FUTURE Local Coverage Determination (LCD): Supervised Exercise Therapy for the Treatment of Peripheral Arterial Disease with Symptomatic Lower Extremity Intermittent Claudication (L37774)

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Please Note: Future Effective Date.

Contractor Information

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LCD Information

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Proposed LCD in Comment Period
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Source Proposed LCD
DL37774

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CMS National Coverage Policy
Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862(a)(1)(D) items and services related to research and experimentation.

Title XVIII of the Social Security Act, §1862(a)(7) states Medicare will not cover any services or procedures associated with routine physical checkups.

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process that claim.

42 CFR §410.26 Services and supplies incident to a physician's professional services: Conditions.

42 CFR §410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or non-physician practitioner's service: Conditions

42 CFR §410.32 (b)(3)(i)(ii) and (iii) Levels of supervision

CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §§60.1.B and 60.2

CMS Internet-Only Manual, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §20.35
Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This Local Coverage Determination (LCD) refers only to supervised exercise therapy (SET) in the treatment of peripheral arterial disease (PAD) in the lower extremities (LE). SET for Symptomatic PAD not involving the lower extremities will be covered as per National Coverage Determination (NCD) 20.35.

SET is an effective treatment for intermittent claudication (IC) secondary to PAD that is covered as per a NCD as noted in Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §20.35. The American College of Cardiology and American Heart Association (ACC/AHA) recommend SET as an initial treatment modality for patients with IC as a Class I level of evidence A recommendation. (Hirsch 2006) As such, the goal of this LCD is to further clarify the NCD and provide a framework for documenting reasonable and necessary SET for PAD services.

A diagnosis of PAD is necessary, but not sufficient for a beneficiary to qualify for SET for the treatment of PAD. Since the benefits of SET are manifested as improvements in mobility, predominantly a reduction in activity limitations related to walking, the clinical documentation must contain relevant evidence-based measures of effect. SET has been shown to improve walking speed, walking distance, and duration of walking with fewer IC symptoms. (Hirsch 2006) However, there is not conclusive evidence showing that SET has an effect on ankle/brachial index, need for amputation, or mortality. (Lane 2017) As such, for SET to be considered reasonable and necessary, the patient must have symptomatic IC, and documented activity limitations in mobility due to the IC. The impairments in body function (e.g., pain due to IC) and their related activity limitations must be the therapeutic target of the SET for PAD interventions.

Activity limitations secondary to the IC must be addressed both in establishing the need for SET and the goals of treatment. It must be clearly established prior to the initiation of SET that IC is causing measurable activity limitations and that the beneficiary’s participation is restricted due to the IC. The activity limitations and participation restrictions (i.e., the activities that the beneficiary is limited in doing or altogether prevented from doing) must be documented in the medical record, with a goal of SET to enable the patient to do these activities more easily or with less discomfort.

There is no requirement as to how providers document a beneficiary’s functional status limitations secondary to PAD so long as the diagnosis, associated symptoms, and the functional capacity in which these symptoms are reproduced are all clearly established. The goal of the SET program must be to improve these functional limitations. In the absence of this information, a meaningful treatment plan and therapeutic goal cannot be established. While it is not required, Palmetto GBA recommends use of the concepts contained within the World Health Organization’s (WHO’s) International Classification of Functioning, Disability, and Health (ICF) to communicate the patient-centered information describing the symptoms and conditions of each beneficiary.

Certifying medical necessity and referral to SET

A beneficiary must be referred by a physician as indicated by the NCD:

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. The treating physician who makes the referral for SET may also be the physician supervising the treatment sessions. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

The documentation of the face-to-face encounter that results in a referral to SET must clearly meet the NCD’s requirements. It must be clear that PAD was a diagnosis being treated in this encounter, that the information above was provided, and that the patient is being referred to SET for symptomatic PAD related to IC.

Part of the referral rationale should be not only that the patient has symptoms to treat but also that the patient’s condition is such that it is reasonable to believe that the beneficiary can tolerate SET and that the potential benefits outweigh the harms. For patients who have absolute contraindications to exercise, as determined by their primary attending physician, SET for PAD will not be covered.

Plan of care

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A plan of care must be established at the outset of treatment. This must include a description of the patient’s baseline functional status, the goals of treatment, a description of the exercise program that the beneficiary will perform, the projected frequency of sessions and duration of treatment. The plan of care must also include a plan for assessing benefits and harms of each SET session. The plan of care must be signed by a physician treating the patient for PAD who is familiar with the patient’s general health, functional status, and medical conditions.

New information may arise during the course of treatment, or the beneficiary’s condition may change such that a change in the plan of care is needed. When this occurs, an addendum to the plan of care should be made and again signed by the treating physician.

Assessing benefits and harms of each SET session

A plan for assessing benefits and evaluating harms in each treatment session must be developed for each beneficiary with the patient’s particular symptoms and comorbid conditions in mind, which must be a component of the SET. This assessment must reflect that the patient’s primary physician does not believe that the patient has an absolute contraindication to exercise. It should also reflect a consideration of how the plan will accommodate any contraindications to specific exercises the patient’s primary physician identifies. A non-exhaustive list of examples includes plans to mitigate risks to a beneficiary’s skin, heart rate parameters, or plans to protect the beneficiary’s bones and joints.

Qualified auxiliary personnel

The NCD notes that SET must “be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD.” The auxiliary personnel delivering SET to a given beneficiary must be those providers whose scope of practice, keeping in mind all relevant national and local laws and regulations, includes making the assessments of benefit and risk included in the plan of care for that particular beneficiary.

Clinicians responsible for supervising SET

The NCD indicates that the beneficiary must be under the direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist who must be trained in both basic and advanced life support techniques. The name and credentials of the supervising clinician must be legible in the record as well as an indication that they were providing direct supervision as defined in 42 CFR §410.32 (b)(3)(ii). This regulation states: Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Frequency of treatment sessions

Class I level of evidence A recommendations by the ACC/AHA are that SET be given at least three times per week to achieve maximal effectiveness. (Hirsch 2006) As such SET sessions should generally be at least three times per week, but the frequency of treatment may be tailored to the needs of the beneficiary so as to maintain or improve the risk to benefit profile of the treatment course for the beneficiary.

Components of treatment

Exercise therapy for PAD has been shown to have a benefit when patients intermittently exercise with an intensity and duration such that the intensity and duration would be sufficient to cause claudication symptoms until the symptoms are of moderate intensity, followed by a brief rest. The duration of exercise a patient does in each session would be expected to increase over the course of treatment. (Hirsch 2006)

The NCD indicates that treatment sessions must be 30-60 minutes. However, the duration of each treatment session should be guided by the individual beneficiary’s needs and progress during the course of treatment. It would generally be expected that as a beneficiary is progressing through treatment and making the expected progress over the covered 12 weeks of treatment, the duration of each treatment session would gradually lengthen or that the fraction time in a treatment session spent exercising compared with resting would increase.
While a reduction in walking limitations secondary to improved pain, strength, and endurance in the LE is the primary evidence-based outcome supporting SET in the treatment of PAD, Palmetto GBA will not stipulate the exercises that may be part of the treatment program since numerous kinds of exercise have been shown to produce similar therapeutic effects. (Lauret 2014) The principal requirement of the exercise program is that it reasonably be expected to produce improvements in IC symptoms and activity limitations directly attributable to the IC symptoms in the beneficiary being treated. Palmetto GBA encourages the treatment plan be tailored to the needs of each beneficiary and represents an evidence-based treatment approach. Providers will be expected to maintain readily available copies of the relevant evidence to support the reasonableness of the therapeutic approach being used for any given beneficiary. Relevant evidence includes sources upon which a beneficiary’s treatment plan is based. Examples are not limited to but may include peer-reviewed studies or professional society recommendations.

Location of treatment
As per the NCD, treatment sessions must occur in a hospital outpatient setting or a physician’s office.

Duration of treatment and number of treatment sessions
Benefits of SET treatment typically become evident by 4-8 weeks, and they may continue to accrue up to 12 or more weeks. (Hirsch 2006) Up to 36 treatment sessions over 12 weeks may be covered initially with a possible 36 additional treatment sessions as specified by the NCD.

Treatment for a beneficiary may continue as long as there is a reasonable expectation that benefits will continue to exceed risks, and treatment must stop when such an expectation is no longer reasonable, even if the patient has not yet reached the threshold of 36 treatment sessions.

Once a beneficiary is having no further limitations in activities secondary to IC symptoms, then additional SET treatment sessions will no longer be considered reasonable and necessary, since there is not a clear treatment benefit at such a point. In patients who are making little or no progress or who are not tolerating SET, continued treatment will be considered reasonable and necessary only if there is a reason to expect future progress or improved tolerance. Notably, a lack of improvement or intolerance to treatment would deviate from the referring physician’s expectations and alter the therapeutic plan for PAD management established by the referring physician. As such, Palmetto GBA recommends that the referring physician be notified in such instances so that a new treatment strategy may be developed.

After the initial 36 treatment sessions or 12 weeks (whichever comes first), beneficiaries may be eligible for an additional 36 treatment sessions with another referral from a physician. The requirements of this second referral are the same as for the initial referral. All requirements of the first 36 treatment sessions or 12 weeks of treatment must be met again for the subsequent 36 treatment sessions.

Since recommendations for SET are that it be done at least three times per week (Hirsch 2006), the initial 36 treatment sessions should generally not take longer than 12 weeks. For beneficiaries who are undergoing SET more than three times per week, 36 treatment sessions will have occurred prior to 12 weeks passing. In such cases, the beneficiary need not wait until the end of 12 weeks to be referred again.

Discharge from SET
Treatment must continue only as long as benefits, as measured by meaningful reductions in activity limitations exceed risks of treatment. For beneficiaries who are not tolerating treatment or progressing as expected, it is encouraged that they be sent back to the referring provider to develop a new treatment strategy for PAD.

For beneficiaries who complete the SET course of treatment either because they no longer have clinically meaningful symptoms or have exhausted the allowable number of treatment sessions, Palmetto GBA encourages providers to make recommendations regarding ongoing exercise to promote both general health and help maintain the level of body function and activity achieved during the SET course of treatment.

Summary of Evidence
Studies have demonstrated evidence supporting the use of exercise therapy in the treatment of IC symptoms secondary to PAD. An early meta-analysis found that exercise programs using intermittent walking to near-maximal pain in the treatment of claudication symptoms resulted in improvements in distance to claudication symptom onset (Gardner 1995). A more recent meta-analysis of exercise therapy in the treatment of claudication symptoms have affirmed this early finding (Lane 2014). This meta-analysis did not find improvements in physiologic parameters associated with PAD, and there were no mortalities in either treatment group. A collaborative guideline from the ACA/AHA recommends supervised exercise therapy as a first line treatment for claudication symptoms in patients with peripheral arterial as a Class I Level of Evidence A recommendation (Hirsch 2006).

A separate meta-analysis examining modes of exercise in the treatment of claudication symptoms found that there is no clear difference between walking and alternative exercise modes (Lauret 2014), with progressive arm-ergometry cycle training demonstrating a similar effect as supervised treadmill walking (Bronas 2011).

A comparative effectiveness review of treatments for claudication symptoms by the Agency for Healthcare Research and Quality (AHRQ) found that supervised exercise therapy was effective in treating claudication symptoms (Jones 2013), and Medicare has determined that supervised exercise therapy should be covered under certain conditions as outlined in NCD 20.35.

Analysis of Evidence
(Rationale for Determination)

Evidence supports the use of supervised exercise therapy for the treatment of IC in PAD, and it is recommended as a first line treatment for claudication symptoms in patients with peripheral arterial as a Class I Level of Evidence A recommendation (Hirsch 2006). While no single exercise protocol is recognized as being optimal, the benefit of exercise therapy has been specifically demonstrated in protocols relying on progressively increased exercise duration and with reductions in rest time. Research has not provided evidence supporting the use of SET to reduce mortality risks or enhance blood flow to affected extremities. In summary, supervised exercise therapy has specifically been found to treat symptomatic IC secondary to PAD and is presently indicated only for this purpose.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

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# Group 1 Paragraph:
The CPT codes are considered medically necessary when the Indications of Coverage are met.

## Group 1 Codes:
93668 PERIPHERAL ARTERIAL DISEASE (PAD) REHABILITATION, PER SESSION

**ICD-10 Codes that Support Medical Necessity**

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<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
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<tr>
<td>I70.211</td>
<td>Atherosclerosis of native arteries of extremities with intermittent claudication, right leg</td>
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<td>I70.212</td>
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<td>I70.213</td>
<td>Atherosclerosis of native arteries of extremities with intermittent claudication, bilateral legs</td>
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**ICD-10 Codes that DO NOT Support Medical Necessity**

All other ICD-10-CM codes not listed under “ICD-10-CM Codes that Support Medical Necessity” will be denied as not medically necessary.

## Group 1 Codes: N/A
General Information

Documentation Requirements

Documentation supporting medical necessity should be legible, maintained in the patient’s medical record and made available to the A/B MAC upon request.

ICD-10-CM diagnosis codes supporting medical necessity must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Any diagnosis submitted must have documentation in the patient’s record to support coverage and medical necessity.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The referral, additional orders if present, and modifications to the treatment protocol if present, must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.

The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.

The medical record documentation must support the medical necessity of the services as directed in this policy.

The medical records documentation should include the order from the prescribing physician for this treatment. This signature is needed at the start of therapy and again if there is any change to the plan of care. At the end of 36 sessions or 12 weeks, a new physician’s order and signature is required.

Utilization Guidelines

In accordance with Federal Register, Volume 81, No 214, dated November 4, 2016 utilization of these services should be consistent with locally acceptable standards of practice.

With continued utilization of additional sessions by a specific provider generally, or for a given beneficiary, the provider should expect medical review of medical records by contractors.

Sources of Information

N/A

Bibliography


Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients...


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Revision History Information

N/A

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A56149 - Response to Comments: Supervised Exercise Therapy for the Treatment of Peripheral Arterial Disease with Symptomatic Lower Extremity Intermittent Claudication LCD(s) DL37774 - Supervised Exercise Therapy for the Treatment of Peripheral Arterial Disease with Symptomatic Lower Extremity Intermittent Claudication

Related National Coverage Documents N/A

Public Version(s) Updated on 09/27/2018 with effective dates 11/19/2018 - N/A

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