

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 207	Date: May 11, 2018
	Change Request 10295

Transmittals 206 and 4016, dated April 3, 2018, are being rescinded and replaced by Transmittals 207 and 4049, dated, May 11, 2018 to remove Pub. 100-04 business requirements 10295.04.1.1 and 10295.04.1.1.1 and to insert the appropriate policy language in both publications 100-3 and 100-04. All other information remains the same.

SUBJECT: Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) issued an NCD to cover SET for beneficiaries with IC for the treatment of symptomatic PAD.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: May 25, 2017

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: July 2, 2018 - for MAC local edits and for Shared System edits

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Chapter 1/Table of Contents
N	1/20.35/Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically

authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 207	Date: May 11, 2018	Change Request: 10295
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SUBJECT: Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

EFFECTIVE DATE: May 25, 2017

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: July 2, 2018 - for MAC local edits and for Shared System edits

I. GENERAL INFORMATION

A. Background: Supervised exercise therapy (SET) involves the use of intermittent walking exercise which alternates periods of walking to moderate-to-maximum claudication, with rest. SET has been recommended as the initial treatment for patients suffering from intermittent claudication (IC), the most common symptom experienced by people with peripheral artery disease (PAD). Despite years of high-quality research illustrating the effectiveness of SET, more invasive treatment options (i.e., endovascular revascularization) have continued to increase. This has been partly attributed to patients having limited access to SET programs. There is currently no national coverage determination (NCD) in effect.

B. Policy: On May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) issued an NCD to cover SET for beneficiaries with IC for the treatment of symptomatic PAD. Up to 36 sessions over a 12 week period are covered if all of the following components of a SET program are met:

The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a hospital outpatient setting, or a physician's office
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. 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.

Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second referral is required for additional sessions.

SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary attending physician.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility									
		A/B MAC		D M E	Shared- System Maintainers				Other		
		A	B		H H H	M A C	F I S S	M C S		V M S	C W F
10295 - 03.1	Effective May 25, 2017, contractors shall cover SET for beneficiaries with IC for the treatment of symptomatic PAD, with a referral from the physician responsible for PAD treatment. Contractors have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second referral is required for additional sessions.	X	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility									
		A/B MAC			D M E	C E D I					
		A	B	H H H			M A C				
10295 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X								

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims) , David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

Table of Contents (Rev.207, Issued: 05-11-18)

20.35 - Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)(Effective May 25, 2017)

20.35 - Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)(Effective May 25, 2017)
(Rev.207, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

A. General

Research has shown supervised exercise therapy (SET) to be an effective, minimally invasive method to alleviate the most common symptom associated with peripheral artery disease (PAD) – intermittent claudication (IC). SET has been shown to be significantly more effective than unsupervised exercise, and could prevent the progression of PAD and lower the risk of cardiovascular events that are prevalent in these patients. SET has also been shown to perform at least as well as more invasive revascularization treatments that are covered by Medicare.

B. Nationally Covered Indications

Effective for services performed on or after May 25, 2017, the Centers for Medicare & Medicaid Services has determined that the evidence is sufficient to cover SET for beneficiaries with IC for the treatment of symptomatic PAD. Up to 36 sessions over a 12-week period are covered if all of the following components of a SET program are met. The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;*
- be conducted in a hospital outpatient setting, or a physician's office;*
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and*
- be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.*

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. 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.

C. Nationally Non-Covered Indications

SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary physician.

D. Other

Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond the nationally covered 36 sessions over a 12-week period. MACs may cover an additional 36 sessions over an extended period of time. A second referral is required for these additional sessions

(This NCD last reviewed May 2017.)