Medical Coverage Policy

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Compression Devices

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benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses pneumatic and non-pneumatic compression devices used in the home environment.

Coverage Policy

Coverage for pneumatic compression devices/lymphedema pumps varies across plans. Refer to the customer's benefit plan document for coverage details.

Furthermore, coverage for the treatment of lymphedema, including lymphedema pumps may be governed by federal and/or state mandates.

Unless excluded from the benefit plan, the following conditions of coverage apply.

Pneumatic Compression Device in the Home Setting

A pneumatic compression device in the home setting is considered medically necessary for EITHER of the following:

- **for the treatment of intractable lymphedema when there is failure of a four-week trial of conservative medical management including ALL of the following**:
  - home exercise program
  - limb elevation
  - compression bandage or compression garment use
- **for the treatment of chronic venous insufficiency (CVI) with venous stasis ulcer(s) of lower extremities, (HCPCS code E0650–E0652, E0660, E0666–E0667, E0669, E0671, E0673) when BOTH of the following criteria are met:**
  - The individual has received medically-supervised treatment of the ulcer(s) for at least 24 weeks using standard wound care treatment, including compression, wound dressings, exercise, and elevation of the limb.
  - Failure of the ulcer(s) to decrease in size or demonstrate improvement despite conventional therapy.

When a pneumatic compression pump has been found to be medically necessary according to the above criteria, the following devices are considered medically necessary limited to the lowest-cost alternative:

- non-segmental/segmental (HCPCS code E0650, E0651)
- segmental with calibrated gradient pressure (HCPCS code E0652) when there is evidence of failure of relief with the non-segmental device or a requirement of specified pressure to a localized area

Pneumatic compression devices in the home setting are not covered or reimbursable if the above criteria are not met.

Continuation of Use

Continuation of use of a pneumatic compression device is considered medically necessary when BOTH of the following criteria are met:

- there is adherence with the use of equipment as ordered by the healthcare professional
- clinical documentation from the health care professional confirms clinical improvement (e.g., improvement in venous stasis ulcers, decrease in edema or lymphedema)

EXPERIMENTAL, INVESTIGATIONAL OR UNPROVEN

Each of the following is considered experimental, investigational or unproven:

- a chest (HCPCS code E0657) and/or trunk (HCPCS code E0656, E0670) pneumatic appliance for use with a pneumatic compression pump
- a non-pneumatic compression pump or non-pneumatic sequential compression garment for any indication (HCPCS codes E0677, K1024, K1025, K1031, K1032, K1033)

NOT COVERED OR REIMBURSABLE

Each of the following is not covered or reimbursable:

- a pneumatic compression device used for arterial insufficiency (HCPCS code E0675)
- an intermittent limb compression device (HCPCS code E0676) utilized in the home setting for ANY indication including but not limited to the prevention of deep vein thrombosis
- a pneumatic compression device, with or without a cooling component, utilized in the home setting for ANY other indication (HCPCS code E0650–E0652, E0655, E0660–E0669, E0671-E0673)

General Background

Pneumatic Compression Devices
Pneumatic compression devices typically consist of an inflatable sleeve that is placed on the arm or leg, and an electrical pneumatic pump that fills the sleeve with compressed air. The sleeve is intermittently inflated and deflated with varying cycle times and pressures. The use of a pneumatic compression device in the home environment may be an alternative to other compression therapies (e.g., stockings, bandages, Unna boots) for patients who are unable or refuse to comply with other methods of treatment or are refractory to standard wound care treatment.

There are several types of pneumatic compression devices. Pumps may be classified as single-chambered, multi-chambered with fixed sequential inflation, or multi-chambered with sequential inflation and manually calibrated gradient chamber pressure. Older models include intermittent single-chamber non-segmented pumps that provide even pressure throughout the limb; however, they may allow backflow of lymphatic fluid. This can cause an increase of fluid in the distal limb. Newer devices have multiple segmented chambers and have the ability to provide sequential compression. Multiple-chamber units typically inflate from distal to proximal, producing a wave of pressure that ascends through the extremity, with the same pressure being delivered in each

garment section. Proponents contend that this wave brings edema fluid with it, allowing the retained fluid to be brought to functional lymphatics.

Segmental pumps that have a calibrated gradient pressure feature are typically used only in patients who require limited pressure to be applied to a specific area (e.g., significant scars, the presence of contracture or pain caused by the clinical condition).

Pneumatic compression pumps include, but are not limited to, the following:

- **Nonsegmented pneumatic compressor (HCPCS code E0650):** This device has a single outflow port on the compressor. Although there is a single tube, air from this single tube may be transmitted to a sleeve with multiple compartments and would be functionally equivalent to a segmented pneumatic compressor with a segmented sleeve; or the device can be used with a nonsegmented sleeve. An example of this type of pump is the Huntleigh Flowtron® Hydroven 3 Pump (ArjoHuntleigh, Addison IL; 1991).

- **Segmented pneumatic compressor (HCPCS codes E0651, E0652):** This device has multiple outflow ports on the compressor that lead to distinct segments on the appliance, which inflates in a sequential manner.
  - (E0651) A segmented device without calibrated pressure is one in which either (a) the same pressure is present in each segment, or (b) there is a predetermined pressure gradient in successive segments but no ability to individually set or adjust pressures in each of the several segments. The pressure is usually set by a single control on the distal segment. Examples of models include the AIROS 6 Sequential Compression Device (AIROS Medical, Inc., Audubon, PA; 2018), and the Sequential Circulator model SC-2004-DL (Bio Compression, Moonachie, NJ; 2021).

  - (E0652) A segmented device with calibrated gradient pressure is characterized by a manual control on at least three outflow ports that can deliver individually determined pressure to each segmental unit. Examples include of models include: AIROS 8 Sequential Compression Device (AIROS Medical, Inc., Audubon, PA; 2018); Sequential Circulator model SC-3004-DL (Bio Compression, Moonachie, NJ; 2014); Flexitouch® Plus System (Tactile Systems Technology, Inc., Minneapolis, MN; 2017); and the Lympha Press Optimal™ (Mego Afek, Kfar Sava, Israel; 2008).

One type of pneumatic compression device combines intermittent pneumatic compression with cold therapy. This pneumatic compression device has been proposed for elimination of knee, shoulder and ankle swelling as a result of traumas or surgery. These devices are also proposed for use on soft tissue injuries such as pulled hamstrings, tendinitis, sprains and inflamed joints.

U.S. Food and Drug Administration (FDA)
There are numerous manufacturers and models of pneumatic compression devices. Pneumatic compression devices are cleared for marketing under the FDA 510(k) premarket notification process as Class II devices intended for use in prevention of blood pooling in a limb by periodically inflating a sleeve around the limb (product code JOW). No clinical data was needed for FDA approval since they existed prior to the passage of the Medical Device Amendments of 1976. Manufacturers include AIROS Medical, Inc., Bio Compression Inc., and Tactile Systems Technology, Inc.

Lymphedema
Lymphedema is swelling due to the accumulation of excessive lymph fluid. The build-up of lymph fluid occurs when the normal clearing function of the lymphatic system is impaired, and/or if there is an excess production of lymph fluid. Primary lymphedema is a result of congenital defects of the

lymphatic system and is rare. Secondary lymphedema is acquired, and due to an obstruction or interruption in the lymphatic system. In the United States, the most common causes of lymphedema are cancer and treatment related to cancer. Patients undergoing breast cancer surgery which includes node dissection or axillary radiation therapy are at high risk of developing lymphedema. The goals of lymphedema treatment are to decrease the excess volume as much as possible and maintain the limb at its smallest size.

When provided as the sole treatment modality, lymphedema pumps are generally reserved for patients with intractable lymphedema for whom an adequate trial of more conservative medical treatment has failed. Established conservative medical treatments include the use of bandaging and compression garments, limb elevation, and home exercise programs. Segmental pumps that have a calibrated gradient pressure feature are typically used only in patients who require limited pressure to be applied to a specific area (e.g., significant scars or the presence of contracture or pain caused by the clinical condition).

Literature Review–Lymphedema: There is no consensus in the scientific literature on optimal pump selection and use. The scientific evidence supporting the use of pneumatic pumps as a solitary treatment modality for lymphedema is extremely limited and of poor quality. There is some evidence to indicate that using pumps as an adjunct to complex lymphedema treatment (CLT) has beneficial effects on the outcome of the therapy. Comparative studies evaluating the most effective pumping times, pressure levels or kind of pump are lacking (Harris, 2001). Optimal pressure ranges, inflation/deflation cycles, and length and frequency of individual pumping sessions have not been established (Kerchner, et al., 2008; Brennan, 1998). There is some evidence to suggest that sequential multi-chambered pumps are more effective than single-chambered pumps. One randomized trial attempted to evaluate pneumatic compression pumps for the treatment of lymphedema. Dini et al. (1998) randomized 80 post-mastectomy women to either intermittent pneumatic compression or no treatment. Women in the treatment group underwent a two-week cycle of five pump sessions per week, followed by a five-week break in treatment and then another two-week cycle of treatment. There was no statistically significant difference in response rates between the two groups. The authors concluded that pneumatic compression pumps have a limited role in the management of patients with lymphedema. Randomized controlled studies and prospective cohort studies have demonstrated that treatment with pneumatic compression devices for lymphedema has resulted in decrease of the lymphedema when the pump is used (Wright, et al., 2023; Maldonado, et al., 2021; Muluk, et al., 2013; Fife, et al., 2012).

Shao et al. (2014) reported on a systematic review and meta-analysis of randomized controlled trials (RCT) to determine whether the use of an intermittent pneumatic pump (IPC) could manage lymphedema effectively. The review included seven clinical randomized controlled trials with 287 patients, with three RCTs (162 patients) included in meta-analysis. The review included patients with prior history of treatment of breast carcinoma and lymphedema defined as an absolute increase in arm volume of at least 10% or 2 cm between the affected and unaffected arms. The primary outcome was the percent of volume reduction, with secondary outcomes subjective symptoms and joint mobility. The types of intervention were routine management of breast carcinoma and lymphedema BCRL with or without IPC. The results indicate that DLT and IPC reduced lymphedema and improved subjective symptoms, and neither of the methods was superior to the other. The studies were limited by small number of patients, the lack of reported details of randomization in many of the studies, and none of the trials stated if allocated concealment was performed.

Ridner et al. (2011) reported on a randomized, controlled trial to compare the therapeutic benefit of truncal/chest/arm advanced pneumatic compression therapy (experimental group) (n=21) verses arm only pneumatic compression (control group) (n=21) in self-care for arm lymphedema

without truncal involvement using the Flexitouch System. The outcomes included self-reported symptoms, function, arm impedance ratios, circumference, volume, and trunk circumference. While the findings indicated a statistically significant reduction in both the number of symptoms and overall symptom burden within each group, there were no statistically significant differences in these outcomes between the two groups. No statistically significant overall change or differential pattern of change between the groups in function was found. A statistically significant reduction in bioelectrical impedance and arm circumference within both of the groups was realized; however, there was no statistically significant difference in reduction between groups. The findings indicate that both treatments appear to be effective, but that there may be no added benefit to advanced pneumatic treatment of the truncal lymphatics prior to arm massage when the trunk is not also affected.

Devoogdt et al. (2010) published a systematic review of combined physical therapy (CPT), intermittent pneumatic compression and arm elevation for the treatment of lymphedema secondary to an axillary dissection for breast cancer. After CPT, the maintenance phase consists of skin care, exercises, wearing a compression sleeve and manual lymphatic drainage if needed. The review included 10 randomized controlled trials (RCT), one pseudo-randomized controlled trial and four non-randomized experimental trials that investigated the effectiveness of combined physical therapy and its different parts, of intermittent pneumatic compression and arm elevation. Five studies (three RCT and two pseudo-RCTs) examined intermittent pneumatic compression. It was noted that the effectiveness of skin care, exercises, wearing a compression sleeve and arm elevation has not been investigated by a controlled trial. The studies indicate that intermittent pneumatic compression is effective, but once the treatment is interrupted, the lymphedema volume increases. The authors concluded that the long-term effect of compression is not yet proven.

Chronic Venous Insufficiency (CVI)
Treatment of CVI is best initiated before the occurrence of venous ulceration. Knee-length heavyweight elastic stockings are recommended. Mild diuretic therapy (e.g., hydrochlorothiazide) may be of some help in persistent edema. The recommended treatment when ulceration occurs is an extended period of bed rest with elevation of the involved extremity well above heart level at all times, combined with moist retentive wound dressings to the ulceration. The patient is encouraged to exercise the calf muscles repeatedly while in bed, ideally against a footboard, to minimize the occurrence of acute DVT (Pascarella and Marston, 2022; Hafner and Sprecher, 2018).

Pressure dressings are an alternative for patients with venous ulcers who are unable to spend extended periods with their legs elevated. The Unna paste venous boot is the standard approach to pressure dressings. Properly applied, this zinc-impregnated gauze pressure bandage can supply good compression and allows the patient to remain ambulatory. The boot is typically changed every 7–10 days and continued for 3–6 months. It is reported that up to 60% of ulcers will heal if continued for one year, with healing occurring in nearly 80% of cases. Once the ulcer is healed, chronic use of a heavyweight elastic stocking is resumed. Surgical referral may be recommended for recurrent or nonhealing ulcerations (Pascarella and Marston, 2022; Hafner and Sprecher, 2018).

Literature Review–Chronic Venous Insufficiency (CVI): Although there is limited evidence in the peer-reviewed published medical literature to support the use of pneumatic compression devices for the treatment of patients chronic venous insufficiency with significant ulceration of the lower extremities who have failed standard therapy (i.e., a compression bandage system or garment, dressings for the wounds, exercise, and elevation of the limb), the treatment has become the standard of care for this subset of patients.

Alvarez et al. (2020) conducted a randomized controlled trial to investigate whether intermittent compression (IPC) assisted the healing of venous ulcers in patients with lymphedema who were already receiving standard compression with short stretch or multilayered compression therapy. The study included 52 subjects with chronic venous insufficiency and hard-to-heal lower leg ulceration (>1-year-old and >20-cm2 surface area) were treated with either intermittent, gradient, pneumatic compression (n=27) plus standard compression therapy or compression therapy alone (control). The median time to wound closure by nine months was 141 days for the intermittent pneumatic compression-treated group and 211 days for the control group ($p=0.031$). The rate of healing was 0.8 ± 0.4 mm/d for the control group and 2.1 ± 0.8 mm/d for the group treated with intermittent pneumatic compression ($p<0.05$). When compared with subjects treated with standard care, the group treated with intermittent pneumatic compression reported less pain at each evaluation point for the first six weeks of the trial. At weeks one, two and three, the visual analog pain scores were significantly lower for the intermittent pneumatic compression-treated group ($p<0.05$). The authors concluded that the results suggest that intermittent pneumatic compression is a valuable adjunct to compression therapy in the management of large or painful venous ulcers.

The effectiveness of intermittent pneumatic compression (IPC) as a treatment for venous leg ulcers was reviewed by Mani et al. (2001) in a Cochrane review and updated by Nelson et al. (2014). The review included nine randomized controlled trials (including 489 people in total) with only one trial at low risk of bias overall having reported adequate randomization, allocation concealment and blinded outcome assessment. The results noted, "In one trial (80 people) more ulcers healed with IPC than with dressings (62% vs 28%; $p=0.002$). Five trials compared IPC plus compression with compression alone. Two of these (97 people) found increased ulcer healing with IPC plus compression than with compression alone. The remaining three trials (122 people) found no evidence of a benefit for IPC plus compression compared with compression alone. Two trials (86 people) found no difference between IPC (without additional compression) and compression bandages alone. One trial (104 people) compared different ways of delivering IPC and found that rapid IPC healed more ulcers than slow IPC (86% vs 61%)." The authors concluded that IPC may increase healing compared with no compression, however, it is unclear whether it can be used instead of compression bandages. It was found that there is some limited evidence that IPC may improve healing when added to compression bandages and rapid IPC was better than slow IPC in one trial. Further trials are required to determine the reliability of current evidence, which patients may benefit from IPC in addition to compression bandages, and the optimum treatment regimen.

Prevention of Deep Vein Thrombosis (DVT)
DVT is generally treated with the anticoagulants warfarin or heparin or a combination of the two drugs. Heparin acts quickly and is often stopped once warfarin starts working, usually two to three days after it is initiated. Other treatments include vena cava filters, which catch existing blood clots before they travel to the lung, and graduated compression stockings. Stockings fit over the foot up to the knee and are tight at the ankle and looser at the knee, creating a gentle pressure up the leg to prevent blood pooling and clotting. With pneumatic compression devices, the application and release of pressure promotes venous blood flow and may prevent DVT in patients who are at risk of developing this condition. Compression devices may be designed to fit over the patient's leg, calf, or foot (foot pumps).

The use of pneumatic compression devices in the hospital setting for the prevention of VTE in high risk patients may be used as an alternative in medical patients with a high risk of bleeding or in whom anticoagulant drugs are contraindicated (e.g., gastrointestinal bleeding, intracranial hemorrhage) and may be considered standard of care. It is theorized that intermittent pneumatic compression (IPC) prevents DVT by enhancing blood flow in the deep veins of the legs, thereby preventing venous stasis (Douketis and Mithoowani, 2023). Pneumatic compression therapy in the home setting for the prevention of VTE including DVT and PE is not considered standard of care in

the practicing medical community. The scientific evidence supporting the use of pneumatic compression therapy as a treatment modality in the home setting for the prevention of VTE including DVT is limited. The literature mainly addresses the use of intermittent compression devices for prevention of DVT in the hospital setting until time of discharge.

Textbooks indicate that the best method of prophylaxis for thromboembolism is debatable. Currently in the inpatient setting, mechanical and pharmacologic modalities are used. It is generally agreed that patients should be mobilized as early and as rapidly as their general condition permits and that active exercises of both lower extremities help reduce venous stasis and thrombus formation. External pneumatic compression devices compare favorably with chemical prophylaxis in some randomized studies. Patient dissatisfaction with these devices occurs, and compliance may be a problem, although mobile units may have better acceptance (Harkess and Crockarell, 2021).

The HCPCS code used for pneumatic compression devices that are used for the prevention of DVT is HCPCS code E0676 – Intermittent limb compression device (includes all accessories), not otherwise specified (Centers for Medicare & Medicaid Services [CMS], 2020). This device (E0676) delivers pressure and inflation/deflation cycles for the prevention of deep venous thrombosis. HCPCS code E0676 is all-inclusive, (i.e., all product variations in pressures, cycle characteristics, timing, control systems, appliance configurations, etc.).

Literature Review–Prevention of Deep Vein Thrombosis (DVT): The published literature for the use of pneumatic pumps for prevention of DVT in the home setting is limited. The published literature mainly addresses the use of pneumatic pumps in the hospital setting post-operatively for prevention of DVT.

Dietz et al. (2022) conducted a randomized trial (n=80) to assess treatment compliance and outcomes for aspirin along with a mobile compression pump versus aspirin alone for venous thromboembolism (VTE) prophylaxis in patients undergoing total hip or knee arthroplasty. Forty subjects in the intervention group received aspirin along with a mobile compression pump (ActiveCare SFT) (ASA/MCP group), while 40 subjects in the control group received aspirin alone (ASA group). In the ASA group, 50% (19/38) of subjects underwent knee arthroplasty versus 56% (20/36) of patients in the ASA/MCP group (p=0.65). Aspirin dosage was 325mg daily for six weeks for all participants. The ASA/MCP group was instructed to wear the device 20 hours per day for two weeks post-discharge. Follow-ups were completed at two and six weeks post-discharge. In the ASA/MCP group, ten patients were compliant with an average time use per day of 88% (standard deviation [SD] ± 5.5), while 26 were noncompliant. Five patients never wore the pumps during the course of the trial. Patients in the ASA group were 94% complaint with aspirin use, and the ASA/MCP group was 97% compliant with their aspirin use (p=0.55). Three patients in the ASA/MCP group were found to have a VTE (two DVTs and one pulmonary embolism [PE]) within 90 days of surgery, while no patients in the ASA group developed VTE (p=0.24). Subjects who were diagnosed with a VTE used the pump an average of 20% of the time. The authors noted the study was not sufficiently powered to detect differences in the rate of VTE. Other study limitations include the short duration of follow-up, relatively small sample size, and reliance on patient-reported outcomes.

Dietz et al. (2020) conducted a prospective cohort study to evaluate outpatient compliance and utilization factors for utilization of portable pneumatic compression pumps in a rural population after elective hip or knee arthroplasty. Utilization for portable pneumatic compression pumps after joint arthroplasty was prospectively recorded in hours with compliance defined as the recommended 20 hours per day. A questionnaire two weeks postoperatively assessed factors that may contribute to noncompliance. Patients were followed up for 90 days postoperatively to record VTE events. Data was collected for 115 joint arthroplasty patients (50 hips, 65 knees). Post-

discharge day one had the highest average usage at 13.2 hours/day (66.0%, range 0%-100%), but this number fell to 4.8 hours/day (24.0, range 0%-100%) by day 14. Patient compliance (>20 hours use/day) was highest on post-discharge day one at 40 patients (34.7%). By post-discharge day 14, patient compliance fell to 17 patients (14.8%). Difficulty using the pumps and pump-associated heat were significantly associated with patient compliance. A deep vein thrombosis and nonfatal pulmonary embolism were recorded in two separate patients. The authors concluded that study demonstrated poor outpatient compliance with portable pneumatic compression devices and poor compliance was related to pump heat and difficulty with pump use. The authors note that future randomized controlled trials should monitor outpatient cost, compliance, and efficacy of portable compression devices compared with standard chemoprophylaxis after total joint arthroplasty. The study is limited by the lack of randomization.

Kim et al. (2019) conducted a retrospective study to assess whether the intermittent pneumatic compression (IPC) device would be an effective prophylaxis for deep vein thrombosis (DVT) following total knee arthroplasty (TKA) in a low incidence population. The study included 1,259 elective primary TKA patients with preoperative diagnosis of primary osteoarthritis in a single institute. They were divided into three groups: those who were managed with chemoprophylaxis (CPX group, 414 cases), with mechanical prophylaxis (IPC group, 425 cases), or without pharmacological and mechanical prophylaxis (control group, 420 cases). All patients underwent preoperative ultrasonography and computed tomographic venography on postoperative day six to assess development of DVT. The incidence of overall, proximal, symptomatic DVT and symptomatic pulmonary embolism (PE) were compared among the groups. Major and minor bleeding complications were also evaluated. The incidence of overall DVT was 14.8% in control group, 6.3% in CPX group and 11.3% in IPC group respectively and CPX group showed significantly lower incidence than other two groups ($p<0.001$). The incidence of proximal DVT was 1.9% in control group, 0.7% in CPX group and 0.9% in IPC group respectively ($p>0.05$). The incidence of symptomatic DVT was 0.7% in control group, 0% in CPX group and 0.7% in IPC group respectively ($p>0.05$). There was no case of symptomatic PE diagnosed during hospital stay in all patients. The authors concluded that single use of IPC device could not reach significant level of DVT prophylaxis compared to control group and only chemoprophylaxis was shown to significantly reduce the incidence of overall DVT following TKA.

Snyder et al. (2017) reported on a randomized controlled trial that examined whether there is a difference in deep vein thrombosis (DVT) occurrence after a limited tourniquet total knee arthroplasty (TKA) using aspirin-based prophylaxis with or without extended use of mechanical compression device (MCD) therapy in low-risk TKA patients. One hundred patients, whose DVT risk was managed with aspirin 325 mg twice daily for 3 weeks, were randomized to either using an MCD during hospitalization only (inpatient VPULSE group-52) or extended use at home up to 6 weeks (postdischarge VPULSE group-48) postoperatively. Lower extremity duplex venous ultrasonography (LEDVU) was completed on the second postoperative day, 14 days postoperatively, and at 3 months postoperatively to confirm the absence of DVT after treatment. The Cothera VPULSE Compression and Cold Therapy System (Cothera, LLC, Plano, TX) was the device used in the study, which provides both compression and cold therapy. There was early rapid mobilization and all received prophylactic aspirin at 325 mg twice daily for 3 weeks immediately postoperatively. The DVT rate for the postdischarge MCD therapy group was 0% and 23.1% for the inpatient MCD group ($p<0.001$). All DVTs resolved by 3 months postoperatively. Patient satisfaction was 9.56 (±0.82) for postdischarge MCD patients vs 8.50 (±1.46) for inpatient MCD patients ($p<0.001$). A data chip in the device was collected for recording the total number of hours of MCD usage; however, the chip did not allow the researchers to examine how this usage was spread over the three weeks and patient compliance in the postdischarge VPULSE group may have dropped off significantly following the first several days postdischarge. The authors concluded that although the study demonstrated a lower incidence of DVT in the post hospital group, this did not establish the best VTE prevention protocol. Additional studies of the use of

aspirin in conjunction with MCD therapy may reinforce the findings of this study and lead to the creation and subsequent implementation of optimized regimens that offer low incidence of VTE in postoperative TKA patients.

Zhao et al. (2014) reported on a Cochrane review to assess the comparative effectiveness and safety of different intermittent pneumatic pump (IPC) devices with respect to the prevention of venous thromboembolism in patients after total hip replacement (THR). One quasi-randomized controlled study with 121 study participants comparing two types of IPC devices met the inclusion criteria. The study found no cases of symptomatic deep vein thrombosis or pulmonary embolism in either the calf-thigh compression group or the plantar compression group during the first three weeks after the THR. The strength of the evidence in this review was determined to be weak since only one trial was included and was classified as having a high risk of bias. The authors concluded that there is a lack of evidence from randomized controlled trials to make an informed choice of IPC device for preventing venous thromboembolism following total hip replacement.

Colwell, et al (2014) reported on a noninferiority study of the mobile compression device compared to the standard pharmacological prophylaxis, including warfarin, enoxaparin, rivaroxaban, and dabigatran, with symptomatic end points and similar patient demographics. The study included following primary knee arthroplasty (1551 patients) or hip arthroplasty (1509) patients from ten sites. The compression device was used perioperatively and continued for a minimum of ten days. Patients with symptoms of deep venous thrombosis or pulmonary embolism underwent duplex ultrasonography and/or spiral computed tomography. All patients were evaluated at three months postoperatively to document any evidence of deep venous thrombosis or pulmonary embolism. The authors hypothesized that the mobile compression device would have approximately the same efficacy as pharmacological prophylaxis without the risk of major bleeding. The study adopted a 1.0% margin in the noninferiority study, with the hypothesis that a 1.0% difference in venous thromboembolism rates between the mobile compression device registry cohort and the pharmacological comparators would not constitute a clinically meaningful difference. Twenty-eight (0.92%) of the patients had venous thromboembolism (twenty distal deep venous thrombi, three proximal deep venous thrombi, and five pulmonary emboli). One death occurred, with no autopsy performed. The authors found that symptomatic venous thromboembolic rates observed in patients who had an arthroplasty of a lower-extremity joint using the mobile compression device were noninferior, at a margin of 1.0%, to the rates reported for pharmacological prophylaxis, including warfarin, enoxaparin, rivaroxaban, and dabigatran, except in the knee arthroplasty group, in which the mobile compression device fell short of the rate reported for rivaroxaban by 0.06%. Limitations of the study included the lack of randomization, the registry had a limited data set, and neither bleeding rates nor compliance were documented, compliance was not documented in the study. In addition, the study was not designed to establish conclusions regarding the use or nonuse of aspirin in addition to the mobile compression device- of the twenty-eight patients who had a venous thromboembolic event, 46% were on the aspirin protocol.

Peripheral Artery Disease

Peripheral artery disease (PAD) is a circulatory problem that develops when the arteries that supply blood to the extremities (usually the legs) become narrowed or blocked, resulting in an insufficient blood supply, or arterial insufficiency. PAD may be silent or present with a variety of symptoms and signs indicative of extremity ischemia (Berger, et al., 2021). Clinical manifestations of arterial insufficiency due to a lack of blood flow to the musculature may result in pain in the affected muscle groups. Other signs and symptom include presence of an extremity ulcer, claudication and rest pain. Treatment for PAD focuses on reduction of symptoms and prevention of further progression of the disease. Most individuals with claudication benefit from a comprehensive medical approach that includes risk factor modification, exercise rehabilitation, and use of standard pharmacotherapy for claudication. Critical limb ischemia is considered to be

present in patients with lower extremity ischemic rest pain, ulceration, or gangrene. If left untreated, severe PAD could lead to major limb amputation. Minimally invasive treatment or surgery may be needed for patients who do not respond to medical intervention. Arterial ulcers, however, should not be compressed for fear of further arterial compromise (American Heart Association [AHA], 2021; Hafner and Sprecher, 2018).

A proposed alternative for individuals with PAD who are ineligible or who fail medical or surgical therapies is the application of high pressures by compression cuffs placed on the thigh, the calf, and/or the foot. These devices intermittently inflate and deflate with cycle times and pressures that vary between devices. These devices offer higher pressures than offered in the typical pneumatic compression device. An example is the ArtAssist© Device (ACI Medical LLC, San Marcos, CA; 2014) a mechanical pneumatic pump consisting of an impulse generator and two plastic inflatable cuffs, applies high pressure in a synchronized manner to the foot and calf. This treatment is usually performed for three hours per day while the patient is sitting upright.

Literature Review—Peripheral Artery Disease: Moran et al. (2015) reported on a systematic review of intermittent pneumatic compression for critical limb ischemia. Two controlled before-and-after (CBA) studies and six case series were identified. No randomized controlled trials (RCTs) or non-randomized controlled trials (NRCTs) were identified. One retrospective CBA study involving compression of the calf reported improved limb salvage and wound healing and 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. There was no difference in all-cause mortality 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. It was noted that all studies had a high risk of bias. The authors concluded that the limited available results suggest that IPC may be associated with improved limb salvage, wound healing and pain management; however, in the absence of additional well-designed analytical studies examining the effect of IPC in critical limb ischemia, the treatment remains unproven.

Abu Dabrh et al (2015) reported on a systematic review that examined evidence about various nonrevascularization-based therapies used to treat patients with severe or critical limb ischemia (CLI) who are not candidates for surgical revascularization. The review included 19 studies (2779 patients) of controlled randomized and nonrandomized studies that compared the effect of medical therapies (prostaglandin E1 and angiogenic growth factors) and devices (pumps and spinal cord stimulators). None of the nonrevascularization-based treatments were associated with a significant effect on mortality. Intermittent pneumatic compression (IPC) use was associated with statistically significant improvements in ulcer healing and amputation, but these results were derived from single small nonrandomized study. The authors note that replication of such results is needed, and the effect needs to be verified in larger randomized controlled trials.

Literature Review–Other Indications
There is a paucity of randomized controlled or comparative trials in the peer-reviewed medical literature supporting the efficacy of pneumatic compression devices for the treatment of other indications in the home setting, including but not limited to, fracture and soft-tissue healing and restless leg syndrome. No standardization of devices exists with the mode of compression, the flow rate, or the type of sleeve. Many of the studies of compression devices are on small groups of patients using more than a single modality (Handoll, et al., 2015; Khanna, et al., 2008; Eliasson and Lettieri, 2007; Labropoulos, et al., 2002).

Restless Leg Syndrome (RLS): In a prospective, randomized, double-blinded, sham-controlled trial (n=35), Lettieri and Eliasson (2009) evaluated the effectiveness of pneumatic compression devices (PCDs) as a non-pharmacologic treatment for restless legs syndrome (RLS). Devices were provided to subjects who were enrolled for home use. Subjects wore a therapeutic or sham device

prior to the usual onset of symptoms for a minimum of one hour daily. Measures of severity of illness, quality of life, daytime sleepiness, and fatigue were compared at baseline and after one month of therapy. 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% versus8 %, 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 one-third of subjects using therapeutic and in no subjects using sham devices. The authors reported 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. This study did not report long-term outcomes. Additionally the authors reported that while effective for RLS treatment, the role of PCDs may be limited. RLS medications are effective, relatively safe, and usually well tolerated. Additionally, medications are obviously easier to use than PCDs, which require patients to remain immobile for one hour each day.

Fracture and Soft-Tissue Healing: In a review of the literature, 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. A total of nine studies on the use of IPC in fracture and soft-tissue healing (e.g., distal radius, ankle, calcaneal fractures, acute ankle sprains) were identified. These studies demonstrated that IPC facilitates both fracture and soft-tissue healing with rapid functional recovery. The authors reported that IPC appears to be an effective modality to enhance fracture and soft-tissue healing however the number of subjects is small, and adequately powered randomized controlled trials are needed to produce stronger clinically relevant evidence.

In a Cochrane review, Handoll et al. (2015) examined the effects of rehabilitation interventions in adults with conservatively or surgically treated distal radial fractures. Of the fifteen trials one trial included the use of intermittent pneumatic compression. The authors reported that there was not enough evidence available to determine the best form of rehabilitation for people with wrist fractures.

Non-Pneumatic Compression Devices

Non-pneumatic compression pumps have recently been developed that do not utilize pneumatics in the compression mechanism. The Koya Dayspring® (Koya Medical, Oakland CA) is a wearable advanced compression device that consists of a programmable, segmental controller with a sleeve garment that can be sized to fit the individual. The garment contains a shape memory alloy made with nickel/titanium (Ni-Ti) that is programmed by a rechargeable controller to shrink in a cyclic manner, applying active gradient pressure from the distal to proximal end of the limb. This mechanistic action is similar to the motion of advanced pneumatic compression devices. Up to 14 independently controlled segments can be programmed to deliver 0–100 mmHg of compression pressure, with typical initial settings in a range of 30–40 mmHg. A mobile phone application can be used to program and individualize pressures; to start, stop, and pause therapy; and to track device usage. The device allows for mobility and range of motion during treatment (Rockson, et al., 2022a). According to the vendor website, the device is built on Flexframe2 technology, a patented mobile platform that provides calibrated sequential gradient compression.

U.S. Food and Drug Administration (FDA)

In April 2021, the Koya Dayspring system obtained FDA approval through the 510(k) premarket notification process as a compressible limb sleeve. The FDA indications for use were as follows:

> "The Koya Dayspring system is a prescription only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as:
> - Lymphedema
> - Primary lymphedema
> - Post mastectomy edema
> - Edema following trauma and sports injuries
> - Post immobilization edema
> - Venous insufficiency
> - Reducing wound healing time
> - Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
> - Lipedema
> - Phlebolymphedema

The Dayspring system is developed on a wearable compression technology platform, which is designed to provide mobility for patients."

In September 2021, the Dayspring Lite device obtained FDA approval via the 510(k) approval process as a compressible limb sleeve. The FDA indications for use were as follows:

> "Dayspring Lite is a prescription only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:
> - Chronic edema
> - Lymphedema
> - Venous insufficiency
> - Wound healing

Dayspring Lite is developed on a wearable compression technology platform, which is designed to provide mobility for patients."

Literature Review—Non-Pneumatic Compression Devices: Rockson et al. (2022a) conducted a nonrandomized open-label pilot study in 40 subjects to evaluate the quality of life (QoL) and limb volume maintenance efficacy of a novel wearable compression system (Dayspring) in the treatment of unilateral upper extremity breast cancer-related lymphedema. Subjects were instructed to use the Dayspring device on one arm at least once a day, and could continue any other prescribed self-care procedures, including the use of compression garments. The contralateral (unaffected) limb was used as a control. After 28 days of use, subjects had a statistically significant 18% ($p<0.001$) improvement in overall QoL as measured by the Lymphedema Quality-of-Life Questionnaire compared with baseline. Individual QoL domains also improved. Limb volume was reduced by an average of 2% ($p=0.042$). Adherence was 98% over the course of the study; the average daily use was 43.9 minutes. The study is limited by the small number of patients, lack of randomization and control group, and short follow-up time period.

Rockson et al. (2022b) completed a nonrandomized, open-label, 12-week pilot study to evaluate the safety and effectiveness of the Dayspring compression device in the treatment of lower extremity lymphedema (LEL). Subjects were directed to wear the device for up to one hour per day, and could continue ongoing maintenance care (bandaging, compression garments, massage).

Outcome measures included quality of life (QOL) using the Lymphedema Quality of Life Questionnaire (LYMQOL), and change in lower limb volume. The contralateral (unaffected) limb was used for comparison. Twenty four subjects were enrolled; 18 completed the study. Overall QOL scores improved by 8% to 16% (mean 12%; p=0.02). The mean change in edema was -427.1 cm^3 (p<0.001, 95% confidence interval [CI] = -677, -178), for an average reduction of 39.4%. Treatment adherence data was not collected. Limitations of the study include the small sample size, lack of randomization and control group, and short duration of follow-up.

Rockson et al. (2022c) conducted a randomized crossover noninferiority trial (n=52) to evaluate the efficacy of the Dayspring compression device versus an advanced pneumatic compression device (Flexitouch Plus) in treating breast cancer-related lymphedema. Subjects in the intervention and control groups were instructed to use the assigned device once a day for at least one hour, for 28 days. Then all subjects had a four week "washout" period, without any use of an active compression device. Subjects then crossed over to the alternate compression device for the following 28 days. Subjects could also continue the use of compression sleeves and/or manual lymph drainage procedures. Outcome measures included reduction in limb volume (treatment response was defined as a >2% reduction in edema volume); quality of life (QOL) using the Lymphedema Quality of Life Questionnaire (LYMQOL); adherence; and adverse or safety events. Two patients were lost to follow up. The intervention group had a mean reduction in edema of 64.6% (95% confidence interval [CI], 31.71-97.58), versus 27.7% (95% CI, 4.80-60.14) in the control group (p<0.05), for an overall response rate of 88% versus 42% (p<0.05), respectively. Adherence was 95.6% ± 7% in the intervention group versus 49.8% ± 26% in the control group (p<0.01). Overall QOL scores were significantly improved in the intervention group (2.44 points; p<0.05), while no significant change was seen in the control group. The study is limited by the small sample size, short follow-up time period, and potential risk of carryover effects.

Professional Societies/Organizations

American Academy of Neurology (AAN): AAN published a practice guideline for treatment of restless legs syndrome (RLS) in adults (2022). The guideline noted that pneumatic compression is likely effective in the treatment of patients with primary moderate to severe RLS (based on one Class I study). The recommendations include that when nonpharmacologic approaches are desired, clinicians should consider prescribing pneumatic compression before usual symptom onset (Level B, moderate evidence).

American Academy of Orthopaedic Surgeons (AAOS): AAOS published guidelines for preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty (AAOS, 2011). The guidelines are not specific to the home setting. The guidelines include these recommendations:

- Suggest the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in patients undergoing elective hip or knee arthroplasty, and who are not at elevated risk beyond that of the surgery itself for venous thromboembolism or bleeding.
  Grade of Recommendation: Moderate
- Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, we are unable to recommend for or against specific prophylactics in these patients.
  Grade of Recommendation: Inconclusive
- In the absence of reliable evidence about how long to employ these prophylactic strategies, it is the opinion of this work group that patients and physicians discuss the duration of prophylaxis.
  Grade of Recommendation: Consensus
- In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who have also had a previous venous

thromboembolism, receive pharmacologic prophylaxis and mechanical compressive devices.
Grade of Recommendation: Consensus

- In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who also have a known bleeding disorder (e.g., hemophilia) and/or active liver disease, use mechanical compressive devices for preventing venous thromboembolism.
  Grade of Recommendation: Consensus

Grades of recommendation:
Moderate: Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.
Implications: Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.

Inconclusive: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.
Implications: Practitioners should feel little constraint in following a recommendation labeled as Inconclusive, exercise clinical judgment, and be alert for emerging evidence that clarifies or helps to determine the balance between benefits and potential harm. Patient preference should have a substantial influencing role.

Consensus: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A Consensus recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.
Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may give it preference over alternatives. Patient preference should have a substantial influencing role.

American College of Cardiology (ACC)/American Heart Association (AHA): These organizations published clinical practice guidelines on the management of patients with lower extremity peripheral artery disease (Gerhard-Herman, et al., 2016). The recommendations note that, "In patients with critical limb ischemia (CLI), intermittent pneumatic compression (arterial pump) devices may be considered to augment wound healing and/or ameliorate severe ischemic rest pain".

Class (strength) of recommendation (COR): IIb
Level of evidence (LOE): B-NR

Recommendation system:

- (COR) Class (strength) of recommendation:
  - IIb: weak
- (LOE) Level (quality) of evidence B-NR:
  - moderate quality evidence from one or more well-designed well-executed nonrandomized studies, observational studies or registry studies
  - meta-analyses of such studies

American College of Chest Physicians: This organization published clinical practice guidelines for prevention of VTE in orthopedic surgery patients (Falck-Ytter, et al., 2012). The guidelines recommend for patients undergoing major orthopedic surgery: total hip arthroplasty (THA), total knee arthroplasty (TKA), hip fracture surgery (HFS):

> Thromboprophylaxis Compared with No Prophylaxis: In patients undergoing THA or TKA, the panel recommends use of one of the following for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, apixaban, dabigatran, rivaroxaban, low-dose unfractionated heparin (LDUH), adjusted-dose vitamin K antagonist (VKA), aspirin (all Grade 1B), or an intermittent pneumatic compression device (IPCD) (Grade 1C).
>
> The expert panel recommends the use of only portable, battery-powered IPCDs capable of recording and reporting proper wear time on a daily basis for inpatients and outpatients. Efforts should be made to achieve 18 h of daily compliance.
>
> Grade 1C: Strong recommendation, low- or very-low-quality evidence

American Venous Forum (AVF)/American Vein and Lymphatic Society (AVLS)/Society for Vascular Medicine (SVM): In 2022, the AVF, AVLS, and the SVM published expert opinion consensus statement on the diagnosis and treatment of lymphedema. Among the statements regarding treatment, there were differing levels of agreement regarding pneumatic compression:

- Sequential pneumatic compression should be recommended for lymphedema patients (92% of the panel agreed with the statement, with 34% strongly agreeing.)
- Sequential pneumatic compression should be used for treatment of early stages of lymphedema. (There was less agreement with this statement, about 62% of respondents, which was below 70% threshold for meeting consensus. The remaining 38% of panelists disagreed with this statement, and 2% strongly disagreed.)

Consensus was reached that all patients with edema due to chronic venous insufficiency should be considered for treatment similar to lymphedema patients (Lurie, et al., 2022).

Society for Vascular Surgery (SVS)/American Venous Forum (AVF): These organizations published clinical practice guidelines for management of venous leg ulcers. The guidelines recommend the use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy (O'Donnell, et al., 2014).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Pneumatic Compression Devices (280.6)	1/14/2002
LCD	CGS Administrators; Noridian Healthcare Solutions	Pneumatic Compression Devices (L33829)	10/22/2023

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0650	Pneumatic compressor, non-segmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Non-segmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Non-segmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Non-segmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Non-segmental 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

ICD-10-CM Diagnosis Codes	Description
I83.001-I83.029	Varicose veins of lower extremity with ulcer
I83.201-I83.229	Varicose veins of lower extremity with both ulcer and inflammation
I87.2	Venous insufficiency (chronic) (peripheral)
I89.0	Lymphedema, not elsewhere classified
I89.1	Lymphangitis
I97.2	Postmastectomy lymphedema syndrome
L97.101-L97.929	Non-pressure chronic ulcer of lower extremity
Q82.0	Hereditary lymphedema

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
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, 2 full legs and trunk
E0677	Non-pneumatic sequential compression garment, trunk
K1024	Non-pneumatic compression controller with sequential calibrated gradient pressure
K1025	Non-pneumatic sequential compression garment, full arm
K1031	Non-pneumatic compression controller without calibrated gradient pressure
K1032	Non-pneumatic sequential compression garment, full leg
K1033	Non-pneumatic sequential compression garment, half leg

Not Covered or Reimbursable:

HCPCS 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

ICD-10-CM Diagnosis Codes	Description
	All codes

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Revision Details

Type of Revision	Summary of Changes	Date
Focused review	• Revised policy statements.	12/3/2023