MEDICAL POLICY	Compression: Outpatient Pneumatic Devices (All Lines of Business Except Medicare)
Effective Date: 7/1/2022	Medical Policy Number: 145
 7/1/2022	Technology Assessment Committee approved Date: 10/13; 9/14; 9/15 Medical Policy Committee approved Date: 7/09; 10/10; 12/11; 8/12; 2/13; 5/16; 7/17; 9/18; 11/19; 04/2020; 06/2021: 6/2022
Medical Officer Date	

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

DOCUMENTATION REQUIREMENTS

While the codes in this medical policy are not subject to routine review for medical necessity, the following documentation must be in the medical record to support medically necessity has been established:

- Type of pneumatic compression device (PCD) requested (e.g., segmental, non-segmental, calibrated, non-calibrated, etc.);
- Diagnosis and history of condition (e.g., length, severity, symptoms experienced, etc.)
- Documentation of conservative therapy tried and outcomes of the therapy(ies);

- Detailed records of measurements, consistently obtained in the same manner each time (including any reference to the same anatomic landmarks), prior to, during, and after the relevant trial and therapy (including bilateral comparisons where appropriate).

POLICY CRITERIA

Lymphedema of the Arm Caused by Breast Cancer-Related Surgery

I. Use of a pneumatic compression device (PCD) to treat lymphedema of the arm caused by a breast cancer-related surgery is considered **medically necessary** (additional criteria below are not applied).

Other Lymphedema *Not* Extending to the Chest, Trunk, and/or Abdomen

II. A PCD (E0650, E0651) may be considered **medically necessary** for both primary and secondary lymphedema in patients with chronic and severe lymphedema when **all** of the following (A.-C.) criteria are met:

A. The patient has a diagnosis of lymphedema (defined in Policy Guidelines section); **and**
B. The patient has persistence of chronic and severe lymphedema as identified by the documented presence of **at least one** of the following (1.-5.) clinical findings:
    1. Marked hyperkeratosis with hyperplasia and hyperpigmentation; **or**
    2. Papillomatosis cutis lymphostatica; **or**
    3. Deformity of elephantiasis; **or**
    4. Skin breakdown with persisting lymphorrhea; **or**
    5. Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology; **and**
C. The lymphedema is unresponsive to conservative therapy over the course of a **4-week** trial, which must include **all** of the following (1.-4.):
    1. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression (See Policy Guidelines below); **and**
    2. Regular exercise; **and**
    3. Elevation of the limb; and
    4. Manual lymphatic drainage (where available) and medication (as appropriate) (e.g., for treatment of congestive failure) are also key components of conservative treatments and should be tried or considered and ruled out with documentation of reasons why.

III. A PCD is considered **not medically necessary and not covered** when criterion I. above is not met including, but not limited to, documented improvement with conservative therapy, or the use of a PCD for the treatment of edema from causes other than lymphedema.

Other Lymphedema Extending to the Chest, Trunk, and/or Abdomen

IV. A segmented PCD with calibrated gradient pressure (E0652) may be considered **medically necessary** for the treatment of lymphedema extending onto the chest, trunk, and/or abdomen when **all** of the following (A.-D.) criteria are met:

A. The patient has lymphedema of an extremity (defined in Policy Guidelines section); **and**
B. The patient meets criterion II. above; **and**
C. The lymphedema extends onto the chest, trunk, and/or abdomen that extends past the limits of a standard compression sleeve; **and**
D. The chest, trunk, and/or abdominal lymphedema has failed to improve with a **4-week** trial of treatment with a non-segmented PCD (E0650) **or** a segmented PCD without calibrated gradient pressure (E0651). The trial must include **all** of the following (1.-8.):
    1. At least 4 weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training, and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided; **and**
    2. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression (See Policy Guidelines below); **and**
    3. Regular exercise; **and**
    4. Elevation where appropriate; **and**
    5. Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 20 minutes per day; **and**
    6. Evaluation of diet and implementation of any necessary change; **and**
    7. Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.); **and**
    8. Correction (where possible) of anemia and/or hypoproteinemia.

V. A PCD with calibrated gradient pressure (E0652) is considered **not medically necessary and not covered** when criterion IV. above is not met including, but not limited to, the treatment of lymphedema not extending onto the chest, trunk, and/or abdomen or the treatment of chronic venous insufficiency (CVI).

Chronic Venous Insufficiency (CVI) with Venous Stasis Ulcers

VI. A PCD (E0650, E0651) may be considered **medically necessary** for the treatment of chronic venous insufficiency (CVI) of the lower extremities when **all** of the following (A.-C.) criteria are met:

A. Patient has edema in the affected lower extremity; **and**
B. One or more venous stasis ulcer(s); **and**
C. The ulcer(s) have failed to heal after a **6-month** trial of conservative therapy directed by the treating practitioner. The trial must include **all** of the following (1.-5.):

1. Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression (See Policy Guidelines below); **and**
2. Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.); **and**
3. Regular exercise; **and**
4. Elevation of the limb; **and**
5. Appropriate wound care for the ulcer (including sharp debridement where appropriate)

VII. A PCD is considered **not medically necessary and is not covered** when criterion VI. above is not met including, but not limited to, the treatment of ulcers in locations other than the lower extremity or ulcers and wounds from other causes.

Peripheral Artery Disease

VIII. A PCD for arterial insufficiency (E0675) is considered **not medically necessary and not covered**.

Deep Venous Thrombosis Prevention

IX. Use of a PCD for the prevention of deep venous thrombosis (DVT) (E0676) may be considered **medically necessary** when **both** of the following (A.-B.) criteria are met:

A. The patient is unable to ambulate for a prolonged period of time (e.g., >2 weeks) due to trauma, orthopedic surgery, neurosurgery, or other acute circumstances; **and**
B. The patient has a contraindication to standard short-term anticoagulation.

X. Use of a PCD is considered **not medically necessary and not covered** when criterion IX. above is not met, including when the patient is able to walk or is no longer bedridden.

Accessories

XI. Pneumatic compression device (PCD) related accessories (E0655-E0673) may be considered **medically necessary** only when the appropriate, related base PCD (E0650, E0651, E0652, E0675) meets the applicable coverage criteria for that type of PCD.

XII. PCD related accessories are considered **not medically necessary and are not covered** when criterion XI. above is not met.

POLICY GUIDELINES

General

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidances:

- Local Coverage Determination (LCD): Pneumatic Compression Devices (L33829)[3]
- Local Coverage Article (LCA): Pneumatic Compression Devices (A52488)[2]
- National Coverage Determination (NCD): Pneumatic Compression Devices (280.6)[1]

Adequate Compression Requirements

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

Definitions

Since this medical policy is largely based on Medicare coverage guidance, definitions as they pertain to the services in this policy are from the relevant LCD (L33829). As of the date of this policy update, those definitions are as follows.

Edema

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

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

Primary lymphedema

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

- Congenital lymphedema due to lymphatic aplasia or hypoplasia
- Milroy's disease, an autosomal dominant familial form of congenital lymphedema
- Lymphedema praecox
- Lymphedema tarda

Secondary lymphedema

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

Chronic Venous Insufficiency (CVI)

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

Peripheral Arterial Disease (PAD)

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

Conservative Therapy Trials

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

Trial for Lymphedema Not Extending Onto the Chest, Trunk, and/or Abdomen

Conservative therapy trial requirements for lymphedema that does **not** extend onto the chest, trunk or abdomen are noted in the criteria above. At the end of the four-week trial, if there has been improvement, then reimbursement for a PCD is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. Only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a PCD considered.

At a minimum, re-assessments conducted for a trial must include detailed measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

Trial for Lymphedema Extending Onto the Chest, Trunk and/or Abdomen

Conservative therapy trial requirements for lymphedema that does extend onto the chest, trunk or abdomen are noted in the criteria above. At the end of the four-week trial, if there has been improvement of the lymphedema extending onto the chest, trunk and/or abdomen, then reimbursement for an E0652 is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. When and only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, an E0652 is eligible for reimbursement.

Trial for Chronic Venous Insufficiency

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

BILLING GUIDELINES

General

This policy addresses the use of pneumatic compression devices as durable medical equipment (DME) in the home setting. If these pneumatic devices are billed for use during ambulatory surgery (POS 24) they will deny as not-covered to the facility fee.

Pneumatic Compression Device Code Selection

Appropriate HCPCS coding of pneumatic compression devices is based on the indication or condition being treated, as well as the type of device:

- A PCD coded as E0650 or E0651 is used for lymphedema or CVI.
- A PCD coded as E0652 is used for a segmented, calibrated gradient pneumatic compression device and has limited coverage.
- A PCD coded as E0675 is used only for peripheral artery disease (PAD). Other HCPCS codes would not be used for PCDs used for this condition.
- A PCD coded as E0676 is used only for prevention of venous thrombosis.

PCDs consist of an electrical pneumatic pump and an inflatable appliance that encloses the applicable body part. The pump fills the appliance with compressed air to predetermined pressures and intermittently alternates inflation and deflation to preset cycle times. The pressures and cycles vary between devices and, in some devices, are user-adjustable.

Miscellaneous

When a foot or hand segment is used in conjunction with any leg or arm appliance respectively, there must be no separate billing for this segment. It is considered included in the code for the leg or arm appliance.

The only products that may be billed to the DME MACs using codes E0650, E0651, E0652 and E0675 are those for which the Pricing, Data Analysis, and Coding (PDAC) contractor has completed a Coding Verification Review. The coding determination subsequently is published on the appropriate Product Classification List.

HCPCS CODES

All Lines of Business Except Medicare	
No Prior Authorization Required	
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
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
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
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
Not Covered	
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)

REVIEW OF EVIDENCE

The use of pneumatic compression devices for the treatment of lymphedema and chronic venous insufficiency is based on Centers for Medicare & Medicaid Services guidance; therefore, an evidence review is not included for these indications.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of pneumatic compression devices for the prevention of deep vein thrombosis. Below is a summary of the available evidence identified through April of 2022.

Systematic Reviews

In 2021, Hayes updated a health technology assessment with an evidence review to evaluate pneumatic compression for the prevention of deep vein thrombosis following knee surgery.[5] The available evidence suggested that pneumatic compression may be effective in reducing the incidence of deep vein thrombosis (DVT) in patients who have undergone knee surgery, particularly when used in combination with other mechanical or pharmacological interventions for prevention of DVT. However, the available studies provide limited and somewhat inconsistent evidence concerning the efficacy of pneumatic compression relative to other strategies for DVT prevention and the optimal DVT prevention strategy for knee surgery patients remains unclear. Pneumatic compression therapy is reasonably safe and caused minor or no complications in the reviewed studies. Additional randomized trials are needed to determine the optimal strategy for DVT prevention, particularly in patients who cannot tolerate treatment with anticoagulants such as low-molecular-weight heparin (LMWH) and aspirin.

Therefore, based on the currently available published evidence, the following Hayes Ratings are assigned:

- "**C** – For pneumatic compression as an adjunct to LMWH for prevention of DVT after knee surgery. This rating reflects the similar safety profiles, but conflicting evidence regarding the efficacy of these approaches.
- **C** – For pneumatic compression as an alternative to warfarin (Coumadin) for prevention of DVT after knee surgery. This rating reflects consistent but limited evidence that these approaches have similar safety and efficacy for prevention of DVT.
- **D2** – For pneumatic compression therapy alone as an alternative to LMWH alone for DVT prevention after knee surgery. This Rating reflects findings from a small body of conflicting evidence, some of which indicate that pneumatic compression therapy is less effective than LMWH.
- **D2**- For pneumatic compression therapy as an alternative to aspirin, graduated compression stockings, or continuous passive motion therapy for DVT prevention. There is insufficient high-quality evidence to determine the relative efficacy and safety of these treatment approaches.
- **D2**- For pneumatic compression therapy as an adjunct to aspirin, graduated compression stockings, or continuous passive motion therapy as alternatives to aspirin alone, compression stockings alone, or continuous passive motion therapy alone for DVT prevention, respectively.

- There is insufficient high-quality evidence to determine the relative efficacy and safety of these treatment approaches."

CLINICAL PRACTICE GUIDELINES

American College of Chest Physicians (ACCP)

The 2012 ACCP evidence-based guideline for the prevention of venous thromboembolism (VTE) in orthopedic surgery patients recommended the following regarding intermittent pneumatic compression devices:

- "In patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA), we recommend 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).
- In patients undergoing hip fracture surgery (HFS), we recommend use of one of the following rather than no antithrombotic prophylaxis for a minimum of 10 to 14 days: LMWH, fondaparinux, LDUH, adjusted-dose VKA, aspirin (all Grade 1B), or an IPCD (Grade 1C).
- For patients undergoing major orthopedic surgery, we suggest extending thromboprophylaxis in the outpatient period for up to 35 days from the day of surgery rather than for only 10 to 14 days (Grade 2B).
- In patients undergoing major orthopedic surgery and increased risk of bleeding, we suggest using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C)."[6]

The 2012 AACP evidence-based guideline for the prevention of venous thromboembolism (VTE) in non-orthopedic surgical patients gave the following recommendations for intermittent pneumatic compression devices:

- "For general and abdominal-pelvic surgery patients at low risk for VTE (~1.5%; Rogers score, 7-10; Caprini score, 1-2), we suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis (Grade 2C).
- For general and abdominal-pelvic surgery patients at moderate risk for VTE (~3.0%; Rogers score, > 10; Caprini score, 3-4) who are not at high risk for major bleeding complications, we suggest low-molecular-weight heparin (LMWH) (Grade 2B), low-dose unfractionated heparin (LDUH) (Grade 2B), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.
- For general and abdominal-pelvic surgery patients at moderate risk for VTE (3.0%; Rogers score, > 10; Caprini score, 3-4) who are at high risk for major bleeding complications or those in whom the consequences of bleeding are thought to be particularly severe, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C).
- For general and abdominal-pelvic surgery patients at high risk for VTE (~6.0%; Caprini score, ≥ 5) who are not at high risk for major bleeding complications, we recommend pharmacologic

prophylaxis with LMWH (Grade 1B) or LDUH (Grade 1B) over no prophylaxis. We suggest that mechanical prophylaxis with elastic stockings (ES) or IPC should be added to pharmacologic prophylaxis (Grade 2C).

- For high-VTE-risk general and abdominal-pelvic surgery patients who are at high risk for major bleeding complications or those in whom the consequences of bleeding are thought to be particularly severe, we suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated (Grade 2C).
- For general and abdominal-pelvic surgery patients at high risk for VTE (6%; Caprini score, ≥ 5) in whom both LMWH and unfractionated heparin are contraindicated or unavailable and who are not at high risk for major bleeding complications, we suggest low-dose aspirin (Grade 2C), fondaparinux (Grade 2C), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.
- For cardiac surgery patients with an uncomplicated postoperative course, we suggest use of mechanical prophylaxis, preferably with optimally applied IPC, over either no prophylaxis (Grade 2C) or pharmacologic prophylaxis (Grade 2C).
- For cardiac surgery patients whose hospital course is prolonged by one or more nonhemorrhagic surgical complications, we suggest adding pharmacologic prophylaxis with LDUH or LMWH to mechanical prophylaxis (Grade 2C).
- For thoracic surgery patients at moderate risk for VTE who are not at high risk for perioperative bleeding, we suggest LDUH (Grade 2B), LMWH (Grade 2B), or mechanical prophylaxis with optimally applied IPC (Grade 2C) over no prophylaxis.
- For thoracic surgery patients at high risk for VTE who are not at high risk for perioperative bleeding, we suggest LDUH (Grade 1B) or LMWH (Grade 1B) over no prophylaxis. In addition, we suggest that mechanical prophylaxis with ES or IPC should be added to pharmacologic prophylaxis (Grade 2C).
- For thoracic surgery patients who are at high risk for major bleeding, we suggest use of mechanical prophylaxis, preferably with optimally applied IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated (Grade 2C).
- For craniotomy patients, we suggest that mechanical prophylaxis, preferably with IPC, be used over no prophylaxis (Grade 2C) or pharmacologic prophylaxis (Grade 2C).
- For craniotomy patients at very high risk for VTE (eg, those undergoing craniotomy for malignant disease), we suggest adding pharmacologic prophylaxis to mechanical prophylaxis once adequate hemostasis is established and the risk of bleeding decreases (Grade 2C).
- For patients undergoing spinal surgery, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C), unfractionated heparin (Grade 2C), or LMWH (Grade 2C).
- For patients undergoing spinal surgery at high risk for VTE (including those with malignant disease or those undergoing surgery with a combined anterior-posterior approach), we suggest adding pharmacologic prophylaxis to mechanical prophylaxis once adequate hemostasis is established and the risk of bleeding decreases (Grade 2C).
- For major trauma patients, we suggest use of LDUH (Grade 2C), LMWH (Grade 2C), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.
- For major trauma patients at high risk for VTE (including those with acute spinal cord injury, traumatic brain injury, and spinal surgery for trauma), we suggest adding mechanical

prophylaxis to pharmacologic prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury.
- For major trauma patients in whom LMWH and LDUH are contraindicated, we suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis (Grade 2C) when not contraindicated by lower-extremity injury. We suggest adding pharmacologic prophylaxis with either LMWH or LDUH when the risk of bleeding diminishes or the contraindication to heparin resolves (Grade 2C)."[7]

American Academy of Orthopedic Surgeons (AAOS)

The 2012 AAOS evidence-based clinical practice guideline on preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty recommended the following regarding pneumatic compression devices:

- "We 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"[8]

American College of Foot and Ankle Surgeons (ACFAS)

The 2015 ACFAS clinical consensus statement for the risk, prevention, and diagnosis of venous thromboembolism disease (VTED) in foot and ankle surgery and injuries requiring immobilization recommended a multimodal approach to VTED prophylaxis for patients at high risk. "This includes addressing any modifiable risk factors, using mechanical prophylaxis, early mobilization, and considering the use of chemical prophylaxis."[9]

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

Women's Health and Cancer Rights Act (WHCRA)

The Women's Health and Cancer Rights Act (WHCRA) of 1998 provides protections to individuals who have opted to undergo breast reconstruction in connection with a mastectomy.[10] Under the WHCRA, coverage is provided for all stages of breast reconstruction for both the affected breast (the breast undergoing the mastectomy procedure) and the contralateral breast (for symmetry) and breast prostheses, as well as treatment of complications caused by the mastectomy, such as lymphedema. While the criteria in this policy are primarily based on Medicare guidance, in accordance with the WHCRA, Company coverage may exceed Medicare coverage for items or services required to treat conditions that are the direct result of a mastectomy.

REFERENCES

1. Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). Effective Date of this Version: 1/14/2002. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225. Accessed 5/27/2022.
2. Centers for Medicare & Medicaid Services Local Coverage Article: Pneumatic Compression Devices - Policy Article (A52488). Revision Effective Date: 01/01/2020. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52488. Accessed 5/27/2022.
3. Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Pneumatic Compression Devices (L33829). Revision Effective Date: For services performed on or after

01/01/2020. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33829. Accessed 5/27/2022.

4. Centers for Medicare & Medicaid Services Local Coverage Article (LCA): A55426, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs. Revision Effective Date: For services performed on or after 01/01/2020. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55426. Accessed 5/27/2022.
5. Hayes Inc. Pneumatic Compression for Prevention of Deep Vein Thrombosis Following Knee Surgery. https://evidence.hayesinc.com/report/dir.pneumatic1975. Published 2021. Accessed 5/27/2022.
6. Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in orthopedic surgery patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest.* 2012;141(2 Suppl):e278S-e325S
7. Gould MK, Garcia DA, Wren SM, et al. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest.* 2012;141(2 Suppl):e227S-e277S
8. Jacobs JJ, Mont MA, Bozic KJ, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on: preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. *The Journal of bone and joint surgery American volume.* 2012;94(8):746-747
9. Fleischer AE AB, Baker JR, Boffeli TJ, Jupiter DC, Schade VL. American College of Foot and Ankle Surgeons' clinical consensus statement: risk, prevention, and diagnosis of venous thromboembolism disease in foot and ankle surgery and injuries requiring immobilization. *Journal of Foot and Ankle Surgery.* 2015;54(3):497-507
10. Centers for Medicare & Medicaid Services. Women's Health and Cancer Rights Act (WHCRA). https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet. Published 1998. Accessed 5/27/2022https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.