapy (SET) to be an effective, minimally invasive method to alleviate the most common symptom associated with PAD – intermittent claudication. SET has been shown to be significantly more effective than unsupervised exercise and could prevent the progression of PAD and lower the risk of cardiovascular events that are prevalent in these patients. SET has also been shown to perform at least as well as more invasive revascularization treatment, which is covered by Medicare.

Up to 36 sessions over a 12-week period are covered if all the following components of a SET program are met:

The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a hospital outpatient setting or a physician's office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa) (5)) who must be trained in both basic and advanced life support techniques.

Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second referral is required for these additional sessions.

CODING

Medicare Advantage Plans

The following CPT code(s) is covered:

93668 Peripheral arterial disease (PAD) rehabilitation, per session

Commercial Products

The following CPT code(s) is covered when criteria above is met:

93668 Peripheral arterial disease (PAD) rehabilitation, per session

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, December 2022

Provider Update, January 2022

Provider Update, February 2021

Provider Update, January 2020

Provider Update, June 2018

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Decision Memo for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N). May 25, 2017. [https://www.cms.gov/medicare-coverage-database/details/nca-decisionmemo.aspx?NCAId=287&NcaName=Supervised+Exercise+Therapy+\(SET\)+for+Symptomatic+Peripheral+Artery+Disease+\(PAD\)&ExpandComments=y&CommentPeriod=0&bc=gCAAAAAACAAAAA%3D%3D& Accessed July 7, 2021.](https://www.cms.gov/medicare-coverage-database/details/nca-decisionmemo.aspx?NCAId=287&NcaName=Supervised+Exercise+Therapy+(SET)+for+Symptomatic+Peripheral+Artery+Disease+(PAD)&ExpandComments=y&CommentPeriod=0&bc=gCAAAAAACAAAAA%3D%3D& Accessed July 7, 2021.)
2. Centers for Medicare and Medicaid (CMS). MLN Matters. February 2018. Revised: February 13, 2019. Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD). <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10295.pdf> Accessed July 7, 2021.
3. Fokkenrood HJ, Bendermacher BL, Lauret GJ, et al. Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication. *Cochrane Database Syst Rev.* 2013;8:CD005263.
1. Vernooij JW, Kaasjager HA, van der Graaf Y, et al; SMART Study Group. Internet based vascular risk factor management for patients with clinically manifest vascular disease: Randomised controlled trial. *BMJ.* 2012;344:e3750.
2. Saxton JM, Zwierska I, Blagojevic M, et al. Upper- versus lower-limb aerobic exercise training on health-related quality of life in patients with symptomatic peripheral arterial disease. *J Vasc Surg.* 2011;53(5):1265-1273.

3. Fakhry F, Spronk S, de Ridder M, et al. Long-term effects of structured home-based exercise program on functional capacity and quality of life in patients with intermittent claudication. Arch Phys Med Rehabil. 2011;92 (7):1066-1073.
4. Franz RW, Garwick T, Haldeman K. Initial results of a 12-week, institution based, supervised exercise rehabilitation program for the management of peripheral arterial disease. Vascular. 2010;18(6):325-335.
5. Banerjee A, Fowkes FG, Rothwell PM. Associations between peripheral artery disease and ischemic stroke: Implications for primary and secondary prevention. Stroke. 2010;41(9):2102-2107.
6. Hayes. Search & Summary. Supervised Exercise Therapy (SET) for the Treatment of Symptomatic Peripheral Artery Disease (PAD). September 1, 2020.
7. National Institute for Health and Care Excellence (NICE). Peripheral arterial disease: diagnosis and management. Clinical guideline [CG147] Published date: August 8, 2012. Last Updated: December 11, 2020. <https://www.nice.org.uk/guidance/CG147/chapter/1-Guidance#management-of-intermittent-claudication>. Accessed July 7, 2021.

DRAFT

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

