

Medicare Advantage Policy Manual

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Gradient Compression Garments (Excluding Burn Garments)

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Gradient compression and pressure aids may be used for a variety of reasons, including use as wound dressings, to improve circulation, as well as treatment of edema, lymphedema, burns and for the treatment and/or prevention of venous stasis ulcers. These garments are available for different parts of the body (e.g., arms, legs, trunk) and come in varying pressures (expressed in millimeters of mercury, or mmHg) and lengths (e.g., below the knee, thigh length, waist length, etc.).

MEDICARE ADVANTAGE POLICY CRITERIA

Note: Durable medical equipment, prosthetics, orthotics and supply (DMEPOS) codes which require prior authorization are listed on the "Medicare Pre-authorization List" web page. While the services described in this medical policy may not be subject to routine medical necessity review, providers are expected to follow Medicare's medical reasonable and

necessary requirements when rendering treatment to beneficiaries. In addition, utilization may be subject to audit.

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	See "Policy Guidelines"
Noridian Healthcare Solutions (Noridian) Local	For compression garments used as surgical dressings [A6531, A6532, and A6545]:
Coverage Determinations (LCDs) and Articles*	 ✓ Surgical Dressings (L33831)) (Companion article is A54563, which can be accessed directly from the LCD)
	According to article A54563, "The only products that may be billed using code A6545 are those for which a written CVR has been made by the PDAC contractor and subsequently published on the PCL If a product is billed to Medicare using a HCPCS code that requires written CVR, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding."
	For compression garments used to treat lymphedema: DMEPOS Benefit Category: Lymphedema Compression Treatment Items – Implementation (<u>MM13286</u>) There is a benefit category for compression garments used to treat lymphedema only. The use of compression garments for other indications may be non-covered by Medicare because they do not fall into a statutory benefit category.) ^[1] Lymphedema Compression Treatment Items - Implementation (<u>MM13286</u>) may be used for additional guidance –
	 informational only. ✓ (<u>Correct billing and coding article</u>)^[2]
	For mastectomy sleeves (L8010):
	 ✓ External Breast Prostheses - Policy Article (<u>A52478</u>) ✓ (Companion determination is L33317, which can be accessed directly from this article.)
	See "Policy Guidelines" for "custom" items; however, customization of an item doesn't imply coverage. Medicare criteria are still applicable.

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**Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

BACKGROUND

The Medicare NCD for *Durable Medical Equipment Reference List* (280.1)^[2] states elastic stockings are non-covered as a "non-reusable supply; not rental-type items (§1861(n) of the Act)." The Medicare NCD for *Porcine Skin and Gradient Pressure Dressings* (270.5)^[3] provides *limited* coverage for gradient compression dressings (Jobst dressings) when used to reduce hypertrophic scarring and joint contractures following burn injury.

In 2003, Medicare expanded coverage of gradient compression stockings for individuals with an open venous stasis ulcer that has been treated by a physician or other healthcare professional requiring medically necessary debridement, and when the gradient stocking can be proven to deliver compression greater than 30 mm Hg. and less than 50 mm Hg.^[4] These expanded coverage criteria are included within the LCD for *Surgical Dressings (L33831)*, as well as a companion local coverage article for *Surgical Dressings - Policy Article (A54563)*.

A6531, A6532, and A6545 are eligible for coverage as secondary surgical dressings and not as lymphedema compression treatment items. The article states, "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..." It adds these items are considered non-covered when used for other conditions that have no qualifying wound, including but not limited to, venous insufficiency without stasis ulcers; prevention of stasis ulcers; prevention of the reoccurrence of stasis ulcers that have healed; or treatment of lymphedema in the absence of ulcers.

Due to the non-specific nature of HCPCS code A6549, this code is frequently used to report "custom" or "custom made" items. In order to be considered a customized DME item, the item must be (1) uniquely constructed or substantially modified for a specific beneficiary to the extent it becomes a "one-of-a-kind" item, fabricated to meet specific needs and (2) so different from other items used for the same purpose that they cannot be grouped together for pricing purposes.^[5] Items which are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use (i.e., custom fitted items) or items which have been assembled by a supplier, or ordered from a manufacturer, using available customized features, modifications or components do not meet the definition of "customized" because these items are not uniquely constructed or substantially modified and can be grouped with other items for pricing purposes. Finally, the use of "customized" options, custom ordered options/accessories or custom fitting of certain parts does not result in the equipment being considered as custom DME.

REQUIRED DOCUMENTATION

Compression garment codes that fit within a benefit category are not routinely reviewed. . For HCPCS code A6549 or in the event an advance benefit determination request is received for review of other related items, the information below <u>must</u> be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Order by the treating provider;
- Indication for which the compression is needed;
 - If treatment is for a wound, the type of wound, as well as information regarding the location, number, and size of wound(s) being treated;
- Medical records and chart notes to support medical need;
- For items considered "custom," the item brand name and description, as well as detailing the differences between the customized item vs. prefabricated models;
- Pressure amount as expressed in millimeters of mercury (mmHg);
- Patient limb measurements; and
- A copy of the manufacturer wholesale invoice.
- Name of specific manufacturer and product name/model

Note: A prescription is not considered to be part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information in the medical record. Medical records [e.g., from the treating practitioner, hospitals, nursing facilities, home health agencies, etc.] are the source used to justify payment of DME items. Records from suppliers or healthcare professionals with a financial interest in the claim outcome are **not** considered sufficient by themselves for determining that an item is reasonable and necessary **and** supplier-produced records and attestation letters (e.g., letters of medical necessity) are deemed **not** to be part of a medical record, even if signed by the treating practitioner.^[6]

REGULATORY STATUS

Examples of associated products may include, but are not limited to, the following:

- Gradient compression aids and non-elastic compression garments for upper and lower extremities (e.g., Jobst stockings, ReidSleeve®, CircAid®, ArmAssist®, LegAssist®);
- Lymphedema garments to control excessive accumulation of lymphatic fluid, such as mastectomy sleeves and gradient pressure aids (e.g., glove) and compression garments for the trunk or chest (e.g., JoVi Vest® or Compressure Comfort[®] Bra [Lightning 2 LLC, dba, Bellisse]);
- Antiembolism (surgical or thrombo-embolic-deterrent [TED]) stockings (these may be purchased over the counter, or OTC).

The Medicare PDAC contractor *Product Classification List* can be used for guidance on the correct coding of these items.

The fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Durable Medical Equipment, Prosthetic and Orthotic Upgrades, Replacements, Duplicates, and Repairs, DME, Policy No. 75

<u>General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics and Supplies</u> (DMEPOS), DME, Policy No. M-88

REFERENCES

- 1. MLN Article: *Lymphedema Compression Treatment Items: Implementation* (MM13286); November 27, 2023; Available at: https://www.cms.gov/files/document/mm13286lymphedema-compression-treatment-items-implementation.pdf [Last Cited 12/8/2023]
- Lymphedema Compression Treatment Items Correct Coding and Billing; December 8, 2023; Available at: <u>https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2023/lymphedema-compression-treatment-items-correct-coding-and-billing</u>
- 3. NCD for Durable Medical Equipment Reference List (280.1) (This NCD can be accessed directly from the <u>Medicare Coverage Database</u> website) [Last Cited 12/08/2023]
- 4. NCD for Porcine Skin and Gradient Pressure Dressings (270.5) (This NCD can be accessed directly from the <u>Medicare Coverage Database</u> website) [Last Cited 12/08/2023]
- Medicare Change Request 2739; Coverage of Compression Garments in the Treatment of Venous Stasis Ulcers; June 20, 2003; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/AB03090.pdf [Last Cited 12/08/2023]
- 6. Customized items; CFR §414.224(a)
- Noridian article for Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426) (This article can be accessed directly from the <u>Medicare Coverage</u> <u>Database</u> website) [Last Cited 12/08/2023]

CODING

NOTE: The Medicare PDAC contractor's (Palmetto GBA) <u>Product Classification List</u> website can be viewed for guidance on the correct coding of some of these items. While they may not be subject to routine medical necessity review, products which the PDAC has assigned HCPCS codes not addressed by this medical policy, providers are expected to follow Medicare's medical reasonable and necessary requirements detailed within any applicable NCD, LCD and/or article. Utilization may be subject to audit.

Codes	Number	Description
CPT	None	
HCPCS	A6520	Gradient compression garment, glove, padded, for nighttime use, each
	A6521	Gradient compression garment, glove, padded, for nighttime use, custom, each
	A6522	Gradient compression garment, arm, padded, for nighttime use, each
	A6523	Gradient compression garment, arm, padded, for nighttime use, custom, each
	A6524	Gradient compression garment, lower leg and foot, padded, for nighttime use, each
	A6525	Gradient compression garment, lower leg and foot, padded, for nighttime use, custom, each
	A6526	Gradient compression garment, full leg and foot, padded, for nighttime use, each
	A6527	Gradient compression garment, full leg and foot, padded, for nighttime use, custom, each
	A6528	Gradient compression garment, bra, for nighttime use, each
	A6529	Gradient compression garment, bra, for nighttime use, custom, each
	A6530	Gradient compression stocking, below knee, 18-30 mm Hg, each
	A6531	Gradient compression stocking, below knee, 30-40 mm Hg, each, used as a surgical dressing
	A6532	Gradient compression stocking, below knee, 40-50 mm Hg, each, used as a surgical dressing
	A6533	Gradient compression stocking, thigh length, 18-30 mm Hg, each
	A6534	Gradient compression stocking, thigh length, 30-40 mm Hg, each
	A6535	Gradient compression stocking, thigh length, 40 mmHg, or greater, each
	A6536	Gradient compression stocking, full-length/chap style, 18-30 mm Hg, each
	A6537	Gradient compression stocking, full-length/chap style, 30-40 mm Hg, each
	A6538	Gradient compression stocking, full-length/chap style, 40 mmHg, or greater, each
	A6539	Gradient compression stocking, waist length, 18-30 mm Hg, each
	A6540	Gradient compression stocking, waist length, 30-40 mm Hg, each
	A6541	Gradient compression stocking, waist length, 40 mmHg or greater, each
	A6544	Gradient compression stocking, garter belt
	A6545	Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each, used as a surgical dressing
	A6549	Gradient compression garment not otherwise specified
	A6552	Gradient compression stocking, below knee, 30-40 mm Hg, each
	A6553	Gradient compression stocking, below knee, 30-40 mmhg, custom, each
	A6554	Gradient compression stocking, below knee, 40 mm Hg or greater, each
	A6555	Gradient compression stocking, below knee, 40 mmhg or greater, custom, each
	A6556	Gradient compression stocking, thigh length, 18-30 mmhg, custom, each
	A6557	Gradient compression stocking, thigh length, 30-40 mmhg, custom, each
	A6558	Gradient compression stocking, thigh length, 40 mmhg or greater, custom, each

	Gradient compression stocking, full length/chap style, 18-30 mmhg, custom, each
A6560 0	Gradient compression stocking, full length/chap style, 30-40 mmhg, custom, each
A6561 0	Gradient compression stocking, full length/chap style, 40 mmhg or greater,
	custom, each Gradient compression stocking, waist length, 18-30 mmhg, custom, each
	Gradient compression stocking, waist length, 30-40 mmhg, custom, each
	Gradient compression stocking, waist length, 30-40 mming, custorn, each Gradient compression stocking, waist length, 40 mmhg or greater, custom,
(each
	Gradient compression gauntlet, custom, each
	Gradient compression garment, neck/head, each
	Gradient compression garment, neck/head, custom, each
	Gradient compression garment, torso and shoulder, each
	Gradient compression garment, torso/shoulder, custom, each
	Gradient compression garment, genital region, each
	Gradient compression garment, genital region, custom, each
A6572 0	Gradient compression garment, toe caps, each
A6573 0	Gradient compression garment, toe caps, custom, each
A6574 0	Gradient compression arm sleeve and glove combination, custom, each
A6575 0	Gradient compression arm sleeve and glove combination, each
A6576 0	Gradient compression arm sleeve, custom, medium weight, each
A6577 0	Gradient compression arm sleeve, custom, heavy weight, each
A6578 0	Gradient compression arm sleeve, each
A6579 (Gradient compression glove, custom, medium weight, each
A6580 (Gradient compression glove, custom, heavy weight, each
A6581 (Gradient compression glove, each
A6582 (Gradient compression gauntlet, each
	Gradient compression wrap with adjustable straps, below knee, 30-50 mm Hg, each
	Gradient compression wrap with adjustable straps, not otherwise specified
	Gradient pressure wrap with adjustable straps, above knee, each
	Gradient pressure wrap with adjustable straps, full leg, each
	Gradient pressure wrap with adjustable straps, foot, each
	Gradient pressure wrap with adjustable straps, arm, each
	Gradient pressure wrap with adjustable straps, bra, each
	Foot pressure off loading/supportive device, any type, each (Noncovered
	by Medicare)
	Accessory for gradient compression garment or wrap with adjustable
	straps, not-otherwise specified
	Gradient compression bandaging supply, bandage liner, lower extremity,
	any size or length, each
	Gradient compression bandaging supply, bandage liner, upper extremity,
	any size or length, each
	Gradient compression bandaging supply, conforming gauze, per linear
	yard, any width, each

A6597	Gradient compression bandage roll, elastic long stretch, linear yard, any width, each
A6598	Gradient compression bandage roll, elastic medium stretch, per linear yard, any width, each
A6599	Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each
A6600	Gradient compression bandaging supply, high density foam sheet, per 250 square centimeters, each
A6601	Gradient compression bandaging supply, high density foam pad, any size or shape, each
A6602	Gradient compression bandaging supply, high density foam roll for bandage, per linear yard, any width, each
A6603	Gradient compression bandaging supply, low density channel foam sheet, per 250 square centimeters, each
A6604	Gradient compression bandaging supply, low density flat foam sheet, per 250 square centimeters, each
A6605	Gradient compression bandaging supply, padded foam, per linear yard, any width, each
A6606	Gradient compression bandaging supply, padded textile, per linear yard, any width, each
A6607	Gradient compression bandaging supply, tubular protective absorption layer, per linear yard, any width, each
A6608	Gradient compression bandaging supply, tubular protective absorption padded layer, per linear yard, any width, each
A6609	Gradient compression bandaging supply, not otherwise specified
A6610	Gradient compression stocking, below knee, 18-30 mmhg, custom, each
L8010	Breast prosthesis, mastectomy sleeve

*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.