

How Are Compression Bandages, Garments, Devices and Supplies Coverable under the Social Security Act?

Revision 8 August 27, 2019

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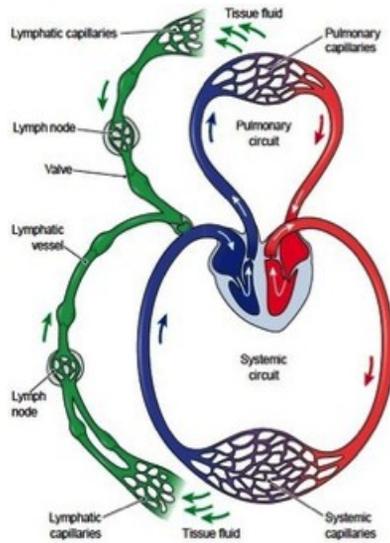
My name is Robert Weiss. I am the spouse of a 27-year survivor of breast cancer who has lymphedema of the right arm as a sequela of her cancer treatment. I have been a lymphedema treatment advocate and activist for over twenty years, advocating for better access to quality treatment of lymphedema for my spouse, and for the 3 million other Americans with, or at risk for, lymphedema.

I am a retired aerospace engineer on fixed income, and derive no benefit from any of the manufacturers of lymphedema medical items, from any physician or therapist, or from any charitable or for-profit organization or foundation for my work.

I have completed 80 hours of lymphedema therapy training with the Dr. Vodder School of North America (2003), am a graduate of the National Breast Cancer Coalition's Project LEAD (2004) and Quality Care LEAD (2007), the National Lymphedema Network's Lymph Science Advocacy Program (2002 and 2004) and was designated Adjunct Courtesy Faculty, University of Missouri Sinclair School of Nursing (2011-2012), and have authored or co-authored a number of peer-reviewed papers on lymphedema treatment.

I assist a limited number of Medicare beneficiaries in using the Medicare appeal procedures to obtain reimbursement for the compression garments they use daily in the medical treatment of their lymphedema. I receive no payment whatsoever for my services. I am also working with the Centers for Medicare and Medicaid Services in developing and changing national and local coverage policy and interpretation of Medicare regulations relating to the narrow field of lymphedema treatment.

The Circulatory & Lymphatic Systems



Circulation system is closed system.

Fluid moves by virtue of a central pump (heart).

Blood pumped from the heart through arteries to capillary beds where arterial capillaries join continuously with venous capillaries and then through veins back to the heart.

The venous system contains valves that prevent backflow.

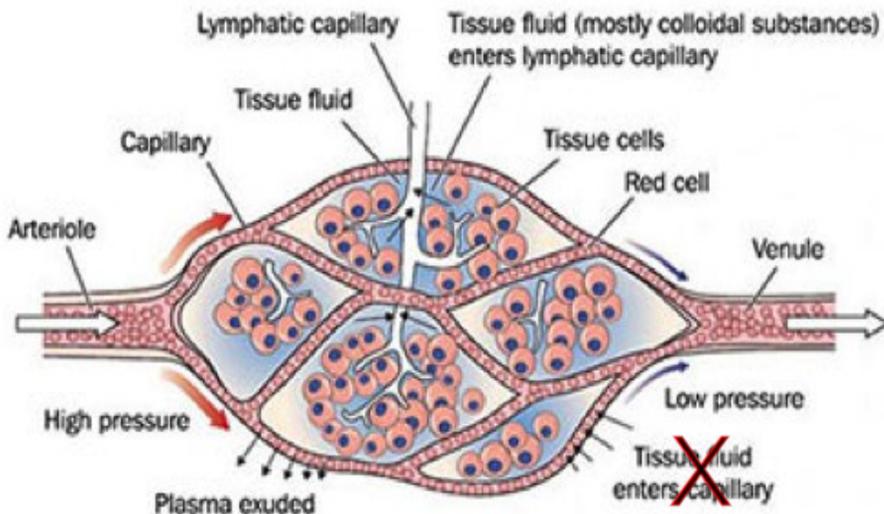
Approximately 10% of the fluid filtrates into the tissue from arterial capillaries.

All tissue fluid returns to the heart through the lymphatic system.

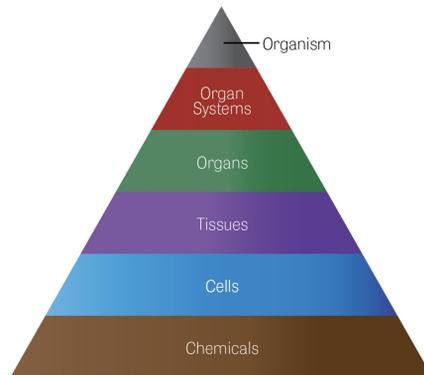
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Capillary bed drainage by lymphatic capillary



Lymphatic Collectors and Lymphangions (Lymph Vessels) are Internal Body Organs



Pyramid represents a hierarchical organization of human body components (<https://toxtutor.nlm.nih.gov/08-003.html>)

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Organ — a group of tissues precisely arranged so that they can work together to perform specific functions.

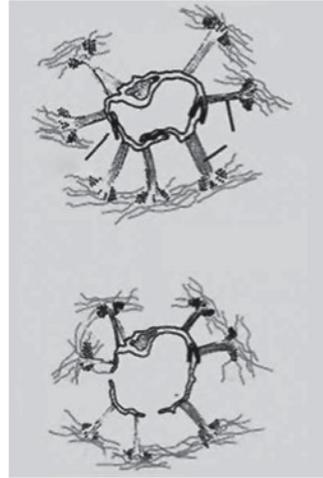
Organ System	Functions	Organs
Lymphatic	<ul style="list-style-type: none"> •Returns tissue fluid to blood •Defends against foreign organisms 	<ul style="list-style-type: none"> •Spleen •Lymph nodes •Thymus •Lymphatic vessels

How the group of different tissues (epithelial, connective, muscle, and nerve) work together as an organ to perform the lymph collection and transport is discussed in **Lymphatic pumping: mechanics, mechanisms and malfunction**, Joshua P. Scallan, et al., *J. Physiology*, 2016; 594.20:5749-5768.

“Lymphatic pump function is essential for normal lymph transport, particularly in dependent extremities. Pump function is determined by the intrinsic properties of lymphatic muscle, which is regulated by lymphatic preload, afterload, spontaneous contraction rate, contractility and neural influences. In addition, normal pump function depends on a coordinated lymphatic muscle cell contraction wave, and proper lymphatic endothelial cell valve and barrier function.”

Microstructure of Lymphatic Capillaries in the Skin

- Lymphatic capillaries are irregular shaped and stay collapsed.
- When the interstitial fluid pressure increases because of fluid accumulation, the anchoring filament bundles pull lymphatic endothelial cells and open up the cell-cell junctions so that the lymph fluids can enter the lumen of lymphatic vessels for transport.
- Source Choi I, Lee S & Hong Y-K, *Cold Spring Harb Perspect Med* 2012; 2:a006445
- (Illustration modified from Skobe and Detmar 2000.)



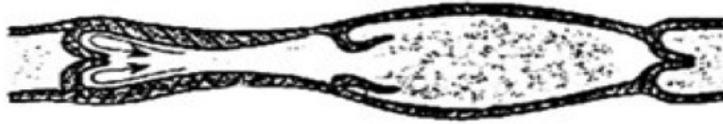
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“There is substantial evidence that with important exceptions such as the renal cortex and medulla, downstream microvessels are not in a state of sustained fluid absorption as traditionally depicted. Although doggedly persistent in textbooks and teaching, the traditional view of filtration–reabsorption balance has little justification in the microcirculation of most tissues. Tissue fluid balance thus depends critically on lymphatic function in most tissues.”

[Microvascular fluid exchange and the revised Starling Principle
J. Rodney Levick¹ and C. Charles Michel *Cardiovasc Res.*
2010;87(2):198-210.]

Structure and Function of the Lymphangion



Mechanical

- Elastic tube about 200um diameter
- Unidirectional valve at each end controlled by pressure
- Suspended from basal tissue by elastic collagen filaments*
- Generally runs in parallel bundles with arteries & veins

Neural and Hormonal

- Autonomous synchronized rhythmic pulsing (“little hearts”)
- Coordinated with pulsing of neighbors
- Internal sensing of state of stretch/fluid pressure/fluid flow
- Intrinsic and extrinsic pumping mechanisms

Ejection Fraction about 60%

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Recent scientific investigations have shown that the lymphatic system, rather than being a static set of drain pipes conducting lymph that is driven by external muscle pulses and static pressure gradients, is a dynamic system. “The principal task of the lymphatic vascular system is transport. The body must impart energy to the lymph via pumping mechanisms to propel it along the lymphatic network and use pumps and valves to generate lymph flow and prevent its backflow. The lymphatic system utilizes both extrinsic pumps, which rely on the cyclical compression and expansion of lymphatics by surrounding tissue forces, and intrinsic pumps, which rely on the intrinsic rapid/phasic contractions of lymphatic muscle. The intrinsic lymph pump function can be modulated by neural, humoral, and physical factors.”

[**Contractile Physiology of Lymphatics**, David C. Zawieja, *Lymphatic Research and Biology*, 2009; 7(2):87-96].

What Is Lymphedema?

Lymphedema is the accumulation of fluid, typically in one part of the body, caused by inadequate collection and transport of interstitial fluid.

Lymphedema can be caused by:

- Interruption of drainage network
 - Surgical removal of nodes and/or lymphangions
 - Scar tissue or cancer blocking flow
 - Inadequate regeneration of functional lymphatic network
- Impaired functionality of lymphatic system
 - Nerve damage enervates lymphatics
 - Fibrosis of collagen filamentary supports
 - Fibrosis or removal of lymphovenous anastomoses
 - Venous hypertension

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What Is Lymphedema?

Lymphedema is an abnormal collection of high-protein fluid just beneath the skin. This swelling, or edema, occurs most commonly in the arm or leg, but it also may occur in other parts of the body including the breast or trunk, head and neck, or genitals. Lymphedema usually develops when lymph vessels are damaged or malfunctioning, or lymph nodes are removed (secondary lymphedema) but can also be present when lymphatic vessels are missing or impaired due to a hereditary condition (primary lymphedema).

Lymphatic fluid is normally transported out of a region of the body by an extensive network of lymph vessels. When the collection of protein-rich fluid persists in a specific area, it can attract more fluid and thus worsen the swelling. In addition to increased fluid in the area, the body experiences an inflammatory reaction resulting in scar tissue called fibrosis in the affected area. The presence of fibrosis makes it even more difficult for the excess fluid to be eliminated from the area. As a result, the increased fluid and fibrosis prevents the delivery of oxygen and essential nutrients to the area, which in turn can delay wound healing, provide a culture medium for bacteria to grow, and increase the risk of infections in or below the skin called cellulitis or lymphangitis.

National Lymphedema Network

<http://www.lymphnet.org/le-faqs/what-is-lymphedema>

Key Take-Away Points Re: Lymphedema

- Lymphedema is caused by inadequate collection and transport of interstitial fluid.
- Lymphedema is not just a “blockage”, but is commonly due to inability of lymphangions to collect and “pump” lymph through the lymphatic system.
- Lymphedema is a “syndrome” and not a “symptom”
 - Syndrome: a group of signs and symptoms that occur together and characterize a particular abnormality or condition [Merriam-Webster]
 - Swelling, proliferation of connective tissue (fibrosis) and lipids (fat cells), inflammation, immunodeficiency, skin degeneration.
- The goals of lymphedema treatment is to restore the defective functions of collection and transport of lymph to still-functioning portions of the lymphatic system, where they can be filtered, broken down, and returned to the circulatory system, and to prevent re-accumulation of interstitial fluid.

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The compression garment’s primary function is to reduce the edema associated with lymphedema and to encourage the flow of lymph fluid out of the affected limb.

Lymphedema, or lymph stasis, is a *syndrome*, and not a *symptom*. Treatment involves assistance of the deficient lymphatic system in its major function of collecting and transporting the collected fluid to other parts of the body with normally operating lymphatic and vascular functions, and to prevent re-accumulation of tissue fluid. These and other functions of compression in the replacement of *the function* of a partially non-functional lymphatic system are described in detail with medical citations on pages 29-31.

The medical mechanism of action of compression in treatment of lymphedema is directed towards restoring the ability of the lymphatic system *to collect and transport interstitial fluid/lymph. This is the function of the lymphangions, or lymph vessels*, and not a function of the nodes. Compression enables the lymphatic system to collect and transport lymph to areas of the body where the lymph can be processed by nodes that are functional. Reduction of swelling is known to reduce inflammation and proliferation of connective and fat tissue—a key to preventing progression of this condition.

That CMS considers compression garments to be a valid treatment of diagnosed lymphedema [syndrome] is illustrated by the requirement for four weeks of “conservative therapy” including compression bandage system or compression garments before approving coverage of a pneumatic compression device.

Standard of Lymphedema Treatment: Complex Decongestive Therapy (CDT)

- Manual Lymph Drainage (MLD)
 - Specially-trained Therapist
- Compression Therapy
 - Bandage System when required, day or night
 - Non-Elastic Compression Sleeve at night
 - Compression Garment during day
- Exercise Program
 - Range of Motion, Strength, Decongestive
- Skin Care

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* Rockson SG, Miller LT, et. al: **“Workgroup III:Diagnosis and Management of Lymphedema”** *Cancer* Dec 15, 1998;83(12 Supplement):2882-5.

* International Society of Lymphology, Executive Committee: **“The Diagnosis and Treatment of Peripheral Lymphedema, Consensus Document”** *Lymphology*, Mar 1995;28:113-7. Updated in *Lymphology*, 2003;36(2):84-91.

* National Cancer Institute: **“Lymphedema (PDQ®) Health Professional Version”**
Updated 07/17/15 URL

http://www.cancer.gov/about-cancer/treatment/side-effects/lymphedema/lymphedema-hp-pdq#section_1
[Accessed 7/11/16].

* National Lymphedema Network: **“Position Statement of the National Lymphedema Network: Treatment”** issued August 10, 2006 and updated February 2011 URL

<http://www.lymphnet.org/pdfDocs/position.papers/Diagnosis.Treatment.pdf>

* **Lymphedema Framework. Best Practice for the Management of Lymphoedema, International consensus, London, MEP Ltd. 2006** Endorsed by the International Society of Lymphology, American Society of Lymphology, National Lymphedema Network, Lymphology Association of North America and a dozen other international organizations.

* Lawenda BD, Mondry TE & Johnstone PAS: **“Lymphedema: A primer on the identification and management of a chronic condition in oncologic treatment”** *CA Cancer J Clin* January 2009;59;8-24.

Need for Compression after MLD

- Manual lymph drainage (MLD) is the most efficacious modality for reducing lymphatic swelling.
- Benefits of MLD are temporary. Limb is placed under compression after MLD to prevent re-swelling.
- “Gold Standard” of compression is binding with short-stretch bandage system.
- Exercise with compression bandages provides additional lymphatic decongestion.
- Non-elastic compression is needed during inactive times.
- Elastic (circular knit) compression is commonly used during the day

*According to the CMS expert Lymphedema Committee, there is intermediate confidence that CDT, CDT with adjuvant pneumatic compression devices (PCDs), **compression bandaging/compression garments**, and PCDs alone “produce clinically meaningful improved health outcomes for patients with secondary lymphedema.” [MEDCAC Meeting on Lymphedema Nov 11, 2009]*

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Lymphedema Framework. Best Practice for the Management of Lymphoedema, International consensus, London, MEP Ltd. 2006

“Multi-layer systems followed by compression garments are more effective than single layer compression garments when used in the initial phase of lymphoedema treatment” [Badger, Peacock & Mortimer 2000]

Position Statement of the National Lymphedema Network

Topic TREATMENT

Compression Garments

Following maximal volume reduction with Phase I CDT, patients should be fitted with a compression garment. **Properly fitted garments are essential for long-term control of LE volume.** Garment style and compression strength should be prescribed to enhance patient compliance and volume control. Garments should be washed regularly to maximize the garment’s longevity and effectiveness. **Garments must be replaced at regular intervals.**

CIGNA Medical Coverage Policy Number 0076,

Complex Lymphedema Therapy (Complete Decongestive Therapy)

Effective Date 12/15/2008

In Phase II, the patient maintains and optimizes the results by applying the techniques learned in the treatment phase, as well as by wearing an elastic sleeve during the day, bandaging the affected limb overnight and exercising for 15 minutes per day while wearing the bandages (Petrek, 2000).

Issues to be Considered On Appeal

- Whether Medicare reimbursement is warranted for compression garments under Medicare Part B, i.e.:
 - Whether the compression garments when used in the treatment of lymphedema meet the coverage criteria for “prosthetic devices” benefits
 - Whether the lymphedema compression garments are reasonable and medically necessary in the medical treatment of chronic lymphedema
 - Whether Medicare regulations provide coverage for replacement compression garments for treatment of lymphedema when determined by a physician to be medically necessary.

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DME MAC Jurisdiction A Supplier Manual Chap. 12 Medical Review Local Coverage Determinations

“An item or service may be covered by Medicare if it meets all of the following conditions:

- It is **one of the benefit categories** described in Title XVIII of the Act
- It is **reasonable and necessary** under Section 1862(a)(1) of the Act”
- It is **not excluded** by Title XVIII of the Act, other than Section 1862(a)(1)

“The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in your favor.” [20 C.F.R. 404.946(a), 42 C.F.R. 404.1032(a)]

The essential issue to be determined is “**Whether the compression garment(s) used in the treatment of the Beneficiary’s lymphedema are covered as “prosthetic devices” as defined in §1861(s)(8) of Title XVIII of the SSA as interpreted in CMS Publication 100-02, Chapter 15, §120**”. All other coverage considerations depend on the resolution of this issue, since the benefit category of the item(s) in dispute will determine which NCD or LCD coverage criteria are to be applied.

Statutory Medicare Benefit Categories Relevant to Lymphedema Treatment

- Title XVIII of the Social Security Act (SSA) confers Medicare benefits to individuals for “medical and other health services” as defined in section 1861 and not excluded by section 1862.
- Sections 1861(g)(p) and (s) establish definitions for services, institutions, and other Medicare terms, including the following:
 - (g) Outpatient Occupational Therapy Services
 - (p) Outpatient Physical Therapy Services
 - (s) Medical and Other Health Services
 - (1) Physicians’ services
 - (5) Surgical dressings, splints and casts
 - (6) Durable medical equipment
 - (8) *Prosthetic devices*
 - (9) Orthotics and Prosthetics
- Section 1862(a)(1)(A) excludes services that are not “*reasonable and medically necessary*” for the diagnosis or treatment of illness or injury or to *improve the functioning of a malformed body member*”

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SELECTED SECTIONS FROM TITLE XVIII OF THE SOCIAL SECURITY ACT

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. [42 U.S.C. 1395y] (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services--

(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or **treatment of illness or injury** or to improve the functioning of a malformed body member,

•Social Security Act, Title XVIII, Section 1861(g) Outpatient Occupational Therapy Services

(g) The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

•Social Security Act, Title XVIII, Section 1861(p) Outpatient Physical Therapy Services

(p) The term "outpatient physical therapy services" means **physical therapy services** furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient--

•Social Security Act, Title XVIII, Section 1861(s): Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(8) **prosthetic devices** (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices...

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

Flow Down of Statutory Requirements

BENEFIT CATEGORY AUTHORITY	STATUTORY DMEPOS BENEFIT CATEGORIES			
	SURGICAL DRESSING S, SPLINTS, CASTS	DURABLE MEDICAL EQUIPMENT	PROSTHETIC DEVICES	PROSTHETICS AND ORTHOTICS
Title XVIII Social Security Act	§1832(a)(1) §1861(s)(5)	§1832(a)(1) §1861(s)(6) §1861(n)	§1832(a)(2)(l) §1861(s)(8)	§1832(a)(2)(l) §1861(s)(9)
Code of Federal Regulations 42 CFR	§410.36(a)(1)	§410.38 §414.202 DME	§410.36(a)(2) §414.202 POD(1)	§410.36(a)(3) §414.202 POD(3)
Benefit Policy Manual Pub. 100-02, Ch. 15	§100	§110 §110.1	§120	§130
NCD Manual Pub. 100-03	§270	§280.1	§§20, 50, 80, 160, 180, 230	
Claims Process. Man. Pub. 100-04, Ch. 20		§10.1.1	§10.1.2	§10.1.3
Example Local Coverage Determinations (LCDs)	L33831	L33829 L33739	L33317 L33798	L33318 L33686 L33737
HCPCS Code Group	A-Code, S-Code	E-Code	L-Code, S-Code	L-Code

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Title XVIII of the Social Security Act confers Medicare benefits. “Benefits provided to an individual” consist of “medical and other health services” which are defined in §1861 [§1832(a) and (b)] and which are not excluded by §1862, i.e. “items which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” [§1862(a)(1)(A)]

Statutory references to the four benefit categories relevant to this case are summarized in the Table together with the CMS Program Manuals and NCDs which allocate and expand the statutory requirements to implementation instructions. These regulations and relevant NCDs (but not LCDs) are binding on all Medicare Contractors, QICs and ALJs. [42 C.F.R. §405.860(a)].

The NCDs and other program policies cited in the Table are all concerned with coverage within a benefit category, and trace their coverage criteria and instructions to the top-level benefit in the Social Security Act (SSA).

A coverage determination establishing coverage criteria for the items in one benefit category can exclude coverage of items in that category because they do not meet the criteria for that benefit category, but it cannot exclude coverage of an item covered in a different category. Even within the same benefit category, there is a distinction between different functional utilization, e.g. the criteria for use of compression stockings for the treatment of venous ulcers are not applicable to the use of compression stockings for the treatment of burns.

Examples of LCDs and LCAs Traceable to the Social Security Act

Examples from Noridian Administrative Services (DME MAC D)

BENEFIT CATEGORY	SSA §	Brief Title	LCD	LCA	CODE
Surgical Dressings	1861(s)(5)	Surgical Dressings	L11460	A23903	A
Durable Medical Equipment	1861(s)(6)	Pneu. Compression Devices	L11492	A37075	E
		External Infusion Pumps	L11570	A19834	E,A,K,
Prosthetics & Orthotics	1861(s)(9)	Orthopedic Footwear	L11456	A35426	L
		Facial Prostheses	L11571	A25364	L
Prosthetic Devices	1861(s)(8)	Enteral Nutrition	L11568	A25361	B
		Parenteral Nutrition	L11576	A37077	B
		External Breast Pros.	L11569	A19833	L
		Ostomy Supplies	L11491	A25375	A
		Tracheostomy Supplies	L166	A33680	A
		Urological Supplies	L11581	A25377	A
Therapeutic Shoes Diabetes	1861(s)(12)	Therapeutic Shoes	L157	A37076	A

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The authority for prosthetic devices is traceable back to the Social Security Act §1861(s)(8) through the Medicare Benefit Policy Manual, CMS Publication 100-02, Chapter 15, §120.

HCPCS Codes, however, are not unique for this benefit category, but may follow the form of the particular device rather than its function. This leads to the erroneous situation where coverability of an item is tested based on its form rather than its medical function.

Function, Not Form, Determines Benefit Category and HCPCS Code Group

- The Social Security Act defines *benefit categories* in terms of *medical function*, for example:
 - §1861(s)(5) “...used for reduction of fractures and dislocations;”
 - §1861(s)(8) “...which replace all or part of an internal organ...”
 - §1861(n) “...used as a wheelchair...”, “...used in the patient’s home...”
- HCPCS codes are generally, but not always, grouped by *benefit categories*
- Coverability of a specific item is determined by whether it meets the *functional requirements* defined in the SSA or in interpretive CMS publications, and not by its HCPCS code.

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CMS guidelines on the Coverage of Compression Garments recognize Medical Function, to Distinguish between Benefit Categories. Examples:

1. Program Memorandum Transmittal AB-03-090 June 30, 2003 and LCD L11471 for Below-the-Knee length Compression Stockings used as secondary surgical dressings in the treatment of Venous Stasis Ulcers in accordance with SSA §1861(s)(5)

Coverage of Compression Garments in the Treatment of Venous Stasis Ulcers outlines coverage criteria for compression stockings when used in the treatment of venous stasis ulcers. Stockings used in this function were classified as prosthetic devices and given an HCPCS designation as L8110 and L8120 [later changed to A6531 and A6532 respectively]

2. LCD L11471 for Compression Garments used in treatment of Burns as Surgical Dressings in accordance with SSA §1861(s)(5)

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. In this function they are given the HCPCS code group COMPRESSION BURN GARMENTS (A6501-A6513).

3. The above two coverage descriptions are *permissive* in that they describe the functional uses of compression garments which meet coverage criteria under the surgical dressing benefit category. They are not *prohibitive* in that they do not prohibit coverage when used in other medical functions and fall into different benefit categories. The same comments hold with respect to LCD L11449/Article A24114 Surgical Dressings

4. There is no LCD or NCD concerning coverage of Compression Garments used for treatment of Lymphedema as prosthetic devices in accordance with SSA §1861(s)(8).

Function, Not Form, Determines Coverability Within a Benefit Category

- A specific item might meet the functional requirements of multiple benefit categories or none. Consider the functions of a compression garment:
 - Covered as a secondary *wound dressing* (Axxxx) [ICD-9-CM: 870-897]
 - Covered as a *burn dressing* (Axxxx) [ICD-9-CM: 940-949]
 - Covered as part of *lymphedema* pump (Exxxx) [ICD-9-CM: 457, 757]
- When an item fails to meet the functional coverage requirements for a particular benefit category it can be excluded because of its failure to meet the coverage criteria for that benefit category:
 - Non-covered as a *leg brace* (fabric supports not covered orthotics)
 - Non-covered as *durable medical equipment* (not rentable)
 - Non-covered for *leg fatigue* (not medically necessary)
- When an item meets the functional requirements of a prosthetic device it should be covered:
 - Compression therapy for *lymphedema* (Lxxxx) [ICD-9-CM: 457, 757]
- There is no NCD concerning coverage or non-coverage of compression garments used for treatment of lymphedema as prosthetic devices in accordance with SSA section 1861(s)(8)

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MLN Matters Number: MM6297 Related Change Request Number: 6297 12/23/08

“Medicare Coverage of Elastic Support Garments

We have received questions regarding coverage of elastic support garments as leg, arm, back, or neck braces (orthotics). The *definition of a brace* in **section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02)** specifies that:

A brace includes rigid and semi-rigid devices which are **used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body**. Elastic stockings, garter belts, and similar devices *do not come within the scope of the definition of a brace*.

Elastic garments or devices in general **do not meet the definition of a brace because they are not rigid or semi-rigid devices**. This includes devices that include stays that do not provide sufficient pressure to restrict or eliminate motion in the body part. While elastic devices may provide compression or warmth to a leg, arm, back, or neck, if they do not restrict or eliminate motion in a diseased or injured part of the body, then they may not be covered **as braces**.”

In section 280.1 of the Medicare National Coverage Determination Manual (Pub. 100-03) Elastic Stockings are listed as **not covered as Durable Medical Equipment** because they are **not rental-type items per §1861(n)** even though they meet all other definitions of DME in §1861(s)(6).

But these same Elastic Support Garments are covered when used as secondary dressings or as burn coverings since they meet the coverage criteria for Surgical Dressing when used in a different medical function. See previous page.

Coverage in the Absence of an Applicable NCD or LCD or Article

- The DME MACs and ZPICs have the authority to review any claim even if there is no formal national or local policy.
- In those situations, the contractor first determines whether the item falls within a statutory benefit category that is within its jurisdiction.
- If it is, then the reviewer determines whether the item is reasonable and necessary for the individual patient.
- This may include a review of pertinent medical literature.
- It also includes review of detailed documentation from the ordering physician/practitioner and supplier supporting the medical necessity of the item.

Ref. DME MAC J-G, Supplier Manual, Chapter 9, Coverage and Medical Policy

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Medicare National Coverage Determination Manual, Chapter 1, Part 1, Section A Purpose

The statutory and policy framework within which National Coverage Decisions are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The National Coverage Determinations Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on §1862(a)(1) of the Act (the “not reasonable and necessary” exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the sole authority for denial. Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. *Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, **based on the law,** regulations, rulings and general program instructions*

Additional Policy Guidance

- Special Circumstances and Individual Consideration
 - If there is no NCD that applies, then special circumstances can be considered. Types of information which may be considered that may be pertinent are:
 - Diagnoses relating to item need
 - Complicating medical conditions
 - Functional abilities and limitations
 - Rehabilitation potential
 - Duration of the condition
 - Overall course (improving or worsening)
 - Prognosis
 - Description of and response to prior treatment
 - Experience with similar items
 - Test results

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DME MAC Jurisdiction C Supplier Manual, Chapter 9, Coverage and Medical Policy

SPECIAL CIRCUMSTANCES/INDIVIDUAL CONSIDERATION

Medical policies are constructed to address the rule, not the exception. Unless there is a National Coverage Determination which provides absolute limits of coverage, special circumstances may be considered. These situations require detailed documentation from the ordering physician and supplier supporting the medical necessity of the item in the individual case.

Types of information (not all-inclusive) that may be pertinent are diagnosis relating to the need for the item, complicating medical conditions, functional abilities and limitations, duration of the condition, overall course (improving or worsening), rehabilitation potential (including recent prior functional level), prognosis, description of and response to prior treatment, experience with similar items, physical examination findings, test results, etc.

Medical Necessity

- Patient diagnosed with Lymphedema by treating physician
- Lymphedema treatment protocols are established, and must be shown to be appropriate for individual patient
- Efficacy of compression for treatment of lymphedema is well established
- Medical necessity for compression garments established by treating physician and qualified lymphedema therapist
- Items prescribed for treatment of diagnosed lymphedema by treating physician
- Medical necessity for compression garments used in the treatment of lymphedema is recognized in Lymphedema Pump NCD [Notes]
- United States ALJs in many states have held that these items are reasonable and medically necessary
- **Compression garments are therefore held to meet the requirements of and are not excluded by section 1862(a)(1)(A)**

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Relevant References

- Yasuhara et. al. 1996; Pappas & O'Donnell 1992; Ko et. al. 1998 [efficacy of compression garments in the treatment of lymphedema.]
 - H. Partsch and M. Jünger, The Lymphoedema Framework. Template for Practice. Compression Hosiery for Lymphoedema, London MEP Ltd., 2006 [clinical evidence of the efficacy of compression stockings in the treatment of lymphedema.]
 - Medicare NCD Manual, Ch. 1, Pt. 4 Coverage Determinations § 280.6 – Pneumatic Compression Devices (Rev. 1, 10-03-03); Medicare Coverage Issues Manual, Section 60-16: “Pneumatic compression devices are covered . . . for the treatment of lymphedema if the patient has undergone . . . conservative therapy . . . The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.”
- The medical necessity of compression is here recognized by Medicare as a mandatory component of conservative lymphedema therapy [i.e. medically necessary] before coverage of a pneumatic pump.***

Benefit Category

- Not all reasonable and medically necessary items are covered by Medicare. Items must fall into a covered benefit category defined in the Social Security Act.
- Compression garments when used in treatment of lymphedema meet all of the requirements of section 1861(s)(8) Prosthetic Devices as interpreted by CMS in Pub. 100-02, Chap. 15, §120 Prosthetic Devices
- **Prosthetic devices** are a benefit category **different from** surgical dressings, **prosthetics**, orthotics or durable medical equipment.
- The crux of the issue is that coverage denials and appeal denials cannot be based on these items as belonging to other, inapplicable benefit categories. Their denial on the basis of not meeting the requirements of an inapplicable category is illogical.

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Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, §120 Prosthetic Devices

Prosthetic devices are items which replace all or part of an internal body organ or *replace all or part of the function of a permanently inoperative or malfunctioning internal body organ*. The test of permanence is considered met if the medical record, including the judgment of the attending physician, indicates that the condition is of long and indefinite duration.

In addition to artificial arms and legs, coverage under this benefit includes, but is not limited to, breast prostheses, eye prostheses, parenteral and enteral nutrition, ostomy supplies, urological supplies in patients with permanent urinary incontinence, and glasses or contact lenses in patients with aphakia or pseudophakia.

Supplies that are necessary for the effective use of a medically necessary prosthetic device are covered. Equipment, accessories and supplies (including nutrients) which are used directly with an enteral or parenteral nutrition device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device are covered.

Repairs, adjustments and replacement of medically necessary prosthetic devices are covered. Dental prostheses (i.e., dentures) are excluded from coverage. Claims for internal prostheses (e.g., intraocular lens, joint implants, etc.) are not processed by the DME MAC.

Statutory Authority—Prosthetic Devices

- Social Security Act, Title XVIII
 - §1832(a)(2)(l) prosthetic devices, prosthetics, orthotics
 - §1833(a) payment of benefits
 - §1834(h)(5)(C) payment for prosthetic devices and prosthetics and orthotics
 - §1861(s)(8) definition of prosthetic devices
- Code of Federal Regulations
 - 42 C.F.R. §414.202 Definitions
 - 42 C.F.R. §410-36(a)(2) payment for prosthetic devices
- National Coverage Determinations
 - (none relating to compression garments as prosthetic devices)
- CMS Manual System
 - Pub. 100-02, Ch. 15, §120 Prosthetic Devices
- DME MAC Jurisdiction D Supplier Manual
 - Chapter 9 Local Coverage Determinations (LCDs) and Policy Articles relating to DMEPOS Claims

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National Coverage Determinations relating to Prosthetics and Prosthetic Devices (NCDs Pub. 100-03, Ch. 1)

20.8	[cardiac pacemakers]
20.9	[artificial hearts]
50.2	[electronic speech aids]
50.3	[cochlear implantation]
50.4	[tracheostomy speaking valve]
80.4	[hydrophilic contact lenses]
80.5	[schleral shell]
160.7	[electrical nerve stimulators]
180.2	[nutritional therapy]
230.10	[incontinence control devices]
230.15	[electrical continence aid]
230.16	[bladder stimulators]
230.17	[urinary drainage bags]

Note that prosthetic devices may be internal implanted replacements or they may be external. If internal they are covered as part of the surgical implantation procedure, and if external they are covered as DMEPOS.

Statutory Authority of the ALJ and QIC With Respect to Applicability of NCDs

- Administrative Law Judge
 - May not set aside or review an NCD
 - May determine whether NCD is properly applied to claim
- Quality Independent Contractor (QIC)
 - NCDs, CMS rulings, applicable laws are binding
 - LCDs, LMRPs program memos, manual instructions not binding
 - Substantial deference may be given *if they are applicable*
 - May decline to follow a policy if policy does not apply to case

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AUTHORITY OF THE ALJ AND QIC WITH RESPECT TO APPLICABILITY OF NCD'S

Authority of the ALJ. (1) An ALJ may not disregard, set aside, or otherwise review an NCD. (2) The ALJ may review the facts of the specific claim to determine whether the NCD has been applied properly to the claim. [42 C.F.R. §405.860(b)]

Authority of the QIC. (1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC. (2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case. (3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed. [42 C.F.R. §405.968(b)]

No Statutory Basis for Coverage Denials (Examples from Actual Medicare Denials)

- “Item not covered by Medicare.” (no regulatory basis given)
- “did not meet the definition of DME. Medical supplies of an expendable nature such as pads, catheters, bandages and irrigating kits are not considered durable.” “...not covered because it is not DME.”
- Do not meet the requirements of “surgical dressings, splints, and other devices used for the reduction of fractures and dislocations”
- Do not meet the definition of “surgical dressings [which] include therapeutic and protective coverings applied to wounds or lesions either on the skin or opening to the skin in connection with a surgical procedure performed by a physician.”
- “The beneficiary has failed to meet her burden of showing that these items meet the definition of durable medical equipment, specifically the definition of ‘durable.’”
- “These types of pressure stockings ... do not meet the meaning of a surgical dressing” according to LCD L11471

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Authority for LCD for Surgical Dressings (L11471 and L11449) is CMS National Coverage Policy: CMS Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.5

“270.5 - Porcine Skin and Gradient Pressure Dressings

Porcine (pig) skin dressings are covered, if reasonable and necessary for the individual patient as an occlusive dressing for burns, donor sites of a homograft, and decubiti and other ulcers. Gradient pressure dressings are Jobst elasticized heavy duty dressings used to reduce hypertrophic scarring and joint contractures following burn injury. They are covered when used for that purpose.”

This NCD allows coverage of gradient pressure dressings as surgical dressings used in burn treatment. It does not and cannot prohibit coverage when they are used in different medical applications and meet the definitions of different benefit categories.

The delineation of the applicability of the surgical dressing LCD L11471 is found in the caveat at the beginning of the LCD:

“Indications and Limitations of Coverage and/or Medical Necessity For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for “reasonable and necessary” are defined by the following indications and limitations of coverage and/or medical necessity.... Surgical dressings ...”

No Statutory Basis for Coverage Denials (Examples from Actual Medicare Denials)

- Does not meet the requirements of, and is specifically excluded by, LCD L11460 Surgical Dressings.
- “The custom made compression arm stocking is not used with a pneumatic compression device, therefore, it cannot be considered under this potential area that recognizes the treatments for lymphedema.” [i. e. DME] [based on Supplier Manual Chapter 9 Section PCD]
- “There simply has been no provision within Medicare laws at this time to allow coverage.” [It is found at §410.36(a)(2)]
- “Finally, section 1861(s)(8) of the Act provides for coverage of prosthetic devices. Prosthetic devices (other than dental) that replace all or part of an internal body organ or the function of a permanently inoperative or malfunctioning internal body organ are covered when reasonable and necessary. Since compression sleeves and other pressure gradient fabric supports do not replace an internal body organ or the function thereof, they do not meet the criteria for coverage as a prosthetic device.” [unsupported opinion, scientifically inaccurate]

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LCD for Surgical Dressings L11460, Noridian Administrative Services, 2/24/2006, CMS Manual System, Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.5

GRADIENT COMPRESSION STOCKINGS: (A6531 and A6532) A gradient compression stocking described by codes A6531 or A6532 **is covered when it is used in the treatment of an open venous stasis ulcer**. Codes A6531 and A6532 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. Gradient compression stockings described by codes A6530 and A6533-A6549 are non-covered for all indications **because they do not meet the definition of a surgical dressing**. A non-elastic binder for an extremity (A4465) is non-covered for all indications **because it does not meet the definition of a surgical dressing**.

Surgical dressings must be tailored to the specific needs of an individual patient. When surgical dressings are provided in kits, only those components of the kit that meet the definition of a surgical dressing, that are ordered by the physician, and that are medically necessary are covered.

Most compression bandages are reusable. Usual frequency of replacement would be no more than one per week unless they are part of a multi-layer compression bandage system.

No Statutory Basis for Coverage Denials (Examples from Actual Medicare Denials)

- A. 07/17/07 Noridian DME MAC Jurisdiction D
 - “This item is excluded from Medicare coverage as mandated by law. Refer to the 2007 Medicare and You publication, page 21 for additional information.”
- B. 10/26/07 Medicare Summary Notice
 - “g. Medicare does not pay for this item or service”
 - “h. The following policies 45-12, 60-9 were used when we made this decision.”
- C. 02/27/08 Letter of Denial Noridian DME MAC Jurisdiction D
 - “Claim is not covered by Medicare”
 - “Medicare will only cover this item if there is ulcers that won’t heal. Refer to Local Coverage Determination, “Surgical Dressings” Policy Number L11460 for more guidelines regarding this item.”

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Why Bases for Denial are Not Valid

None deal with criteria for coverage as prosthetic devices

- A. This item is nowhere excluded from Medicare coverage by any statute. Page 21 of 2007 Medicare and You has no exclusion for compression stockings used in the treatment of lymphedema. On the contrary, **this item fits the definition of a Prosthetic/Orthotic Item listed as a covered service on page 18.**
- B. Coverage Issues Manual §60-9 denies coverage for fabric supports and elastic stockings on the basis that they are “not reusable supplies” and are “not rental-type items”, with reference to section **1861(n)**, governing the **durable medical equipment benefit category**.
Coverage Issues Manual §45-12 deals with coverage of porcine (pig) skin dressings if reasonable and necessary for the individual patient as an occlusive dressing for burns, donor sites of a homograft, and decubiti and other ulcers. Gradient pressure dressings are Jobst elasticized heavy duty dressings used to reduce hypertrophic scarring and joint contractures following burn injury are covered when used for that purpose. These coverages for burn control are governed by **§1861(s)(5) surgical dressing benefits**.
- C. Local Coverage Determination L11460 covers surgical dressings for **wound treatment under §1861(s)(5)**.

Neither Coverage nor Denials Can be Based on HCPCS Code

- Establishment of HCPCS codes is CMS’s responsibility
 - 42 C.F.R. §414.40 Coding and ancillary policies
- HCPCS Code is an administrative tool only
 - Existence of a code does not establish coverage
 - Existence or absence of a code does not imply coverage policy
- “Existing codes adequately describe the array of products available [used in the treatment of lymphedema].”
- Claimed code invalidity cannot be used to justify denials of medical service.
- Valid basis for denial might be that item does not fall into a statutory benefit category.

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Excerpts From CMS 2008 Alphanumeric HCPCS, Nov 1, 2007

“The Level II HCPCS codes, which are established by CMS’s Alpha-Numeric Editorial Panel, primarily represent items and supplies and non-physician services not covered by the American Medical Association’s Current Procedural Terminology-4 (CPT-4) codes; Medicare, Medicaid, and private health insurers use HCPCS procedure and modifier codes for claims processing.”... ***“Inclusion or exclusion of a procedure, supply, product, or service does not imply any health insurance coverage or reimbursement policy.”***

Excerpts from HCPCS Working Group

Meeting Item #07-109, May 1, 2007

“Request to establish a series of new codes for the full range of prosthetic devices and supplies used in the treatment of lymphedema from all causes.” including restoration of graduated compression stockings from the A-code group to the L-code group and the placing of compression sleeves from the S-code group to the L-code group.

“No insurer (I.e. Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish unique codes to distinguish all the products listed in this application. ***Existing codes adequately describe the array of products available.***”

Denials of service Correct Coding for Items Used to Treat Edema

(2005 Medicare Advisory)

“Other items are non-covered by Medicare when used for the treatment of edema because they do not fall into a statutory benefit category.” **[OH, BUT THEY DO]**

Unintended Consequences of 2006 Administrative Change of HCPCS Code

- Compression stockings have been listed in the HCPCS Code Book as “prosthetic devices” (L8100-8239).
- Use of compression stockings in the treatment of venous stasis ulcers was approved effective Oct 1, 2003, requiring an AW modifier indicating use with a primary surgical dressing.
- Since the L-Code Group Lxxxx was inappropriate for use of these stockings *in their function* as secondary surgical dressings, coding for these items was changed January 1, 2006 to “secondary dressings” (A6530-6549).
- Use of the A-Code for compression garments led to denials of compression garments used in the treatment of lymphedema since the coverage criteria for surgical dressings requires a debridable wound.
- Recognition of *the function* of compression bandage systems, compression garments and compression devices *used in the treatment of lymphedema* as “prosthetic devices” warrants assignment with L-Codes and coverage by Medicare under §1861(s)(8).

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Compression Garments in the Treatment of Venous Stasis Ulcers - Coverage (Reference: Program Memorandum Change Request 2739; Transmittal AB-03-090)

Effective for items furnished on or after October 1, **2003**, Medicare will cover gradient compression stockings that serve a therapeutic or protective function and that are needed to secure a primary dressing as surgical dressings when the requirements below are met:

- The beneficiary has an open venous stasis ulcer that has been treated by a physician or other healthcare professional requiring medically necessary debridement,
- The gradient stocking can be proven to deliver compression greater than 30 mmHg and less than 50 mmHg

HCPCS

L8110 Gradient compression stocking, below knee, 30-40 mmHg, each

L8120 Gradient compression stocking, below knee, 40-50 mmHg, each

Modifier AW Item furnished in conjunction with a surgical dressing

Codes L8110 and L8120, with modifier AW, should be used for gradient compression stockings only when all of the requirements have been met.

Medicare Policy on Prosthetic Devices

- **Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 5, §120**
 - “A. General.--Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), *or replace all or part of the **function** of a permanently inoperative or malfunctioning internal body organ* are covered when furnished on a physician's order.”
- **DME MAC Jurisdiction D Supplier Manual, Chapter 9**
 - **Prosthetic Devices**—Prosthetic devices are items which replace all or part of an internal body organ or *replace all or part of the **function** of a permanently inoperative or malfunctioning internal body organ*. The test of permanence is considered met if the medical record, including the judgment of the attending physician, indicates that the condition is of long and indefinite duration.

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Noridian Administrative Services, Supplier Manual, Durable Medical Equipment Chapter 9 - Local Coverage Determinations (LCD) and Policy Articles, General Medical Policy Information

The Local Coverage Determinations (LCDs) and Policy Articles define coverage criteria, payment rules and documentation that will be applied to DMEPOS claims processed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The policies are a combination of national and local decisions. **The Centers for Medicare & Medicaid Services (CMS) defines national policy in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Medicare Program Integrity Manual (CMS Pub. 100-08), and Medicare National Coverage Determinations Manual (CMS Pub. 100-03). The DME MACs are required to follow national policy where it exists. However, when there is no national policy on a subject, the DME MACs have the authority and responsibility to establish local policy.** Because many DMEPOS suppliers operate nationally, CMS requires that the LCDs published by the DME MACs be identical in each region. Effective December 2003, contractors no longer develop Local Medicare Review Policies (LMRPs) and instead develop LCDs and Policy Articles. LCDs must be developed through a formal process that is coordinated by the DME MAC Medical Directors (see section entitled “LCD Development Process”).

What are Prosthetic Devices?

- Social Security Act §1861(s): “The term “medical and other health services” means any of the following items or services:”
 - (8): “prosthetic devices (other than dental) which replace all or a part of an internal organ...”
- CMS Pub. 100-2, Chapter 15 §120. “PROSTHETIC DEVICES.
 - A. General.--Prosthetic devices (other than dental) which replace all or part of an internal *body* organ (*including contiguous tissue*), or *replace all or part of the function of a permanently inoperative or malfunctioning internal body organ* are covered when furnished on a physician's order.”
- Code of Federal Regulations 42 C.F.R. §414.202 Definitions
 - “Prosthetic and orthotic devices means—(1) Devices that replace all or a part of an internal body organ...”
 - “The following are neither prosthetic nor orthotic devices—
 - Parenteral and enteral nutrients, supplies, and equipment;
 - Interocular lenses;
 - Medical supplies such as catheters, catheter supplies, ostomy bags, ...;
 - Dental prostheses.”

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DMERC Region D Supplier Manual, Chapter 9, Introduction, Pages 1-8, Revised 04/2006.

Prosthetic Devices: Prosthetic devices are items which replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The test of permanence is considered met if the medical record, including the judgment of the attending physician, indicates that the condition is of long and indefinite duration. In addition to artificial arms and legs, coverage under this benefit includes, but is not limited to, breast prostheses, eye prostheses, parenteral and enteral nutrition, ostomy supplies, urological supplies in patients with permanent urinary incontinence, and glasses or contact lenses in patients with aphakia or pseudophakia. Supplies that are necessary for the effective use of a medically necessary prosthetic device are covered. Equipment, accessories and supplies (including nutrients) which are used directly with an enteral or parenteral nutrition device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device are covered. Repairs, adjustments and replacement of medically necessary prosthetic devices are covered. Dental prostheses (i.e., dentures) are excluded from coverage. Claims for internal prostheses (e.g., intraocular lens, joint implants, etc.) are not processed by the DMERC.

How are Compression Bandages and Garments “Prosthetic Devices”?

- Statutory definition of an item as a “prosthetic device” relies solely on its **function**, and not on its **form**.
- In this specific case the “internal body organs” are the lymphangions and collecting lymphatic capillaries.
- Lymphedema results when the “malfunctioning internal body organ” results from blockage, partial removal, fibrosing, or dysfunctioning of lymphatics.
- Compression *replaces part of the function of the malfunctioning lymphatic system* by:
 - Preventing reflux by reducing capillary filtration;
 - Increasing coupling between collectors and lymphatic & venous returns;
 - Increasing lymphatic uptake by increasing tissue pressure;
 - Stimulating pumping action of lymphangions (lymph vessels);
 - Increasing lymphatic flow rate by reducing lymphangion diameter;
 - Amplifying decongestive lymph-pumping effect of arm and leg muscles;
 - Breaking down fibrosed tissue
 - Providing support for heavy, aching limbs

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Serving as a physical barrier protecting skin from further trauma.

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References supporting the description of the function of compression in treating lymphedema. Full abstracts can be provided on request.

- Földi E, Jünger M, Partsch H: “**The science of lymphoedema bandaging**” in European Wound Management Association (EWMA). Focus Document: Lymphoedema bandaging in practice. London: MEP Ltd, 2005.
- Földi M, Földi E, Kubik S (Eds). Textbook of Lymphology for Physicians and Lymphedema Therapists. San Francisco, CA: Urban & Fischer, 2003.
- Weissleder H & Schuchhardt C (Eds.): Lymphedema: Diagnosis and Therapy Third Edition, Viavital Verlag, Köln 2001. pp. 187-91.
- Weissleder H: "Kompressionsbestrumpfungen beim Lymphodem-eine Bestandsaufnahme" in German LymphForsch. 1997;1:76-80.
- Schingale F-J : “Compression Therapy” in Daróczy J, Schingale F-J & Mortimer PS: Practical Ambulant Lymphology Munich, Verlag medical concept GmbH, 1996:26-30.
- Chikly B: “External Medical Compression” Part Four, Chapter 6 in Silent Waves. Theory and practice of Lymph Drainage Therapy I.H.H. Publishing, Scottsdale, Arizona, 2001:261-275.
- Klose G: Lymphedema Bandaging. Practical Bandaging Instructions for Lymphedema Patients and Therapists Lohmann & Rauscher GmbH, Neuwied, Ger. 1998:11
- Partsch H: Contributions towards Compression Therapy Lohmann GmbH, Neuwied, Ger. 1990:12.
- Zuther JE: Lymphedema Management. The comprehensive guide for practitioners Thieme, New York, Stuttgart, 2005:112-3.

How are Compression Garments “Prosthetic Devices”? Continued

- Reference “Lymphedema Management”, Cheville AL, McGarvey CL, Petrek JA, Russo SA, Taylor ME and Thiadens SRJ, *Seminars in Radiation Oncology* 2003;13(3):290-301
 - Compression therapy increases tissue pressure, improves venous and lymphatic return, facilitates filling of initial lymph vessels ²⁹
 - Compression provides counter pressure against muscle pump and breaks down protein in the tissue of fibrotic limbs.
 - Compression garments are essential to maintain edema reduction and to compensate for the elastic insufficiency of the skin after volume reduction. ²²
 - Compression garments
 - Improve lymphatic flow and reduce accumulated protein
 - Improve venous return
 - Properly shape and reduce the size of the limb
 - Maintain skin integrity
 - Protect the skin from potential trauma ²³

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22. Casley-Smith JR: Modern Treatment for Lymphedema, 5th Edition, Adelaide, Australia, The Lymphedema Association of Australia, 1997.

23. Thiadens SRJ: “The use of three compression sleeves in complete decongestive therapy: a comparative study of clinical effectiveness” *NLN Newsletter* Jul-Sep 1999 11(3):1-3.

29. Mridha M & Odman S: “Fluid translocation measurement: A method to study pneumatic compression treatment of postmastectomy lymphoedema” *Scand J Rehabil Med.* 1989;21(2):63-9.

Mechanisms & Effects of Compression Therapy in Lymphedema

<u>Mechanism</u>	<u>Effect</u>
<ul style="list-style-type: none"> • Increased interstitial pressure 	<ul style="list-style-type: none"> • Reduced capillary filtration⁶⁻⁸ and production of lymph; limb volume decrease
<ul style="list-style-type: none"> • Shift of fluid into uncompressed areas 	<ul style="list-style-type: none"> • Proximal volume increase accommodated by normally working lymphatics in that region and assisted by manual lymphatic drainage⁹
<ul style="list-style-type: none"> • Increased lymph reabsorption and stimulation of lymphatic contractions 	<ul style="list-style-type: none"> • Improvement of lymph kinetics as shown by lymphoscintigraphy¹⁰ and intra lymphatic measurement of flow and pressure^{11,12}
<ul style="list-style-type: none"> • Breakdown of fibrosclerotic tissue 	<ul style="list-style-type: none"> • Softening of tissue as shown by ultrasound¹³ and durometer¹⁴
<ul style="list-style-type: none"> • Improvement of venous pump in patients with venolymphatic dysfunction 	<ul style="list-style-type: none"> • Increased expelled blood volume; reduction of venous reflux and ambulatory venous hypertension¹⁵

Reference: Table 1 of Partsch H & Jünger M: "Evidence for the use of compression Hosiery in lymphoedema" in **Lymphoedema Framework: Template for Practice: Compression Hosiery in Lymphoedema** London MEP Ltd. 2006

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6. Bates DO, Levick JR, Mortimer PS: "Subcutaneous interstitial fluid pressure and arm volume in lymphoedema" *Int J Microcirc Clin Exp* 1992; 11(4): 359-73.

7. Partsch H: "Understanding the pathophysiological effects of compression" In: European Wound Management Association (EWMA). Position Document: Understanding compression therapy. London: MEP Ltd, 2003: 2-4.

8. Levick JR: An Introduction to Cardiovascular Physiology. London: Arnold, 2003

9. Földi E, Földi M: "Die Anatomischen Grundlagen der Lymphodembehandlung" *Schweiz Runds Med Prax* 1983; 72(46): 1459-64.

10. Leduc O, Bourgeois P, Leduc A: "Manual lymphatic drainage: Scintigraphic demonstration of its efficacy on colloidal protein resorption" In: Partsch H (ed) Progress in Lymphology XI. Amsterdam: Excerpta Medica, 1988; 551-4.

11. Olszewski WL: "Lymph pressure and flow in limbs" In: Olszewski WL (Ed). Lymph Stasis: pathophysiology, diagnosis and treatment. Boca Raton, FL: CRC Press, 1991: 109-55.

12. Franzeck UK, Spiegel I, Fischer M, et al: "Combined physical therapy for lymphoedema evaluated by fluorescence microlymphography and lymph capillary pressure measurements" *J Vasc Res* 1997; 34(4): 306-11.

13. Gniadecka M: "Dermal oedema in lipodermatosclerosis: distribution, effects of posture and compressive therapy evaluated by high-frequency ultrasonography" *Acta Derm Venereol*. 1995; 75(2): 120-4.

14. Falanga V, Bucalo B: "Use of a durometer to assess skin hardness" *J Am Acad Dermatol*. 1993; 29(1): 47-51.

15. Partsch H: [Improving the venous pumping function in chronic venous insufficiency by compression as dependent on pressure and material] in German *Vasa* 1984; 13(1): 58-64.

State and Medicaid Coverage of Lymphedema Bandages and Garments

- Virginia
- California
- North Carolina
- Maryland

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- Code of **Virginia** § 38.2-3418.14 B. Coverage for lymphedema. Coverage under this section shall include benefits for equipment, supplies, complex decongestive therapy, and outpatient self-management training and education for the treatment of lymphedema, if prescribed by a health care professional legally authorized to prescribe or provide such items under law.
- **California** Code of Regulations 28 CCR §1300.67.005 Essential Health Benefits Subsection (d)(9)(B)(iii) includes Other Health Benefits required to be covered as Prosthetic and orthotic services and devices including compression burn garments and lymphedema wraps and garments
- **North Carolina** General Statutes § 58-3-167 Coverage for the diagnosis and treatment of lymphedema (a) The coverage required by this section shall include benefits for equipment, supplies, complex decongestive therapy, gradient compression garments, and self-management training and education,
- Annotated Code of **Maryland** § 15-853 (C) provides coverage for the medically necessary diagnosis, evaluation, and treatment of lymphedema, including equipment, supplies, complex decongestive therapy, gradient compression garments, and self-management training and education.

Provider Guidelines From NY to CA Recognize the Function of Compression Garments in Lymphedema Treatment

- New York State Medicare Contractor Policy on Surgical Stockings
 - Eligible for coverage as a **prosthetic/orthotic** for lymphedema
- California Kaiser Permanente Health Plan
 - Covers compression burn garments and lymphedema wraps and garments as **“external prosthetics and orthotics”**.
- Widely-used Milliman insurance guidelines recognize compression garments as covered for the treatment of lymphedema, coded as prosthetic services.

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- According to the **New York State Medicare Contractor Policy on Surgical Stockings**, “**Surgical Stockings** or graduated compression stockings are custom-made or custom-fitted support for the lower extremities. Surgical stockings (e.g., Jobst, Sigvaris, and CircAid) are **eligible for coverage as a prosthetic/orthotic** for the following indications: Venous insufficiency; Varicose veins; Phlebitis/Thrombophlebitis; DVT prophylaxis during pregnancy and postpartum; Orthostatic hypotension; Ulceration due to chronic venous insufficiency; **Lymphedema**” [Excellus Blue Cross Blue Shield]
- Since July 1, 2000 Kaiser provides the following benefits **“for the treatment of lymphedema when prescribed by a Plan physician as part of a lymphedema treatment plan**: adjustable manual compression garments [e.g. Reid, CircAid, MedAssist, etc] , **elastic compression garments**, low-elastic extremity wraps, and pneumatic lymphedema pumps and appliances. Some coverage, like the pneumatic lymphedema pumps and appliances, is subject to the member having a Supplemental Durable Medical Equipment benefit in addition to their basic health care coverage. All members, however, are entitled to receive as a covered benefit the particular types of compression garments and extremity wraps that their clinical situation requires. Up to two of each required item will be initially provided. Replacement items will be issued when the existing items are no longer functional, and replacements will consist of up to two items of each type required. The need for replacements must be determined and documented by a Plan physician in order to be a covered benefit.” The bandages and sleeves are provided as **“Prosthetic and Orthotic Devices”** and are listed in the Evidence of Coverage under "external devices". Coverage is provided for "Compression burn garments and lymphedema wraps and garments.”
- **Insurance Guideline on Compression Stocking Coverage** Milliman Care Guideline ACG:A-0336 5/12/06:
 - “**Compression stockings** are indicated for all patients with lymphedema after **axillary dissection** for tumor staging [C](11)”
 - “[C] Start early in treatment and replace compression stockings every 4 to 6 months or sooner if they become loose...”
 - “Codes – CPT® or HCPCS: L8100 through L8239 (graduated **compression stockings**) ICD-9 Diagnosis: 457.0, 457.1, 757.0 (lymphedema all causes, upper and **lower limbs, congenital or secondary**)”

CIGNA Healthcare Coverage Position

- Lymphedema Pumps and Sleeves Coverage Position Number 0354, Revision Date 5/15/2006
- Related Coverage Positions
 - Complex Decongestive Therapy
 - Physical Therapy
 - Pneumatic Compression Devices
- “CIGNA HealthCare covers the purchase of a lymphedema compression sleeve as medically necessary for the treatment of lymphedema.”
 - S8420 Gradient pressure aid (sleeve and glove combination), custom made
 - S8421 Gradient pressure aid (sleeve and glove combination), ready made

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Lymphedema Sleeves

Compression garments or sleeves have been widely used in treatment of lymphedema. They are used alone or in combination with other treatments, including lymphedema pumps and complex lymphedema treatment. They are used for the purpose of preventing an increase in lymphedema and maintaining the reduction of lymphedema after treatment. They may be custom fitted or prefabricated and have varying degrees of elasticity. The type of sleeve used is dependent on the size needed and whether the patient correctly fits the parameters of the prefabricated garment. It is important that the garment fit correctly and provide adequate, graduated compression. A glove or gauntlet may also be used if lymphedema is present in the hand. The sleeve will usually need replacement when elasticity is lost, approximately every 4-6 months. Types of compression sleeves include Jobst® Armsleeve (BSN-JOBST, Inc., Charlotte, NC) and Juzo® compression arm sleeves (Juzo, Cuyahoga Falls, OH) [Brennan, 1998; Harris, 2001].

The ReidSleeve® (Peninsula Medical, Inc., Scotts Valley, CA) is a custom-fitted, non-elastic sleeve that provides compression to assist in flow of lymphatic fluid. According to the manufacturer’s website, the sleeve contains a foam insert and works by applying high and low pressure to different parts of the affected area. The high-pressure zones force excess fluid into the areas under lower pressure, forming channels via which the lymphatic fluid can be removed through the lymphatic and venous system. The Contour® and Optiflow® sleeves are made by the same manufacturer as the ReidSleeve and use the same technology but are lighter sleeves that are intended for patients with mild to moderate lymphedema. ArmAssist® and LegAssist® (MedAssist Group, Tampa, FL) are other custom-fabricated, non-elastic compression sleeves. CircAid® (CircAid Medical Products Inc., San Diego, CA) is a non-elastic compression sleeve that is available prefabricated and custom fitted.

Administrative Law Judge Decisions

- I have been representing Medicare Beneficiaries with their appeals of denials of lymphedema treatment compression bandages and garments for over 15 years.
- The preceding material has been used as the basis of these appeals, i.e. that compression bandages and garments and devices used in the compression treatment of lymphedema meet the coverage criteria for prosthetic devices and are covered by Medicare.
- The majority of the ALJs who read and understood the medico-legal logic made favorable determinations for the Appellants, and reversed DME MAC denials.
- The following material is a sample of favorable ALJ decisions with summaries of their determinations.

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Stealth Appeals

Methods of reducing ALJ-overtaken denials are becoming more common with the increased activity of the Administrative QIC (AdQIC). One of the functions of this CMS contractor is to “analyze ALJ decisions for possible Department Appeals Board (DAB) review”.

Valid bases for **Referral** of an ALJ decision to the DAB are: 1) an error of law material to the outcome of the claim; 2) broad policy or procedural issue of public interest; 3) decision not supported by the preponderance of evidence, and: 4) abuse of discretion. These cases are referred by CMS to the DAB Medicare Appeals Council for initiating its own review of whether the ALJ made an error of law, or made a decision that would lead to an error of law.

This effectively creates another pathway to reduce the number of ALJ reversals of MAC denials, i.e. by auditing FAVORABLE decisions and claiming that the ALJ made an error of law leading to an incorrect decision.

We have so far in 2019 had two FULLY FAVORABLE ALJ determinations that the lymphedema garments purchased to treat two Medicare Beneficiaries’ lymphedema met the requirements for Prosthetic Device Benefits. Both of these cases were subject to “stealth appeals” based on “junk science” and “junk law.” The ALJ-directed reimbursement is being withheld pending completion of the DAB review.

Medicare ALJ Decisions Prior to 2006

<u>Date</u>	<u>State</u>	<u>Level</u>	<u>Item</u>	<u>HCPCS Code</u>
08/05	MI	ALJ	Tribute DFG	E1399
06/05	CA	ALJ	JoVi Pak DFG	L3999
01/02	NY	HO	Sleeve	L8010
01/02	NY	HO	Gauntlet	L3999
08/01	GA	MAC	Sleeve	L8220
04/01	VT		Sleeve	L8010
04/01	VT		Glove	L3912
05/00	NC	ALJ	Reid Sleeve	Exxxx
08/99	CA	ALJ	Stockings	Exxxx
06/99	CA	ALJ	Stockings	Exxxx
u/k	CA	ALJ	Stockings	Exxxx
08/97	IN	ALJ	Reid Sleeve	E1399

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Early Appeals decisions for lymphedema treatment services tended to be rendered on the basis that these items meet all of the coverage criteria for durable medical equipment [with the arguable exception of the “rentability” provision of §1861(n)].

Later decisions recognized that they were, by their function, better fitted the prosthetic devices category, and HCPCS L-Codes were used.

When, on January 1, 2006, CMS transferred the block of L-Coded compression garments to the surgical dressing benefits category, they started to be denied because they do not meet the coverage criteria for surgical dressings. But more recent ALJ appeal decisions recognize that these materials meet the statutory definition of prosthetic devices and are covered by Medicare, regardless of their coding.

Summaries of more recent relevant cases follow on the next few pages.

ALJ Decision of June 22, 2005 Compression Sleeves

- Findings
 - Beneficiary received mastectomy sleeves (L8010).
 - Mastectomy sleeves (L8010) meet the Medicare coverage definition of durable medical equipment.
 - The durable medical equipment received by the beneficiary was medically reasonable and necessary
 - The beneficiary should be reimbursed for the durable medical equipment.
- Revised Medicare Summary Notice
 - Previously disallowed Mastectomy sleeves (L8010-LT) were allowed as Lower extremity prosthesis (L5999-LTCC)

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ALJ Docket Number 999-32-9443

This case is significant since it is one of the first in this advocate's experience where an ALJ reversed a denial of lymphedema compression sleeves on the basis of meeting Medicare statutes, but assigned the sleeves to the durable medical equipment benefit category.

But when reimbursement was made to the beneficiary, the Medicare Summary Notice showed a reclassification from durable medical equipment to prosthetic procedures, with an L-code. [The code modifier LT means "left arm" and the modifier CC means that the HCPCS Code was administratively changed.]

Landmark ALJ Decision August 16, 2006 Compression Bandages, Sleeves, Garments

- Beneficiary received medical treatment and supplies for treatment of lymphedema of left arm
- Items received should be categorized as “a prosthetic device and supplies”
- Skin care supplies remain denied
- “The billed items should be categorized for prosthetic treatment”
- All items except the Skin Care Supplies should be paid under Medicare Part B pursuant to Section 1861 of the Social Security Act”
- “Payment is to be made on the beneficiary’s behalf for the reasonable and necessary medical services rendered and billed.”

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ALJ Appeal No. 1-309290019

The ALJ decision of August 16, 2006 is notable since it included, as prosthetic device benefits, most of the services used in the treatment of lymphedema. The items in dispute in this case, and found to be covered Medicare benefits included:

Tribute Directional Flow Garment (L8039)

Graduated Compression Sleeves (L8010)

Compression Gauntlets (L8010)

Short-Stretch Compression Bandages and supplies (A4460)

Office Visits for Garment Measurement and Fitting (99244)

The only item denied in this case were skin care lotions.

This case took over 4 years to resolve, and involved three ALJ hearings and two DAB/MAC actions.

ALJ Decision of Mar 14, 2007 Graduated Compression Stockings

- “The qualified beneficiary ... received compression stockings for the treatment of lymphedema of the leg.”
- “The compression stocking is reasonable and necessary for reimbursement as a [prosthetic device](#).”
- “The beneficiary’s medical diagnosis meets Medicare guidelines for reimbursement for compression stockings in consonance with the applicable statutes and regulations.”
- “The record establishes that Medicare regulations provide coverage of the compression stockings as a [prosthetic device](#) in consonance with the applicable statutes and regulations.”
- “It is the decision of the Administrative Law Judge that the appellant is entitled to Medicare coverage of Compression Stockings for lymphedema control.”

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ALJ Appeal No. 1-62035959

This ALJ determination is a recent determination that compression stockings when used in the treatment of lymphedema are covered as a prosthetic device benefit under Medicare law.

This case was appealed by the Provider to the Medicare Appeals Council. The ALJ findings and ruling were confirmed by the Medicare Appeals Council in a decision dated February 20, 2008 (See Page 42)

ALJ Decision of Sep 13, 2007 Custom Compression Sleeves

- “I find that the compression garments at issue here are indeed prosthetic devices within the meaning of Section 1861(s)(8) of the Act, and should be covered by Medicare.”
- “The record establishes that the billed items (L8210 and A6542-LT) were reasonable and medically necessary for the Appellant to treat her lymphedema, and **meet** Medicare coverage criteria as prosthetic devices, as discussed herein.”
- “The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.”

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ALJ Appeal No. 1-177650171

ALJ Decision of November 20, 2007 Compression Sleeve and Glove

- "...There was no justification [for denial of Appellant's claim] based upon the beneficiary's diagnosis of lymphedema for what it characterized as a surgical dressing."
- "... the prior reconsideration decision [to deny coverage] of the Part B QIC, RiverTrust Solutions, is set aside."
- "...the Appellant thus made a compelling argument that the subject durable medical equipment should be characterized as a prosthetic [device]; the Appellant thus met the conditions and limitations of payment set forth at §1861(s)(8).
- "The subject compression sleeve and glove are there[for] not properly excluded from coverage pursuant to §1862(a)(1)(A) of the Social Security Act."
- "Appellant is eligible for coverage of the subject compression sleeve and glove apparatus..."

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ALJ Appeal No. 1-198722081

ALJ's footnote to the case record:

"The record contains the lengthy position paper of Mr.. Robert Weiss, the Appellant's representative. The Appellant through her representative asserts that [the Supplier] used an improper HCPCS/CPT Code, A6542, to bill Medicare, which led to a misapplication of the coverage regulations. The Appellant states that the compression system is properly characterized as a prosthetic [device], not a surgical dressing, as it was prescribed to treat the beneficiary's lymphedema. The undersigned accepts the Appellant's premise that the River Trust emphasized form over substance in accepting [the Supplier]'s miscoding in applying Local Coverage Determination L11460: it is clear from the description of what the compression sleeve and glove are intended to treat that, though the garment resembles a surgical dressing, it cannot be categorized as such based on the medical evidence presented."

Feb 20, 2008 Medicare Appeals Council Decision Re: ALJ Decision of Mar 14, 2007

- Section 1861(s)(8) defines prosthetic device coverage
- CMS Pub. 100-02 §120 expands definition to include *functional* replacement of part of internal body organ
- Beneficiary's physician prescribed compression stockings for lymphedema control
- ALJ concluded requested items were prosthetic devices--they replace function of body organ
- All qualifications of a prosthetic device were met
- There is no NCD that specifically states whether gradient compression stockings are covered [as prosthetic devices]
- Medicare Contractor has not provided sufficient support for its assertion that the requested "stockings do not replace the lymphatic system [function] but merely assist"
- "The ALJ's decision stands as the final decision of the Secretary"

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ALJ Decision of June 19, 2008 **Lower Limb Compression Device** **[ALJ Appeal No. 1-262756470]**

- "The nighttime edema garment (E1399) [Solaris Tribute Lower Limb Garment identical to the garment in dispute in this current case] and supplies provided to the Beneficiary are covered under Medicare policy.
- Therefore, as a matter of law, they are reasonable and necessary under §1862(a) of the Act and the documentation requirements of §1833(e) of the Act were sufficiently satisfied for Medicare to provide payment.

ALJ Decision of December 8, 2008 Lymphedema Compression Sleeves

- “The evidence leads to but one conclusion, and that is the compression sleeves replace the function of the malfunctioning lymphatic system damaged in the fight against breast cancer and qualify as a “prosthetic device” as defined in *Publication 100-2, Medicare Benefit Policy Manual, Ch. 15 §120.*”
- “Accordingly, the compression sleeves furnished ... meet Medicare coverage requirements as the compression sleeves are a prosthetic device pursuant to 1861(s)(8) of the Social Security Act and were medically reasonable and necessary pursuant to 1862(a)(1) of the Social Security Act.”
- “The Appellant has satisfied the applicable coverage criteria for reimbursement under Part B of Title XVIII of the Act for compression sleeves (L8010) furnished to the Beneficiary ... as the compression sleeves are a prosthetic device pursuant to 1861(s)(8) of the Social Security Act and were medically reasonable and necessary pursuant to 1862(a)(1) of the Social Security Act.”

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ALJ Appeal No. 1-332428125 (Aggregating ALJ Appeal No. 1-337126021)

ALJ Decision of December 29, 2008 Custom Compression Stockings and CircAids

- The items at issue are supplies, as they are so coded and defined.
- The beneficiary's medical need for these items is well-established.
- The Medicare Contractor and QIC relied on LCD L11471 to deny the items at issue. LCD L11471 provided coverage for surgical dressings. In this case the Administrative Law Judge finds nothing in the LCD that would specifically prevent payment of HCPCS codes A4465 and A6542 for the beneficiary's condition. Though the LCD appears to contemplate coverage of these supplies for wound care as surgical dressings, the LCD does not specifically exclude coverage of these items for the [treatment of the] beneficiary's condition or as these items are being used.
- Payment may be made for those items billed as HCPCS codes A4465 and A6542 on the basis that these items are reasonable and necessary for treatment of the beneficiary's condition.

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ALJ Appeal No. 1-334422387

Items in Dispute:

- 2 CircAid Graduate non-elastic lower extremity binders
- 1 Elvarex Custom compression stocking
- 2 Elvarex Custom Compression foot caps

ALJ Decision of January 27, 2009 Compression Sleeves

- Evidence of Coverage contract between [Provider] and Appellant does not explicitly exclude coverage of compression sleeves for treatment of lymphedema.
- 42 C.F.R. §414.202 does not explicitly exclude compression sleeve as a prosthetic device.
- Compression sleeves were medically reasonable and necessary for treatment of lymphedema.
- NCD 280.6, although not directly on point, supports the use of compression garment for treatment of lymphedema.
- Compression sleeves do *not* fall under the benefit category for surgical dressings, therefore LCDs/Policy Articles A23903 and A5835 ... are not applicable in this appeal.
- The ALJ finds that the compression sleeve in question falls under the benefit category for prosthetic devices because it meets the definition of a prosthetic device under section 1861(s)(8) of the Social Security Act, as interpreted by section 120, Chapter 15 of CMS's Medicare Benefit Policy Manual... Moreover [the provider] does provide coverage for prosthetic devices, as indicated ... in its Evidence of Coverage.

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ALJ Appeal No. 1-339495791

ALJ Decision of February 25, 2009 Directional Flow Lymphedema Garment

- “The ALJ finds that the garment at issue does not qualify as a DME because the garment is not re-usable, according to the definition in NCD 280.1 (the item could normally be rented and used by successive patients.)”
- “The garment at issue is specifically termed a “Directional Flow Lymphedema Garment.” While the ALJ finds that the Carrier did indeed misapply the LCD for surgical dressings, ...”
- “The ALJ finds that the garment falls within the benefit category of a prosthetic [device] because it replaces all or part of [the function of] a patient’s lymphatic system.”

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ALJ Appeal No. 1-361867001

ALJ’s decision in this case was unfavorable to the Beneficiary on the basis that “the documentation does not demonstrate that the item was furnished pursuant to a physician’s order/instruction.” and that there was no written order on the record which met the requirements Chapter 5 of the Program Integrity Manual entitled “Written Orders”. The physician’s written order has since been sent to the Appeals Council.

The ALJ did find, after extensive analysis of the statutes defining various benefit categories, that **the item did meet the statutory definition of of a prosthetic device as interpreted by CMS in the Medicare Benefit Policy Manual Publication 100-02, Ch. 15, §120.**

ALJ Decision of February 26, 2009
Custom Gradient Compression Garment
ALJ Appeal No. 1-336005856

- “Appellant’s custom gradient compression garment (A6542 months is covered by Medicare Part B of Title XVIII of the Social Security Act, and the Medicare Advantage Plan [deleted] must provide coverage for it. As a matter of law, the above-described garment prescribed for Appellant was medically reasonable and necessary, under §1862(a) of the Act and satisfied all applicable statutory, and CMS manual requirements and guidelines for Medicare reimbursement every four to six months.”
- “The subject gradient compression garment meets the Medicare definition of a prosthetic device, because it replaces [the function of] a malfunctioning part of the lower extremity lymphatic system, which malfunction resulted from uterine cancer and its treatment.”
- “The subject garment falls within the definition of a “prosthetic device” in Social Security Act, §1861(s)(8), not within the definition of “durable medical equipment” in Social Security Act, §1861(n).”

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ALJ Decision of September 11, 2009
Directional Flow Lymphedema Garment
& 2 Graduated Compression Sleeves
ALJ Appeal No. 1-457724425

Decision

“ ... fabric graduated compression sleeves and upper extremity directional flow sleeve ... [are] covered under the regulations governing Medicare.”

Analysis

“ ... the ALJ is convinced that the compression sleeves at issue ... may be considered “prosthetic devices” within the meaning of that statute.”

“The medical documentation supports that the compression garments serve as a substitute or replacement for a part of the function of a malformed internal body organ, here, the lymphatic system, ...”

“A reasonable analogy can be made that the compression garments at issue here serve as prosthetic devices within the meaning of Section 1861(s)(8) of the Act, and should be covered by Medicare.

ALJ Decision of Dec 8, 2009
CircAid Leggings Toe Bandages, Gauze Sleeves
ALJ Appeal No. 1-498717133

- **Principles of Law**
 - The Social Security Act, Title XVIII, §1861(s)(8) Prosthetic Devices
 - The Social Security Act, Title XVIII, §1862(a)(1) Medical Necessity
 - Medicare Benefit Policy Manual Pub. 100-02, Ch. 15, §§120 & 260.4
 - Medicare Claims Processing Manual Pub. 100-04, Ch. 20, §§10.1.2 & 10.1.3 Prosthetic Devices & Prosthetics & Orthotics
- **Analysis**
 - The 2 non-elastic extremity binders and tubular dressings ... are covered under Medicare policy.
 - As a matter of law they are reasonable and necessary under §1862(a) of the act and the documentation requirements of §1833(e) were sufficiently satisfied for Medicare to provide payment.

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ALJ Decision of Dec 23, 2009
4 Custom Knee-High Compression Stockings
ALJ Appeal No. 1-501580801

A preponderance of credible evidence supports Appellant's Representative's argument that the lymphatic system is part of the body system, and that because the custom gradient compression garments (A6542) correct a malfunction of that body system, they are a prosthetic [device] and not just as a bandage.

The lymphatic system is an internal organ, and in lymphedema is not collecting lymphatic fluid. The custom gradient hosiery provides support to the collapsed tissue, reinforcing the vessels including those of the lymphatic system. Therefore, that hosiery is a prosthetic [device] that is covered by Medicare.

The custom gradient compression garments (A6542) provided to the Appellant on February 7, 2008 are covered under Medicare.

**ALJ Decision of Oct 18, 2010
2 Compression Sleeves + 1 Glove
ALJ Appeal No. 1-639937079**

- “The compression garments at issue here are prosthetic devices within the meaning of Section 1861(s)(8) of the Act, and the garments provided to appellant on date of service [deleted] **are reasonable and necessary** to improve the functioning of appellant’s permanently malformed lymphatic system.”
- “The compression sleeves and glove ordered by her doctor are deemed prosthetic devices, **and are covered benefits.**”
- “The contractor [Noridian Administrative Services, Fargo, ND] is hereby directed to process the claims submitted for payment for compression sleeves and gloves...”

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**ALJ Decision of January 5, 2011
Upper Limb Custom Sleeve, Glove & Non-Elastic Binder
ALJ Appeal No. 1-647452179**

- “The custom, gradient pressure sleeve, glove and non-elastic binder (E1399) ... are reasonable and necessary under § 1862(a) of the Act and must be covered by the Plan.”
- “These items are clearly not intended to be used over an open wound. The Medicare Advantage Medical Policy Bulletin E-75 and Article A10116, which pertain to surgical dressings, are therefore inapplicable.”
- “The ALJ finds that the evidence supports the Appellant’s position that the item is a prosthetic device, appropriately billed under E1399.”

2011-2013 FULLY FAVORABLE ALJ Decisions

- May 3, 2011 ALJ Case 1-735855097 involving gradient compression stockings used in the treatment of beneficiary's lower limb lymphedema: "As a prosthetic device, the stockings are covered by Medicare".
- July 22, 2011 ALJ Case 1-703204533 involving a ready-made Juzo graduated compression sleeve and a CircAid non-elastic adjustable night sleeve used in the treatment of the beneficiary's lymphedema: "The compression sleeve and arm sleeve are prosthetic devices as defined above." and "...the lymphedema compression sleeve, arm sleeve and all related services are medically reasonable and necessary under §1862(a) of the Act."
- August 25, 2011 ALJ Case 1-753060950 involving gradient compression stockings used in the treatment of beneficiary's lower limb lymphedema: "Provided items were reasonable and necessary and met Medicare coverage criteria for prosthetic devices." and "...the gradient compression stockings at issue were not ordered for use as surgical dressings and consequently LCD L11460 and Policy Article A23903 [Surgical Dressings] do not apply."

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• February 29, 2012 ALJ Case 1-807969151 involving custom and pre-sized compression sleeves and gloves, finger bandages, donning aid and CircAid strapped custom sleeve. The ALJ concluded that "the lymphedema treatment garments provided ... are medically reasonable and necessary, and should be covered by Medicare." "Under the particular facts of this case, the lymphedema treatment garments at issue were proven to be medically reasonable and necessary as prosthetic devices under the MBPM..." The ALJ further clarified that NCD 280.1 "... concerns elastic stockings, which are not at issue in this case, the NCD reference list does not preclude payment for the lymphedema treatment garments." Also, LCD L11471, "... an LCD that provides coverage criteria for surgical dressings is not determinative" and "does not control the coverage of the lymphedema treatment garments at issue here."

• January 23, 2013 ALJ Case 1-1211410338 involved 2 gradient compression sleeves for the treatment of breast cancer related lymphedema. "The Administrative Law Judge finds nothing in [LCD L27222 Surgical Dressings or its associated Article A47232] that would specifically prevent payment of the compression sleeve/stockings for the beneficiary's condition." "In this case the evidence is sufficient to demonstrate that the compression sleeves/stockings at issue are medically necessary, in this particular instance, and may be considered reasonable and necessary under § 1862(a)(1). Therefore, the items at issue are covered under sections 1832 and 1862 of the Social Security Act."

2014 FULLY FAVORABLE ALJ Decisions

- May 28, 2014 ALJ Cases 1-1809652464 and 1-2144261189 involving gradient compression sleeves and gloves used in the treatment of beneficiary's upper limb lymphedema. "...compression devices at issue ... replace the functioning of a malfunctioning part of extremity affected by malformed lymphatic system." and "...the garments at issue fall within the definition of prosthetic devices within the meaning of the statute".
- September 23, 2014 ALJ Case 1-2565356834 involving gradient compression sleeves and gloves used in the treatment of beneficiary's bilateral upper limb lymphedema. "... the preponderance of evidence submitted in the record by Appellant established the DME[POS] at issue met the necessary coverage requirements in accordance with the aforementioned Medicare provisions of Title XVIII of the Social Security Act."

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- November 14, 2014 ALJ Case 1-2158037630 involving a compression sleeves used in the treatment of the Beneficiary's lymphedema. The ALJ concluded that "the sleeve ... supports medical reasonableness and necessity..." "As prescribed to and used by Appellant, the sleeve ... replaces a portion of her lymphatic system". "I therefore find the compression sleeve provided to Appellant is covered by Medicare."

2015 FULLY FAVORABLE ALJ Decisions

- May 20, 2015 ALJ Case 1-3051049678 was a “favorable” determination for compression sleeves and gloves. “Under Medicare policy, prosthetic devices which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician’s order. The record demonstrates the compression garments meet the definition of a prosthetic device in this case and establishes medical necessity for the garment.”
- June 3, 2015 ALJ Case 1-3157301269 was a “wholly favorable” determination regarding 4 custom compression sleeves (A6549) and 4 custom gauntlets (A6549) which “fit within Medicare’s prosthetic devices coverage category because they replace part of the lymphatic system function which is permanently inoperative due to breast cancer, a double mastectomy and multiple bilateral axillary nodes dissections.”

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June 18, 2015 ALJ Case 1-3092604751 was a “wholly favorable” determination in a case of compression sleeve and gauntlet. “The ALJ finds that the A6549 compression sleeve and gauntlet fit within Medicare’s prosthetic device coverage category because they replace part of the lymphatic system function which is permanently inoperative due to breast cancer, a double mastectomy, and multiple bilateral axillary nodes dissections.”

November 23, 2015 ALJ Case 1-3751819001 was a “favorable” determination for compression sleeves and gloves. “Under Medicare policy, prosthetic devices which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician’s order. The record demonstrates the compression garments meet the definition of a prosthetic device in this case and establishes medical necessity for the garment. ...The undersigned Administrative Law Judge finds that the Appellant is entitled to Medicare coverage for the compression sleeves (A9270x3) and related services (A9901x2) provided to the beneficiary on February 27, 2015 because the Appellant File contains sufficient evidence to support medical reasonableness and necessity.”

2017 FULLY FAVORABLE ALJ Decisions

- July 28, 2017 OMHA Case 1-6290456911 in the case of custom-made compression garments, the ALJ ruled that “...the compression garments at issue are prosthetic devices within the meaning of Section 1861(s)(8) of the Act, and are reasonable and necessary for the Beneficiary under Section 1862(a)(1)(A) of the Act.”
- September 19, 2017 ALJ Case 1-1153087746R1 in the case of compression stockings used in the treatment of lower limb lymphedema, the ALJ ruled “Appellant correctly argues that the actual use of compression stockings used in the treatment of lymphedema in this case, in fact replaces the function of the lymphatic and circulatory systems. Accordingly, the items at issue meet the requirements for the benefit category of prosthetic devices and, as such, are ruled by § 1861(s)(8) of the Act.”

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2019 FULLY FAVORABLE ALJ Decisions

- April 16, 2019 ALJ Case 1-8222429107 in the case of custom-made Elvarex sleeves and gloves “The ALJ finds that the compression garments were medically reasonable and necessary for the treatment of the Beneficiary’s specific condition. All Medicare Part B coverage requirements have been satisfied and coverage exists pursuant to Sections 1861(s)(8) and 1862(a)(1)(A) of the Act.”
- June 20, 2019 OMHA Appeal No. 1-8345782594 in a case concerning four compression gloves, two compression sleeves, and a strapped night garment. The ALJ found that “The lymphedema compression garments provided to the Appellant ... are covered by Medicare.” The ALJ referred to meeting the requirements of 42 CFR §410.36(a)(2) and the Medicare Benefit Policy Manual, Chapter 15, § 120 Prosthetic Devices although he inadvertently referred to the items as “orthotics”—possibly because they were erroneously assigned an orthotic HCPCS code by the DME MAC.

Summation

- Compression bandages systems, garments and devices are reasonable and necessary for treatment of diagnosed lymphedema.*
- Compression bandages systems, garments and devices meet all of the regulatory requirements for coverage by Medicare as prosthetic devices.*
- A National Coverage Determination should be made to clarify the coverability as prosthetic devices of compression bandage systems, garments and devices when used in the treatment of lymphedema.

* Based on the findings of Administrative Law Judges around the country

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The preceding material is the opinion of an unpaid patient advocate and may not reflect the positions of any organization or governmental agency. The statements made herein are based on personal experience and research, the Representative's interpretation of relevant statutes and determinations of selected Administrative Law Judges in similar cases. Citations are made to primary sources whenever possible. The foregoing material should not be taken as medical or legal advice.

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Postscript

- It is of utmost importance to Medicare beneficiaries with lymphedema that the national coverage policies on MLD, compression therapy and pneumatic pumps be updated and coordinated in accordance with *current medical standards of lymphedema treatment*.
- Prompt and effective treatment of lymphedema will *save Medicare millions of dollars each year* in avoided costs of treatment of cellulitis.

**Treatment of Lymphedema is
Good Business as well as Good Medicine.**