Title: Pressure Gradient Garments and Support Stockings

Description/Background

Gradient compression garments are constructed using elastic fibers or rubber. These fibers help compress the limb, aiding in circulation. The degree of squeezing or compression gradually decreases up the leg. By compressing the surface veins, arteries and muscles, the circulating blood is forced through narrower circulatory channels. As a result, the arterial pressure is increased, which causes more blood to return to the heart and less blood to pool in the extremities.

The physical presence of the stocking also helps control the size (diameter) of superficial veins beneath the stocking. The stocking does not allow these superficial veins to over-expand with blood. This action helps prevent pooling. As a result, the venous blood flows more quickly up the leg toward the heart.

Pressure gradient garments are designed to promote and restore normal fluid circulation to the extremities as well as to minimize excessive scarring responses in burn victims. The 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. Advancements in technology allow many of the 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 an affected limb and 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.

---

**Medical Policy Statement**

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

---

**Inclusionary and Exclusionary Guidelines**

For prescription custom-made or custom-fitted surgical stockings/graduated compression garments (e.g., Jobst, Sigvaris, Circaid, Juzo, ReidSleeve®, Sigvaris, Solaris, including the Tribute™ garment, and Belisse® garments), the following inclusions/exclusions apply:

**Inclusions:**
1. **Pressure Gradient Support Garments:**
   - Pressure gradient support stockings are covered when medically necessary for the treatment of severe circulatory conditions, high-risk pregnancy or post-surgical care. The garments must be obtained from a Health Plan approved supplier.
   - 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-phlebitic 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
  - Must be at or above 18 mmHg

**Limitations:**
- No more than four (4) support garments per year.
- Additional support garments will be covered if 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.

2. **Burn Pressure Garments:**
Covered for when medically necessary to enhance healing, reduce swelling, treat contractures and hypertrophic scars suffered by severely burned patients.

**Limitations:**
None

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 medically appropriate 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-phlebitic 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:
BCN does not cover:
• Pressure garments of any kind (including burn pressure garments) are not covered for BCN certificates 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.
• Compression garments for the chest, labia, trunk or neck are experimental/investigational. There is a lack of peer-reviewed published literature evaluating the clinical utility of compression garments for these types of lymphedema.
• Gradient compression stockings solely for the purpose of air travel in those individuals at low-risk for DVT are not medically necessary, as they do not improve patient outcomes.
• Silver impregnated compression stockings are considered not medically necessary 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 medically necessary 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
- Osteoarthrosis
- 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  A6530  A6531  A6532  A6533  A6534
A6535  A6536  A6537  A6538  A6539  A6540
A6541  A6544  A6545  A6549  S8420  S8421
S8422  S8423  S8424  S8425  S8426  S8427
S8428  S8429  L8010

**Other codes (investigational, not medically necessary, not a benefit, etc.):**
A4490  A4495  A4500  A4510  A4467

**Rationale**

Clinical evidence shows that pressure gradient garments and support stockings play a part in lowering the risk of deep vein thrombosis 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 high-risk 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.

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.

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=AgAAgAAAAAAA&.

Local:
CGS Administrators, LLC
Local Coverage Determination (LCD) L33831 Surgical Dressings
Original effective date 10/01/2015
Revision effective date 05/01/2021

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 05/01/2021

The following are examples of wound care items which are non-covered under the surgical dressing benefit because they do not meet the statutory definition of a dressing (not all-inclusive):
- Gradient compression stockings (A6530, A6533, A6534, A6535, A6536, A6537, A6538, A6539, A6540, A6541, A6544, A6549)
  These dressings are noncovered under the surgical dressing benefit.

Claims for products that are not able to be used as a primary or secondary dressing on a qualifying wound of the skin or that are composed of materials that do not serve a therapeutic or protective function will be denied as statutorily non-covered, no benefit.
GRADIENT COMPRESSION STOCKINGS/WRAPS (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.

(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 Treatment and Equipment

References


The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 2023, the date the research was completed.
<table>
<thead>
<tr>
<th>Date</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/16/01</td>
<td>Updated format of policy</td>
</tr>
<tr>
<td>7/22/04</td>
<td>Routine review of established policy; expanded text sections of policy; clinical intent remains same.</td>
</tr>
<tr>
<td>5/4/05</td>
<td>Review of established policy with criteria change.</td>
</tr>
<tr>
<td>1/18/06</td>
<td>Policy updated to include codes A6501-6512 (compression burn garments) and deleted codes for surgical stockings (A4490-A4510). Added coverage guidelines for SRO and FEHB.</td>
</tr>
<tr>
<td>12/19/07</td>
<td>Routine maintenance; codes updated.</td>
</tr>
<tr>
<td>3/18/09</td>
<td>Routine maintenance</td>
</tr>
<tr>
<td>3/31/10</td>
<td>Routine maintenance; codes updated and reformatted. Medicare and Medicaid information updated and references updated.</td>
</tr>
<tr>
<td>5/21/10</td>
<td>Added information regarding noncoverage of compression bras and garments for the treatment of truncal edema.</td>
</tr>
<tr>
<td>5/16/12</td>
<td>Routine maintenance; Clarified Medicare coverage information. References updated.</td>
</tr>
<tr>
<td>5/15/13</td>
<td>Routine update, policy status unchanged.</td>
</tr>
<tr>
<td>7/16/14</td>
<td>Routine maintenance; policy status unchanged.</td>
</tr>
<tr>
<td>8/19/15</td>
<td>Routine maintenance; added S codes to policy; policy status remains unchanged.</td>
</tr>
<tr>
<td>8/17/16</td>
<td>Routine policy maintenance. Updated Medicare/Medicaid coverage.</td>
</tr>
<tr>
<td>8/16/17</td>
<td>Routine policy maintenance, deleted code A4466 (1/1/17) and added code A4467 as replacement. No change in policy status.</td>
</tr>
<tr>
<td>10/18/17</td>
<td>Added code L8010 to policy, covered for commercial members.</td>
</tr>
<tr>
<td>11/14/18</td>
<td>Removed Medicaid section. Routine policy maintenance.</td>
</tr>
<tr>
<td>1/23/19</td>
<td>Clarified severe circulatory conditions under inclusions. No change in policy status.</td>
</tr>
<tr>
<td>09/24/2019</td>
<td>Routine policy maintenance, no change in policy status.</td>
</tr>
<tr>
<td>7/9/20</td>
<td>Updated local coverage determination under government section. No change in policy status.</td>
</tr>
<tr>
<td>7/15/21</td>
<td>Routine policy maintenance, no change in policy status.</td>
</tr>
<tr>
<td>7/7/22</td>
<td>Routine policy maintenance, CGS LCD updated, CGS Article added</td>
</tr>
<tr>
<td>7/13/23</td>
<td>Routine policy maintenance, no change in policy status. Vendor: Northwood. (ky)</td>
</tr>
</tbody>
</table>

Next Review: 3rd Qtr. 2024
MEDICAL POLICY TITLE: PRESSURE GRADIENT GARMENTS AND SUPPORT STOCKINGS
BCN BENEFIT ADMINISTRATION

I. Coverage Determination

<table>
<thead>
<tr>
<th>Commercial HMO (includes Self-Funded groups unless otherwise specified)</th>
<th>Covered; criteria apply.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Burn pressure garments are covered when prescribed by the member’s plan physician to enhance healing, reduce swelling and control scarring in case of severe burns. Pressure gradient supports are covered for severe circulatory conditions, high-risk pregnancy and post-surgical care. No coverage for pressure garments for patients with autism. Benefits are available for no more than four supports per calendar year. Additional supports may be covered if Plan Physician determines that they are necessary because of a significant weight gain or loss.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BCNA (Medicare Advantage)</th>
<th>See government section</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
</tr>
</tbody>
</table>

II. Administrative Guidelines

- The member's contract must be active at the time the service is rendered.
- 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 benefits 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.