



## Kaiser Foundation Health Plan of Washington

### Clinical Review Criteria

### Supervised Exercise Therapy on Patients with Intermittent Claudication from Peripheral Vascular Disease (SET for IC in PAD)

**NOTICE:** Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

### Criteria

#### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (20.35)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

#### For Non-Medicare Members

Kaiser Permanente considers medical supervision of peripheral vascular rehabilitation programs medically necessary for the treatment of persons with symptomatic peripheral artery disease (PAD) (i.e., intermittent claudication).

#### Program Description

- Up to 36 sessions over a 12-week period are considered medically necessary if **ALL of the following** components of a supervised exercise therapy (SET) program are met:
  - consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in members with claudication; *and*
  - be conducted in a hospital outpatient setting, or a physician's office; *and*
  - be delivered by qualified auxiliary personnel to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; *and*
  - be under the direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist trained in both basic and advanced life support techniques; *and*
  - Member must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET program. At this visit, the member must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

Kaiser Permanente considers medical supervision of peripheral vascular rehabilitation programs experimental and investigational for persons with absolute contraindications to exercise and for all other indications because the value of such supervision for other indications is not well documented by the available peer-reviewed published medical literature.

Kaiser Permanente 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.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Atherosclerosis is a systemic disease that affects arteries of different sizes including large and medium arteries. Atherosclerosis narrows the lumen of the arteries because of an accumulation of fibrous material in the inner layers of the arteries. When the arteries of the lower extremities are affected, the disease is called lower extremity peripheral artery disease (PAD) (Linda Harris et al., 2019).

The prevalence of lower extremity PAD is less than 12% but increases after the age of 40. Risk factors for peripheral artery disease are the same as those for coronary disease. These include smoking, hypertension, hypercholesterolemia, diabetes, and metabolic syndrome. Other factors include age, gender, ethnicity, family history and genetic influences, and homocysteinemia (Hageman, Fokkenrood, Gommans, van den Houten, & Teijink, 2018) (Linda Harris et al., 2019).

Symptoms of peripheral artery disease include lower extremity pain, nonhealing wound or ulcer, skin discoloration or gangrene. Lower extremity pain includes pain in the calf, thigh, buttock, or foot. The pain is associated with activity and relieved with rest (intermittent claudication). The pain can be atypical or occurs at rest (ischemic rest pain). Intermittent claudication, the most common symptom, is defined as a leg pain that occurs during walking, forces the patient to stop walking, and resolves after 10 minutes of rest, after which the patient can resume walking with pain occurring again after walking the same distance. Claudication can be unilateral or bilateral. Ischemic rest pain is due to diffuse ischemia and is limited to the forefoot and toes. The pain can be diffuse and severe with numbness, paralysis of the extremity, pallor, coolness, and lack of pulses (David Neschis et al., 2019).

Diagnosis is made with history of risk factors, symptoms of PAD, and physical examination. However, ankle-brachial index (ABI)  $\leq 0.9$  establishes the diagnosis in individuals with atypical symptoms or ambiguous pulse examination (David Neschis et al., 2019).

The objective of the treatment is to control the claudication and reduce the risk of cardiovascular disease complications. Treatment can be medical or surgical. Initial treatment includes cardiovascular risk modification, exercise, and pharmacotherapy. In the absence of improvement after initial treatment, revascularization (percutaneous intervention, surgical bypass) is recommended. For patients with lifestyle-limiting claudication, cilostazol (100 mg twice daily) may be indicated (Mark Davies et al., 2019).

Nevertheless, it seems that exercise, particularly supervised exercise therapy, is the mainstay of the treatment for improving walking performance and quality of life (Hageman, Fokkenrood, Gommans, van den Houten, & Teijink, 2018).

Supervised exercise therapy (SET) consists of several sessions, on a treadmill, lasting 45 to 60 minutes per session. Each session comprises 35 minutes of intermittent walking including 5 to 10 minutes of warm-up and cool-down periods. In addition, five minutes are added to the walking time to allow the patient to achieve 50 minutes of intermittent walking. SET consists of three weekly sessions lasting more than three months. During the exercise, medical professionals such as physiologist, physical therapist, or nurse supervise the sessions on person to person basis and monitor patient's claudication threshold and cardiovascular system. If there is suspicion of angina, or the patient is unable to continue the exercise, he or she is referred to a physician (Mark Davies et al., 2019).

## Medical Technology Assessment Committee (MTAC)

### ***Supervised Exercise Therapy on patients with intermittent claudication from peripheral vascular disease (SET for IC in PAD)***

**Date:** 10/14/2019

#### **Evidence Conclusion:**

- Moderate-quality evidence indicates that supervised exercise therapy may be more effective than usual care or placebo or walking advice in terms of walking performances in patients with intermittent claudication due to atherosclerosis who are fit for exercise on the short-term.
- Moderate evidence suggests that supervised exercise therapy may improve quality of life compared to usual care, or placebo in patients with intermittent claudication due to peripheral artery disease on the short-term.
- The evidence is insufficient to draw conclusion on the effectiveness of supervised exercise therapy vs medications.

- Moderate-quality evidence indicates that SET may be more effective than unsupervised exercise therapy on the short-term. However, there is no difference in quality of life between the groups.

**Articles:** PubMed was searched through September 2019 with the following search terms: Supervised Exercise Therapy AND (intermittent claudication OR peripheral vascular disease) with the filter meta-analysis. Randomized controlled trials were also searched for. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded twenty-six items, but 17 were selected after reading their titles. Of the 17 articles, two were thoroughly reviewed. See [Evidence Table](#).

The use of Supervised Exercise Therapy on patients with intermittent claudication from peripheral vascular disease (SET for IC in PAD) does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® or HCPC Codes	Description
93668	Peripheral arterial disease (PAD) rehabilitation, per session

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).**

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
10/14/2019	11/05/2019 <sup>MPC</sup> , 11/03/2020 <sup>MPC</sup> , 11/02/2021 <sup>MPC</sup> , 11/01/2022 <sup>MPC</sup> , 11/07/2023 <sup>MPC</sup> , 11/05/2024 <sup>MPC</sup>	01/07/2020

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
11/05/2019	MPC approved to adopt clinical criteria for commercial members
01/07/2020	MPC approved proposed criteria for commercial members