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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Pneumatic Compression Devices

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

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
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

Effective after October 15, 2018

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
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

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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.

Criteria

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:
   A. Marked hyperkeratosis with hyperplasia and hyperpigmentation
   B. Papillomatosis cutis lymphostatica,
   C. Deformity of elephantiasis,
   D. Skin breakdown with persisting lymphorrhea,
   E. 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 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:

A. 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 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. Regular exercise
C. 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 below, 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

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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 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
KPWA 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
KPWA 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 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.

KPWA 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

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 not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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.

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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 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.

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

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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
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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 insure 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.

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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]	7/10/2018

[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

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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

Codes

CPT: E0660, E0666, E0667, E0669, E0671, E0673, E0650, E0651, E0652, E0655, E0656, E0657, E0665, E0668, E0670, E0671, E0672, E0673, E0675, E0676

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