

Peripheral Arterial Disease

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Disclosures

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Sometimes its really important to spot something before it finds you



Reimbursement Update: Medicare Billing Requirements for Supervised Exercise Therapy (SET) for Peripheral Artery Disease (PAD)

CMS (Centers for Medicare & Medicaid Services) has published of SET for symptomatic PAD.

The Medicare Claims Processing Manual (Transmittal 3969) provides coding and billing information based on the National Coverage Determination (NCD 20.35). The CPT code is <u>93668</u>, under Peripheral Arterial Disease Rehabilitation. A list of appropriate ICD-10 codes for SET are listed in the Medicare Claims Processing Manual and MLN Matters (MM 10295).

MACs (Medicare Administrative Contractors) have the discretion to cover SET beyond 36 sessions and may cover an additional 36 sessions over an extended period of time. A second referral is required for additional sessions. Because there is no mechanism for pre-authorization, AACVPR recommends completing a SET PAD course of up to 36 sessions of SET within a 12-week window.

For CY 2018, fee-for-service Medicare and Medicare Advantage Plans will reimburse hospital outpatient SET PAD \$55.96 (national average). This Medicare payment amount includes a co-payment amount of \$11.20 that a supplemental plan or the beneficiary is responsible for.

Magnitude of the Problem

- Prevalence
- Mortality
- Progression
- Treatment



Atherosclerotic Plaque Pathogenesis Healing;



Inflammatory leukocytes















Inflamammatory mediators; tissue factor







Thrombosis

occurs

narrowed lumen

Endothelial erosion

















Age-Dependent Prevalence of PAD



Adapted from Criqui MH et al. Circulation.1985;71:510-5.

Relative 5-Year Mortality Rates *American Cancer Society. Cancer Facts and Figures, 100 2000. [†]Criqui MH et al. N Engl J Med. 1992;326:381-6. 86 80 60 **Patients** (%) 39 **40** 32 23 18 * 20 8 0 Hodgkin's PAD Colorectal Lung **Prostate Breast Cancer*** Disease **Cancer* Cancer*** **Cancer***

PAD – Progression of Symptoms
* Grade 0 – Asymptomatic, Silent.
* Grade 1 – Intermittent Claudication (IC) – muscle pain with walking.

 * Grade 2 – Ischemic Rest pain – burning foot pain with elevation.

* Grade 3 – Minor or Major Tissue loss –
 Non-healing ulcers, gangrene.

Pathophysiology Grade 3



PAD – Natural History

- * 30% Require intervention.
- * 5% Result in amputation.
- * 30% Mortality in 5 years.
- * 50% Mortality in 10 years.
- * 60% die from an MI
- * 12% die from a stroke.



Adapted from Criqui et al.1

Diagnostic Strategies

- Physical exam
- <u>ABI</u>
- Ultrasound
- Angiography
- CT
- MRA
- Exercise Testing



Right ABI $\frac{\text{Higher Right Ankle Pressure}}{\text{Higher Arm Pressure}} = \frac{\text{mm Hg}}{\text{mm Hg}}$ Left ABI Higher Left Ankle Pressure _____ mm Hg ____ Higher Arm Pressure

mm Hg

ABI Measurements



| ABI | Interpretation | |
|-----------|----------------|----|
| 0.90–1.30 | Normal | |
| 0.70–0.89 | Mild | N. |
| 0.40-0.69 | Moderate | |
| ≤0.40 | Severe | |

| Ankle brachial index and mean annual decline in six-minute walk performance | | | | | | |
|---|-----------------------------------|------|--|--|--|--|
| Baseline ABI | Walking distance (ft) (95% CI) | p | | | | |
| <0.50 | -73.0 (-142 to -4.2) | 0.02 | | | | |
| 0.50 to <0.90 | -58.8 (-83.5 to -34.0) | 0.02 | | | | |
| 0.90 to 1.50 | -12.6 (-40.3 to15.1) | 0.02 | | | | |

McDermott M et al. JAMA 2004; 292:453-461.

Duplex Imaging

* Uses ultrasound to image and analyze narrowing.

* No risk, no radiation, affordable.



Catheter Angiography

- * "Gold Standard"
- * Precise anatomic information.
- * Invasive.
- * Iodinated contrast.
 - * Renal failure.
 - * Allergies.
- * Bleeding.
- * Embolization.





MRA

- * Good detail.
- * 3-D capable.
- * Non-invasive.
- * Non-iodinated contrast.
- * Claustrophobia.
- * Poor resolution of small vessels.





CT Angiogram

- * Good detail.
- * 3-D capable.
- * Non-invasive.
- * Iodinated contrast.
- * Fair resolution of small vessels.





Contemporary Management

- Endovascular and Surgical Management
- Medical Therapy
- Risk Factor Reduction
- Exercise Medically Supervised Walking

Balloon Angioplasty

- * Minimally invasive.
- * Catheter based.
- * Shorter lesions.
- * Evolving technology:
 - * Drug coated stents.
 - * Smaller delivery.



Balloon Angioplasty



Bypass Operations

- * Diversion of bloodflow around blockage.
 * Surgical exposure.
 * Conduit:
 - * Vein.
 - * Synthetic.





Bypass Operation

Medical Therapy



* Pletal.

- * FDA approved.
- Antiplatelet agents.
 - * Plavix
 - * ASA
- Blood thinners.



Exercise.



<u>Therapeutic Lifestyle Changes</u>

- Risk Factor Management
- Exercise Medically Supervised Walking Program
- Tobacco Cessation
- Nutritional Intervention for BP
 and Lipid control

Prevention of Ischemic Events* Managing Risk Factors

- Achieve optimal blood pressure control
- Achieve optimal control of diabetes mellitus
- Tobacco Cessation
- LDL cholesterol < 100 mg/dl
- Initiate therapy to increase HDL cholesterol
- Initiate therapy to normalize serum triglycerides
- Administer antiplatelet therapies

*Society for Vascular Medicine and Biology

SMOKING CESSATION

SCIENTIFIC RATIONALE BASIC PRINCIPLES



With the QuitSmart System, it's easier than you think!

Dr. Robert Shipley Director, Duke Stop Smoking Clinic

with Dr. Jed Rose Inventor, Nicotine Skin Patch





Lyon Heart Study

Randomly assigned patients (N=219) with a Hx of CAD to either a "Mediterranean" diet or a "Western" diet. During 4 years of F/U, only 11% of patients on Mediterranean diet had a major cardiac event compared to 40% consuming a Western diet.

De Lorgeril M, Renaud S, Mamelle, N, et al. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. Lancet. 343: 1454-59, 1994.

Willet WC, Sacks F, Trichopoulou A, et al. Mediterranean diet pyramid: a cultural model for healthy eating. *Am J Clin Nutr*. 61:1402S-6S,1995.



Eat More Fish!

The Best Treatment is Prevention



Walking Impairment Questionnaire

 Please place a √ in the box that best describes how much difficulty you have had walking due to pain, aches or cramps during the last week. The response options range from 'No Difficulty' to 'Great Difficulty,'

| During the last week, how much difficulty have you had walking due to: | No Difficulty | Slight Difficulty | Some Difficulty | Much Difficulty | Great Difficulty |
|--|------------------|----------------------|--------------------|--------------------|---------------------|
| a. Pain, aching, or cramps in your calves? | | D 2 | 3. | 4 | . s. |
| b. Pain, aching, or cramps in your buttocks? | | 2 | 3 | 4 | 5 |

For the following questions, the response options range from 'No Difficulty' to 'Unable to Do.' If you **cannot physically perform** a specified activity, for example walk 2 blocks without stopping to rest because of symptoms such as leg pain or discomfort, please place a $\sqrt{}$ in the box labeled 'Unable to Do.'

However, if you **do not perform** an activity for reasons unrelated to your circulation problems, such as climbing a flight of stairs because your home is one level or your apartment has an elevator, please place a $\sqrt{}$ in the box labeled 'Don't Do For Other Reasons.'

 Please place a √ in the box that best describes how hard it was for you to walk on level ground without stopping to rest for each of the following distances during the last week:

| During the last week, how difficult was it for you to: | No Difficulty | Slight Difficulty | Some Difficulty | Much Difficulty | Unable to Do | Didn't Do for Other Reasons |
|---|------------------|----------------------|--------------------|--------------------|-----------------|-----------------------------------|
| a. Walk indoors, such as around your home? | | 2 | 3 | 4 | 5 | 6 |
| b Walk 50 feet? | | 2 | | 4 | 5 | 6 |
| c. Walk 150 feet? (1/2 block)? | | 2 | 3 | 4 | C s | 6 |
| d. Walk 300 feet? (1 block)? | | 2 | 3 | 4 | 5 | 6 |
| e. Walk 600 feet? (2 blocks)? | | 2 | 3 | 4 | 5 | 6 |
| f. Walk 900 feet? (3 blocks)? | | | 3 | 4 | 5 | 6 |
| g. Walk 1500 feet? (5 blocks)? | | 2 | | Ģ | | 6 |

Regensteiner JG, Steiner JF, Panzer RJ, Haitt WR. Evaluation of walking impairment by questionnaire In patients with peripheral artery disease. *J Vasc Med Biol.* 1990; 2: 142-152.

C.L.E.V.E.R. Clinical Trial

CLaudition Exercise Vs Endoluminal Revascularation

Cost-Effectiveness of Supervised Exercise, Stenting, and Optimal Medical Care for Claudication Results From the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) Trial Matthew R. Reynolds, MD, Msc; Patricia Apruzzese, MA; Benjamin Z. Galper, MD, MPH; Timothy P. Murphy, MD; Alan T. Hirsch, MD; Donald E. Cutlip, MD; Emile R. Mohler, III, MD; Judith G. Regensteiner, PhD; David J. Cohen, MD, MSc

Exercise Testing

- Document ABI and pre-exercise HR.
- Use the Gardner Protocol* (2 mph with 2% increase in grade each stage). Each stage is 2 min.
- Document ICD (time before the onset of claudication) in minutes and seconds.
- Rate pain using the following 5 point scale: 1=onset of pain;
 2=mild pain; 3=moderate; 4=intense pain; 5=maximal
- Patient must walk until they reach pain level = 3+.
- Document maximal walking duration (MWD), in minutes and seconds; maximal HR and maximal BP.
- Once the test is completed; immediately transfer the patient to a stretcher and obtain ABI every 2 minutes for 10 minutes.

*Murphy TP, Hirsch AT, Ricotta JJ, Cutlip DE, Mohler E, Regensteiner JG, Comerota AJ, Cohen DJ. The Claudication: Exercise Vs. Endoluminal Revascularization (CLEVER) study: rationale and methods. J Vasc Surg. 2008; 47:1356–1363

Intermittent Claudication (IC)Pain Scale* (Cramping, Aching, Fatigue, Muscle Tightness, Discomfort, Frank Pain)

1 = **Onset of pain** (Definite discomfort or pain, but only of initial or modest levels; established, but minimal)

2 = **Mild pain** (mild discomfort or pain from which the patient's attention can easily be diverted by a number of common stimuli e.g. music, conversation)

3 = **Moderate pain** (from which the patient can be diverted by coaching, however, the patient will normally stop the activity that brought on this pain i.e. self-limiting)

4 = **Intense pain** (pain from which the patient's attention cannot be diverted except by catastrophic events e.g. fire, explosion)

5 = **Maximal pain** (excruciating and unbearable)

*Murphy TP, Hirsch AT, Ricotta JJ, Cutlip DE, Mohler E, Regensteiner JG, Comerota AJ, Cohen DJ. The Claudication: Exercise Vs. Endoluminal Revascularization (CLEVER) study: rationale and methods. J Vasc Surg. 2008; 47:1356–1363.

Exercise Prescription - ExRx

- Frequency 3-5 days per week
- Intensity 40-70% of HRR; or use workloads from exercise test; set initial workload at ICD; ask patient to walk at ICD until 3+ claudication; rest and repeat. Next session add 2% grade until 3+ claudication; rest and repeat. Once patient can walk ≥10 min at 2mph 12% grade, increase speed by 0.5 mph until reaching 3 mph 12% grade; once ≥10 min without 3+ pain increase grade by 2% until 3 mph 12% grade is obtained; subsequently increase speed 0.5 mph each session as tolerated.
- Time(Duration) 15-40 minutes per session excluding a warm-up of 5 minutes and a cool-down of 5 minutes.
- Persistence lifetime commitment
- Realization that Improved Functional Capacity = Increased Functional Independence

*Murphy TP, Hirsch AT, Ricotta JJ, Cutlip DE, Mohler E, Regensteiner JG, Comerota AJ, Cohen DJ. The Claudication: Exercise Vs. Endoluminal Revascularization (CLEVER) study: rationale and methods. J Vasc Surg. 2008; 47:1356–1363.

ExRx for Patient's with PAD

| Warm-up 5 min | Initial Workload | Next Session | Subsequent Sessions | Cool-down 5 min. |
|---|---|---|--|---|
| 2 mph/ 0% grade or | Speed and Grade @ ICD | Speed remains @ 2 mph/ increase grade 2% | 2 mph and increase grade by 2% until | 2 mph/ 0% grade or |
| If IC prevents that level | Walk @ that S/G until 3+ on Pain scale | Walk @ that S/G until 3+ on Pain scale | 2 mph/ 12% grade is tolerated for ≥ 10 minutes at | If IC prevents that level of walking |
| Patient may warm-up on cycle ergometer @ 12 Watts | Rest | Rest | Pain scale ≤ 3+ then ↑ speed by .5 mph | Patient may cool-down on cycle ergometer @ 12 Watts |
| | Repeat until ≥10 minutes without 3+ pain | Repeat until ≥10 minutes without 3+ pain | Repeat per session until 3 mph/ 12% grade | |



"What fits your busy schedule better, exercising one hour a day or being dead 24 hours a day?"

PAD Summary

- PAD strongly predicts cardiac events
- PAD has a high prevalence in those over 55 years of age
- PAD is a strong predictor of coronary heart disease with up to 75% of patients with PAD dying from cardiac events
- PAD is a marker for global atherosclerotic vascular disease



Therapeutic lifestyle changes (TLC) remain an essential modality in clinical management of patients with PAD and when fully integrated with pharmacological and technological approaches offers our best hope to alter the progression of athersclerotic disease, improve clinical outcomes and improve the quality of life of the patients we serve.

The quest for knowledge is not found in the answers you provide but in the **Questions** you ask? Imagination is more important than knowledge.

Einstein