



<b>CLINICAL MEDICAL POLICY</b>	
<b>Policy Name:</b>	Supervised Exercise Therapy for Peripheral Artery Disease (PAD)
<b>Policy Number:</b>	MP-077-MD-DE
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice Date:</b>	01/15/2019
<b>Issue Date:</b>	02/18/2019
<b>Effective Date:</b>	02/18/2019
<b>Annual Approval Date:</b>	12/11/2019
<b>Revision Date:</b>	N/A
<b>Products:</b>	Highmark Health Options Medicaid
<b>Application:</b>	All participating hospitals and providers
<b>Page Number(s):</b>	1 of 6

**DISCLAIMER**

**Highmark Health Options 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 Health Options 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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

## **DEFINITIONS**

**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.

## **PROCEDURES**

### 1. Medical Necessity Guidelines

Highmark Health Options may provide coverage for up to 36 sessions over a 12-week period if all of the following components of a SET program are met:

- A. The program must consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in members 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 to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; AND
- D. The member 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 member must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET program.
  - 1) At the visit, the member must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

### 2. Contraindications

Highmark Health Options considers SET programs of peripheral vascular disease (PAD) to be experimental and investigational for members with absolute contraindications to exercise and for all other indications because the value for other indications is not well documented by the available peer-reviewed literature.

### 3. When the SET program is not covered

Supervised Exercise Therapy (SET) services are not covered for conditions other than those listed above because the scientific evidence has not been established.

Highmark Health Options considers the PADnet System and testing program experimental and investigational for evaluation of peripheral artery disease 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 Health Options at any time pursuant to the terms of your provider agreement.

### 5. Place of Service

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

## 6. Length of Coverage

Highmark Health Options 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.

## **CODING REQUIREMENTS**

### Procedure Codes

CPT Code	Description
93668	Peripheral arterial disease (PAD) rehabilitation, per session

### Diagnosis Codes

ICD-10 Codes	Description
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
I70.611	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

## **REIMBURSEMENT**

Participating facilities will be reimbursed per their Highmark Health Options contract.

## **SUMMARY OF LITERATURE**

Peripheral artery disease (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). Supervised Exercise Therapy (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 (Hageman, 2018). SET demonstrated improvement in patients’ walking ability to a greater extent than the patients who completed home-based exercise or walking advice (Hageman, 2018). 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).

In May 2017, CMS announced extended coverage for supervised exercise therapy (SET) to treat peripheral artery disease (PAD). According to CMS (2017), other studies and trials have showed decreases in mortality, reduced cardiovascular risk factors, increases in capacity, and increases in quality of life in older adults (APTA, 2017).

In 2014, the National Institute for Health and Care Excellence (NICE) created guidelines and recommendations for supervised exercise programs. The guideline does not recommend any home-based exercise programs (NICE, 2014). Key points in the NICE 2014 clinical evidence update include:

- Management of intermittent claudication - Exercise programs
- Supervised exercise is associated with increases in maximal walking distance (MWD) compared with home-based or other unsupervised exercise programs.
- Supervised exercise is associated with greater increases in walking distance in people with aorto-iliac disease than either stenting or optimum medical care.
- Supervised exercise appears to be more cost effective than either angioplasty alone or supervised exercise plus angioplasty in people with IC due to femora-popliteal occlusion.

The American College of Cardiology (ACC)/American Heart Association (AHA) recommended the SET programs and developed guidelines (2016):

- 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)
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- 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 minute/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

## **POLICY SOURCE(S)**

Centers for Medicare and Medicaid Services: Medicare National Coverage Determination for Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease (PAD) (NCD 20.35) Publication No. 100-3, Version 1. Effective Date 5/25/2017. Accessed on October 5, 2018.

Centers for Medicare and Medicaid Services: Decision memo for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N). May 25, 2017. Accessed on October 5, 2018.

Hayes, Inc. Supervised Exercise Therapy (SET) for the Treatment of Symptomatic Peripheral Artery Disease (PAD). Publication Date: July 13, 2017. Accessed on October 5, 2018.

National Institute for Health and Care Excellence (NICE). Lower limb peripheral arterial disease. Evidence update November 2014. Evidence Update 69. London, UK: NICE; November 2014. Accessed on October 5, 2018.

Hirsch AT, Haskal ZJ, Hertzner NR, et al; American Association for Vascular Surgery; Society for Vascular Surgery; Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; Society of Interventional Radiology; ACC/AHA Task Force on Practice Guidelines Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease; American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; Vascular Disease Foundation. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): A collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *J Am Coll Cardiol.* 2006;47(6):1239-1312. Accessed on October 5, 2018.

Heschis, D.G., Golden, M.A. Clinical features and diagnosis of lower extremity peripheral artery disease. UpToDate®, June 11, 2018. Accessed on October 5, 2018.

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.

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**Policy History:**

<b>Date</b>	<b>Activity</b>
10/03/2018	Initial policy developed
12/11/2018	QI/UM Committee approval
02/18/2019	Provider effective date