



<b>CLINICAL MEDICAL POLICY</b>	
<b>Policy Name:</b>	Supervised Exercise Therapy (SET) in the Management of Peripheral Artery Disease
<b>Policy Number:</b>	MP-077-MD-PA
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice/Issue Date:</b>	02/01/2024; 01/01/2023; 11/19/2021; 11/23/2020; 02/17/2020; 03/18/2019
<b>Effective Date:</b>	03/01/2024; 02/01/2023; 12/20/2021; 12/21/2020; 02/17/2020; 03/18/2019
<b>Next Annual Review:</b>	10/2024
<b>Revision Date:</b>	10/18/2023; 10/19/2022; 10/20/2021; 10/21/2020; 10/16/2019
<b>Products:</b>	Highmark Wholecare <sup>SM</sup> Medicaid
<b>Application:</b>	All participating hospitals and providers
<b>Page Number(s):</b>	1 of 9

**Policy History**

<b>Date</b>	<b>Activity</b>
03/01/2024	Provider Effective date
01/08/2024	PARP Approval
10/18/2023	QI/UM Committee review
10/18/2023	Annual Review: No changes to clinical criteria. Removed the following ICD-10 codes: I70.219, I70.419, I70.519, I70.619, I70.719, I73.9 per CMS guidance. Updated 'Summary of Literature' and 'Reference Sources' sections.
02/01/2023	Provider Effective date
12/13/2022	PARP Approval
10/19/2022	QI/UM Committee review
10/19/2022	Annual Review: No changes to clinical criteria. Added specific contraindications based on AACVPR published guidance. Updated 'Summary of Literature' and 'Reference Sources' sections. Removed the following 'Contraindication' bullet point: "Chronic infectious disease (e.g., mononucleosis, hepatitis, AIDS)" per PARP direction. Added the following ICD-10 diagnosis codes: I73.00, I73.01, I73.1, I73.81, I73.89, & I73.9.
12/20/2021	Provider effective date
11/11/2021	PARP Approval
10/20/2021	QI/UM Committee review

10/20/2021	Annual Review: No changes to clinical criteria. Updated Summary of Literature and References. Coding reviewed.
12/21/2020	Provider effective date
11/10/2020	PARP approval
10/21/2020	Annual Review: Revised medical necessity statement. Reformmated Governing Bodies Approval Section. Updated Summary of Literature and References. Added ICD-10 codes I70.219, I70.319, I70.419, I70.519, I70.619, I70.719.
10/21/2020	QI/UM Committee review
02/17/2020	Provider effective date
12/16/2019	PARP approval
10/16/2019	Annual Review: added definition for SET; under Length of Coverage added total number of services considered medically necessary; added information regarding CMS determination; updated Gateway Health Plan to Gateway Health; updated references; format revisions
10/16/2019	QI/UM Committee Review Approval
03/18/2019	Provider effective date

### **Disclaimer**

Highmark Wholecare<sup>SM</sup> medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### **Policy Statement**

Highmark Wholecare<sup>SM</sup> may provide coverage under the therapy benefits of the Company's Medicaid products for medically necessary supervised exercise therapy (SET) for the treatment of patients with symptomatic peripheral artery disease (PAD).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

## Definitions

**Prior Authorization Review Panel (PARP)** – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

**Intermittent claudication (vascular claudication)** - A symptom that describes muscle pain or mild exertion, classically in the calf muscle, which occurs during exercise, such as walking, and is relieved by a short period of rest.

**Supervised Exercise Therapy (SET)** - The use of intermittent walking exercise, which alternates periods of walking to moderate-to-maximum claudication, with rest.

## Procedures

### 1. Medical Necessity Guidelines

SET may be considered medically necessary for individuals with PAD and/or IC, for up to 36 sessions over a 12-week period, when ALL of the following components of the SET program are met:

- A. The program must consist of sessions lasting 30-60 minutes, comprising a therapeutic exercise-training program for PAD in patients with claudication; AND
- B. The program must be conducted in a hospital outpatient setting, ambulatory outpatient, or a physician's office; AND
- C. The program must be delivered by qualified auxiliary personnel who are trained in exercise therapy for PAD to ensure the benefits exceed any harms; AND
- D. The patient must be under the supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist trained in both basic and advanced life support techniques; AND
- E. The patient must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET program. At the visit, the patient must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

### 2. Contraindications

The following risk stratification is based on the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR). Cardiac rehabilitation services are contraindicated in patients with the following conditions:

- A recent significant change in the resting ECG suggesting significant ischemia, recent MI (within 2 days), or other acute cardiac event
- Severe residual angina
- Uncompensated heart failure
- Uncontrolled arrhythmias
- Symptomatic severe aortic stenosis
- Severe ischemia, LV dysfunction, or arrhythmia during exercise testing
- Poorly controlled hypertension
- Acute pulmonary embolism or pulmonary infarction
- Acute myocarditis or pericarditis

- Suspected or known dissecting aneurysm
- Acute systemic infection, accompanied by fever, body aches, or swollen lymph glands
- Hypertensive or any hypotensive systolic blood pressure response to exercise

Relative contraindications to exercise include:

- Left main coronary stenosis
- Moderate stenotic valvular heart disease
- Electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia)
- Severe arterial hypertension (i.e., systolic BP If greater than 200mm Hg and/or diastolic BP of greater than 110 mm Hg) at rest
- Tachydysrhythmia or bradydysrhythmia
- Hypertrophic cardiomyopathy and other forms of outflow tract obstruction
- Neuromuscular, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
- High-degree atrioventricular block
- Ventricular aneurysm
- Uncontrolled metabolic disease (e.g., diabetes, thyrotoxicosis, or myxedema)
- Mental or physical impairment leading to inability to exercise adequately

3. When the SET program are considered not medically necessary

SET programs are considered not medically necessary for conditions other than those listed above because the scientific evidence has not been established. Highmark Wholecare<sup>SM</sup> considers the PADnet System and testing program experimental and investigational for evaluation of PAD and other indications because of insufficient evidence of its effectiveness.

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare<sup>SM</sup> at any time pursuant to the terms of your provider agreement.

5. Place of Service

The proper place of service for SET is ambulatory outpatient, physician office, or hospital outpatient setting.

6. Length of Coverage

Highmark Wholecare<sup>SM</sup> may cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second physician referral is required for additional sessions. SET services beyond 72 session are not covered.

7. Related Policies

- MP-057-MD-PA Cardiac Rehabilitation, Phase II Outpatient

## **Governing Bodies Approval**

The Center for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (20.35)

## **Summary of Literature**

Worldwide, more than 200 million individuals suffer from peripheral artery disease (PAD). Lower-extremity PAD is a burdensome condition caused by the underlying process of atherosclerosis that manifests itself in the leg arteries. It represents a spectrum of clinical manifestations that can include atypical lower-extremity symptoms, intermittent claudication, rest pain, and tissue loss secondary to ischemia. Patients with PAD are at a significantly increased risk for morbidity and mortality attributable to cardiovascular events not involving the lower extremities (Saxon, Safley, Mena-Hurtado, et al., 2020).

SET for PAD is a physician referred exercise and education based program that is designed to help people walk longer without pain in the hope of improving their overall quality of life. According to the Center for Medicare and Medicaid (2017), “Research has shown that SET is an effective, minimally invasive method to alleviate claudication (the most common symptom of PAD) and may also prevent the progression of PAD and lower the risk of other cardiovascular events in these patients.” A Cochrane study was performed on SET and included 21 trials in which a total of 1400 participants with intermittent claudication (65% male, mean age 66 years) had been assigned to either SET, home-based exercise, or walking advice. According to the study, SET demonstrated improvement in patients’ walking ability to a greater extent than the patients who completed home-based exercise or walking advice. Before SET, the patients’ maximal pain-free walking distance was 140 meters. After three months of SET, patients could walk 120 and 210 meters farther than the maximal walking distance for those who followed a home-based exercise program or received walking advice (Hageman, 2018).

PAD is a common chronic cardiovascular condition that affects the lower extremities and can substantially limit daily activities and quality of life (Heschis, 2018). Arterial obstruction and symptoms of arterial insufficiency are caused by reduced blood flow (Heschis, 2018). Many PAD patients do not have symptoms but some PAD patients develop intermittent claudication. Physical activity and medications are two forms of treatment for patients with PAD. Exercise therapy provides significant benefits for patients with PAD and symptoms of intermittent claudication (Hageman, 2018).

There are four noninvasive treatments recommended by the American College of Cardiology (ACC) /American Heart Association (AHA) performance measures for PAD:

1. Statin medications (the prescription of any available 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor)
2. Antiplatelet therapy (the use of aspirin at a dose of 75 to 325 mg daily or clopidogrel at a dose of 75 mg daily)
3. Smoking cessation therapy and/or counseling (verbal instructions, referral to a special program or formal counseling, as well as pharmacological therapy)
4. Referral to a PAD-specific supervised exercise training (SET) program (Saxon, Safley, Mena-Hurtado, et al., 2020)

The AHA/ACC provides guidelines on the management of PAD note that data supporting the efficacy of supervised exercise programs as an initial treatment for claudication continue to develop and remain convincing, building on many earlier RCTs. Trials with long-term follow-up from 18 months to 7 years have demonstrated a persistent benefit of supervised exercise in patients with claudication. The risk–benefit ratio for supervised exercise in PAD is favorable, with an excellent safety profile in patients screened for absolute contraindications to exercise such as exercise-limiting cardiovascular disease, amputation or wheelchair confinement, and other major comorbidities that would preclude exercise

#### ACC/AHA Recommendation for Supervised Exercise Therapy:

- In patients with claudication, a supervised exercise program is recommended to improve functional status and QoL and to reduce leg symptoms. (COR I) (LOE A)
- A supervised exercise program should be discussed as a treatment option for claudication before possible revascularization. (COR I) (LOE B-R)
- Supervised exercise program definitions (COR I) (LOE A)
  - Program takes place in a hospital or outpatient facility
  - Program uses intermittent walking exercise as the treatment modality
  - Program can be standalone or within a cardiac rehabilitation program
  - Program is directly supervised by qualified healthcare provider(s)
  - Training is performed for a minimum of 30-45 minutes/session; sessions are performed at least 3 times/week for a minimum of 12 weeks
  - Training involves intermittent bouts of walking to moderate-to-maximum claudication, alternating with periods of rest
  - Warm-up and cool-down periods precede and follow each session of walking

#### Rationale

A 2017 systematic review of the research provided high-quality evidence showing that exercise therapy should play an important part in the care of selected patients with intermittent claudication, to improve walking times and distances. Effects were demonstrated following three months of supervised exercise, although some programmes lasted longer than one year. Limited data suggest that an effect is sustained for up to two years. Exercise did not improve ankle brachial index (ABI), and investigators detected no differences in the effect of exercise between groups in terms of amputation or mortality. Exercise may improve quality of life when compared with placebo or usual care.

The study also showed that antiplatelet agents were less effective than exercise in improving walking distance but should continue to be used because of benefits in reducing cardiovascular events and death. In contrast, pentoxifylline was more effective than exercise but may have fewer beneficial effects on the cardiovascular system in general. Iloprost led to less improvement in walking time than exercise. The study data showed no clear effect on walking distances when pneumatic foot and calf compression was compared with exercise. However the number of participants in these studies is small and data are limited (Lane, 2017).

A 2019 randomized control trial highlights a new opportunity for PAD patients to gain cardiovascular and functional benefits from conservative management when exercise is limited or not tolerable. For these patients and possibly patients with other exercise-limiting conditions, a greater measure of cardiovascular conditioning and functional improvement becomes possible. Heat therapy on its own or in conjunction with what supervised exercise is feasible may limit the need for more invasive and costly interventions. It may also allow for improved cardiovascular conditioning in workup for better surgical outcomes. To realize this, further studies to confirm the clinical benefits of heat therapy will be required along with the

refinement of systems to provide heat therapy in a safe and efficient way. The mechanisms of action and long-term adherence to this conditioning method also require further exploration (Akerman, 2019).

The AHA has published the Patient-Centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories (PORTRAIT) study. The PORTRAIT study is a multicenter, prospective study of patients presenting for specialty vascular care with new-onset, or an exacerbation of, lower-extremity symptoms. Patients with new onset or worsening of PAD symptoms were screened for enrollment at the time of referral to subspecialty vascular care sites. Patients with a resting ankle brachial index  $\leq 0.90$  or drop in post-exercise ankle pressure of  $\geq 20$  mm Hg were eligible for inclusion. The participating centers consisted of 10 sites in the United States, 5 sites in The Netherlands, and 1 site in Australia (16 total). The study measured the adherence rate to the 4 noninvasive interventions recommendations of the current 2016 treatment guidelines: (1) antiplatelet therapy, (2) statin therapy, (3) SET, and (4) smoking cessation counseling. Unstructured and home-based exercise therapy was not considered to have met the recommendation, given that this was not supported by the 2010 American College of Cardiology/American Heart Association performance measures and is currently not a Class I recommendation.

A total of 1275 patients with new or an exacerbation of symptoms prompting referral to a vascular specialty clinic were enrolled in the study. The study showed that PAD performance measures that include pharmacotherapy (statins and antiplatelet therapy) seem to be relatively feasible and well adhered to by vascular specialists. However, adherence to nonpharmacological risk-mitigation strategies, including smoking cessation referral and SET, is not well realized in the specialty care setting. Along with the great variability in performance rates across sites, this requires future deeper exploration as to why nonpharmacological guideline-recommended risk-prevention strategies are not successfully realized. Structural reasons, including coverage, availability, as well as patient, practice, and provider preferences, are factors that will need to be considered in our search to optimize key risk-management strategies and outcomes for PAD (Saxon, Safley, Mena-Hurtado, et al., 2020).

## **Coding Requirements**

### Procedure Code

<b>CPT Code</b>	<b>Description</b>
93668	Peripheral arterial disease (PAD) rehabilitation, per session

### Diagnosis Codes

<b>ICD-10 Codes</b>	<b>Description</b>
I70.211	Atherosclerosis of native arteries of extremities with intermittent claudication, right leg
I70.212	Atherosclerosis of native arteries of extremities with intermittent claudication, left leg
I70.213	Atherosclerosis of native arteries of extremities with intermittent claudication, bilateral legs
I70.218	Atherosclerosis of native arteries of extremities with intermittent claudication, other extremity
I70.311	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.312	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.313	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs

I70.318	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.319	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.411	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, right leg
I70.412	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, left leg
I70.413	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.418	Atherosclerosis of autologous vein bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.511	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, right leg
I70.512	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, left leg
I70.513	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.518	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.611	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, right leg
I70.612	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, left leg
I70.613	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.618	Atherosclerosis of nonbiological bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.711	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.712	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.713	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.718	Atherosclerosis of other type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I73.00	Raynaud's syndrome without gangrene
I73.01	Raynaud's syndrome with gangrene
I73.1	Thromboangiitis obliterans [Buerger's disease]
I73.81	Erythromelalgia
I73.89	Other specified peripheral vascular diseases

### **Reimbursement**

Participating facilities will be reimbursed per their Highmark Wholecare<sup>SM</sup> contract.



## **Reference Sources**

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease (PAD) (NCD 20.35) Effective Date May 25, 2017. Implementation date July 2, 2018. Accessed on October 6, 2023.

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Hageman D, Fokkenrood HJP. Supervised exercise therapy vs home-based exercise therapy vs walking advice for patients with leg pain while walking (intermittent claudication). April 8, 2018. Accessed on October 5, 2018.

Centers for Medicare and Medicaid Services (CMS). MLN Matters. Supervised exercise therapy (SET) for symptomatic rules and expansion of International Classification Diseases tenth Edition (ICD-10) Diagnosis codes (MM11022). Release date February 1, 2019. Effective date May 25, 2017. Accessed on October 8, 2023.

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Saxon JT, Safley DM, Mena-Hurtado C, et al. Journal of the American Heart Association. Adherence to Guideline-Recommended Therapy—Including Supervised Exercise Therapy Referral—Across Peripheral Artery Disease Specialty Clinics: Insights From the International PORTRAIT Registry. Volume 9, No. 3. January 24, 2020. Accessed on September 20, 2022.