## Prior Authorization Review Panel
### MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 10/01/2019</th>
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<tr>
<td>Policy Number: 0458</td>
<td>Effective Date:</td>
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<tr>
<td></td>
<td>Revision Date: 08/16/2018</td>
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<tr>
<td>Policy Name: Peripheral Vascular Rehabilitation Programs</td>
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### Type of Submission – Check all that apply:

- [ ] New Policy
- [ ] Revised Policy*
- [x] Annual Review – No Revisions
- [ ] Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

**CPB 0458 Peripheral Vascular Rehabilitation Programs**

Clinical content was last revised on 08/16/2018. No additional non-clinical updates were made by Corporate since the last PARP submission.

<table>
<thead>
<tr>
<th>Name of Authorized Individual (Please type or print):</th>
<th>Signature of Authorized Individual:</th>
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<tbody>
<tr>
<td>Dr. Bernard Lewin, M.D.</td>
<td>[Signature]</td>
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Revised July 22, 2019
Peripheral Vascular Rehabilitation Programs

**Number:** 0458

**Policy**

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna 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

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**Policy History**

- **Last Review:** 08/16/2018
- **Effective:** 10/04/2000
- **Next Review:** 05/09/2019

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**Definitions**

**Additional Information**
• 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.

Aetna 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.

Aetna 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.

Background

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.

There has been insufficient evidence in the medical literature demonstrating superior outcomes of such supervised exercise programs over exercise without supervision.
The American College of Cardiology/American Heart Association's 2005 practice guidelines for the management of patients with peripheral arterial disease (Hirsch et al, 2006) recommended a program of supervised exercise training (treadmill or track walking, a minimum of 30 to 45 mins, in sessions performed at least 3 times per week for a minimum of 12 weeks) as an initial treatment modality for patients with intermittent claudication.

On the other hand, McDermott et al (2006) reported that among patients with peripheral arterial disease, self-directed walking exercise performed at least 3 times weekly is associated with significantly less functional decline during the subsequent year. Similar trends were also seen in the subset of asymptomatic patients with peripheral arterial disease. In addition, Fabbian et al (2006) stated that a rehabilitation program performed at home at a specific velocity, just below the pain threshold speed appeared to be well-suited for hemodialysis patients with peripheral arterial disease because it induced functional improvements and vascular adaptations with low costs.

Furthermore, a Cochrane systematic evidence review (Bendermacher et al, 2006) found that supervised exercise therapy has not been proven to be better than non-supervised exercise therapy in managing patients with intermittent claudication. The Cochrane review compared the effects of supervised versus non-supervised exercise therapy on the maximal walking time or distance for individuals with this condition (Bendermacher et al, 2006). The Cochrane Peripheral Vascular Diseases Group searched their specialized register and the Cochrane Central Register of Controlled Trials (CENTRAL) database in the Cochrane library. In addition, these investigators hand-searched the reference lists of relevant articles for additional trials. There was no restriction on language of publication. Randomized and controlled clinical trials comparing supervised exercise programs with non-supervised exercise programs for people with intermittent claudication were selected. Two authors independently selected trials and extracted data. One author assessed trial quality and this was confirmed by a second author. For all continuous outcomes the authors extracted the number of participants, the mean differences, and the standard deviation. If data were available, the standardized mean difference was calculated using a fixed-effect model. These researchers identified 27 trials, of which 19 had to be excluded because the control group received no exercise therapy at all. The remaining 8 trials involved a total of 319 male and female participants with intermittent claudication. The follow-up ranged from 12 weeks to 12 months. In general, the supervised exercise regimens
consisted of 3 exercise sessions per week. All trials used a treadmill walking test as one of the outcome measures. The overall quality of the included trials was good, though the trials were all small with respect to the number of participants, ranging from 20 to 59. Supervised exercise therapy showed statistically significant and clinically relevant differences in improvement of maximal treadmill walking distance compared with non-supervised exercise therapy regimens in the short-term, with an overall effect size of 0.58 (95% confidence interval: 0.31 to 0.85) at 3 months. This translated to a difference of approximately 150 meters increase in walking distance in favor of the supervised group. However, there is a high possibility of a training effect as the supervised exercise therapy groups were trained primarily on treadmills (and the home based were not) and the outcome measures were treadmill based. The authors concluded that supervised exercise therapy is suggested to have clinically relevant benefits compared with non-supervised regimens in the short-term, which is the main prescribed exercise therapy for people with intermittent claudication. However, the clinical relevance has not been demonstrated definitely and will require additional studies with a focus on durability of outcomes and improvements in quality of life (Bendermacher et al, 2006).

In a systematic review of the clinical evidence for home-based versus center-based exercise programs for older adults, Ashworth et al (2005) has observed that home based programs for peripheral vascular disease appear to have a significantly higher long-term adherence rate than supervised center-based programs. However, this conclusion was based primarily on the one study (with the highest quality rating of the studies found) of sedentary older adults. This showed an adherence rate of 68% in the home-based program at 2-year follow-up compared with a 36% adherence in the center-based group.

Crowther and colleagues (2008) examined the effects of a 12-month exercise program on lower limb mobility (temporal-spatial gait parameters and gait kinematics), walking performance, peak physiological responses, and physical activity levels in individuals with symptoms of intermittent claudication due to peripheral arterial disease (PAD-IC). Participants (n = 21) with an appropriate history of PAD-IC, ankle-brachial pressure index (ABI) less than 0.9 in at least one leg and a positive Edinburgh claudication questionnaire response were prospectively recruited. Subjects were randomly allocated to either a control PAD-IC group (CPAD-IC) (n = 11) that received standard medical therapy and a treatment PAD-IC group (TPAD-IC) (n = 10), which also took part in a 12-month
supervised exercise program. A further group of participants (n = 11) free of PAD (ABI greater than 0.9) and who were non-regular exercisers were recruited from the community to act as age and mass matched controls. Lower limb mobility was determined via 2-dimensional video motion analysis. A graded treadmill test was used to assess walking performance and peak physiological responses to exercise. Physical activity levels were measured via a 7-day pedometer recording. Differences between groups were analyzed via repeated measures analysis of variance. The 12-month supervised exercise program had no significant effect on lower limb mobility, peak physiological responses, or physical activity levels in TPAD-IC compared with CPAD-IC participants. However, the TPAD-IC participants demonstrated significantly greater walking performance (171 % improvement in pain-free walking time and 120 % improvement in maximal walking time compared with baseline). The authors concluded that these findings confirmed that a 12- month supervised exercise program will result in improved walking performance, but does not have an impact on lower limb mobility, peak physiological responses, or physical activity levels of PAD-IC patients.

Franz and co-workers (2010) evaluated the effectiveness of a 12-week, institution-based, supervised exercise rehabilitation program with atherogenic risk factor modification in improving cardiovascular profile, ambulatory function, and quality of life of patients with PAD by comparing pre- and post-program measurements. Participants were prospectively enrolled. Cardiovascular profile variables, ambulatory function tests, and quality of life questionnaires were evaluated. Of 101 institution-based program participants, 69 completed the 12-session minimum and 47 completed a post-program evaluation. Mean post-program results were significantly different from pre-program results, corresponding to improvement, for the following variables: triglyceride levels (p < 0.036), both function tests (p < 0.001 for both), 4 of 5 Walking Impairment Questionnaire measurements, and Intermittent Claudication Questionnaire score (p < 0.001). The authors concluded that this supervised exercise program improved the cardiovascular profiles, ambulatory function, and quality of life of PAD patients completing the program and is a viable adjunct to drug therapy and surgical intervention. These initial findings were skewed by the modest completion rate (68 %) and the low post-program evaluation rate (47 %).

In a review on the associations between PAD and ischemic stroke and the implications for primary and secondary prevention, Banerjee and colleagues (2010) concluded that in both primary and secondary prevention settings, PAD...
indicates a high-risk of future events. They noted that data on which additional preventive measures are beneficial in this patient group are lacking, but the presence of PAD does have implications for current management in both primary and secondary prevention of stroke.

In a randomized controlled trial, Saxton et al (2011) investigated the effects of upper- and lower-limb aerobic exercise training on disease-specific functional status and generic health-related quality of life (QoL) in patients with IC. The study recruited 104 patients (mean age of 68 years; range of 50 to 85) from the Sheffield Vascular Institute. Patients were randomly allocated to groups that received upper-limb (ULG) or lower-limb (LLG) aerobic exercise training, or to a non-exercise control group. Exercise was performed twice-weekly for 24 weeks at equivalent limb-specific relative exercise intensities. Main outcome measures were scores on the Walking Impairment Questionnaire (WIQ) for disease-specific functional status, the Medical Outcomes Study Short Form version 2 (SF-36v2), and European Quality of Life Visual Analog Scale (EQ-VAS) for health-related QoL. Outcomes were assessed at baseline, and at 6, 24, 48, and 72 weeks. After 6 weeks, improvements in the perceived severity of claudication (p = 0.023) and stair climbing ability (p = 0.011) versus controls were observed in the ULG, and an improvement in the general health domain of the SF-36v2 versus controls was observed in the LLG (p = 0.010). After 24 weeks, all 4 WIQ domains were improved in the ULG versus controls (p ≤ 0.05), and 3 of the 4 WIQ domains were improved in the LLG (p < 0.05). After 24 to 72 weeks of follow-up, more consistent changes in generic health-related QoL domains were apparent in the ULG. The authors concluded that these findings supported the use of alternative, relatively pain-free forms of exercise in the clinical management of patients with IC.

In a comparative longitudinal cohort study, Fakhry et al (2011) evaluated effects of a structured home-based exercise program on functional capacity and QoL in patients (n = 142) with IC after 1-year follow-up, and compared these results with those from a concurrent control group who received supervised exercise training (SET). Main outcome measures included the maximum (pain-free) walking distance and the ABI (at rest and post-exercise) were measured at baseline and after 6 and 12 months' follow-up. Additionally, QoL was evaluated using a self-administered questionnaire consisting of the Euroqol-5D (scale 0 to 1), rating scale (scale 0 to 100), SF-36 (scale 0 to 100), and the Vascular QoL Questionnaire (VascuQol; scale 1 to 7). Comparison of the groups was performed with adjustment for the non-randomized setting using propensity scoring. Patients with
IC started the structured home-based exercise program, of whom 95 (67\%) completed 12 months’ follow-up. The mean relative improvement compared with baseline was statistically significant after 12 months’ follow-up for the maximum and pain-free walking distance (342\%, 95\% confidence interval [CI]: 169 to 516; \(p < 0.01\) and 338\%, 95\% CI: 42 to 635; \(p = 0.03\), respectively) and for the ABI post-exercise (mean change of 0.06; 95\% CI: 0.01 to 0.10; \(p = 0.02\)). For the QoL outcomes, the improvement compared with baseline was statistically significant after 12 months for the VascuQol (mean change of 0.42; 95\% CI: 0.20 to 0.65; \(p < 0.01\)) and for the SF-36 physical functioning (mean change of 5.17; 95\% CI: 0.77 to 9.56; \(p = 0.02\)). Compared with the structured home-based exercise program, patients in the control group showed significantly better results in the mean relative improvement of maximum and pain-free walking distance and change in the ABI at rest after 12 months’ follow-up. The authors concluded that structured home-based exercise training is effective in improving both functional capacity and QoL in patients with IC and may be considered as a feasible and valuable alternative to SET.

The BioMedix PADnet Lab was approved by the U.S. Food and Drug Administration on October 12, 2004. PADnet (Peripheral Arterial Disease-Internet Ready) system is a non invasive cardiovascular blood flow monitor to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. It uses automated means to obtain Ankle-Brachial Index/Toe-Brachial Index (ABI/TBI) values and Pulse Volume Recording (PVR) waveforms. The device is capable of sending test results instantly via the web to a vascular specialist for interpretation. Ankle-Brachial Index and Pulse Volume Recording values are used to identify the obstructive disease and determine whether medical or surgical treatment is necessary. The device uses a supplied laptop with specifications, hardware and a user interface. The PADnet is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for use on or near non intact skin.

In a Cochrane review, Fokkenrood et al (2013) provided an accurate overview of studies evaluating the effects of supervised exercise programs (SETs) versus non-supervised exercise therapy on maximal walking time or distance on a treadmill for people with intermittent claudication. For this update, the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched September 2012) and CENTRAL (2012, Issue 9). In
addition, these investigators hand-searched the reference lists of relevant articles for additional trials. No restriction was applied to language of publication. Randomized clinical trials comparing SETs with non-supervised exercise programs (defined as walking advice or a structural home-based exercise program) for people with intermittent claudication were selected for analysis; studies with control groups, which did not receive exercise or walking advice or received usual care (maintained normal physical activity), were excluded. Two review authors independently selected trials and extracted data; 3 review authors assessed trial quality, and this was confirmed by 2 other review authors. For all continuous outcomes, these researchers extracted the number of participants, the mean differences, and the standard deviation. The 36-Item Short Form Health Survey (SF-36) outcomes were extracted to assess quality of life. Effect sizes were calculated as the difference in treatment normalized with the standard deviation (standardized mean difference) using a fixed-effect model. A total of 14 studies involving a total of 1,002 male and female participants with PAD were included in this review. Follow-up ranged from 6 weeks to 12 months. In general, supervised exercise regimens consisted of 3 exercise sessions per week. All trials used a treadmill walking test as one of the outcome measures. The overall quality of the included trials was moderate to good, although some trials were small with respect to the number of participants, ranging from 20 to 304. Supervised exercise therapy showed statistically significant improvement in maximal treadmill walking distance compared with non-supervised exercise therapy regimens, with an overall effect size of 0.69 (95% CI: 0.51 to 0.86) and 0.48 (95% CI: 0.32 to 0.64) at 3 and 6 months, respectively. This translated to an increase in walking distance of approximately 180 meters that favored the supervised group. Supervised exercise therapy was still beneficial for maximal and pain-free walking distances at 12 months, but it did not have a significant effect on quality of life parameters. The authors concluded that SET has statistically significant benefit on treadmill walking distance (maximal and pain-free) compared with non-supervised regimens. Moreover, they stated that the clinical relevance of this has not been demonstrated definitively; additional studies are needed that focus on quality of life or other disease-specific functional outcomes, such as walking behavior, patient satisfaction, costs, and long-term follow-up.

In a meta-analysis, Li and colleagues (2015) examined the effect of structured home-based exercise (SHE) programs on maximal walking time (MWT), pain-free walking time (PFWT), and self-reported walking ability in patients with PAD. These investigators searched the databases including MEDLINE, EMBASE, ISI Web of Knowledge, and the Cochrane Library from inception to December 2013 for
randomized controlled trials (RCTs) that assessed the effect of SHE programs on walking ability in patients with PAD. Meta-analysis was performed based on the searched results. Moreover, these researchers made a systemic review regarding the results along with their knowledge. Of all the 348 publications retrieved from the databases, 5 RCTs covering 547 patients reached the inclusion criteria and were involved in the present study. Both inverse-variance fixed-effects and random-effects model were used to perform meta-analysis. SHE programs improved MWT by mean difference of 66.78 sec (95% confidence interval [CI], 5.15-128.41; P = 0.03), heterogeneity across studies was significant. When the trial accounting for significant heterogeneity was omitted, SHE programs improved MWT by mean difference of 91.21 sec (95% CI: 51.96 to 130.45; p < 0.0001). In contrast, there was no significant heterogeneity across the studies with regard to PFWT and Walking Impairment Questionnaire (WIQ) score; SHE programs improved both PFWT and WIQ scores (mean difference of PFWT, 57.76s; 95% CI: 20.42 to 95.10; p = 0.002; mean difference of WIQ distance score, 8.67; 95% CI: 3.86 to 13.49; p = 0.0004; mean difference of WIQ speed score, 8.05, 95% CI: 4.46 to 11.64; p < 0.0001; mean difference of WIQ stair-climbing score, 6.44; 95% CI: 2.55 to 10.34; p = 0.001). The authors concluded that SHE programs improved walking ability in patients with PAD.

In a review on PAD, Kullo and Rooke (2016) stated that supervised exercise for PAD is not reimbursed by insurers in the United States. A home-based, group-mediated, cognitive behavioral walking intervention that included goal setting, self-monitoring, managing pain during exercise, and walking at least 5 days per week lengthened the 6-minute walk distance by 53 m over the distance walked by the control group that received health education alone.

Lawall and colleagues (2017) stated that the prevalence of PAD is increasing worldwide and is strongly age-related, affecting about 20% of Germans over 70 years of age. Recent advances in endovascular and surgical techniques as well as clinical study results on comparative treatment methods strengthened the need for a comprehensive review of the published evidence for diagnosis, management, and prevention of PAD. The inter-disciplinary guideline exclusively covers distal aorta and atherosclerotic lower extremity artery disease. A systematic literature review and formal consensus finding process, including delegated members of 22 medical societies and 2 patient self-support organizations were conducted and supervised by the Association of Scientific Medical Societies in Germany, AWMF; 3 levels of recommendation were defined, A = "is recommended/indicated", B = "should be
considered", and C = "may be considered", means agreement of expert opinions due to lack of evidence. A total of 294 articles, including 34 systematic reviews and 98 RCTs have been analyzed. The key diagnostic tools and treatment basics have been defined. In patients with intermittent claudication endovascular and/or surgical techniques are therapeutic options depending on appropriate individual morphology and patient preference. In critical limb ischemia, re-vascularization without delay by means of the most appropriate technique is key. If possible and reasonable, endovascular procedures should be applied first. The TASC classification is no longer recommended as the base of therapeutic decision process due to advances in endovascular techniques and new crural therapeutic options. The authors stated that limited new data on rehabilitation and follow-up therapies have been integrated. They summarized major new aspects of PAD treatment from the updated German Guidelines for Diagnosis and Treatment of PAD; and noted that limited scientific evidence still calls for randomized clinical trials to close the present gap of evidence.

On May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) published a national coverage determination (NCD) for supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD), with implementation date of July 7, 2018. CMS reviewed the technology assessment of SET. In addition to the evidence submitted by the American Heart Association, CMS reviewed PubMed publications from January 1995 to October 2016. Decision determination was based on review of the evidence in published medical literature from pertinent clinical trials of SET.

The CMS review included an AHRQ sponsored study that included a systematic review which assessed the comparative effectiveness of antiplatelet therapy, medical therapy, exercise, and endovascular and surgical revascularization in PAD patients with intermittent claudication (IC) or critical limb ischemia (CLI). Thirty-five studies (27 RCTs, 8 observational) evaluated the comparative effectiveness of cilostazol, pentoxifylline, exercise therapy, endovascular revascularization, or surgical revascularization in IC patients, with the majority of the studies comparing one intervention with either placebo or one other intervention. The authors found that exercise training improved maximal walking distance (16 RCTs), and exercise training and endovascular intervention improved initial claudication distance (12 RCTs) compared with usual care. Quality-of-life scores (10 RCTs) showed a significant improvement from cilostazol, exercise training, endovascular intervention, and surgical intervention compared with usual care. The authors
concluded that for IC patients, exercise therapy, cilostazol, and endovascular intervention all had an effect on improving functional status and QoL; however, the impact of these therapies on cardiovascular events and mortality is uncertain (Jones et al, 2013).

Findings of the Jones et al, 2013 report included (Source: CMS, 2017):

- SET and the combination of endovascular revascularization + exercise training resulted in large improvements in maximal walking time (MWD) in adults with IC (when compared with usual care). The average age of participants for studies of SET versus usual care was 63 years to 76 years. Strength of Evidence: Moderate.
- A network meta-analysis found no individual treatment (exercise training, cilostazol, endovascular intervention) to have a statistically significant effect when compared to others for adults with IC with MWD or ACD as an outcome.
- Exercise training was found to have moderate to large effects on initial claudication distance and pain free walking time (ICD/PFWD). Strength of Evidence: Low.
- A network meta-analysis found no individual treatment (cilostazol, exercise training, endovascular intervention) to have statistically significant effect when compared to others for adults with IC with ICD/PFWD as an outcome.
- Exercise training was found to have moderate to large effects on QoL when compared with usual care. Strength of Evidence: Low
- A network meta-analysis found no individual treatment (cilostazol, exercise training, endovascular, surgical) to have statistically significant effect when compared to others for adults with IC with QoL as the outcome.
- Inconclusive evidence for exercise training (and cilostazol and ER) in IC for nonfatal MI, nonfatal stroke, amputation, and general safety. Strength of Evidence: Insufficient.
- There were no studies for exercise training (and cilostazol and ER) in IC for composite cardiovascular events, wound healing, pain, and safety in subgroups. Strength of Evidence: Insufficient.

Murphy et al. (2015) described the results of the CLEVER study at 18 months. The CLEVER study was a randomized, multicenter clinical trial conducted at 29 centers in the United States and Canada. The goal of this study was to report the 18-month efficacy of supervised exercise compared with stenting and optimal medical care.
Of 111 patients (mean age 64 yrs) with aortoiliac PAD randomly assigned to receive optimal medical care (OMC), OMC plus supervised exercise (SE), or OMC plus stent revascularization (ST), 79 completed the 18-month clinical and treadmill follow-up assessment. SE consisted of 6 months of supervised exercise and an additional year of telephone-based exercise counseling. Primary clinical outcomes included objective treadmill-based walking performance and subjective quality of life. Peak walking time improved from baseline to 18 months for both SE (5.0 ± 5.4 min) and ST (3.2 ± 4.7 min; p < 0.001) compared with OMC (0.2 ± 2.1 min, p = 0.04). The difference between SE and ST was not significant (p = 0.16).

Improvement in claudication onset time (COT) was greater for SE compared with OMC, but not for ST compared with OMC. Many disease-specific quality-of-life scales demonstrated durable improvements that were greater for ST compared with SE or OMC. The authors concluded that both supervised exercise (SE) and stent revascularization (ST) had better 18-month outcomes than optimal medical care. SE and ST provided comparable durable improvement in functional status and in QoL up to 18 months. The authors state that durability of claudication exercise interventions merits its consideration as a primary PAD claudication treatment.

CMS also referenced the National Institute for Health and Care Excellence (NICE) 2014 update which recommends offering a supervised exercise program to all people with intermittent claudication. The guideline does not recommend any home-based exercise programs. Al-Jundi et al. (2013) did a systematic review of 17 studies of home-based exercise programs for people with intermittent claudication (n=1457). Home-based exercise was compared with supervised exercise in 5 studies, and was compared with usual care in 4 studies. One 3-arm study compared home-based exercise with both supervised exercise and with usual care. Seven studies had a single-group design. For home-based exercise compared with supervised exercise, 5 studies (n=382) reported that supervised exercise improved walking capacity and quality of life to a greater extent. Two of these 5 studies reported that home-based exercise resulted in little change from baseline. In 1 additional study (n=119), improvements in walking capacity were higher in the supervised exercise group than in the home-based exercise group. Although these differences may have been clinically significant, they were not statistically significant. Overall 15 of the 17 included trials were rated as low quality. Limitations of individual studies included lack of description of randomization, no blinding of outcome assessors, small sample size, and recruitment to strict criteria in a single site, uncertainty about consistency of intervention delivery, no intention-to-treat analysis, and short-term follow-up (NICE, 2014).
Key points in the NICE 2014 clinical evidence update include (Source: CMS, 2017):

- 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 femoro-popliteal occlusion.

CMS (2017) cited Vemulapalli et al. (2015) who conducted a systematic review and meta-analysis that included 28 articles from 27 studies (24 RCTs and 4 observational) with over 2,000 patient evaluations. The review assessed the comparative effectiveness of supervised exercise (SE) vs unsupervised exercise (UE) in patients with IC. Outcomes assessed were walking parameters, claudication parameters, patient-reported outcomes (from SF-36, peripheral artery questionnaire, and WIQ). The authors found that compared with UE, SE was associated with a moderate improvement in maximal walking distance at 6 months (p < .001) and 12 months (p < .001). Supervised exercise also improved claudication distance to a moderate extent compared with UE at 6 months (p < .001) and 12 months (p = .001). There was no statistical difference in the Short Form-36 quality of life at 6 months (p = .84) or walking impairment questionnaire distance (p = .08) or speed (p = .11). The authors concluded that SE is more effective than UE at improving maximal walking and claudication distances in patients with claudication; however, there was no difference in general QoL or patient-reported community-based walking. The authors reported that more studies are needed to investigate the relationship between functional gain and disease-specific QoL.

American College of Cardiology (ACC)/American Heart Association (AHA) Practice Guideline (2016):

- Recommendations for supervised exercise:
• 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 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


- Recommendations for exercise therapy:

  • “As first-line therapy a supervised exercise program consisting of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks to all suitable patients with IC.” Grade 1; LOA: A
  • “Home-based exercise, with a goal of at least 30 minutes of walking three to five times per week when a supervised exercise program is unavailable or for long-term benefit after a supervised exercise program is completed.” Grade 1; LOE B
  • “In patients who have undergone revascularization therapy for IC, exercise (either supervised or home based) for adjunctive functional benefits.” Grade 1; LOE B

(Source: CMS, 2017)
Per CMS (2017), “practice guidelines from the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) recommend SET as the initial treatment for patients suffering from IC (Gerhard-Herman et al., 2016). While experts seem to agree that exercise therapy should be the initial treatment for PAD/IC, the number of endovascular revascularization (ER) procedures has been increasing (Spronk et al., 2008). The preference of physicians and patients for the more invasive ER treatment can be partly attributed to the limited access to SET programs, and the immediate result that is observed with ER (Spronk et al., 2008; van den Houten et al., 2016). ER has remained a more popular treatment option for claudication than SET, despite the ACCF/AHA recommendation that ER be reserved for cases where the patient is too functionally impaired for SET (Anderson et al., 2013).”

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<th>Code</th>
<th>Code Description</th>
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<td>I70.319</td>
<td>intermittent claudication</td>
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<td>Atherosclerosis of nonbiological bypass graft(s) of the extremities with</td>
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<td>I73.9</td>
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The above policy is based on the following references:

http://www.aetna.com/cpb/medical/data/400_499/0458.html 09/20/2019


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0458 Peripheral Vascular Rehabilitation Programs

There are no amendments for Medicaid.