KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Pneumatic Compression Devices

- Treatment of Lymphedema and Chronic Venous Insufficiency
- Prevention of Deep Vein Thrombosis

Intermittent Pneumatic Compression for the Treatment of Peripheral Arterial Occlusive Disease

- ArtAssist Device
- ArterialFlowTM System
- Flow MedicTM System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pneumatic Compression Devices (280.6)
Local Coverage Determinations (LCD)	Pneumatic Compression Devices (L33829)
Local Coverage Article	Pneumatic Compression Devices (A52488)

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

Prevention of Post-Operative Deep Vein Thrombosis in the outpatient setting
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.

For Non-Medicare Members

***Definitions**

Edema: Edema is a non-specific term for the accumulation of fluid in tissue, most often in the extremities. There are numerous causes for edema, ranging from systemic disorders (e.g. congestive heart failure, etc.) to local conditions (post-surgery, congenital abnormalities, etc.). (Examples are not all-inclusive).

Lymphedema, as discussed below, is just one group of conditions that can be a cause of accumulation of fluid in the tissue. Lymphedema arises from disorders of the lymphatic system. It is essential to rule out other causes of edema in order to diagnose lymphedema. Edema from other causes is not classified as lymphedema for purposes of Medicare reimbursement for PCDs (E0650-E0652).

Primary lymphedema: Primary lymphedema is a disorder of the lymphatic system that occurs on its own. It is inherited and uncommon. Examples (not all-inclusive) are:

A. Congenital lymphedema due to lymphatic aplasia or hypoplasia
B. Milroy's disease, an autosomal dominant familial form of congenital lymphedema
C. Lymphedema praecox

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D. Lymphedema tarda

Secondary lymphedema: Secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more common than primary lymphedema. It is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. (See below)

Chronic Venous Insufficiency (CVI): Lymphedema may also be caused by CVI when fluid leaks into the tissues from the venous system. CVI of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. The incidence of lymphedema from CVI is not well established.

Peripheral Arterial Disease (PAD)

Peripheral artery disease is a circulatory problem in which narrowed arteries reduce blood flow to limbs, resulting in compromised blood flow to the distal tissue and failure to keep up with oxygen demands.

Service	Criteria
Effective until June 1, 2024 I. **Lymphedema** A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema*, see definitions above, in beneficiaries with chronic and severe lymphedema when **ALL** of the following three requirements are met: 1. The beneficiary has a diagnosis of lymphedema as defined below, and 2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings: ○ Marked hyperkeratosis with hyperplasia and hyperpigmentation ○ Papillomatosis cutis lymphostatica, ○ Deformity of elephantiasis, ○ Skin breakdown with persisting lymphorrhea, ○ Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and 3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial* (see below for trial guidelines): A. A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include **ALL** of the following: 1. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression a. Adequate compression is defined as (1) sufficient pressure at the lowest	**Effective June 1, 2024** **LCD Pneumatic Compression Devices L33829** **I. LYMPHEDEMA** A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in beneficiaries with chronic and severe lymphedema when all of the following three requirements are met: 1. The beneficiary has a diagnosis of lymphedema as defined above, and 2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings: ○ Marked hyperkeratosis with hyperplasia and hyperpigmentation, ○ Papillomatosis cutis lymphostatica, ○ Deformity of elephantiasis, ○ Skin breakdown with persisting lymphorrhea, ○ Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and 3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial. (See below for trial guidelines.) A PCD coded as E0650 or E0651 used to treat lymphedema that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary. A PCD coded as E0650 or E0651 used to treat edema from causes other than lymphedema is not eligible for

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pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
   b. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
2. Regular exercise
3. Elevation of the limb

II. Chronic Venous Insufficiency with Venous Stasis Ulcers (CVI)

A PCD coded as E0650 or E0651 is covered for the treatment of CVI*, see definitions above, of the lower extremities only if the patient has **ALL** of the following:

A. Edema in the affected lower extremity
B. One or more venous stasis ulcer(s)
C. The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician. (See below for trial guidelines)

Six-Month Trial for CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include **ALL** of the following:

A. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
   a. Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
   b. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
B. Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)
C. Regular exercise
D. Elevation of the limb
E. Appropriate wound care for the ulcer (including sharp debridement where appropriate)

At the end of the six-month trial, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no further improvement has occurred for a continuous reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of lymphedema of the extremities alone even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

Four-Week Trial for Lymphedema

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
  - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement, and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
  - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Regular exercise
- Elevation of the limb

When available, manual lymphatic drainage is a key component of conservative treatment as is appropriate medication treatment when there is concurrent congestive heart failure.

The medical necessity determination for a PCD by the treating practitioner must include symptoms and objective findings, including measurements, to establish the severity of the condition.

The documentation by the treating practitioner of the medical necessity of a PCD must include:

- The patient's diagnosis and prognosis;
- Symptoms and objective findings, including measurements which establish the severity of the condition;
- The reason the device is required, including the treatments which have been tried and failed; and
- The clinical response to an initial treatment with the device

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of PCD (E0650, E0651, E0652). This

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period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

III. Continuation of Use
Kaiser Permanente covers continuation of use of a pneumatic compression device as medically necessary when **BOTH** of the following criteria are met:
A. there is adherence with the use of equipment as ordered by the healthcare professional
B. clinical documentation from the health care professional confirms clinical improvement (e.g., improvement in venous stasis ulcers, decrease in edema or lymphedema)

IV. Not covered

Kaiser Permanente does not cover an advanced pneumatic compression pump or a pump with additional features (HCPCS code E0652*) (e.g., specific programming to treat problem areas, a pre-therapy phase) because it has not been demonstrated to be superior to a standard segmented, calibrated gradient system, and is not considered the lowest-cost alternative and thus is not medically necessary. These devices include but are not limited to:
A. Flexitouch® System
B. Lympha Press Optimal™
*HCPCS code E0652 is covered when used to report a standard segmented, calibrated gradient system. Not covered when used to report an advanced pneumatic compression pump or a pump with additional features.

Kaiser Permanente does not cover **ANY** of the following because each is considered experimental, investigational or unproven:
A. A chest (HCPCS code E0657) and/or trunk (HCPCS code E0656, E0670) pneumatic appliance for use with a pneumatic compression pump
B. A compression garment for trunk or chest
C. A pneumatic compression device, with or without a cooling component, utilized in the home setting for ANY other indication including but not limited to the prevention of deep vein thrombosis

assessment may be performed by the treating practitioner or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

II. CHRONIC VENOUS INSUFFICIENCY (CVI) WITH VENOUS STASIS ULCERS

A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has all of the following:
- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating practitioner. (See below for trial guidelines.)

A PCD coded as E0650 or E0651 used to treat CVI that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat ulcers in locations other than the lower extremity or ulcers and wounds from other causes is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of CVI even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections

III. **LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN** and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

Six-Month Trial for CVI
A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
    - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to

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move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
    - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Medications as appropriate (e.g. diuretics and/or other treatment of congestive heart failure)
- Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

At the end of the six-month trial, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no significant improvement has occurred for a continuous period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of PCD (E0650, E0651, E0652). This assessment may be performed by the treating practitioner or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's CVI treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

IV. LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN

A segmented, calibrated gradient PCD (E0652) is only covered when the individual has unique characteristics which prevent them from receiving adequate satisfactory pneumatic compression treatment using a nonsegmented device along with a segmented appliance or compression device without manual control of the pressure in each chamber.
A PCD coded as E0652, is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when all of the following are met:

- The beneficiary has lymphedema of an extremity as defined above
- The coverage criteria for an E0650 or E0651 are met
- The beneficiary has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard

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compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial. (See below for trial guidelines.)

A PCD coded as E0652 used to treat lymphedema extending onto the chest, trunk and/or abdomen that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 used to treat lymphedema not extending onto the chest, trunk and/or abdomen or CVI is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

Four-Week Trial for Lymphedema Extending Onto the Chest, Trunk and/or Abdomen
A four-week trial of conservative therapy demonstrating failed response to treatment with and E0650 or E0651 is required. The four-week trial of conservative therapy must include all of the following:

- At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
    - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
    - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Regular exercise
- Elevation where appropriate
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- Evaluation of diet and implementation of any necessary change
- Medications as appropriate (e.g. diuretics and/or other treatment of congestive heart failure)
- Correction (where possible) of anemia and/or hypoproteinemia

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of PCD (E0650, E0651, E0652). This assessment may be performed by
the treating practitioner or any other licensed/certified medical professional (LCMP) directly involved in the

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beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

V. PERIPHERAL ARTERY DISEASE (PAD)

A PCD coded as E0675 to treat PAD is not eligible for reimbursement. There is insufficient evidence to demonstrate that reimbursement is justified. Claims for E0675 will be denied as not reasonable and necessary.

VI. DEEP VENOUS THROMBOSIS (DVT) PREVENTION

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

ACCESSORIES

PCD related accessories (E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673) are eligible for reimbursement only when the appropriate, related base PCDs (E0650, E0651, E0652, E0675) meets the applicable coverage criteria for that type of PCD. If the base PCD is not covered, related accessories are not eligible for reimbursement. Claims for related items will be denied as not reasonable and necessary.

PCD CODE SELECTION (E0650, E0651, E0652, E0675, E0676)

A PCD coded as E0650 or E0651 is used for lymphedema or CVI. An E0650 compressor with a segmented appliance/sleeve (E0671, E0672, E0673) is considered functionally equivalent to an E0651 compressor with a segmented appliance/sleeve (E0667, E0668, E0669).

A segmented, calibrated gradient PCD (E0652) is only covered when the individual has unique characteristics which prevent them from receiving adequate satisfactory pneumatic compression treatment using a nonsegmented device along with a segmented appliance or compression device without manual control of the pressure in each chamber.

The only "unique characteristics" identified in the clinical literature that requires the use of an E0652 device is lymphedema extending onto the chest, trunk and/or abdomen which has remained unresponsive to all other therapies.

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	A PCD coded as E0675 is used only for peripheral artery disease. Other PCD codes are not used for this condition. A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.
Intermittent Pneumatic Compression for the Treatment of Peripheral Arterial Occlusive Disease • ArtAssist Device • ArterialFlowTM System • Flow MedicTM System	**Effective until June 1, 2024** 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. **Effective June 1, 2024** **LCD Pneumatic Compression Devices L33829**

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

Prevention of Post-Operative Deep Vein Thrombosis in the outpatient setting
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, Kaiser Permanente 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

Pneumatic Compression Device

Thromboembolic disease is a common complication following surgery particularly total joint replacement arthroplasty. It has been reported that without prophylaxis the rate of deep vein thrombosis (DVT) is as high as 88% after total knee arthroplasty and as high as 50% after total hip arthroplasty. It is also reported that lower extremity DVT is the origin of 90% of symptomatic pulmonary embolism (PE). Prophylaxis for DVT has become the standard of care for total joint arthroplasty. Chemical prophylaxis with warfarin or low-molecular weight heparin effectively reduces the incidence of DVT but carries a risk of bleeding. Orthopedic surgeons thus often use mechanical methods of prophylaxis as an alternative to chemoprophylaxis in patients with higher bleeding risk. Other surgeons also use it in standard risk patients in conjunction with the anticoagulant-based prophylaxis (Edwards 2008, Zywiel 2010).

Graduated compression stockings (GCSs) and intermittent pneumatic compression (IPC) are the two predominant mechanical methods used for DVT prevention. These have quite different methods of action; graduated compression stockings apply a constant pressure to the limb with the aim of maintaining a reduced venous caliber and preventing the static accumulation of blood. Intermittent pneumatic compression actively empties the deep veins of the limb in a predetermined cycle of pressure, producing a pulse of blood that travels proximally preventing stasis. On deflation of the cuff, the veins will refill, the intermittent nature of the system will insure periodic blood flow through the deep veins, as long as there is a supply. The IPC cuffs are normally

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wrapped around a limb, secured by velcro, and attached with tubes to an electric pump to regulate the pressure applied (Morris 2004, Morris 2010, Sobieraj-Teague 2011).

GCSs do not require attachment to any device and allow the patient to move freely. They come in a range of sizes and the limb has to be measured accurately to prevent incorrect pressure gradients, which may increase the risk of DVT. Intermittent compression devices are available in different forms; the cuff can cover the whole leg, the calf, or just the feet, it may inflate uniformly or sequentially with graded pressure; and can have rapid or moderate inflation rates. These characteristics my influence patient compliance which is critical as the longer the device is used, the better is the protection. The major disadvantages for standard IPC devices used in hospitals are their size, weight, and reliance on external power source, all of which result in poor patient compliance and in turn limit the efficacy of the device (Morris 2004, Froimson 2009).

In an attempt to overcome the problem of poor patient compliance with traditional mechanical compression systems, several lightweight, portable, battery-powered devices were developed to allow their use by the patient while ambulating in the hospital or at home after discharge. Many of these devices have received FDA clearance.

Background

Intermittent Pneumatic Compression for the Treatment of Peripheral Arterial Occlusive Disease

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).

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The ArtAssist device as well as the Flow MedicTM system, and ArterialFlowTM 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)

Portable Compression Devices for Prevention of Post op DVT

4/16/2012: MTAC REVIEW

Evidence Conclusion: The published trials on the use of portable compression devices for the prophylaxis against DVT mainly compared the devices to chemoprophylaxis. Generally, patients randomized to the portable compression devices also received chemoprophylaxis, and in one study they also used graduated compression stockings (GCS). There were no head-to-head trials that compared the portable devices to the GCS. The trials reviewed were randomized and controlled, but were not blinded, used different definitions of major bleeds, and were financially supported by the manufacturers of the devices. Colwell and colleagues, 2010 (Evidence table 1) compared a new portable intermittent calf compression device (Continuous Enhanced Circulation Therapy Plus Synchronized Flow Technology [CECT+SFT]) versus a low molecular weight heparin (LMWH), for the prevention of thromboembolic disease after total hip replacement in 410 patients. The compression device was applied preoperatively and the LMWH was started the morning after the surgery. Patients in the compression group were allowed to receive 81mg of aspirin daily after surgery according to the surgeon's discretion. Both treatments were continued for 10 days, and the patients were followed-up clinically for 10 weeks. Bleeding was the primary outcome of the trial and rate of thromboembolic events was a secondary outcome. Overall, the results of the trials showed that the rate of major bleeds was significantly lower among the patients randomized to the portable compression group. There was no difference in the rate of thromboembolic events, but this was a secondary outcome and the study was not designed to determine equivalence. Edwards and colleagues, 2008 (Evidence table 2) compared an earlier version of the portable intermittent calf compression device (CECT) given together with LMWH versus LMWH alone in the prevention of VTE in patients undergoing either total hip or total knee arthroplasty. Patients randomized to the CECT group had the device applied in the operating room and continued during hospitalization, and the two groups received a LMWH for 7-8 days after surgery. The results of the study showed a significantly lower rate of DVT in patients in the portable compression device plus LMWH after a total knee arthroplasty compared to those using chemoprophylaxis alone, with a NNT of 8. No such significant difference was observed among those who underwent total hip replacement. In a similar trial Gelfer and colleagues (2006) compared prophylaxis with the CECT and aspirin versus LMWH and showed significant reduction in the incidence of DVT in the compression group vs. the LMWH group. In a more recent RCT, Sobieraj-Teague and colleagues, 2012 (Evidence table 3) examined the efficacy and tolerability of a new portable intermittent calf compression device (Venowave) in high risk neurosurgical patients. Patients were randomized to usual care alone or in addition to the portable compression device, and all participants in the two groups were prescribed below the knee graduated compression stockings. They could also receive pharmacological prophylaxis (aspirin, LMWH, or unfractionated heparin) according to the discretion of the neurosurgeon. The overall results indicate the rate of DVT was significantly lower in the study group that used a portable compression device in addition to the graduated compression stocking and chemoprophylaxis as needed in this high risk neurosurgical patients. The portable devices used in the trials had an average compliance rate around 80%, and the associated side effects were mainly discomfort especially at night, pruritis, and sweating.

Articles: The literature search revealed a number of earlier RCTs that compared the graduated compression stockings to intermittent compression therapy. However, IPC systems used in these studies were the standard devices used in the hospitals and not the portable IPCs which are the focus of this review. There were three RCTs that compared the use chemoprophylaxis given alone or with IPC using portable devices after total joint arthroplasty, and one trial that evaluated the efficacy of using a portable compression device in addition to graduated compression stockings and chemoprophylaxis in high risk neurosurgical patients. The following studies were selected for critical appraisal;

Colwell CW Jr, Froimson MI, Mont MA, et al. Thrombosis prevention after total hip arthroplasty: a prospective, randomized trial comparing a mobile compression device with low-molecular-weight heparin. J Bone Joint Surg Am. 2010; 92:527-535. See Evidence Table

Edwards JZ, Pulido PA, Ezzet K A, et al. Portable compression device and low-molecular-weight heparin compared with low-molecular-weight heparin for thromboprophylaxis after total joint arthroplasty. J Arthroplasty. 2008; 23:1122-1127. See Evidence Table

Sobieraj-Teague M, Hirsh J, Yip G, Gastaldo F, et al. Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients. J Thromb Haemost. 2012; 10:229-235. See Evidence Table

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The use of portable compression devices does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Portable Compression Devices

BACKGROUND

Thromboembolic disease is a common complication following surgery particularly total joint replacement arthroplasty. It has been reported that without prophylaxis the rate of deep vein thrombosis (DVT) is as high as 88% after total knee arthroplasty and as high as 50% after total hip arthroplasty. It is also reported that lower extremity DVT is the origin of 90% of symptomatic pulmonary embolism (PE). Prophylaxis for DVT has become the standard of care for total joint arthroplasty. Chemical prophylaxis with warfarin or low-molecular weight heparin effectively reduces the incidence of DVT but carries a risk of bleeding. Orthopedic surgeons thus often use mechanical methods of prophylaxis as an alternative to chemoprophylaxis in patients with higher bleeding risk. Other surgeons also use it in standard risk patients in conjunction with the anticoagulant-based prophylaxis (Edwards 2008, Zywiel 2010). Graduated compression stockings (GCSs) and intermittent pneumatic compression (IPC) are the two predominant mechanical methods used for DVT prevention. These have quite different methods of action; graduated compression stockings apply a constant pressure to the limb with the aim of maintaining a reduced venous caliber and preventing the static accumulation of blood. Intermittent pneumatic compression actively empties the deep veins of the limb in a predetermined cycle of pressure, producing a pulse of blood that travels proximally preventing stasis. On deflation of the cuff, the veins will refill, the intermittent nature of the system will ensure periodic blood flow through the deep veins, as long as there is a supply. The IPC cuffs are normally wrapped around a limb, secured by velcro, and attached with tubes to an electric pump to regulate the pressure applied (Morris 2004, Morris 2010, Sobieraj-Teague 2011). GCSs do not require attachment to any device and allow the patient to move freely. They come in a range of sizes and the limb has to be measured accurately to prevent incorrect pressure gradients, which may increase the risk of DVT. Intermittent compression devices are available in different forms; the cuff can cover the whole leg, the calf, or just the feet, it may inflate uniformly or sequentially with graded pressure; and can have rapid or moderate inflation rates. These characteristics my influence patient compliance which is critical as the longer the device is used, the better is the protection. The major disadvantages for standard IPC devices used in hospitals are their size, weight, and reliance on external power source, all of which result in poor patient compliance and in turn limit the efficacy of the device (Morris 2004, Froimson 2009). In an attempt to overcome the problem of poor patient compliance with traditional mechanical compression systems, several lightweight, portable, battery-powered devices were developed to allow their use by the patient while ambulating in the hospital or at home after discharge. Many of these devices have received FDA clearance.

04/16/2012: MTAC REVIEW

Portable Compression Devices

Evidence Conclusion: The published trials on the use of portable compression devices for the prophylaxis against DVT mainly compared the devices to chemoprophylaxis. Generally, patients randomized to the portable compression devices also received chemoprophylaxis, and in one study they also used graduated compression stockings (GCS). There were no head-to-head trials that compared the portable devices to the GCS. The trials reviewed were randomized and controlled, but were not blinded, used different definitions of major bleeds, and were financially supported by the manufacturers of the devices. Colwell and colleagues, 2010 (Evidence table 1) compared a new portable intermittent calf compression device (Continuous Enhanced Circulation Therapy Plus Synchronized Flow Technology [CECT+SFT]) versus a low molecular weight heparin (LMWH), for the prevention of thromboembolic disease after total hip replacement in 410 patients. The compression device was applied preoperatively and the LMWH was started the morning after the surgery. Patients in the compression group were allowed to receive 81mg of aspirin daily after surgery according to the surgeon's discretion. Both treatments were continued for 10 days, and the patients were followed-up clinically for 10 weeks. Bleeding was the primary outcome of the trial and rate of thromboembolic events was a secondary outcome. Overall, the results of the trials showed that the rate of major bleeds was significantly lower among the patients randomized to the portable compression group. There was no difference in the rate of thromboembolic events, but this was a secondary outcome and the study was not designed to determine equivalence. Edwards and colleagues, 2008 (Evidence table 2) compared an earlier version of the portable intermittent calf compression device (CECT) given together with LMWH versus LMWH alone in the prevention of VTE in patients undergoing either total hip or total knee arthroplasty. Patients randomized to the CECT group had the device applied in the operating room and continued during hospitalization, and the two groups received a LMWH for 7-8 days after surgery. The results of the study showed a significantly lower rate of DVT in patients in the portable compression device plus LMWH after a total knee arthroplasty compared to those using chemoprophylaxis alone, with a NNT of 8. No such significant difference was observed among those who underwent total hip replacement. In a similar trial Gelfer and colleagues (2006) compared prophylaxis with the CECT and aspirin versus LMWH and showed significant

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reduction in the incidence of DVT in the compression group vs. the LMWH group. In a more recent RCT, Sobieraj-Teague and colleagues, 2012 (Evidence table 3) examined the efficacy and tolerability of a new portable intermittent calf compression device (Venowave) in high risk neurosurgical patients. Patients were randomized to usual care alone or in addition to the portable compression device, and all participants in the two groups were prescribed below the knee graduated compression stockings. They could also receive pharmacological prophylaxis (aspirin, LMWH, or unfractionated heparin) according to the discretion of the neurosurgeon. The overall results indicate the rate of DVT was significantly lower in the study group that used a portable compression device in addition to the graduated compression stocking and chemoprophylaxis as needed in this high-risk neurosurgical patients. The portable devices used in the trials had an average compliance rate around 80%, and the associated side effects were mainly discomfort especially at night, pruritis, and sweating.
Articles: The literature search revealed a number of earlier RCTs that compared the graduated compression stockings to intermittent compression therapy. However, IPC systems used in these studies were the standard devices used in the hospitals and not the portable IPCs which are the focus of this review. There were three RCTs that compared the use chemoprophylaxis given alone or with IPC using portable devices after total joint arthroplasty, and one trial that evaluated the efficacy of using a portable compression device in addition to graduated compression stockings and chemoprophylaxis in high risk neurosurgical patients.
The following studies were selected for critical appraisal; Colwell CW Jr, Froimson MI, Mont MA, et al. Thrombosis prevention after total hip arthroplasty: a prospective, randomized trial comparing a mobile compression device with low-molecular-weight heparin. J Bone Joint Surg Am. 2010; 92:527-535. See Evidence Table. Edwards JZ, Pulido PA, Ezzet K A, et al. Portable compression device and low-molecular-weight heparin compared with low-molecular-weight heparin for thromboprophylaxis after total joint arthroplasty. J Arthroplasty. 2008; 23:1122-1127. See Evidence Table. Sobieraj-Teague M, Hirsh J, Yip G, Gastaldo F, et al. Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients. J Thromb Haemost. 2012; 10:229-235. See Evidence Table.

The use of portable compression devices does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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 dropout 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 Nicolaides (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.
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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.*

Applicable Codes

Effective until June 1st, 2024
Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

HCPC Codes	Description
E0650	Pneumatic compressor, nonsegmental home mode
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg

Effective until June 1st, 2024
Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

HCPC Codes	Description
E0650	Pneumatic compressor, nonsegmental home mode
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg

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E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg

Effective until June 1st, 2024

Medicare: Considered not medically necessary

HCPC Codes	Description
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
A4600	Sleeve for intermittent limb compression device, replacement only, each *(used for devices described by E0676)*

Effective until June 1st, 2024

Non- Medicare: Considered not medically necessary

HCPC Codes	Description
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
A4600	Sleeve for intermittent limb compression device, replacement only, each *(used for devices described by E0676)*

Effective June 1st, 2024

Medicare & Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

HCPC Codes	Description
E0650	Pneumatic compressor, nonsegmental home mode
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg

Effective June 1st, 2024

Medciare & Non-Medicare: Considered not medically necessary

HCPC	Description

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Codes	
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
A4600	Sleeve for intermittent limb compression device, replacement only, each *(used for devices described by E0676)*

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/01/2012	05/01/2012[MDCRPC], 06/05/2012[MDCRPC], 04/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	01/09/2024

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/21/2015	Title Change
03/08/2016	Updated Medicare links
05/08/2018	Added Policy article language for non-coverage of E0676
7/10/2018	Added new review criteria for pneumatic devices for Non-Medicare members with effective date 10/15/2018
04/05/2022	Updated applicable codes
04/18/2023	Updated Medicare Pneumatic Compression Devices – Policy Article A52488
01/09/2024	MPC approved to adopt the Medicare LCD Pneumatic compression devices L33829 for commercial members. Requires 60-day notice, effective June 1st, 2024. Merged Intermittent Pneumatic Compression Device with this criteria set.

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