



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Intermittent Pneumatic Compression for the Treatment of Peripheral Arterial Occlusive Disease

- ArtAssist Device
- ArterialFlow™ System
- Flow Medic™ System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pneumatic Compression Devices (280.6)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Peripheral arterial disease (PAD) is a common condition that affects approximately 8-12 million people in the US. The prevalence of the disease increases rapidly with age, and is associated with significant morbidity and mortality. PAD commonly affects the arteries supplying the leg and is mostly caused by atherosclerosis. Restriction of blood flow due to arterial stenosis or occlusion is commonly clinically presented as intermittent claudication which is pain in the calf muscles that occurs on walking or exercising, and is rapidly relieved by resting.

The clinical course of patients with intermittent claudication is variable. Most patients either improve or have a stable condition, but over one fourth will experience deterioration in symptoms. These patients may eventually develop critical leg ischemia or gangrene which can lead to amputation. Fontaine classified chronic leg ischemia into four stages: Stage I: asymptomatic, stage II: intermittent claudication, stage III: ischemic rest pain, and stage IV: ulceration, gangrene, or both (Hirsch 2001, Leng 1993, Delis 2000, 2005, Beard 2000).

The treatment of PAD aims at increasing blood flow to alleviate symptoms and prevent arterial leg ulcers, critical leg ischemia, and major complications. Management options for claudication include a structured program of regular exercise, smoking cessation, control of risk factors or associated medical diseases, percutaneous transluminal angioplasty, and surgical revascularization. Drug therapy, even with the most effective agents, was found to result in only a modest improvement. Surgical bypass reconstruction is indicated for severe cases and after failure of other forms of conservative therapy. Patients with non-healing ulcers may not be suitable for revascularization for technical reasons, frail condition, or rejection of surgical intervention. Due to the limited non-operative treatment options, long-term graft failure, perioperative deaths, and imitations or contraindications to

intervention, researchers have focused their attention on mechanical methods as potential means for augmenting arterial volume flow in lower limbs (Delis 2000, Montori 2002, 2005).

The concept of using mechanical means to increase blood flow to an ischemic limb dates back to 1930s when a group of investigators applied alternating external pressure to ischemic legs with advanced atherosclerotic peripheral vascular disease. They were however unable to measure blood flow or optimize pneumatic compression. The interest in using intermittent pneumatic compression was renewed in the late 1970s when researchers observed that intermittent pneumatic compression can temporarily increase the arterial blood flow to the limbs. The devices developed apply high pressures by compression cuffs placed on the thigh, calf, and/or foot, intermittently inflate and deflate with cycle times and pressures that vary between devices.

The ArtAssist® Device (ACI Medical Inc., San Marcos, California), is a mechanical pneumatic pump consisting of an impulse generator and two plastic inflatable cuffs. It applies high pressure in a synchronized manner to the foot and calf. This outpatient treatment usually performed for three 1-hour sessions per day while the patient is sitting upright. According to the manufacturer, when the device compresses tissue below the knee, venous blood is emptied and the venous pressure drops to near zero. The resultant increase in the arteriovenous pressure gradient increases arterial blood inflow. Another potential mechanism also described by the manufacturer involves the release of vasodilating substances as endothelial nitric oxide due to the decreased local vascular resistance. Stimulation of collateral blood vessel formation may also occur (ACI medical Inc. Web site).

The ArtAssist device as well as the Flow Medic™ system, and ArterialFlow™ system are all FDA approved for use to improve blood circulation in the lower extremities to help prevent and reduce complications of poor circulation.

Medical Technology Assessment Committee (MTAC)

Intermittent Pneumatic Compression

02/04/2008: MTAC Review

Evidence Conclusion: The trials on intermittent pneumatic compression (IPC) studied the efficacy of the therapy, mainly using the ArtAssist device, for patients with stable intermittent claudication. There were no RCTs with clinical outcomes that evaluated the IPC for use among patients with more severe condition or those who failed revascularization. All published trials were small, single centered, conducted among highly selected groups of patients, were not blinded, short-term, and none compared IPC to a sham therapy. Kakkos and colleagues (2005), randomized 34 highly selected patients with stable intermittent claudication to receive IPC (n=13), supervised exercise (n=12), or unsupervised exercise (n=9). The study was too small, was unblinded, and had a high drop out rate. Its results show that compared to the unsupervised exercise, both IPC and supervised exercise increased the initial claudication distance (ICD) and the absolute claudication distance (ACD). The difference in improvement observed was statistically significant at the end of the six month treatment and after six additional months of follow-up. There was no significant difference however between the IPC and supervised exercise groups. In their pilot study, Ramaswami and colleagues (2005) evaluated the efficacy of IPC among 34 patients with stable intermittent claudication who were randomized to receive IPC with daily unsupervised exercise or to just perform daily unsupervised exercise. IPC was not compared to sham treatment or to a supervised exercise program. The results showed an increase in the initial and absolute claudication distances with IPC at 4 and 6 months of treatment and the improvement was sustained at 1 year. Delis and Nicolaidis (2005) also evaluated the effectiveness of IPC in 41 highly selected patients with stable intermittent claudications. These were randomly assigned to receive IPC and salicylic acid (75 mg/dL), or salicylic acid (75 mg/dL) alone. All participants in the two groups were encouraged to exercise daily and were followed up for 12 months after the treatment period. The results of the trial show that the ICD, ACD, increased significantly in the IPC group starting at the first month of treatment and was sustained for one year after completing the therapy. Only a small insignificant change was observed in the control group, and the difference between the two study groups was significant. The quality of life also improved significantly in the IPC group, but not in the control group. **Conclusion:** The available evidence from these trials as well as other earlier studies and case series suggest that intermittent pneumatic compression therapy of the foot and calf with ArtAssist device might be associated with improvement in the arterial blood flow and in the walking distance over a short term among patients with stable intermittent claudication. However, the studies included highly selected groups patients with stable claudications who had superficial femoral artery occlusion, and patent iliac arteries (also patent popliteal artery as indicated by some studies). Those with a history of a lower extremity revascularization history were excluded, as well as those with several other comorbidities. Moreover, the studies had control groups not placebo groups undergoing a sham IPC treatment. There were no long-term outcomes beyond one year of follow-up, and the studies did not determine the effectiveness of treatment in improving rest pain, ulcer healing, or reducing amputation rate, all of which may limit generalization of the results. In conclusion there is insufficient evidence to determine the efficacy of pneumatic compression

devices for the treatment intermittent claudication, or more severe symptoms among patients with peripheral artery occlusive disease.

Articles: There were five small RCTs, one nonrandomized controlled study, and several prospective and retrospective small case series with no control or comparison groups. The majority of trials were conducted among patients with stable claudication. There was a small trial, with intermediate outcomes that compared three modes of IPC in healthy limbs as well as those with successful grafts. The literature search did not reveal RCT that evaluated the IPC use for patients with more severe condition or those who failed revascularization. *Studies with an appropriate comparison group and/or longer follow-up duration were selected for critical appraisal:* Kakkos SK, Geroulakos G, Nicolaides AN. Improvement of the walking ability in intermittent claudication due to superficial femoral artery occlusion with supervised exercise and pneumatic foot and calf compression: A randomized controlled trial. *Eur J Vasc Endovasc Surg.* 2005;30:164-175. See [Evidence Table](#)
 Ramaswami G, D'ayala M, Hollier LH, et al., rapid foot and calf compression increases walking distance in patients with intermittent claudication: Results of a randomized study. *J Vasc Surg.* 2005;41:794-801. See [Evidence Table](#)
 Delis KT, Nicolaides AN. Effect of intermittent pneumatic compression on foot and calf on walking distance, hemodynamics, and quality of life in patients with arterial claudication. A prospective randomized controlled study with 1-year follow-up. *Ann Surg* 2005;241:431-441 See [Evidence Table](#)

The use of Intermittent pneumatic compression in the treatment of peripheral arterial occlusive disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Creation Date	Review Date	Date Last Revised
02/26/2008	04/06/2010 ^{MDCRPC} , 02/10/2011 ^{MDCRPC} , 12/06/2011 ^{MDCRPC} , 10/02/2012 ^{MDCRPC} , 08/06/2013 ^{MPC} , 06/03/2014 ^{MPC} , 04/07/2015 ^{MPC} , 02/02/2016 ^{MPC} , 12/06/2016 ^{MPC} , 10/03/2017 ^{MPC} , 08/07/2018 ^{MPC}	02/04/2008

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description

Codes

HCPCS: E0675