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Intermittent pneumatic compression for peripheral artery disease

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Policy contains: Arterial insufficiency; compression therapy; intermittent pneumatic compression; peripheral artery disease.

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Coverage policy

Intermittent pneumatic compression is investigational/not clinically proven and, therefore, not medically necessary for treatment of peripheral artery disease.

All other indications for intermittent pneumatic compression in the home setting, excluding chronic venous insufficiency and refractory lymphedema, are investigational/not medically necessary.

Alternative covered services

- Prescription drug therapy.
- Compression bandages or garments.
- Complex decongestive therapy.
- Surgical intervention.

Background

Intermittent pneumatic compression is a therapeutic technique comprised of an inflatable jacket (sleeve, glove, pant leg, or boot) that encloses the limb and an electric air pump that inflates the jacket and pressurizes the enclosed tissues (Zhao, 2014). The alternating inflation and deflation of intermittent or sequential compressions

of the sleeves is thought to encourage movement of blood and lymphatic fluid in and out of the pressurized area. Its hemodynamic effects are to promote venous return, increase arterial flow, and reduce edema. In addition, it may enhance fibrinolytic activity and the release of tissue factor pathway inhibitors to block the initiation of blood coagulation.

The U.S. Food and Drug Administration classifies intermittent pneumatic compression as a Class II device that periodically inflates a compressible sleeve around a limb to prevent pooling of blood in the limb (21CFR870.5800). Multiple devices have been approved for commercial use in the United States (U.S. Food and Drug Administration, 2021). These devices may be simple single-chamber or multi-chamber cuffs with limited adjustability or advanced devices that synchronize with cardiac ventricular contraction. They differ in the number and location of air bladders, programmability, patterns for compression cycles, and duration of inflation time and deflation time. They may be portable or battery-powered and may be combined with cold therapy.

There is a growing need for independent, home-based self-management where intermittent pneumatic compression can be administered safely, comfortably, and effectively. Newer-generation devices provide lower delivery pressures, which may expand the indications for use in the home setting.

Findings

For this policy, we included evidence from three systematic reviews (Abu Dabrh, 2015; Moran, 2015; Oresanya, 2018) and two guidelines (Conte, 2019; Gerhard-Herman, 2017) that addressed intermittent pneumatic compression in the home setting to aid wound healing and limb salvage for patients with peripheral artery disease. We also included several systematic reviews and randomized controlled trials for other indications, excluding venous insufficiency or refractory lymphedema.

The overall evidence examining indications for intermittent pneumatic compression in the home setting is very limited in quantity and quality. Few randomized controlled trials have been conducted, and existing trials have significant methodological limitations that call for cautious interpretation of the results. Adverse events and their resolution, particularly those related to increased swelling, were rarely reported systematically across studies.

Differences in the devices and treatment protocols prevent meaningful comparison across studies, and some models assessed in earlier research are no longer commercially available. There is a need for additional higher-quality and adequately powered trials with uniform criteria and standardized treatment protocols and outcome measures to confirm preliminary results using newer-generation devices. Quality of life, functional outcomes, and patient satisfaction would be important considerations to ensure adherence to intermittent pneumatic compression protocols at home.

Current evidence is insufficient to support intermittent pneumatic compression for treatment of peripheral artery disease. A joint guideline of the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies (Conte, 2019) recommended intermittent pneumatic compression in carefully selected patients (e.g., those with rest pain or minor tissue loss) in whom revascularization was not possible. Their recommendations were based on the results of a systematic review that identified one low-quality nonrandomized trial suggesting an association between intermittent pneumatic compression and reduced risk of amputation (odds ratio 0.14, 95% confidence interval 0.04 to 0.55). Both Conte (2019) and Abu Dabrh (2015) called for confirmation in experimental studies.

The American College of Cardiology/American Heart Association guideline (Gerhard-Herman, 2017) issued a weak recommendation for intermittent pneumatic compression to augment wound healing or ameliorate severe ischemic rest pain based on evidence from a systematic review by Moran (2015), which included two controlled before-and-after studies and six case series. Moran (2015) found some improvement in limb salvage, wound healing, and pain management, but the high risk of bias in these studies prevented determination of a true

treatment effect. Both Gerhard-Herman (2017) and Moran (2015) acknowledge the need for higher quality evidence to confirm a clinical role.

In another systematic review (Oresanya, 2018) of eight randomized controlled studies (n = 290 patients), high-pressure intermittent limb compression (applied rapidly and sequentially at pressures of > 100 mm Hg to the calf, foot, or both) increased absolute claudication distance compared to no compression therapy (the mean between-group difference from baseline to follow-up = 125 m, 95% confidence interval 58.38 to 191.63 m; $P < .01$). Limited evidence suggests some subjective improvement in ambulatory function may translate into improved quality of life. However, few studies compared limb compression to other therapies that are considered the standard of care.

Other indications

For several other indications for intermittent pneumatic compression that have potential home application, we included evidence from three systematic reviews and several individual randomized controlled trials. The trials were conducted primarily in hospitalized patients. The overall quality of the evidence was low with a high risk of bias that prevents determination of a clinical benefit for the following indications:

- To augment circulation during hemodialysis (Torres, 2019; n = seven studies).
- To treat long-term pain, swelling, and instability of ankle sprains (Hansrani, 2015; 12 studies, n = 1,701 total patients, including one study of intermittent pneumatic compression).
- Alone or with cryotherapy to improve symptomatic knee osteoarthritis (Sari, 2019, n = 89 patients).
- Alone or with cryotherapy to reduce pain, swelling, inflammation, or infection after orthopedic surgery:
 - Rotator cuff repair (Kraeutler, 2015, n = 46 total patients).
 - Total knee arthroplasty (Su, 2012, n = 280 total patients).
 - Anterior cruciate ligament reconstruction (Waterman, 2012, n = 36 total patients).
 - Ankle fracture surgery (Winge, 2017, eight studies; Winge, 2018, n = 153 total patients).
 - Volar plate fixation of distal radial fractures (Alkner, 2018; n = 115 total patients).

References

On March 25, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “leg ulcer/therapy” (MeSH), “compression devices, intermittent pneumatic” (MeSH), “lymphedema/therapy” (MeSH), “intermittent pneumatic compression,” and “lymphedema pump.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

21CFR870.5800 Compressible limb sleeve.

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Policy updates

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