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

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**Type of Submission – Check all that apply:**

- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions
- [ ] Statewide PDL

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

Please provide any clarifying information for the policy below:

**CPB 0500 Intermittent Pneumatic Compression Devices**

Clinical content was last revised on 07/19/2018. No additional non-clinical updates were made by Corporate since the last PARP submission.

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<th>Name of Authorized Individual (Please type or print):</th>
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<td>Dr. Bernard Lewin, M.D.</td>
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Intermittent Pneumatic Compression Devices

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna considers full-leg or half-leg pneumatic compression devices for home use medically necessary durable medical equipment (DME) for the treatment of chronic venous insufficiency of the legs of members who have venous stasis ulcers that have failed to heal after a 6-month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

When a pneumatic compression device is determined to be medically necessary, a non-segmented device or segmented device without manual control of the pressure in each chamber is generally considered adequate to meet the clinical needs of the member. A segmented device with manual control of the pressure in each chamber is considered medically necessary only if there is clear documentation of medical necessity in the individual case. A segmented device with manual control of the pressure in each chamber is considered medically necessary only when there is documentation that the individual has unique characteristics that prevent
satisfactory pneumatic compression treatment using a non-segmented device with a segmented appliance/sleeve or a segmented device without manual control of the pressure in each chamber.

Aetna considers intermittent pneumatic compression devices of the lower extremities medically necessary DME to stimulate circulation and reduce the chances of deep venous thromboses for members who are bedridden due to trauma, orthopedic surgery, neurosurgery or other circumstances preventing ambulation. **Note:** the presence of a cast or splint, the use of an assistive device (e.g., walker, crutches), or non-weightbearing status alone due to injury or surgery are not considered "bedridden" for the purpose of this policy.

Aetna considers intermittent pneumatic compression devices experimental and investigational for the following (not an all-inclusive list) because there is inadequate evidence of their effectiveness for these indications:

- Enhancement of Achilles tendon rupture healing
- Enhancement of fracture and soft-tissue healing
- Management of edema following femoro-popliteal bypass surgery
- Prophylaxis of venous thromboembolism in neurosurgery
- Rehabilitation for distal radial fractures
- Treatment of critical limb ischemia
- Treatment of peripheral arterial occlusive disease/arterial insufficiency
- Treatment of restless legs syndrome
- Treatment of sensory impairment in the upper limb following stroke
- Treatment of upper extremity lymphedema following surgery
- Treatment of upper extremity vascular ulcers

Aetna considers a single patient use intermittent pneumatic compression device (e.g., the VenaPro Vascular Therapy System) not medically necessary.

Aetna considers intermittent pneumatic trunk compression for the prevention of thrombosis following orthopedic surgery experimental and investigational because its effectiveness has not been established.

**Note:** For persons with a medically necessary inflatable compression garment (e.g., Flowtron Compression Garment, Jobst Pneumatic Compressor), a pump needed to inflate the compression garment is considered medically necessary.
See also CPB 0069 - Lymphedema (../1_99/0069.html) for Aetna's policy on pneumatic compression devices for arm lymphedema and CPB 0482 - Compression Garments for the Legs (../400_499/0482.html).

**Background**

Gradient elastic stockings, such as those made by Jobst, Sigvaris, Juzzo, or Medi, are generally viewed as the principle means of preventing complications of chronic venous insufficiency. Intermittent pneumatic compression devices compress the leg and/or foot and ankle and act as a pump to improve circulation in the lower extremities. Pneumatic compression devices consist of an inflatable garment for the leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices.

Intermittent pneumatic compression (IPC) boots are generally accepted as a method for preventing deep venous thromboses (DVT) and complications of venous stasis in persons after trauma, orthopedic surgery, neurosurgery, or who for other reasons are unable to walk.

Use of the IPC device has expanded to ambulatory persons who suffer from chronic venous insufficiency (CVI) of the legs and consequent edema, stasis dermatitis, ulcerations, and cellulitis. CVI of the legs is caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins.

A systemic review of the literature concluded that the effectiveness of the addition of IPC in treatment of venous leg ulcers is unknown. The systemic review identified 3 small, randomized controlled trials (RCTs) of IPC; all of these trials were different in design. Upon pooling of the results, using a random effects model, the reviewers found no difference in healing rates. The review concluded that "[t]hree small [randomized controlled trials] found no evidence of a significant effect on healing with intermittent pneumatic compression in conjunction with compression bandages."
There is no evidence that IPC devices are superior to gradient compression stockings in preventing complications of chronic venous disease. Compliance with gradient compression stockings has been shown to be essential to their effectiveness; the stockings do not work unless they are worn. There are no studies, however, that have demonstrated that compliance with IPC devices is significantly greater than compliance with gradient compression stockings.

The A-V Impulse System FootPump and the KCI Plexipulse are brands of IPC boots on the market; others include those manufactured by Jobst, Chattanooga, Kendal, and Nutech.

The Canadian Coordinating Office of Health Technology Assessment (2004) concluded that “EPC [external pneumatic compression] reduces the risk of DVT for patients who cannot walk due to trauma, joint surgery or neurosurgery. There is still limited evidence, however, supporting the effect of EPC on the healing of venous ulcers and other disorders resulting from chronic VI [venous insufficiency].”

Current evidence supporting the use of pneumatic compression devices in peripheral arterial disease is limited to small pilot studies with short-term follow up. In a pilot study (n = 30), Ramaswami et al (2005) examined the usefulness of rapid, high-pressure, intermittent pneumatic calf and foot compression (IPCFC) in patients with stable intermittent claudication. These investigators concluded that “IPCFC improves walking distance in patients with stable intermittent claudication. The combination of IPCFC with other treatment such as risk-factor modification and daily exercise may prove useful in patients with peripheral arterial occlusive disease. It may be a useful first line of therapy in patients with disabling claudication who are unfit for major reconstructive surgery. Improved walking on long-term follow-up and experience from different centers may establish a role for this treatment modality in the future.”

Kakkos et al (2005) compared the effect of unsupervised exercise, supervised exercise and IPCFC on the claudication distance, lower limb arterial hemodynamics and quality of life of patients with intermittent claudication (n = 34). These researchers concluded that IPCFC achieved improvement in walking distance comparable with supervised exercise. Long-term results in a larger number of patients will provide valuable information on the optimal treatment modality of intermittent claudication.
Khanna et al (2008) stated that current methods of fracture care use various adjuncts to try and decrease time to fracture union, improve fracture union rates and enhance functional recovery; and one such modality is IPC. These researchers performed a literature review on this approach. A total of 16 studies on the use of IPC in fracture and soft-tissue healing were identified. These studies demonstrated that IPC facilitates both fracture and soft-tissue healing with rapid functional recovery. The authors concluded that IPC appears to be an effective modality to enhance fracture and soft-tissue healing. Moreover, they noted that the number of subjects in human studies is small, and adequately powered RCTs are needed to produce stronger clinically relevant evidence.

In a prospective, randomized, double-blinded, sham-controlled trial, Lettieri and Eliasson (2009) evaluated the effectiveness of pneumatic compression devices (PCDs) as a non-pharmacologic treatment for restless legs syndrome (RLS). Subjects wore a therapeutic or sham device prior to the usual onset of symptoms for a minimum of 1 hour daily. Measures of severity of illness, quality of life, daytime sleepiness, and fatigue were compared at baseline and after 1 month of therapy. A total of 35 subjects were enrolled. Groups were similar at baseline. Therapeutic PCDs significantly improved all measured variables more than shams. Restless legs severity score improved from 14.1 +/- 3.9 to 8.4 +/- 3.4 (p = 0.006) and Johns Hopkins restless legs scale improved from 2.2 +/- 0.5 to 1.2 +/- 0.7 (p = 0.01). All quality of life domains improved more with therapeutic than sham devices (social function 14 % versus 1 %, respectively, p = 0.03; daytime function 21 % versus 6 %, respectively, p = 0.02; sleep quality 16 % versus 8 %, respectively, p = 0.05; emotional well-being 17 % versus 10 %, respectively, p = 0.15). Both Epworth sleepiness scale (6.5 +/- 4.0 versus 11.3 +/- 3.9, respectively, p = 0.04) and fatigue (4.1 +/- 2.1 versus 6.9 +/- 2.0, respectively, p = 0.01) improved more with therapeutic devices than sham devices. Complete relief occurred in 1/3 of subjects using therapeutic and in no subjects using sham devices. The authors concluded that PCDs resulted in clinically significant improvements in symptoms of RLS in comparison to the use of sham devices and may be an effective adjunctive or alternative therapy for RLS. Moreover, the authors stated that before PCD therapy is ready for more wide-spread use, it will be important to see validating studies in various populations of RLS patients.

In a prospective, randomized trial, te Slaa et al (2011) examined the effects of IPC for the treatment and prevention of post-reconstructive edema following femoro-popliteal bypass surgery. Patients were assigned to one of two groups. All patients
suffered from peripheral arterial disease, and all were subjected to autologous femoro-popliteal bypass reconstruction. Patients in group 1 used a compression stocking (CS) above the knee exerting 18 mm Hg (class I) on the leg post-operatively for 1 week (day and night). Patients in group 2 used IPC on the foot post-operatively at night for 1 week. The lower leg circumference was measured pre-operatively and at 5 post-operative time points. A multi-variate analysis was done using a mixed model analysis of variance. A total of 57 patients were analyzed (n = 28 for CS; n = 29 for IPC). Indications for operation were severe claudication (CS 13; IPC 13), rest pain (10/5), or tissue loss (7/11). Revascularization was performed with either a supra-genicular (CS 13; IPC 10) or an infra-genicular (CS 15; IPC 19) autologous bypass. Leg circumference increased on day 1 (CS/IPC): 0.4 %/2.7 %, day 4 (2.1 %/6.1 %), day 7 (2.5 %/7.9 %), day 14 (4.7 %/7.3 %), and day 90 (1.0 %/3.3 %) from baseline (pre-operative situation). On days 1, 4, and 7 there was a significant difference in leg circumference between the 2 treatment groups. The authors concluded that edema following femoro-popliteal bypass surgery occurs in all patients. For the prevention and treatment of edema following femoro-popliteal bypass surgery, the use of a class I CS proved superior to treatment with IPC. The authors concluded that the use of CS remains the recommended practice following femoro-popliteal bypass surgery.

Pfizenmaier et al (2005) noted that ischemic vascular ulcerations of the upper extremities are an uncommon and frequently painful condition most often associated with scleroderma and small vessel inflammatory diseases. Digital amputation has been advocated as primary therapy because of the poor outcome with medical care. Intermittent pneumatic compression pump therapy can improve ulcer healing in lower extremity ischemic ulcerations; however, the value of this treatment in upper extremity ischemic ulcerations is not known. This observational pilot study consisted of a consecutive series of 26 patients with 27 upper extremity ischemic vascular ulcers seen at the Mayo Gonda Vascular Center from 1996 to 2003. Inclusion criteria were documented index of ulcer size and follow-up ulcer size and use of the IPC pump as adjunctive wound treatment. Twenty-six of 27 ulcers (96 %) healed with the use of the IPC pump. Mean baseline ulcer size was 1.0 cm² (SD = 0.3 cm²) and scleroderma was the underlying disease in 65 % (17/26) of cases. Laser Doppler blood flow in the affected digit was 7 flux units (normal greater than 100). The mean ulcer duration before IPC treatment was 31 weeks. The average pump use was 5 hours per day. The mean time to wound healing was 25 weeks. Twenty-five of 26 patients reported an improvement in wound pain with pump use. The authors concluded that intensive IPC pump use is
feasible and associated with a high rate of healing in upper extremity ischemic ulcers. Furthermore, they stated that prospective, RCTs of IPC is needed to determine whether IPC treatment improves wound healing compared to standard medical care.

Handoll et al (2006) examined the effects of rehabilitation interventions in adults with conservatively or surgically treated distal radial fractures. These investigators searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (December 2005), the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 4, 2005), MEDLINE, EMBASE, CINAHL, AMED, PEDro, OTseeker and other databases, conference proceedings and reference lists of articles. No language restrictions were applied. Randomized or quasi-RCTs evaluating rehabilitation as part of the management of fractures of the distal radius sustained by adults. Rehabilitation interventions such as active and passive mobilization exercises, and training for activities of daily living, could be used on their own or in combination, and be applied in various ways by various clinicians. The authors independently selected and reviewed trials. Study authors were contacted for additional information. No data pooling was done. A total of 15 trials, involving 746 mainly female and older patients, were included. Initial treatment was conservative, involving plaster cast immobilization, in all but 27 participants whose fractures were fixed surgically. Though some trials were well-conducted, others were methodologically compromised. For interventions started during immobilization, there was weak evidence of improved hand function for hand therapy in the days after plaster cast removal, with some beneficial effects continuing 1 month later (1 trial). There was weak evidence of improved hand function in the short-term, but not in the longer term (3 months), for early occupational therapy (1 trial), and of a lack of differences in outcome between supervised and unsupervised exercises (1 trial). For interventions started post-immobilization, there was weak evidence of a lack of clinically significant differences in outcome in patients receiving formal rehabilitation therapy (4 trials), passive mobilization (2 trials), ice or pulsed electromagnetic field (1 trial), or whirlpool immersion (1 trial) compared with no intervention. There was weak evidence of a short-term benefit of continuous passive motion (post-external fixation) (1 trial), IPC (1 trial) and ultrasound (1 trial). There was weak evidence of better short-term hand function in participants given physiotherapy than in those given instructions for home exercises by a surgeon (1 trial). The authors concluded...
that the available evidence from RCTs is insufficient to establish the relative
effectiveness of the various interventions used in the rehabilitation of adults with
fractures of the distal radius.

In a preliminary study, Cambier et al (2003) evaluated the effectiveness of IPC in
treating sensory impairments in the hemiplegic upper limb in stroke patients. A
total of 23 stroke patients were enrolled in this RCT that compared the application
of IPC with a passive treatment strategy. The experimental group (n = 11) received
standard physiotherapy combined with IPC treatment (10 cycles of 3 mins with a
peak of 40 mmHg) for their hemiplegic upper limb. The control group (n = 12)
received supplementary to their conventional physiotherapy a placebo treatment,
namely sham short-wave therapy on the hemiplegic shoulder for 30 mins. Sensory
impairments were clinically assessed at 3 occasions over a period of 4 weeks using
the Nottingham Sensory Assessment scale. Both groups improved in somato-
sensation over time, but the experimental group improved more than the control
group (p = 0.036) or 81.1% improvement versus 30.9 %. The authors concluded
that the use of IPC in the rehabilitation of stroke patients may be of clinical
importance for the restoration of sensory function. Drawbacks of this study
included small sample size and short follow-up period.

Doyle et al (2010) examined the effects of interventions that target upper limb
sensory impairment after stroke. These investigators searched the Cochrane
Stroke Group Trials Register (last searched October 8, 2009), the Cochrane
Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2009,
Issue 1), MEDLINE (1966 to January 2009), EMBASE (1980 to January 2009), and
6 further electronic databases to January 2009. They also hand-searched relevant
journals, contacted authors in the field, searched doctoral dissertation databases,
checked reference lists, and completed citation tracking. Randomized controlled
trials and controlled trials comparing interventions for sensory impairment after
stroke with no treatment, conventional treatment, attention placebo or with other
interventions for sensory impairment were included in this analysis. Two review
authors selected studies, assessed quality and extracted data. They analyzed
study data using mean differences and odds ratios as appropriate. The primary
outcome was sensory function; and secondary outcomes included upper limb
function, activities of daily living, impact of stroke and quality of life as well as
adverse events. These researchers included 13 studies, with a total 467
participants, testing a range of different interventions. Outcome measures included
36 measures of sensory impairment and 13 measures of upper limb function. All
but 2 studies had unclear or high-risk of bias. While there is insufficient evidence to reach conclusions about the effects of interventions included in this review, 3 studies provided preliminary evidence for the effects of some specific interventions, including mirror therapy for improving detection of light touch, pressure and temperature pain; a thermal stimulation intervention for improving rate of recovery of sensation; and IPC intervention for improving tactile and kinesthetic sensation. These researchers could not perform meta-analysis due to a high-degree of clinical heterogeneity in both interventions and outcomes. The authors concluded that there is insufficient evidence to support or refute the effectiveness of the described interventions in improving sensory impairment, upper limb function, or participants' functional status and participation. Moreover, they stated that there is a need for more well-designed, better-reported studies of sensory rehabilitation.

The American College of Chest Physicians' evidence-based clinical practice guidelines on “Antithrombotic and thrombolytic therapy for ischemic stroke” (Lansberg et al, 2012) provided recommendations on the use of antithrombotic therapy in patients with stroke or transient ischemic attack (TIA). These investigators generated treatment recommendations (Grade 1) and suggestions (Grade 2) based on high (A), moderate (B), and low (C) quality evidence. In patients with acute ischemic stroke, these researchers recommended IV recombinant tissue plasminogen activator (r-tPA) if treatment can be initiated within 3 hrs (Grade 1A) or 4.5 hrs (Grade 2C) of symptom onset; these investigators suggested intra-arterial r-tPA in patients ineligible for IV tPA if treatment can be initiated within 6 hrs (Grade 2C); they suggested against the use of mechanical thrombectomy (Grade 2C) although carefully selected patients may choose this intervention; and they recommended early aspirin therapy at a dose of 160 to 325 mg (Grade 1A).

In patients with acute stroke and restricted mobility, the authors suggested the use of prophylactic-dose heparin or IPC devices (Grade 2B) and suggested against the use of elastic compression stockings (Grade 2B). In patients with a history of non-cardioembolic ischemic stroke or TIA, they recommended long-term treatment with aspirin (75 to 100 mg once-daily), clopidogrel (75 mg once-daily), aspirin/extended release dipyridamole (25 mg/200 mg bid), or cilostazol (100 mg bid) over no anti-platelet therapy (Grade 1A), oral anticoagulants (Grade 1B), the combination of clopidogrel plus aspirin (Grade 1B), or triflusal (Grade 2B). Of the recommended anti-platelet regimens, the authors suggested clopidogrel or aspirin/extended-release dipyridamole over aspirin (Grade
In patients with a history of stroke or TIA and atrial fibrillation, they recommended oral anti-coagulation over no anti-thrombotic therapy, aspirin, and combination therapy with aspirin and clopidogrel (Grade 1B).

Zhao and colleagues (2012) noted that total hip replacement (THR) is an effective treatment for reducing pain and improving function and quality of life in patients with hip disorders. While this operation is very successful, DVT and pulmonary embolism (PE) are significant complications after THR. Different types of IPC devices have been used for thrombosis prophylaxis in patients following THR. Available devices differ in compression garments, location of air bladders, patterns of pump pressure cycles, compression profiles, cycle-length, duration of inflation time and deflation time, or cycling mode such as automatic or constant cycling devices. Despite the widely accepted use of IPC for the treatment of arterial and venous diseases, the relative effectiveness of different types of IPC systems as prophylaxis against thrombosis after THR is still unclear. In a Cochrane review, these investigators evaluated the comparative safety and effectiveness of different IPC devices with respect to the prevention of venous thromboembolism in patients after THR. The Cochrane Peripheral Vascular Diseases Group Trials Search Coordinator searched the Specialized Register (May 2012), CENTRAL (2012, Issue 4), MEDLINE (April Week 3 2012) and EMBASE (Week 17 2012). Clinical trial databases were searched for details of ongoing and unpublished studies. Reference lists of obtained articles were also screened. There were no limits imposed on language or publication status. Randomized and quasi-RCTs were eligible for inclusion. Two review authors independently selected trials, assessed trials for eligibility and methodological quality, and extracted data. Disagreement was resolved by discussion or, if necessary, referred to a third review author. Only 1 quasi-RCT with 121 study participants comparing 2 types of IPC devices met the inclusion criteria. The authors found no cases of symptomatic DVT or PE in either the calf-thigh compression group or the plantar compression group during the first 3 weeks after the THR. The calf-thigh pneumatic compression was more effective than plantar compression for reducing thigh swelling during the early post-operative stage. The strength of the evidence in this review was weak as only 1 trial was included and it was classified as having a high-risk of bias. The authors concluded that there is a lack of evidence from RCTs to make an informed choice of IPC device for preventing venous thromboembolism (VTE) following THR. They stated that more research is needed, ideally a multi-center, properly designed RCT.
including a sufficient number of participants. Clinically relevant outcomes such as mortality, imaging-diagnosed asymptomatic VTE and major complications must be considered.

Dennis et al (2013) evaluated the effectiveness of IPC to reduce the risk of DVT in patients who have had a stroke. The CLOTS 3 trial is a multi-center parallel group randomized trial assessing IPC in immobile patients (i.e., who cannot walk to the toilet without the help of another person) with acute stroke. These researchers enrolled patients from day 0 to day 3 of admission and allocated them via a central randomization system (ratio 1:1) to receive either IPC or no IPC. A technician who was masked to treatment allocation did a compression duplex ultrasound (CDU) of both legs at 7 to 10 days and, wherever practical, at 25 to 30 days after enrolment. Care-givers and patients were not masked to treatment assignment. Patients were followed up for 6 months to determine survival and later symptomatic VTE. The primary outcome was a DVT in the proximal veins detected on a screening CDU or any symptomatic DVT in the proximal veins, confirmed on imaging, within 30 days of randomization. Patients were analyzed according to their treatment allocation. Between December 8, 2008, and September 6, 2012, a total of 2,876 patients were enrolled in 94 centers in the United Kingdom. The included patients were broadly representative of immobile stroke patients admitted to hospital and had a median age of 76 years (IQR 67 to 84). The primary outcome occurred in 122 (8.5%) of 1,438 patients allocated IPC and 174 (12.1%) of 1,438 patients allocated no IPC; an absolute reduction in risk of 3.6% (95% confidence interval [CI]: 1.4 to 5.8). Excluding the 323 patients who died before any primary outcome and 41 without any screening CDU, the adjusted odds ratio (OR) for the comparison of 122 of 1,267 patients versus 174 of 1,245 patients was 0.65 (95% CI: 0.51 to 0.84; p = 0.001). Deaths in the treatment period occurred in 156 (11%) patients allocated IPC and 189 (13%) patients allocated no IPC died within the 30 days of treatment period (p = 0.057); skin breaks on the legs were reported in 44 (3%) patients allocated IPC and in 20 (1%) patients allocated no IPC (p = 0.002); falls with injury were reported in 33 (2%) patients in the IPC group and in 24 (2%) patients in the no-IPC group (p = 0.221). The authors concluded that IPC is an effective method of reducing the risk of DVT and possibly improving survival in a wide variety of patients who are immobile after stroke.

It is interesting to note that an UpToDate review on “Prevention of venous thromboembolic disease in medical patients” (Pai and Douketis, 2014) states that “Data on the efficacy and safety of IPCs are limited. However, one large
randomized trial in patients with stroke suggested that IPCs reduce the incidence of VTE [Dennis et al., 2013]. A multicenter, randomized trial of 2,876 immobile patients with acute stroke (CLOTS 3) reported that, compared to no device, IPC use was associated with a lower rate of VTE at 30 days (12 versus 8.5 percent; absolute risk reduction 3.6 percent; 95% CI 1.4 to 5.8) without altering mortality (13 versus 11 percent). While use of low molecular weight heparin was similar in both groups (32 versus 30 percent), more patients in the IPC group wore compression stockings (15 versus 6 percent) which may have biased results in favor of IPC use”.

Ye et al. (2018) examined various definitions of immobility used in recent pharmacological thromboprophylaxis clinical trials. PubMed and relevant references from articles/reviews from 2008 to 2016 were searched. RCTs and other clinical studies involving adult hospitalized medical patients in acute care hospital settings that used the term immobility were selected. Two investigators independently abstracted data in duplicate, and accuracy was checked by a third investigator. Twenty-one clinical studies were included. There was heterogeneity among individual VTE risk factors, with respect to the definition of immobility in medical inpatients in these trials. Thirteen studies utilized objective criteria to define “immobility” including duration (12 studies) and distance or time walked (6 studies). In contrast, 7 studies focused principally on subjective definitions (ie, describing the nature of immobility rather than specifying its quantitative measurement). Three RCTs vaguely defined the level of patient’s immobility after hospitalization. The authors concluded that despite the well-known effectiveness of pharmacological thromboprophylaxis for the prevention of VTE in acutely ill medical patients, there is no current consensus on how to define immobility. The heterogeneous nature of definitions of immobility has led to uncertainty about the importance of immobility in VTE risk assessment models. Although clinical studies have incorporated varying definitions of immobility into their inclusion criteria, immobility as a specific VTE risk factor has not been clearly defined.

Kwak et al. (2017) conducted a retrospective comparative study to evaluate intermittent pneumatic compression (IPC) for the prevention of VTE after total hip arthroplasty. A total of 379 adult patients were included of which 233 patients were in the intervention group and 146 patients in the control group. All patients took low-dose aspirin for 6 weeks after surgery. IPC was applied to both legs just after surgery and maintained all day until discharge. When a symptom or a sign suspicious of VTE, such as swelling or redness of the foot and ankle, Homans’ sign, and dyspnea was detected, computed tomography (CT) angiogram or duplex
ultrasonogram was performed. For both groups, patients were excluded if they were younger than 17 years, taking anticoagulant stronger than aspirin for any reason, had history of previous VTE, could not take aspirin for any reason, and were followed up for less than 3 months after surgery. Both calves were compressed all day long except when patients were out of bed. All patients started active leg muscle contraction exercise when recovered from anesthesia and started crutch walking as soon as possible. Patients were discharged when they could walk with a walker or crutches. Until 3 months after surgery, symptomatic VTE occurred in three patients in the IPC group and in 6 patients in the control group. The incidence of VTE was much lower in the IPC group (1.3%) than in the control group (4.1%), but the difference was not statistically significant. Complications associated with the application of IPC were not detected in any patient. Patients affected by VTE were older and hospitalized longer than the unaffected patients. The incidence of VTE in the IPC group was less than 30% of that in the control group. The authors concluded that IPC might be an effective and safe method for the prevention of postoperative VTE. Limitations include retrospective study with a relatively small number of cases and only the patients with suspicious symptoms or signs were examined by CT or US.

Critical Limb Ischemia:

In a systematic review, Abu Dabrh and associates (2015) synthesized the existing evidence about various non-revascularization-based therapies used to treat patients with severe or critical limb ischemia (CLI) who are not candidates for surgical revascularization. These investigators searched multiple databases through November 2014 for RCTs and non-randomized studies comparing the effect of medical therapies (prostaglandin E1 and angiogenic growth factors) and devices (pumps and spinal cord stimulators). They reported ORs and 95% CIs of the outcomes of interest pooling data across studies using the random effects model. These researchers included 19 studies that enrolled 2,779 patients; none of the non-revascularization-based treatments was associated with a significant effect on mortality. Intermittent pneumatic compression (OR, 0.14; 95% CI: 0.04 to 0.55) and spinal cord stimulators (OR, 0.53; 95% CI: 0.36 to 0.79) were associated with reduced risk of amputation. A priori established subgroup analyses (combined versus single therapy; randomized versus non-randomized) were not statistically significant. The authors concluded that very low-quality evidence, mainly due to
imprecision and increased risk of bias, suggested that IPC and spinal cord stimulators may reduce the risk of amputations; and evidence supporting other medical therapies is insufficient.

Moran and colleagues (2015) stated that IPC is designed to aid wound healing and limb salvage for patients with CLI who are not candidates for revascularisation. These researchers conducted a systematic review of the literature to identify and critically appraise the evidence supporting its use in this population. A search was conducted in Embase, MEDLINE and clinical trial registries up to the end of March 2013. No date or language restrictions were applied. Quality assessment was performed by 2 investigators independently. Quality was assessed using the Cochrane risk of bias tool and the NICE case-series assessment tool. Two controlled before-and-after (CBA) studies and 6 case series were identified. One retrospective CBA study involving compression of the calf reported improved limb salvage and wound healing (OR 7.00, 95 % CI: 1.82 to 26.89, p < 0.01). One prospective CBA study involving sequential compression of the foot and calf reported statistically significant improvements in claudication distances and SF-36 quality of life scores. No difference in all-cause mortality was found. Complications included pain associated with compression, as well as skin abrasion and contact rash as a result of the cuff rubbing against the skin. All studies had a high risk of bias. The authors concluded that the limited available results suggested that IPC may be associated with improved limb salvage, wound healing and pain management. However, they stated that in the absence of additional well-designed analytical studies examining the effect of IPC in CLI, this treatment remains unproven.

Enhancement of Achilles Tendon Rupture Healing:

Abdul Alim and colleagues (2017) noted that adjuvant IPC during leg immobilization following Achilles tendon rupture (ATR) has been shown to reduce the risk of DVT. These researchers examined if IPC can also promote tendon healing. A total of 150 patients with surgical repair of acute ATR were post-operatively leg-immobilized and prospectively randomized. Patients were allocated for 2 weeks of either adjuvant IPC treatment (n = 74) or treatment-as-usual (n = 74) in a plaster cast without IPC. The IPC group received 6 hours daily bilateral calf IPC applied under an orthosis on the injured side. At 2 weeks post-operatively, tendon healing was assessed using micro-dialysis followed by enzymatic quantification of tendon callus production, procollagen type I (PINP) and type III (PIIINP) N-terminal...
propeptide, and total protein content. A total of 14 IPC and 19 cast patients (control group) consented to undergo micro-dialysis. During weeks 3 to 6, all subjects were leg-immobilized in an orthosis without IPC. At 3 and 12 months, patient-reported outcome was assessed using reliable questionnaires (ATRS and EQ-5D). At 12 months, functional outcome was measured using the validated heel-rise test. At 2 weeks post-rupture, the IPC-treated patients exhibited 69% higher levels of PINP in the ruptured Achilles tendon (AT) compared to the control group (p = 0.001). Interestingly, the IPC-treated contralateral, intact AT also demonstrated 49% higher concentrations of PINP compared to the non-treated intact AT of the plaster cast group (p = 0.002). There were no adverse events (AEs) observed associated with IPC. At 3 and 12 months, no significant (n.s.) differences between the 2 treatments were observed using patient-reported and functional outcome measures. The authors concluded that patients in post-operative lower limb immobilization after ATR demonstrated a significantly enhanced early healing response when using adjuvant calf IPC for 2 weeks. They noted that that IPC in addition to exert a prophylactic effect against DVT also may be a viable and effective treatment to prevent immobilization-induced impairments on the healing process. Moreover, they stated that further studies should examine if prolonged IPC usage during the whole immobilization time could shorten the time to recovery and optimize final outcome.

The authors stated that a potential drawback of this study was that they could not conclude the exact time length that the enhanced healing response associated with adjuvant IPC therapy will persist. The observations of equal patient-reported and functional outcome measures between the 2 groups at 3 and 12 months post-operatively demonstrated that the 2 weeks IPC intervention did not improve outcome measures from 3 months onwards. However, after the end of the IPC intervention at week 2, both treatment groups received immobilization in an orthosis until 6 weeks post-operatively when immobilization was ended. This suggested that the healing stimulatory effects of the IPC therapy did not persist after cessation of treatment when continued immobilization was applied. This conclusion needs additional studies where the IPC therapy should be applied during the whole time of post-operative lower limb immobilization. By applying IPC treatment during 6 weeks the therapy would impact both the proliferative as well as the regenerative healing phases during immobilization, which could conceivably affect also the patient-reported and functional outcome measures as well as lead to earlier return to activity. These researches stated that whether mechanical compression therapy should be administered as an out-patient treatment for leg-immobilized patients is,
with the present and another published study in mind, a matter of both preventing the development of DVT as well as of counteracting the impaired healing associated with immobilization. As for yet, no cost-benefit analysis has been performed, yet the therapy is highly accepted by the patients. They stated that further investigation of the health economics of IPC intervention ought to be conducted to permit an informed decision on implementation at a population level.

Prophylaxis of Venous Thromboembolism in Neurosurgery:

Chibbaro et al (2018) noted that the incidence of VT in neurosurgical practice is astonishingly high, representing a major cause of morbidity and mortality. Prophylaxis strategies include elastic stockings, low-molecular-weight heparin (LMWH), and IPC devices. These investigators evaluated the safety and efficacy of 2 different VT prophylaxis protocols implemented in a European neurosurgical center. All patients admitted for neurosurgical intervention between 2012 and 2016 were stratified as low-, moderate-, and high-risk of VT and received a combination of elastic stockings and LMWH. The protocol was modified in 2014 with the inclusion of peri-operative IPC devices for all patients and only in the high-risk group also post-operatively. At time of post-hoc analysis, data obtained from patients included in this study before 2014 (Protocol A, 3,169 patients) were compared with those obtained after the introduction of IPC (Protocol B, 3,818 patients). Among patients assigned to protocol A, 73 (2.3 %) developed DVT and 28 (0.9 %) developed PE, 9 of which were fatal (0.3 %). Among patients assigned to protocol B, 32 developed DVT (0.8 %) and 7 (0.18 %) developed PE, with 2 eventually resulting in the death of the patient. A post-hoc analysis confirmed that the use of pre-operative LMWH was not associated with a statistically significant greater risk of post-operative bleeding. The authors concluded that this study, despite its limitations of the non-randomized design, appeared to suggest that peri-operative IPC devices are a non-negligible support in the prophylaxis of clinically symptomatic DVT and PE.

Treatment of Upper Extremity Lymphedema Following Surgery:

Moseley et al (2007) noted that secondary arm lymphedema is a chronic and distressing condition which affects a significant number of women who undergo breast cancer treatment. A number of health professional and patient instigated conservative therapies have been developed to help with this condition, but their comparative benefits are not clearly known. This systematic review undertook a
broad investigation of commonly instigated conservative therapies for secondary arm lymphedema including; complex physical therapy, manual lymphatic drainage, pneumatic pumps, oral pharmaceuticals, low level laser therapy, compression bandaging and garments, limb exercises and limb elevation. It was found that the more intensive and health professional based therapies, such as complex physical therapy, manual lymphatic drainage, pneumatic pump and laser therapy generally yielded the greater volume reductions, while self-instigated therapies such as compression garment wear, exercises and limb elevation yielded smaller reductions. The authors concluded that all conservative therapies produced improvements in subjective arm symptoms and quality of life issues, where these were measured. Moreover, they stated that despite the identified benefits, there is still the need for large scale, high level clinical trials in this area.

The Canadian Agency for Drugs and Technologies in Health (CADTH)’s guidelines on “Intermittent pneumatic compression devices for the management of lymphedema” (Tran and Argaez, 2017) stated that “There is no cure for lymphedema. The complex decongestive therapy (CDT) is a multimodal therapy, which is recognized as a conservative management of lymphedema and consists of compression therapy (i.e., multilayer bandaging), manual lymphatic drainage (MLD), exercise and skin care. Intermittent pneumatic compression (IPC) can be used in the treatment of lymphedema as an adjunct to CDT, particularly in patients with compromised mobility or physical exercise. Although lymphedema reduces after application, the use of IPC remains controversial due to its adverse effects, including the recurrence of edema due to residual proteins remaining in the interstitial space, and potential lymphatic structure damage due to high pressure application”. The guideline also noted that the Japan Lymphedema Study Group “recommended” that “Currently, there is no evidence that IPC decreases the circumferential diameter of limbs with lymphedema (Recommendation grade: D)”.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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</table>
| Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>29581</td>
<td>Application of multi-layer compression system, leg (below knee), including ankle and foot</td>
</tr>
<tr>
<td>29582</td>
<td>thigh and leg, including ankle and foot, when performed</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>A4600</td>
<td>Sleeve for intermittent limb compression device, replacement only, each</td>
</tr>
<tr>
<td>E0650</td>
<td>Pneumatic compressor; non-segmental home model</td>
</tr>
<tr>
<td>E0651</td>
<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
</tr>
<tr>
<td>E0652</td>
<td>Pneumatic compressor, segmental home model with calibrated gradient pressure</td>
</tr>
<tr>
<td>E0655</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, half arm</td>
</tr>
<tr>
<td>E0656</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, trunk</td>
</tr>
<tr>
<td>E0657</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, chest</td>
</tr>
<tr>
<td>E0660</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor; full leg</td>
</tr>
<tr>
<td>E0665</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
</tr>
<tr>
<td>E0666</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0667</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full leg</td>
</tr>
<tr>
<td>E0668</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
</tr>
<tr>
<td>E0669</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0670</td>
<td>Segmental gradient pressure pneumatic appliance; full leg</td>
</tr>
<tr>
<td>E0671</td>
<td>Segmental gradient pressure pneumatic appliance, full arm</td>
</tr>
<tr>
<td>E0672</td>
<td>Segmental gradient pressure pneumatic appliance, half leg</td>
</tr>
<tr>
<td>E0673</td>
<td>Segmental gradient pressure pneumatic appliance, half leg</td>
</tr>
<tr>
<td>E0675</td>
<td>Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>E0676</td>
<td>Intermittent limb compression device (includes all accessories), not otherwise specified [not covered for single patient use pneumatic compression device]</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>E0675</td>
<td>Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A6530 - A6549</td>
<td>Gradient compression stockings</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I83.001 - I83.229</td>
<td>Varicose veins of lower extremities</td>
</tr>
<tr>
<td>I87.311 - I87.319</td>
<td>Chronic venous hypertension (idiopathic) with ulcer</td>
</tr>
<tr>
<td>I87.331 - I87.339</td>
<td>Chronic venous hypertension (idiopathic) with ulcer and inflammation</td>
</tr>
<tr>
<td>Z74.01</td>
<td>Bed confinement status [covered for members who are bedridden due to trauma, orthopedic surgery, neurosurgery or other circumstances preventing ambulation]</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>G25.81</td>
<td>Restless leg syndrome</td>
</tr>
<tr>
<td>I69.098, I69.198, I69.298, I69.398, I69.898, I69.998</td>
<td>Other sequelae of cerebrovascular disease</td>
</tr>
<tr>
<td>I70.201 - I70.799</td>
<td>Atherosclerosis</td>
</tr>
<tr>
<td>I73.00 - I73.99, I77.70 - I77.79, I79.1 - I79.8</td>
<td>Other peripheral vascular disease</td>
</tr>
<tr>
<td>I74.2 - I74.4</td>
<td>Embolism and thrombosis of arteries of the extremities</td>
</tr>
<tr>
<td>I99.8</td>
<td>Other disorder of circulatory system[critical limb ischemia]</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


http://www.aetna.com/cpb/medical/data/500_599/0500.html


http://www.aetna.com/cpb/medical/data/500_599/0500.html


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0500 Intermittent Pneumatic Compression Devices

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania