
Medical Policy



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***Current Policy Effective Date: 5/1/24**
(See policy history boxes for previous effective dates)

Title: Pressure Gradient Garments and Support Stockings

Description/Background

Gradient compression garments and support stockings are used to give external compression to the extremities, which prevents or reduces swelling, enhances venous circulation and prevents venous pooling and venous hypertension in individuals with incompetent venous circulation (i.e., varicose veins). They may also be used as prophylaxis against venous thrombosis and to enhance healing of extremity wounds by reducing venous pressure and edema. Special silicone compression garments may be prescribed in burn patients to minimize scarring responses in deep burns.

Some garments are custom made from precise measurements of the body and can vary from lymphedema sleeves for the arm, knee-length to full-length stockings, waist-high leotard, to various other body parts such as the hands. Custom-ordered/fitted compression garments require fitting and measuring by a specially trained individual and require a physician's order. Advances in technology allow many of compression garments to be pre-made. Very few need to be custom made unless the degree of gradient pressure is one that cannot be provided in a pre-made garment.

A *lymphedema sleeve* is a custom-fabricated garment that applies gradient pressure to a limb affected by loss of lymphatic channels, usually as a result of cancer surgery and/or radiation therapy. It is worn to reduce or maintain the volume of the upper limb (e.g., ReidSleeve®, ArmAssist, Jobst, Juzo, Circaid, Sigvaris, Tribute™ by Solaris). There are two types of lymphedema sleeves; those made of specialized elastic knit two-way stretch sleeves or stockings (e.g., Jobst or Juzo) and those in which gradient compression is achieved through high to low pressure ratios created by variations in density, type, size, proportion and insertion pressure of foam (e.g., Reidsleeve® or Tribute by Solaris). The elastic garments are usually prescribed for the initial treatment of lymphedema and worn under clothing during the day (including while exercising). Lymphedema sleeves such as the Reidsleeve® or Tribute™ by

Solaris garments are used in addition to the elastic garments and typically after decongestive therapy to maintain limb volume. These sleeves can replace bandaging of the affected extremity and are usually worn at night. They are usually prescribed for intractable lymphedema (lymphedema which has been difficult to manage and nonresponsive to decongestive treatment). The Tribute™ by Solaris garment can also be used for the treatment of lymphedema of the lower extremity. The garment is boot-shaped, applies gradient compression to the lower extremity and usually replaces bandaging of the affected extremity.

The Compressure Comfort® Bra by Belisse® is contoured similarly to a bra however it is not considered a mastectomy bra. The garment applies gentle compression all around the torso and is used for treatment of lymphedema of the armpit, chest, breast, and/or back.

High compression support stockings, socks and hosiery provide increased support for relief from:

- Moderate to severe varicosities (varicose veins)
- Moderate edema (swelling) of legs, ankles and feet
- Moderate to severe varicose veins during pregnancy
- Severe edema and lymphedema

They may also be used for:

- Management of active venous ulcerations
- Preventing recurrence of venous ulcerations
- Preventing post-thrombotic syndrome. This is a complication that may follow a deep vein thrombosis and includes symptoms such as edema, purpura, increased skin pigmentation, itchiness, rash, ulceration and cellulitis.

Regulatory Status

The Women's Health and Cancer Rights Act of 1998 mandates coverage for treatment of physical complications of mastectomy including lymphedema for all contracts that provide medical and surgical benefits.

The FDA classifies compression stockings for general medical purposes as a class I device exempt from FDA 510k pre-market notification requirements.

Medical Policy Statement

The safety and effectiveness of pressure gradient garments and supports stockings are established. They may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines

The garments must be obtained from a Health Plan approved supplier.

Inclusions:

1. Pressure Gradient Support Garments:

The pressure gradient support garments must be at or above 18 mmHg and meet **one** of the following criteria:

- Pressure gradient support stockings are considered established for the treatment of severe circulatory conditions, moderate to severe varicose veins during pregnancy or post-surgical care.
- Treatment of complications of chronic venous insufficiency:
 - Varicose veins (except spider veins)
 - Stasis dermatitis (venous eczema)
 - Venous ulcers (stasis ulcers)
 - Venous edema
 - Lipodermatosclerosis
 - Treatment of phlebitis and thrombophlebitis
 - Prevention of thrombosis in immobilized persons (eg, immobilization due to surgery, trauma, general debilitation, etc.)
 - Post-thrombotic syndrome (post-phlebotic syndrome)
 - Chronic intractable lymphedema (lasting longer than 3 months), including lymphedema as a physical complication of mastectomy (eg, lymphedema sleeves)
 - Edema following surgery, fracture, burns, or other trauma
 - Post sclerotherapy
 - Postural hypotension/orthostatic hypotension
 - Severe edema in pregnancy
 - Deep vein thrombosis (DVT) prophylaxis during pregnancy and postpartum
 - Edema accompanying paraplegia, quadriplegia, etc.
 - Significant burn with risk of post burn contracture, skin grafting and hypertrophic scarring

2. Burn Pressure Garments:

Considered established to enhance healing, reduce swelling, treat contractures and hypertrophic scars suffered by severely burned patients.

3. Custom-ordered/fitted compression garments or surgical stockings (e.g., Jobst, Sigvaris, Circaid, Juzo, ReidSleeve®, Sigvaris, Solaris, including the Tribute™ garment, and Belisse® garments)

Custom-ordered/fitted compression garments (e.g., stocking/burn garment/gradient pressure aid garment/sleeve) are considered established for patients when the garment functions as a gradient pressure aid with a degree of pressure which is at least 18 mm Hg, requires a physician order (prescription) to be dispensed, standard compression garments have been tried and/or ruled out, and meets **one or more** of the following conditions:

- Treatment of complications of chronic venous insufficiency:
 - Varicose veins (except spider veins)
 - Stasis dermatitis (venous eczema)
 - Venous ulcers (stasis ulcers)
 - Venous edema
 - Lipodermatosclerosis
- Treatment of phlebitis and thrombophlebitis
- Prevention of thrombosis in immobilized persons (e.g., immobilization due to surgery, trauma, general debilitation, etc.)
- Post-thrombotic syndrome (post-phlebotic syndrome)
- Chronic intractable lymphedema (lasting longer than 3 months), including lymphedema as a physical complication of mastectomy (e.g., lymphedema sleeves).
- Edema following surgery, fracture, burns, or other trauma
- Post sclerotherapy
- Postural hypotension/orthostatic hypotension
- Severe edema in pregnancy
- DVT prophylaxis during pregnancy and postpartum
- Edema accompanying paraplegia, quadriplegia, etc.
- Significant burn with risk of post burn contracture, skin grafting and hypertrophic scarring

Exclusions:

- No more than four (4) pressure gradient support garments per year unless the member's primary care physician determines they are required due to significant gain or loss in weight or change in the patient's condition.
- Pressure garments of any kind (including burn pressure garments) are not covered for individuals that do not have coverage for external prosthetics or orthotics.
- Pressure garments and non-prescription support garments such as "support hose" used for comfort, or for conditions other than described above. Support hose A4490 - A4510 are not covered.
- Over the counter TED hose, elastic stockings, support hose, foot coverings, leotards, surgical leggings and fabric supports that typically have a compression of less than 18 mm Hg are not a benefit.
- Pressure garments worn by a patient in order to provide sensory and body awareness for conditions characterized by impaired motor control, such as autism, autism spectrum disorder, proprioceptive deficits, deep-sensory deficits or hypersensitivity are not covered.
- Gradient compression stockings solely for the purpose of air travel in those individuals at low-risk for DVT are not considered established, as they do not improve patient outcomes.
- Silver impregnated compression stockings are not considered established because there is insufficient evidence that silver impregnated compression stockings are superior to standard compression stockings.

- Compression garments are considered experimental/investigational for members with severe peripheral arterial disease or septic phlebitis because they are contraindicated in these conditions.
- Gradient compression garments/stockings are not considered established for any one of the following conditions with or without a written physicians order (this list may not be all inclusive):
 - Backache
 - Carpal tunnel syndrome
 - Cellulitis
 - Chest pain
 - Chronic airway obstruction
 - Cystocele
 - Esophageal reflux
 - Fibromatosis
 - Hammer toe
 - Lupus erythematosus
 - Neurogenic bladder
 - Osteoarthritis
 - Osteomyelitis
 - Paralysis agitans
 - Sleep apnea
 - Sprained and/or strained joints or ligaments
 - Tendonitis
 - Urine retention

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

A6501	A6502	A6503	A6504	A6505	A6506
A6507	A6508	A6509	A6510	A6511	A6512
A6513	A6520	A6521	A6522	A6523	A6524
A6525	A6526	A6527	A6528	A6529	A6530
A6531	A6532	A6533	A6534	A6535	A6536
A6537	A6538	A6539	A6540	A6541	A6544
A6545	A6549	A6552	A6553	A6554	A6555
A6556	A6557	A6558	A6559	A6560	A6561
A6562	A6563	A6564	A6565	A6566	A6567
A6568	A6569	A6570	A6571	A6572	A6573
A6574	A6575	A6576	A6577	A6578	A6579
A6580	A6581	A6582	A6583	A6584	A6585
A6586	A6587	A6588	A6589	A6593	A6594
A6595	A6596	A6597	A6598	A6599	A6600
A6601	A6602	A6603	A6604	A6605	A6606
A6607	A6608	A6609	A6610	S8420	S8421

S8422	S8423	S8424	S8425	S8426	S8427
S8428	S8429	L8010			

Other codes (investigational, not medically necessary, etc.):

A4467	A4490	A4495	A4500	A4510
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Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Clinical evidence shows that pressure gradient garments and support stockings play a part in lowering the risk of deep vein thrombosis (DVT) in post-surgical patients and those hospitalized patients who are confined to bed. They are also used in the treatment of venous leg ulcers, severe circulatory conditions, burns and moderate to severe varicose veins during pregnancy. There is no published literature to support the efficacy of the use of compression garments for the treatment of truncal edema.

The American College of Chest Physicians (ACCP) 2008 guidelines for prevention of venous thromboembolism recommend:

- Mechanical methods (including GCS) for prevention of DVT be used primarily in patients who are at high risk of bleeding or as an adjunct to anticoagulant-based prophylaxis, and
- Long distance travelers at high risk for venous thromboembolism (VTE) may benefit from the use of properly fitted gradient compression stockings for prevention of DVT.

Conservative medical practices that may be used in the management of varicose veins include leg elevation, analgesia for symptom relief, avoidance of prolonged periods of standing and compression therapy. The use of custom-fit compression stockings with pressure gradients, is often attempted prior to more invasive procedures. The stockings should be put on when first arising in the morning, preferably before getting out of bed.

In a Cochrane review, O'Meara et al (2012) noted that the main treatment for venous (or varicose or stasis) ulcers is the application of a firm compression garment (bandage or stocking) in order to aid venous return. There is a large number of compression garments available and it was unclear whether they are effective in treating venous ulcers and, if so, which method of compression is the most effective. These researchers performed a systematic review of all randomized controlled trials (RCTs) evaluating the effects on venous ulcer healing of compression bandages and stockings. Specific questions addressed by the review are: does the application of compression bandages or stockings aid venous ulcer healing? And which compression bandage or stocking system is the most effective? Randomized controlled trials recruiting people with venous leg ulceration that evaluated any type of compression bandage system or compression stockings were eligible for inclusion. Eligible comparators included no compression (e.g., primary dressing alone, non-compressive bandage) or an alternative type of compression. Randomized controlled trials had to report an objective measure of ulcer healing in order to be included (primary outcome for the review). Secondary outcomes of the review included ulcer recurrence, costs, quality of life, pain, adverse events and withdrawals. There was no restriction on date, language or publication status of RCTs.

Details of eligible studies were extracted and summarized using a data extraction table. Data extraction was performed by 1 review author and verified independently by a 2nd review author. A total of 48 RCTs reporting 59 comparisons were included (4,321 participants in total). Most RCTs were small, and most were at unclear or high-risk of bias.

Single-component compression bandage systems are less effective than multi-component compression for complete healing at 6 months (1 large RCT). A 2-component system containing an elastic bandage healed more ulcers at 1 year than one without an elastic component (1 small RCT). Three-component systems containing an elastic component healed more ulcers than those without elastic at 3 to 4 months (2 RCTs pooled), RR 1.83 (95 % CI: 1.26 to 2.67), but another RCT showed no difference between groups at 6 months. An individual patient data meta-analysis of 5 RCTs suggested significantly faster healing with the 4-layer bandage (4LB) than the short stretch bandage (SSB).

The authors concluded that compression increases ulcer healing rates compared with no compression. Multi-component systems are more effective than single-component systems. Multi-component systems containing an elastic bandage appear to be more effective than those composed mainly of inelastic constituents. Two-component bandage systems appear to perform as well as the 4LB. Patients receiving the 4LB heal faster than those allocated the short stretch bandage SSB. More patients heal on high-compression stocking systems than with the SSB. They stated that further data are required before the difference between high-compression stockings and the 4LB can be established.

Government Regulations

National:

There is currently no National Coverage Determination (NCD) for Surgical Stockings and Compression Garments. Please refer to the following NCD Durable Medical Equipment Reference List website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&bc=AgAAqAAAAAAA&>.

Local:

CGS Administrators, LLC

Local Coverage Determination (LCD) L33831 Surgical Dressings

Original effective date 10/01/2015

Revision effective date 01/01/2024

Gradient Compression Wrap (A6545)

A gradient compression wrap is only covered when it is used as a primary or secondary dressing over wounds that meet the statutory requirements for a qualifying wound (surgically created or modified, or debrided).

Claims for gradient compression wraps used without a qualifying wound or when used for other non-qualifying conditions will be denied as statutorily non-covered, no benefit. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES for information about the statutory benefit requirements.

Utilization of a gradient compression wrap (A6545) is limited to one per 6 months per leg. Quantities exceeding this amount will be denied as not reasonable and necessary. Refer to the related Surgical Dressings Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information concerning non-coverage once the ulcer has healed.

Compression Burn Garments (A6501-A6513)

Compression burn garment codes are found in the Group 1 code list.

CGS Administrators, LLC

Local Coverage Article Surgical Dressings – Policy Article (A54563)

Original effective date 10/01/2015

Revision effective date 01/01/2024

Gradient compression stockings (A6530, A6533, A6534, A6535, A6536, A6537, A6538, A6539, A6540, A6541, A6544, A6549) are non-covered under the surgical dressing benefit because they do not meet the statutory definition of a dressing; however, they may be considered for coverage under the lymphedema compression treatment items benefit and billed in accordance with CMS Final Rule CMS-1780-F.

GRADIENT COMPRESSION STOCKINGS/WRAPPS (A6531, A6532, A6545)

A gradient compression stocking described by codes A6531 or A6532 or a non-elastic gradient compression wrap described by code A6545 is only covered when it is used in the treatment of an open venous stasis ulcer that meets the qualifying wound requirements described above.

Codes A6531, A6532, and A6545 are non-covered for the following conditions:

- Venous insufficiency without stasis ulcers;
- Prevention of stasis ulcers;
- Prevention of the reoccurrence of stasis ulcers that have healed;
- Treatment of lymphedema in the absence of ulcers.

In these situations, since there is no ulcer, the stockings/wraps do not meet the definition of a surgical dressing, as there is no qualifying wound. Claims for these uses will be denied as non-covered, no benefit.

COMPRESSION BURN GARMENTS (A6501, A6502, A6503, A6504, A6505, A6506, A6507, A6508, A6509, A6510, A6511, A6512, A6513)

Compression burn garments are covered under the Surgical Dressings benefit when they are used to reduce hypertrophic scarring and joint contractures following a burn injury.

**MLN Matters Number: MM13286 Related Change Request (CR) Number: CR 13286
Lymphedema Compression Treatment Items: Implementation Effective Date: January 1,
2024 Related CR Release Date: January 24, 2024 Revised**

Section 4133 of the Consolidated Appropriations Act (CAA), 2023, establishes a new Medicare DMEPOS benefit category for standard and custom-fitted compression garments and additional lymphedema compression treatment items to service a medical purpose. Starting January 1, 2024, authorized practitioners may prescribe these items to treat lymphedema. Medicare didn't cover compression garments for treating lymphedema before the CAA legislation as there was no benefit category.

CMS will add 2 new indicators to the Alpha-Numeric HCPCS file for lymphedema compression treatment items:

- A HCPCS pricing indicator of 40
- A HCPCS Berenson-Eggers Type of Service (BETOS) Code of O1L

TOS indicator S will apply to the new codes for lymphedema compression treatment items. The January 2024 Alpha-Numeric HCPCS file will include these pricing indicators.

We'll also add a new Common Working File (CWF) category for lymphedema compression treatment items. Some codes that describe lymphedema compression treatment items, A6530-A6549, are currently in CWF category 21 for surgical dressings, with codes A6531, A6532, and A6545 describing garments currently covered as secondary surgical dressings. We're keeping codes A6531, A6532, and A6545, with a modification to the descriptor to add "used as a surgical dressing," for use in billing surgical dressings. Starting January 1, 2024, use the following new codes with lymphedema compression treatment items only:

- A6552 - Gradient compression stocking, below knee, 30-40 mmhg, each
- A6554 - Gradient compression stocking, below knee, 40 mmhg or greater, each
- A6583 - Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each

Per Section 4133 of the CAA, 2023, only enrolled DMEPOS suppliers may provide lymphedema compression treatment items. The DME MACs will process all claims for lymphedema compression treatment items. We'll add the codes for these items to CWF category 60, as well as the new CWF category added specifically for these items. Suppliers of lymphedema compression treatment items will be subject to the DMEPOS:

- Supplier standards
- Accreditation requirements
- Quality standards
- All other requirements that apply to enrolled DMEPOS suppliers Lymphedema compression treatment items are subject to the DMEPOS Competitive Bidding Program (CBP).

We'll add lymphedema compression treatment item codes and national Medicare payment amounts to the DMEPOS fee schedule file for processing claims with dates of service on or after January 1, 2024. Coinsurance and the Medicare Part B deductible apply. Payment is equal to 80% of the lesser of the supplier's actual charge or the national payment amount on the DMEPOS fee schedule file. We'll update the national payment amounts annually. Also, the field on the DMEPOS fee schedule file for the payment category indicator for lymphedema compression treatment items codes will include indicator LC for lymphedema compression treatment items.

The general scope of the new benefit includes the following:

- Standard daytime gradient compression garments
- Custom daytime gradient compression garments
- Nighttime gradient compression garments
- Gradient compression wraps
- Accessories, such as zippers, linings, paddings, or fillers, necessary for the effective use of a gradient compression garment or wrap
- Compression bandaging systems and supplies

Custom-fitted or non-standard garments are uniquely sized and shaped to fit the exact dimensions of the affected extremity of a person to give accurate gradient compression to treat lymphedema. Gradient compression garments are designed differently for daytime or nighttime use. Daytime garments give a higher level of compression. Nighttime garments offer milder compression and are less snug against the skin.

Payment for all necessary services associated with providing gradient compression garments and wraps, including fitting and measurements, is included in the national payment amounts made to the supplier of the item.

The frequency limitations for replacement of lymphedema compression treatment items are:

- Once every 6 months for 3 gradient compression garments or wraps with adjustable straps per each affected extremity or part of the body
- Once every 2 years for 2 nighttime garments per each affected extremity or part of the body

We'll deny payment if you exceed frequency limitations unless a replacement is needed due to a change in medical need or because a garment or wrap is lost, stolen, or irreparably damaged. When you bill for replacement, you must use the RA modifier.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Lymphedema – Surgical Treatments
 - Pneumatic Compression Pumps and Appliances (e.g., Flexitouch System) for Lymphedema
 - Pneumatic Compression Pumps and Appliances for Venous Ulcers
 - Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis
 - Bioimpedance Devices for Cancer Related Extremity Lymphedema
 - Treatment of Varicose Veins/Venous Insufficiency
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13. Centers for Medicare and Medicaid Services. CGS Administrators, LLC. Local Coverage Determination (LCD) Surgical Dressings, L33831, effective 01/01/2024. <https://www.cms.gov/medicare-coverage-database/>. Accessed 2/1/2024.

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15. CMS MLN Matters Number: MM13286 Related Change Request (CR) Number: CR 13286 Lymphedema Compression Treatment Items: Implementation Effective Date: January 1, 2024. <https://www.cms.gov/files/document/mm13286-lymphedema-compression-treatment-items-implementation.pdf> Accessed 2/20/24.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 1, 2024 the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/24	2/21/24		<p>Joint policy established</p> <p>Vendor: Northwood</p> <p>Per code update nomenclature revised for codes A6531, A6532, A6535, A6538, A6541, A6545, and A6549 effective 1/1/2024.</p> <p>Per code update added codes A6552 to A6610 under EST effective 1/1/2024. This is per related change request (CR) number: CR 13286 Lymphedema Compression Treatment Items: Implementation effective date: 1/1/24. (ky)</p>

Next Review Date: 1st Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PRESSURE GRADIENT GARMENTS AND SUPPORT STOCKINGS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.