


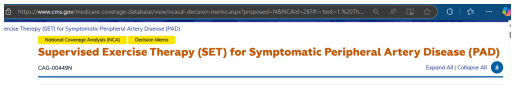


Ambulation / physical therapy for PAD is now covered by Medicare: why is it so poorly prescribed and what can be done to enhance its use?

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

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Decision Summary


A. The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover supervised exercise therapy (SET) for beneficiaries with intermittent claudication (IC) for the treatment of symptomatic peripheral artery disease (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 a qualified provider (physician, nurse, physical therapist, exercise specialist, or nurse practitioner) who is trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1862.103.3), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1862.103.6) who must be present in both bases and demonstrate the 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 routine assessments.

B. 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 these additional sessions.



Background

- Guidelines recommend the use of SET to improve functional status and QOL in people with symptomatic PAD
- CMS has reimbursed the cost of SET since 2017
- Despite a Class IA recommendation, reports indicate low utilization and completion of SET
- Retrospective chart review of patients referred to SET from 2017-2022
- 5320 total patients with PAD analyzed

SET referral and enrollment patterns

- Of 5320 patients, 773 referred to SET (14.5%).
- Only 415 patients actually enrolled (7.8% of total PAD patients, but 53.6% of those actually referred).
- Most frequent referrals came from vascular medicine and vascular surgery specialists.
- Common reasons for discontinuation:
 - Medical conditions
 - Copy or financial concerns
 - Many reasons unknown or not recorded



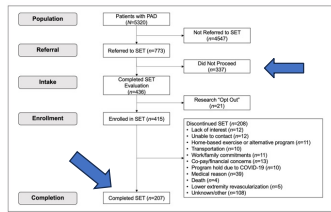




Figure 1. Flowchart of patients with PAD, referrals, and those included in the present study. Multiple reasons for discontinuation were included, if provided. PAD, peripheral artery disease; SET, supervised exercise therapy.




Table 2. Supervised exercise therapy session attendance and adherence among all patients (N = 415) and those who completed the supervised exercise therapy (n = 207).

Characteristic	Overall (N = 415)	Completed SET (n = 207)				
	Mean (SD)	Range	n (%)	Mean (SD)	Range	n (%)
No. of sessions completed	17.8 (11.3)	1-36	23.8 (9.9)	7-36	135 (59.8)	
Completed ≥ 24 sessions			18 (23.8)		82 (39.2)	
Completed ≥ 20 sessions			87 (21.5)			

Table 3. Changes in physical function outcomes following 12 weeks of supervised exercise therapy (n = 207).

Characteristic	Baseline	12 Weeks	t	p	CI	
					Lower	Upper
6-minute walk test						
Classification onset distance, m (n = 167)	1181 (73.8)	1764 (83.3)	9.78	< 0.001	44.0	47.7
Classification onset time, sec (n = 75)	127 (68)	172 (88)	5.02	< 0.001	27	42
Total distance, m (n = 206)	2784 (97.3)	3321 (91.8)	11.97	< 0.001	44.8	82.4
TUG, sec (n = 171)	9.1 (3.8)	8.4 (3.4)	-4.89	< 0.001	-0.73	-0.30
Timed MFT (n = 186)	2.7 (0.9)	2.9 (1.2)	27.64	< 0.001	1.2	1.2
VasOx4-6 (n = 112)	14.0 (3.3)	16.9 (3.1)	9.46	< 0.001	2.4	3.4

95% CI, 95% confidence interval; TUG, timed up and go test; VasOx4-6, Vascular Quality of Life-4 questionnaire.

Uptake and outcomes of SET

- Study Conclusions: SET referral and completion rates are low
- SET is effective in improving patient functional capacity and quality of life
- Efforts needed to increase availability, referrals and to reduce barriers

SET participation rates – demographics and geographic variation

- National Study
- Among 129,699 patients with a diagnosis of intermittent claudication, only 1735 (1.3%) were enrolled in SET during a study period from 2017-2018
- Median number of sessions attended was 16.
- Only 89 patients completed the program of 36 sessions
- Compared with those who did not enroll, SET patients were slightly older, more likely to be White than Black, and more likely to be male.
- A majority of patients enrolled in SET were from the Midwest and Northeast regions of the United States.

Characteristics	SET (n=1735)	Non-SET (n=127,954)	p value	SET (n=1735)	Non-SET matched cohort	p value
Age, y, mean (SD)	73.6±8.0	73.1±8.1	0.02	73.6±8.0	73.7±8.5	0.84
Dual Medicaid/Medicare enrollment, n (%)	221 (12.7%)	28,642 (22.4%)	<0.001	221 (12.7%)	672 (12.9%)	0.85
Female, n (%)	677 (39.0%)	54,438 (42.5%)	0.003	677 (39.0%)	2041 (39.2%)	0.89
Race, n (%)			0.002			0.86
White	1512 (87.2%)	10,7438 (84.0%)		1512 (87.2%)	4900 (87.6%)	
Black	153 (8.8%)	13,970 (10.9%)		153 (8.8%)	453 (8.7%)	
Other	13 (0.7%)	1,349 (1.1%)		13 (0.7%)	42 (0.8%)	
Asian	5 (0.3%)	1,027 (0.8%)		5 (0.3%)	13 (0.2%)	
Hispanic	37 (1%)	1,982 (1.5%)		37 (1%)	58 (1.1%)	
Chronic kidney disease	795 (45.8%)	62,322 (48.7%)	0.02	795 (45.8%)	2359 (45.3%)	0.72
Congestive heart failure	550 (31.7%)	41,522 (32.3%)	0.6	550 (31.7%)	1587 (30.7%)	0.43
Diabetes	651 (37.5%)	63,021 (49.3%)	0.11	651 (37.5%)	1,925 (37.5%)	0.85
Ischemic heart disease	1,211 (69.8%)	88,757 (69.4%)	0.7	1,211 (69.8%)	3618 (69.5%)	0.62
Stroke/transient ischemic attack	116 (6.7%)	9,938 (7.8%)	0.1	116 (6.7%)	333 (6.4%)	0.67
Hypertension	1,366 (78.7%)	101,318 (79.2%)	0.65	1,366 (78.7%)	4,114 (79.0%)	0.78
Hyperlipidemia	1,494 (86.1%)	113,489 (88.7%)	<0.001	1,494 (86.1%)	4,469 (85.5%)	0.8
Tobacco use	160 (9.2%)	14,339 (11.1%)	0.04	160 (9.2%)	2,027 (34.2%)	0.34
Total comorbidities, mean (SD)	6.6±3.1	7.1±3.0	<0.001	6.6±3.1	6.4±2.9	0.15

Barriers to participation in SET

- Goal to identify barriers to participation in SET
- Of 489 questionnaire participants with PAD:
 - 416 (85.1%) reported that their MD had never prescribed nor recommended SET
- Overall, 357 (73.2%) reported willingness to travel 3X weekly for SET participation
- However, of these, 214 (59.9%) reported that they were unwilling or unable to pay the \$115 per session copay required.
- Of 51 PAD patients who had prior participation in SET, only 5 (9.8%) completed 12 weeks.

Barriers to participation in SET

Table III. Associations of age, race, sex, and baseline 6-minute walk distance on questionnaire responses (N = 489)

	Race		Age		Sex		Baseline 6-minute walk	
	Participants who were Black (n = 293)	Participants who were not Black of 70.7 years of age (n = 241)	Below median age (n = 241)	Above median age (n = 241)	Male (n = 293)	Female (n = 294)	Six-minute walk below median (n = 241)	Six-minute walk above median (n = 241)
Has your doctor prescribed or recommended supervised treadmill exercise?	44 (15.0)	29 (12.1)	35 (14.4)	38 (15.8)	41 (14.4)	32 (10.7)	41 (16.9)	32 (13.3)
If your doctor were to prescribe supervised treadmill exercise, would you be willing to travel three times per week for 12 weeks to exercise?	207 (70.6)	150 (65.8)	185 (76.5)	170 (69.7)	208 (73.0)	149 (51.4)	183 (75.9)	169 (70.1)

Barriers to participation in SET

Barriers to participation in supervised exercise therapy reported by people with peripheral artery disease

Reason	No. (%) of participants who selected this reason as their primary reason for lack of interest in supervised exercise	No. (%) of participants who selected this reason as among their top three reasons for lack of interest in supervised exercise
Too time-consuming	26 (9.9)	72 (23.0)
Too inconvenient	20 (7.5)	60 (18.8)
Not interested in walking on a treadmill	19 (7.4)	37 (11.2)
No transportation	10 (7.6)	17 (5.0)
Too difficult	9 (6.1)	24 (7.5)
Not interested in exercising	4 (3.1)	10 (7.6)
Other health issues	3 (2.3)	11 (3.4)
No insurance coverage	1 (0.8)	2 (0.5)
Other	40 (20.5)	68 (21.3)

Of those, 23 reported that they already had a treadmill and were already exercising at home on their own.

Study Conclusions

- Two to four years following CMS approval for SET, participation rates were low in a large urban area
- The required copayment was among the most common barrier to SET participation

ARTICLE HIGHLIGHTS

- Type of Research:** Observational, cross-sectional
- Key Findings:** Of 149 people with peripheral artery disease in Chicago, 85% reported that their physician had never mentioned or recommended supervised exercise therapy. Of 227 who were interested in participating in supervised exercise, 24% (56/227) were unwilling or unable to pay the \$10/month copayment for supervised exercise covered by the Centers for Medicare and Medicaid Services.
- Take Home Message:** Two to four years after the Centers for Medicare and Medicaid Services began covering supervised exercise for peripheral artery disease, participation rates were low in this cohort of people with peripheral artery disease in a large urban area. The required copayment was among the most common barriers to supervised exercise participation.

Patient reported barriers to SET- comparison

- Patients who enrolled in SET compared to those who did not.
- There was **no difference** in age, ABI, smoking status, and distance away from SET center.
- Patients who participated in SET were more likely to be male.
- Top self reported barriers for patients who declined participation included:
 - Transportation / distance
 - Preference for independent walking
 - Inability to commit to 3X week sessions
 - Lack of interest

Table 1. Characteristics of patients who were eligible for enrollment in supervised exercise therapy for symptomatic peripheral artery disease

Characteristic	Total (n=176)	Enrolled in SET (n=106)	Did not enroll (n=70)	P value
Age (mean ± SD)	62.4 ± 10.1	62.1 ± 10.2	62.9 ± 9.9	0.88
Male (%)	78.4	79.2	77.1	0.88
Female (%)	21.6	20.8	22.9	0.88
Smoking status (%)				0.12
Never	38.6	39.7	36.4	
Former	58.5	58.3	59.5	
Current	3.9	1.9	4.1	
Distance from SET center (miles)	10.2 ± 10.1	10.1 ± 10.2	10.3 ± 9.9	0.92
ABI (mean ± SD)	0.55 ± 0.15	0.55 ± 0.15	0.55 ± 0.15	0.92

Patient reported barriers to SET

- Patients who declined participation in SET had similar disease status and access to care than participating counterparts.
- However, top reported barriers included transportation / distance, and cost, which highlight areas of focus to **increase equitable access** to these services.

Table 2. Barriers to participation in supervised exercise therapy for classification

Barrier	Total (n=176)	Participants (n=106)	Nonparticipants (n=70)	P value
Stability to walk safely on the treadmill	28 (15.7)	11 (10.7)	17 (20.2)	0.077
Cost with walking on the treadmill	41 (23.3)	37 (35.2)	28 (33.3)	0.001
Other medical condition breaks PACE	46 (26.2)	22 (21.3)	24 (28.6)	0.150
Cost	41 (23.3)	23 (22.0)	18 (21.5)	0.194
Family commitment	27 (15.3)	10 (9.5)	17 (20.2)	0.021
COVID-19 risk	23 (13.1)	2 (1.9)	21 (25.0)	0.001
Transportation/distance	45 (25.6)	12 (11.2)	33 (39.3)	0.005
Prefer independent walking	38 (21.6)	11 (10.7)	27 (32.1)	<0.001
Commitment to 3 x/week program	34 (19.3)	12 (11.2)	22 (26.3)	0.011
Lack of program on treadmill	21 (11.9)	4 (3.8)	17 (20.2)	0.002
Lack of interest	20 (11.3)	1 (0.9)	19 (22.5)	0.001
Total number of perceived barriers (median, IQR)	1 (0-2)	1 (0-2)	1 (0-2)	0.001


Patient Reported Barriers for Participation in Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease

Participants versus Non-Participants

• What can we do?

Incentives and Individualized Coaching

- Prospective quality improvement protocol.
- Three pronged approach was utilized to improve completion of SET Program
 - Financial incentives up to \$180
 - Scheduled coaching with advanced practitioner staff
 - Informational materials on the importance of SET and lifestyle modification
- 73 patients enrolled/ 56 patients completed SET Program, increasing SET completion rate to 76.7% over a two year study period.
- Patients who completed program noticed improved symptoms, and total walking distance and duration both subjectively and objectively.



Journal Pre-proof
 Incentives and individualized coaching improve completion rates of supervised exercise therapy for claudication
 National assessment of availability, awareness, and utilization of supervised exercise therapy for peripheral artery disease patients with intermittent claudication
 Authors: [List of authors]
 Published: [Date]

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Increase physician awareness

- Questionnaire sent to 900 vascular surgeons, cardiologists and vascular medicine physicians
- 135 responses to the survey.
- Majority of responders (54%) stated that there was no SET Program at their facility
 - Of those who had a SET program, 81% were associated with cardiac rehabilitation
 - Only 19% had a PAD specific program
- 49% of physicians had never referred a patient for SET
- 26% were not aware that CMS covered SET session
- Even of the physicians who were aware of CMS reimbursement, 36% had never referred a patient to SET

Journal Pre-proof
 National assessment of availability, awareness, and utilization of supervised exercise therapy for peripheral artery disease patients with intermittent claudication
 Authors: [List of authors]
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	Yes	No
Have you ever referred a patient to a SET program?	51% (93)	49% (96)
Were you aware that CMS has approved reimbursement for SET since May 2020?	74% (100)	26% (35)
Would you refer claudicants to a SET program if you had one available to you?	98% (132)	2% (3)

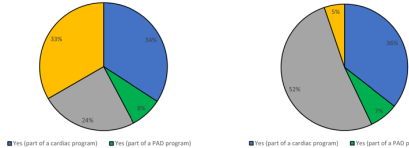


Fig 1. Response to whether a supervised exercise therapy (SET) program was offered in the community where the physician practiced. PAD, Peripheral artery disease.

Fig 2. Response to whether a supervised exercise therapy (SET) program was offered in the practice setting. PAD, Peripheral artery disease.

Fig 3. Response to whether a supervised exercise therapy (SET) program was offered in the community where the physician practiced. PAD, Peripheral artery disease.

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Increase physician awareness

- There is a lack of availability and use of SET for patients with PAD despite guideline recommendations and CMS reimbursement.
- Study highlights the need to increase awareness among physicians treating claudication as well as the patients.

Journal Pre-proof
 National assessment of availability, awareness, and utilization of supervised exercise therapy for peripheral artery disease patients with intermittent claudication
 Authors: [List of authors]
 Published: [Date]

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Home-Based Walking Programs

- Consider home based walking programs
- Data from two randomized trials
- Among 376 PAD participants, age, sex, race, income and medical comorbidities did not affect that likelihood that home-based exercise meaningfully improved 6 minute walk.
- Home based exercise improved 6MW by at least 20 meters in 54.9% of participants

Journal Pre-proof
 Effect and Safety of Home-Based Walking Programs for Peripheral Artery Disease
 Authors: [List of authors]
 Published: [Date]

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Home based exercise

- However, compared to control, exercise was associated with significantly higher rates of serious adverse events in Black individuals and those with heart disease
- Serious adverse events consisted of overnight hospitalizations or death
 - Requires further study

Journal Pre-proof
 Effect and Safety of Home-Based Walking Programs for Peripheral Artery Disease
 Authors: [List of authors]
 Published: [Date]

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Conclusions

- ❖ SET works and is guideline-based treatment for claudication
- ❖ There is a lack of awareness of among treating physicians
- ❖ There are a lack of appropriate available programs
- ❖ There are multiple barriers from the patient perspective including lack of program availability as well as time, travel and cost considerations
- ❖ Potential ways to increase participation:
 - ❖ Increase physician awareness
 - ❖ Increase program availability
 - ❖ Decrease barriers
 - ❖ Coaching and incentives
 - ❖ Consider home based exercise programs

