REVIEW

# Supervised Exercise Training for Symptomatic Peripheral Artery Disease

Jonathan K. Ehrman, PhD, ACSM-CEP[1], Karen Lui, BSN, MS [2], Diane Treat-Jacobson, PhD, RN [3]

## ABSTRACT

In May 2017 the Centers for Medicare and Medicaid Services (CMS) published a final decision memo for supervised exercise therapy for symptomatic peripheral artery disease. This was because there was sufficient evidence demonstrating the benefit of exercise training for improving pain-free and peak walking time. This training can take place in a clinic setting or within a cardiac rehabilitation program. There were specific instructions for what must take place during supervised exercise training during each session day a patient was present. The goal of this review is to provide background information about the research that led to this decision from CMS. It will also review specifics of a supervised exercise training session and conclude with specifics about the CMS decision memo language as it relates to implementing a supervised exercise training session. *Journal of Clinical Exercise Physiology*. 2017;6(4):78–83.

**Keywords:** claudication, Medicare, pain free

## INTRODUCTION

Peripheral artery disease (PAD) is a progressive atherosclerotic disease that affects more than 8 million Americans (1). Symptoms of PAD are caused by insufficient arterial blood flow to the lower extremities, which often results in ischemia-induced debilitating pain associated with walking (claudication). This significant limitation to ambulation contributes to a sedentary lifestyle, increased functional impairment and deconditioning, decreased quality of life, and results in a cycle of disability and continued deterioration. Breaking this cycle of disability by improving exercise capability is a major goal in the treatment of individuals with PAD (2,3).

In 2012 the results of the CLEVER (Claudication: Exercise Vs. Endoluminal Revascularization) trial demonstrated efficacy for improving pain and walking distances in patients who exercise trained (4). In fact, the benefits were equivalent to peripheral stenting for pain-free walking distance and superior for the primary outcome of peak walking distance. A subsequent paper (5) from the CLEVER trial demonstrated a superior cost effectiveness of exercise training versus stenting, leading the author to conclude, "Given the increased expense and marginal benefits of stent relative to supervised exercise, there would appear to be no rational justification for covering stenting but not supervised exercise training for the treatment of claudication." Subsequently, in May 2017 the Centers for Medicare and Medicaid Services (CMS) issued a decision memo approving supervised exercise training (SET) for symptomatic PAD (6). This paper briefly addresses contemporary exercise training studies and exercise training guidelines, and it reviews the CMS decision memo regarding referral and billing issues.

## EXERCISE TRAINING LITERATURE

The efficacy of SET for improving walking capacity in individuals with claudication from PAD is well documented (7,8). Both national and international patient care guidelines for patients with PAD state that supervised exercise therapy should be part of initial treatment for patients with claudication (9,10).

The mechanism of improvement following exercise training is multi-faceted. There are local conditioning

[1]Division of Cardiovascular Medicine, Henry Ford Health System, Detroit, Michigan
[2]GRQ Consulting, Sarasota, Florida
[3]University of Minnesota School of Nursing, Minneapolis, Minnesota

Address for correspondence: Jonathan K. Ehrman; (313) 575 2923; e-mail: Jehrman1@hfhs.org.

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TABLE 1. Changes in pain-free and peak walking distance following supervised exercise treadmill walking into moderately severe claudication symptoms.

| | Change in PFWD | | Change in PWD | |
|---|---|---|---|---|
| Duration | M | % | M | % |
| 12 Weeks (n = 8) | 157 M | 103% | 283 M | 79% |
| 24-52 Weeks (n = 7) | 251 M | 167% | 334 M | 92% |
| Overall (n = 15) | 203 M | 128% | 307 M | 82% |

PWD = Peak walking distance on a graded treadmill test; PFWD = Pain-free walking distance on a graded treadmill test; M = meters

effects, which include changes in muscle metabolism stimulated by exercising specific muscles affected by limited blood flow. Systemic adaptations, including improvement of cardiovascular conditioning and endothelial function resulting from exercise training also appear to contribute to the clinical improvements seen in those with claudication (11).

Treadmill-based exercise therapy for PAD consists of intermittent bouts of walking exercise into moderate to moderately severe discomfort, followed by short periods of rest until symptoms resolve. These exercise/rest bouts are repeated over a 30- to 60-minute session. Exercise capability is measured as pain-free walking time or distance (PFWD) and peak walking time or distance (PWD). This form of exercise training has been shown to result in a range of responses. Changes in PFWD and PWD in 15 studies included in a meta-analysis by Parmenter and colleagues (8) are summarized in Table 1. These participants walked into moderately severe discomfort during their supervised exercise bouts. Exercise programs that were 12 weeks in duration showed overall smaller improvement than those that were 24 to 52 weeks duration.

While treadmill exercise to ischemic pain is the most recommended form of exercise therapy for symptomatic patients, other modes of exercise have also been studied. Several randomized trials have investigated the efficacy of supervised pain-free treadmill training. In contrast to the requirement that patients walk up to moderate to moderately severe ischemic pain, these programs instructed participants to stop just before the onset of claudication symptoms. Three studies (12-14) compared a total of 196 subjects who either participated in 3 months of treadmill walking until the onset of claudication or participated in a usual care control group who did not change their activity habits. The results from these studies were consistent, showing an average increase in PFWD of 110% (217 M) and in PWD of 52% (247 M).

Another study (15) directly compared traditional treadmill training where participants walk to moderate claudication with pain-free treadmill training. Fifty-two subjects completed 12 weeks of moderate or pain–free training. Both groups had significant improvement in PFWD and PWD over time and there were no significant differences between groups. The moderate training group had a 120% (125 M) increase in PFWD and a 100% (393 M) increase in PWD. The pain-free training group had a 93% (141 M) increase in PFWD and a 98% (465 M) increase in PWD. These studies provide evidence that pain-free treadmill training improves walking capability in patients with claudication and this improvement might be similar to that observed with training that requires patients to walk to moderate claudication pain.

A series of studies (totaling 212 participants) (16,17) have been conducted comparing arm ergometry (i.e., arm cranking) versus leg cycling and no exercise control group or versus a control group only. Exercise training consisted of 2 times per week for 40-minute sessions (20 minutes of exercise per session) and the program duration ranged from 12 to 24 weeks. Those participating in the arm cycling groups showed an average 50% improvement in PFWD and 30% in PWD. The Exercise Training for Claudication study (18,19) randomized 41 participants to 12 weeks of 3 times per week supervised treadmill or arm ergometry training alone, or in combination, versus 'usual care' in patients with claudication. The arm-ergometry trained participants had a 133 M (82%) improvement in PFWD versus 92 M (54%) in the treadmill group. PWD improved by 182 M (53%) in the arm-ergometry group versus 295 M (69%) in the treadmill group. There were no improvements in the control group (18).

Several investigators have evaluated the effects of resistance training on changes in walking ability in patients with claudication with mixed results. Two studies (20,21) noted that treadmill walking was superior to resistance training, while a third study (22) found comparable results. Another study (23) reported that high-intensity was superior to low-intensity resistance training for improving walking distance in individuals with PAD (Table 2).

In summary, supervised exercise is a beneficial and cost-effective therapy for patients with PAD. Treadmill walking into ischemic pain is the mode of exercise most often studied, but other modes of exercise also have been shown to be effective. Additional research is needed to further determine the optimal exercise training methods for this population. More randomized trials directly comparing different exercise training modes, duration, and amount of supervision are needed. Standardized testing methods and reporting of outcomes would allow for better comparison across studies. An understanding of the variability in individual response and non-response to different exercise therapies will enhance the clinician's ability to tailor the therapy

TABLE 2. Efficacy of resistance training on walking ability in patients with peripheral artery disease.

| Author | Sample Size | Comparison | Duration | Change with RT | Change with TT |
|---|---|---|---|---|---|
| Hiatt et al. (20) | n = 29 | RT vs. TT | 12 weeks | PWD: + 107 M (30%)<br>PFWD: +1.6 M | PWD: + 273 M (74%)<br>PFWD: +182 M |
| McDermott et al. (21) | n = 156 | RT vs. TT | 26 weeks | PWD: + 129 M (34%)<br>PFWD: +102 M (60%) | PWD: +212 M (51%)<br>PFWD: +156 M (110%) |
| Ritti-Dias et al. (22) | n = 30 | RT vs. TT | 12 weeks | PWD: +157 M (25%)<br>PFWD: +146 M (42%) | PWD: +149 M (26%)<br>PFWD: +127 M (37%) |
| Parmenter et al. (23) | n = 22 | High-intensity RT vs. Low-intensity RT | 26 weeks | High-Intensity RT:<br>6MWT PWD: +60M (19%)<br>6MWT PFWD: +77M (77%) | Low-Intensity RT:<br>6MWT PWD: -9M (-12%)<br>6MWT PFWD: -3M (-2%) |

PWD = Peak walking distance on a graded treadmill test; PFWD = Pain-free walking distance on a graded treadmill test; 6MWT = 6-Minute Walk Test; RT = resistance training; TT = treadmill training

for different patient abilities and preferences. Finally, inclusion of functional and quality of life outcomes in all intervention studies for claudication will provide broader understanding of impact of these therapies on patients' lives. This is particularly important as we move from studying this intervention in randomized clinical trials to clinical application in a 'real-world' population.

## SUPERVISED EXERCISE TRAINING PROCEDURES

Exercise training for symptomatic PAD can focus on 1 of 2 primary aims: (1) improving walking ability, and (2) improving cardiorespiratory fitness. This section will focus on the former. The Clinical Exercise Physiologist should initially evaluate patients with questions to determine if they can initially participate in the SET PAD protocol. Those who likely cannot initially complete the training protocol should begin with non-weight-bearing exercises to limit their claudication pain and to enhance their cardiorespiratory fitness. Once the patient's fitness level is increased the SET PAD training protocol can be initiated.

A structured exercise program that is planned and provides individual recommendations for the type, frequency, intensity, and duration of exercise training is recommended for maximal improvement of pain-free walking ability (9). This type of training can take place either in a supervised exercise setting, such as a cardiac rehabilitation program, or in a community- or home-based setting. The American Heart Association/American College of Cardiology guidelines on managing PAD suggest that exercise be performed in a supervised setting when possible by giving it the highest (IA) level rating, while community- or home-based training received a IIB rating (9).

As noted previously, maximal improvement of pain-free walking ability is accomplished when pain occurs during exercise training. In most patients this will occur during walking, although some patients with significant flow-limiting disease may experience pain performing seated exercise (e.g., cycle ergometer, seated-stepper). The training program for symptomatic PAD patients is aggressive and therefore it is recommended to perform 3 times a week. Although other days may also be used for exercise so that an individual is performing exercise on 5 to 7 days of the week, these other days should not implement the SET PAD training protocol. The intensity of training is determined primarily by the amount of pain experienced by the individual. Figure 1 is the pain scale that should be used. A rating of "2", or moderate pain, is the point at which exercise should be stopped. At this point the patient should rest until the pain has completely subsided before continuing another walking bout. Ideally the

| Rating | Pain | Description |
|---|---|---|
| 0 | None | During rest or early exercise |
| 1 | Mild | 1st feeling of any pain |
| 2 | Moderate | Level at which an exercise training bout should cease |
| 3 | Intense | Nearly maximal pain |
| 4 | Unbearable | Maximal, equivalent to most severe pain experienced |

FIGURE 1. Claudication training pain scale.

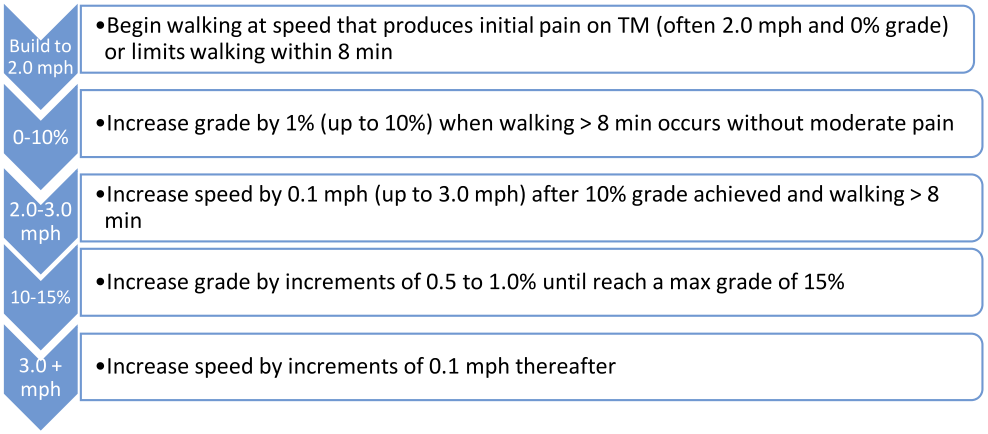


FIGURE 2. SET PAD treadmill walking progression.

patient will sit between bouts as this is the quickest way to alleviate pain. Since in some cases sitting may not be practical, the patient could also stand or walk very slowly.

Reevaluation and progression should occur consistently as the patient adapts. Typically this will occur rapidly during the initial weeks of training. When an individual can walk longer than 8 minutes without reaching a moderate pain level (i.e., level 2) the intensity can then be increased. Initially this should occur by increasing the treadmill elevation (grade) by 1% increments (Figure 2). Once a 10% elevation is reached then the speed can increase by 0.1 mph increments. Elevation is then again increased once a 1.0 mph increase is attained (note the example begins at 2.0 mph and increases to 3.0 mph). Then the elevation can be increased until a 15% level is reached. Few patients will get to these levels, but for those who do, the speed can again be increased. Overall the goal is to provide small increases each time the individual adapts to the current intensity. Each exercise session should last between 30 and 45 minutes and can progress up to 60 minutes. This includes both exercise and resting time. To maximize results, up to 6 months of training is required. However, significant increases can occur in a 12-week period in which the individual trains 3 times per week for a total of 36 sessions.

Non-weight-bearing exercise modes may also increase pain-free walking ability and can be used to increase cardiorespiratory fitness. These modes include upper-body ergometry as well as lower body modes including cycling, stepping, and elliptical machines. Training for these modes should be similar to typical continuous training programs (e.g., 30 to 60 minutes, moderate intensity, 3+ days per week). Additionally, resistance training has been shown to improve walking ability in those with symptomatic PAD. Although the focus of resistance training should primarily be on the lower body, the upper body should also be trained (24). Training should include 2-3 sets per major muscle group, for 8-12 repetitions and 6-8 exercises per session.

Since these individuals have limited blood flow to the lower extremities, it is recommended that the feet and legs be regularly assessed for color, sores, or signs of infections. These may occur due to weight-bearing exercises or improper footwear, and patients with neuropathy may not feel any injuries. Therefore occasional visual inspection of the legs and feet are necessary. Finally, during training when claudication pain occurs it is important for the Clinical Exercise Physiologist to continually encourage and demonstrate progress to the patient. It is difficult to keep patients motivated through the pain of walking and realizing improvement that is occurring can be encouraging and possibly promote adherence to the training protocol. Another option for patients who may find it difficult to continually exercise in pain is pain-free treadmill exercise. The potential benefits were reviewed in the previous section, and this type of training might be more palatable to some patients for whom walking into pain is less well tolerated, which could result in greater compliance with a walking program and better patient outcomes.

## MEDICARE APPROVAL OF SUPERVISED EXERCISE TRAINING FOR PERIPHERAL ARTERY DISEASE

After a thorough review of current evidence, CMS recently released a national coverage policy for SET for patients with symptomatic PAD. This new National Coverage Determination (CAG-00449N) was published with an effective date of May 25, 2017 (6).

Medicare beneficiaries with intermittent claudication are eligible to receive up to 36 sessions of supervised exercise over a 12-week period. This service must be provided in either a hospital outpatient setting or a physician office setting to be reimbursed by CMS. There is no restriction or requirement for a specific number of days per week that a beneficiary may receive supervised exercise. One session per day is billable if the session is a minimum of 31 minutes in duration. This is not equivalent to exercise duration as CMS recognizes that individuals will vary in their ability to exercise, particularly initially. There is no maximum duration for the daily session.

To be referred to a SET PAD program, Medicare beneficiaries must have a face-to-face office appointment with the physician managing the patient's disease. At this visit, the patient must receive information about cardiovascular disease and PAD risk factors. This could involve education or

counseling, behavioral interventions, and outcomes assessments. Once this is obtained, a patient is eligible for referral and enrollment in a SET PAD program. There are no ankle-brachial index (ABI) or level of pain criteria.

Exercise sessions should last 30 to 60 minutes in duration. This does not mean the patient must be capable of exercising for that length of time. It is understood that patients with claudication may initially be more limited and that each individual will progress as tolerated.

CMS has published coding and billing instructions for providers (25). Current Procedure Terminology procedure code 93668 is provided to bill for each session of SET PAD rehabilitation. Payment in 2018 for an on-campus hospital outpatient setting will be in the $55/session range. Medicare reimbursement calculations vary based on geographic location.

SET PAD is to be delivered by qualified auxiliary staff who are "trained in exercise therapy for PAD." CMS will not define what constitutes *qualified* further than this statement. Thus, Clinical Exercise Physiologists are qualified to provide this training, under the guidance of a physician who has approved a Clinical Exercise Physiologist to deliver SET. While SET PAD is *not* cardiac rehabilitation, cardiovascular patients often share this co-morbidity. Program requirements, however, are different. For example, with SET PAD, there are no requirements for 30-day individualized treatment plans, for electrocardiogram (ECG) monitoring with exercise, and no educational components are included in the supervised exercise therapy program. Your plan of care should be one that best serves your program for effective communication between staff and with each patient to document exercise progress and goals.

CMS has determined that the program is under a level of supervision defined as "direct physician supervision" (26). For SET PAD, this means that an MD or DO, or an advanced practice practitioner (i.e., physician assistant, nurse practitioner, or clinical nurse specialist) must be immediately and physically available, although not necessarily in the exercise room itself while the program is being delivered. The person providing the daily direct supervision must be trained in both basic life support and advanced life support techniques.

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