Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

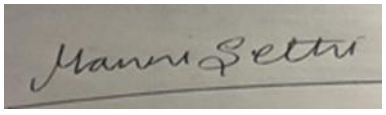
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 7/1/2025
Policy Number: CCP.1491	Effective Date: 7/6/2021 Revision Date: 6/2025
Policy Name: Intermittent pneumatic compression for peripheral artery disease	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Intermittent pneumatic compression for peripheral artery disease

Clinical Policy ID: CCP.1491

Recent review date: 6/2025

Next review date: 10/2026

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

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

Alternative covered services

- Compression bandages or garments.
- Complex decongestive therapy.
- Prescription drug 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, 2023). 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

The body of evidence examining indications for intermittent pneumatic compression in the home setting remains limited in both quantity and quality. Few randomized controlled trials have been conducted, and existing trials exhibit significant methodological limitations necessitating cautious interpretation. Variations in devices and treatment protocols prevent meaningful comparison across studies, with some evaluated models no longer commercially available. Adverse events and their resolution, particularly increased swelling, were rarely reported systematically. Additional higher-quality, adequately powered trials with uniform criteria and standardized protocols are needed to validate preliminary results with newer-generation devices. Quality of life, functional outcomes, and patient satisfaction represent important considerations to ensure adherence to home-based intermittent pneumatic compression protocols.

Clinical Guidelines for Peripheral Artery Disease

Current professional guidelines offer limited support for intermittent pneumatic compression in treating peripheral artery disease. The joint guideline from the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies (Conte, 2019) recommended intermittent pneumatic compression only for carefully selected patients with conditions such as rest pain or minor tissue loss in whom revascularization was not possible. These recommendations derived from a systematic review identifying one low-quality nonrandomized trial suggesting an association between intermittent pneumatic compression and reduced amputation risk (odds ratio 0.14, 95% confidence interval 0.04 to 0.55). Both Conte (2019) and Abu Dabrh (2015) emphasized the need for confirmation through 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. This recommendation was based on evidence from a systematic review by Moran (2015), which incorporated two controlled before-and-after studies and six case series. While Moran (2015) found some improvement in limb salvage, wound healing, and pain management, the high risk of bias in included studies prevented determination of a true treatment effect. Both Gerhard-Herman (2017) and Moran (2015) acknowledged the need for higher-quality evidence to confirm clinical utility.

The 2024 guideline from the American College of Cardiology and the American Heart Association states that arterial intermittent pneumatic compression may be considered for individuals with chronic limb-threatening ischemia who have no remaining revascularization options (Class IIb, moderate-quality evidence drawn from nonrandomized studies). Because this recommendation is weak, pertains to a very narrow “no-option” subgroup, and is not supported by randomized trials demonstrating improved amputation-free survival, it does not alter the broader conclusion that intermittent pneumatic compression remains investigational and not clinically proven for peripheral artery disease in general (Gornik, 2024).

Systematic Reviews for Peripheral Artery Disease

Systematic reviews provide modest evidence supporting intermittent pneumatic compression for specific outcomes in peripheral artery disease. Oresanya (2018) examined eight randomized controlled studies (n = 290 patients) and found that high-pressure intermittent limb compression (applied rapidly and sequentially at pressures exceeding 100 mm Hg to the calf, foot, or both) increased absolute claudication distance compared to no compression therapy (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 this subjective improvement in ambulatory function may translate into improved quality of life. However, few studies compared limb compression to therapies considered standard of care.

The literature review by Nickles (2023) strongly supports the use of intermittent pneumatic compression for peripheral artery disease patients. The research examined approximately ten studies demonstrating that these devices effectively treat claudication and critical limb ischemia in patients without revascularization options. Evidence shows compression therapy in peripheral artery disease patients definitively improved multiple outcomes: increased absolute claudication distance by 80–200%, enhanced limb salvage rates, accelerated wound healing, reduced pain, and improved exercise ability. These devices typically deliver sequential pressure in 15–20 second cycles ranging from 85–130 mm Hg with treatment protocols varying from one hour twice daily for four months to three hours twice daily for three to six months. While the review confirms effectiveness, it highlights the need for standardized protocols regarding optimal device selection, session duration, and pressure parameters.

Venous Thromboembolism Prevention

More substantial and recent evidence supports intermittent pneumatic compression in preventing venous thromboembolism. A 2024 systematic review of 16 randomized controlled trials focusing on surgical patients found that intermittent pneumatic compression significantly reduced deep vein thrombosis incidence compared to no prophylaxis. While this review indicated intermittent pneumatic compression alone was not as effective as pharmacologic prophylaxis (e.g., heparin) and offered no added benefit when combined with drugs, it crucially noted that intermittent pneumatic compression use was associated with fewer bleeding complications than anticoagulants. This positions home-based intermittent pneumatic compression devices as a valuable prophylactic alternative for high-risk surgical patients who cannot tolerate anticoagulation (Kim, 2024).

These newer findings build upon earlier reviews, such as Kakkos (2022) and Duval (2022), which showed that adding drug prophylaxis to intermittent pneumatic compression reduced venous thromboembolism events, and Herring (2023), which suggested intermittent pneumatic compression may be superior to graduated compression stockings alone and that combination therapy may benefit high-risk patients, albeit based on low-quality evidence at the time.

Other Potential Home-Based 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:

- Head and Neck Lymphedema: A 2023 systematic review (23 studies) addressed head and neck cancer–associated lymphedema and the use of intermittent pneumatic compression garments for head/neck – as among the promising adjunct treatments to standard therapy. The review concluded these rehabilitative interventions appear safe and beneficial, although evidence is still limited and adherence can be a challenge. Home use of intermittent pneumatic compression (e.g., nightly neck compression therapy) can thus play a role in comprehensive management for these patients (Cheng, 2023)
- 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).
- To treat patients (n = 186) after varicose vein surgery (Kappa-Markovi, 2021).
- 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).

In 2025, we reorganized the findings section and added new systematic reviews (Cheng, 2023; Kim, 2024; Nickles, 2023) and a new guideline American College of Cardiology and American Heart Association (Gornik, 2024).

References

On May 11, 2025, 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

6/2021: initial review date and clinical policy effective date: 7/2021

6/2022: Policy references updated.
6/2023: Policy references updated.
6/2024: Policy references updated. No policy changes warranted.
6/2025: Policy references updated.