

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

Revision X March 25, 2021

For NLN Lymphedema Awareness Session

Robert Weiss, M.S.

Porter Ranch, CA

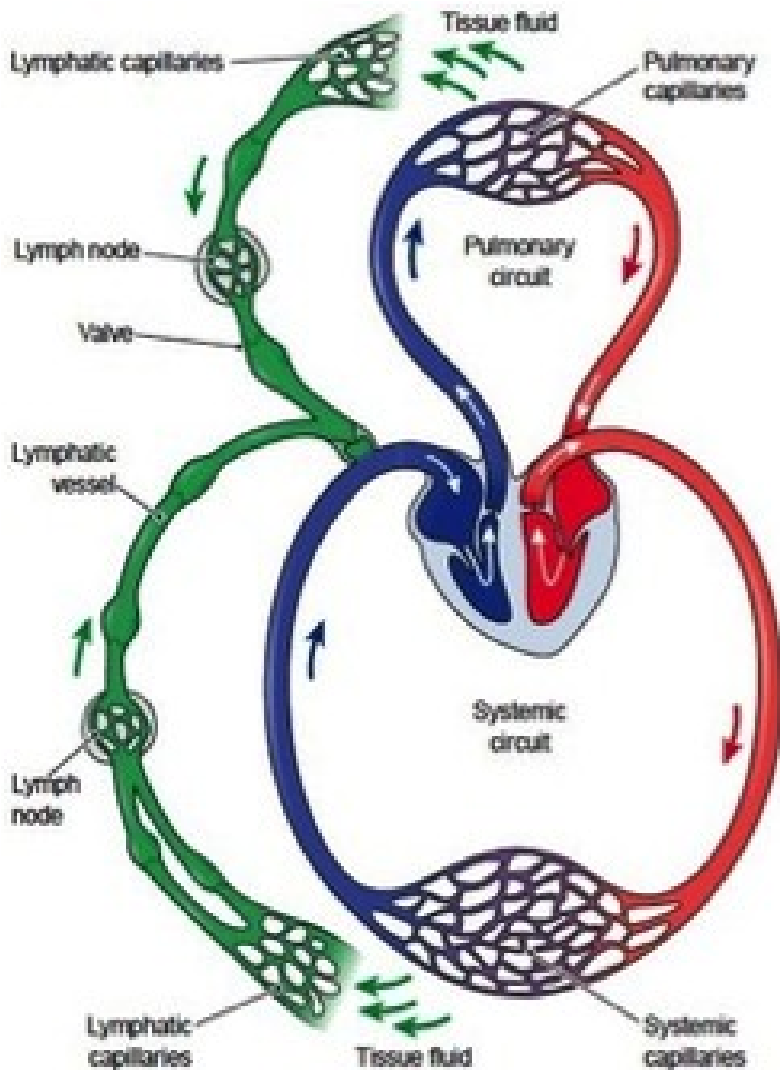
[LymphActivist@aol.com](mailto:LymphActivist@aol.com)

[www.lymphactivist.org](http://www.lymphactivist.org)

# Roadmap

- The Science
  - Tissue Fluid collection and transport
  - Lymphedema as a partial failure of lymphatic system function
- The Law
  - Flowdown of Title XVIII Medicare law
  - Prosthetic Device benefit category
- The Proposal
  - Lymphedema Compression Items are Prosthetic Devices
- Administrative Law Judges Responses to The Proposal

# The Circulatory & Lymphatic Systems



Circulation system is closed system.

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

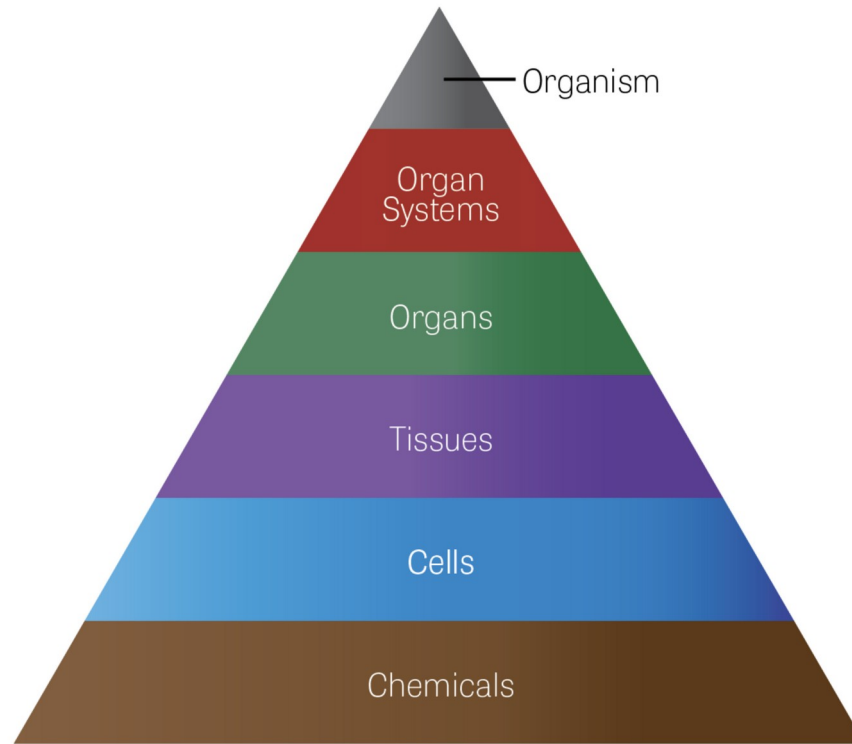
Blood pumped from the heart through arteries to capillary beds where arterial capillaries join continuously with venous capillaries and then through veins back to the heart.

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.***

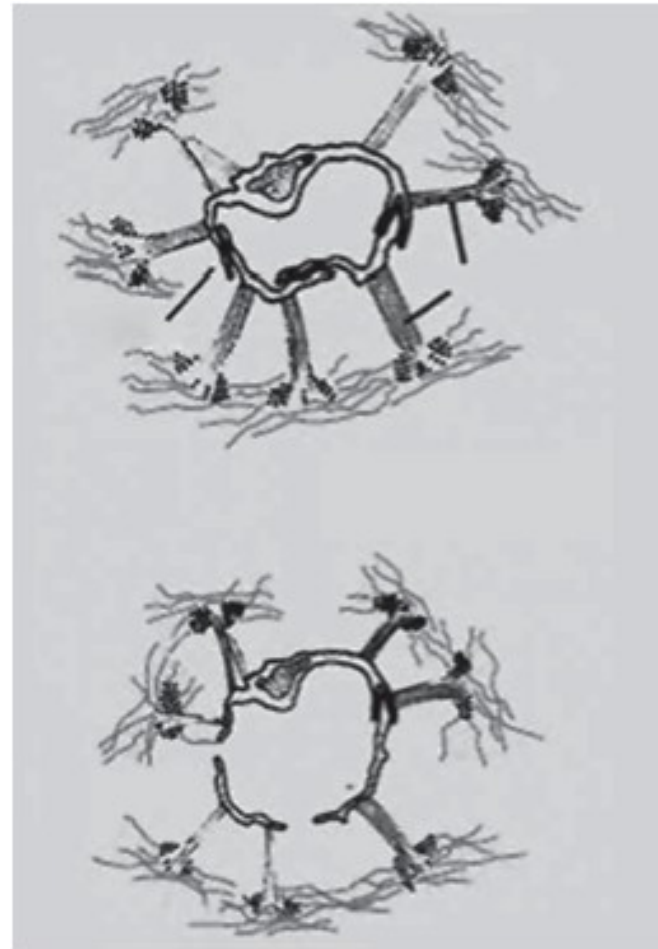
# Lymphatic Collectors and Lymphangions (Lymph Vessels) are Internal Body Organs



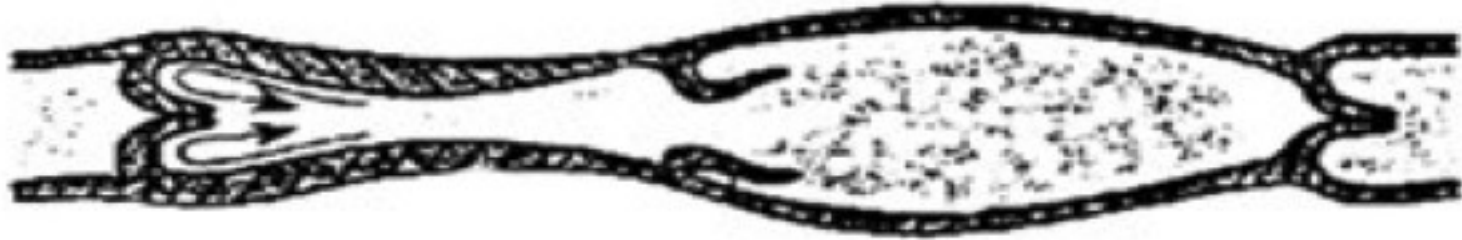
Pyramid represents a hierarchical organization of human body components  
(<https://toxtutor.nlm.nih.gov/08-003.html>)

# 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.)



# 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%

# 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
  - Stagnation or reduction in lymph flow

# 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.



# 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

# 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]*

# 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 [Ref. SSA §1861]
  - Whether the lymphedema compression garments are reasonable and medically necessary in the medical treatment of chronic lymphedema [Ref. SSA §1862]
  - Whether Medicare regulations provide coverage for replacement compression garments for treatment of lymphedema when determined by a physician to be medically necessary.

# Statutory Medicare Benefit Categories Relevant to Lymphedema Treatment

- 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
- 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.
  - 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***”

# Prosthesis (n.) VS Prosthetic (adj.)

- Dictionary Definition of Prosthetic [pros-thet-ik]
  - **adjective**
    - of or relating to an artificial body part
      - He was fitted for a [prosthetic arm](#).
  - **noun**
    - an artificial body part; a [prosthesis](#)
      - Hundreds of amputees volunteered to test the new [prosthetics](#).
- Medicare Definition per 42 CFR §414.202 [Prosthetic and orthotic devices](#)
  - (1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;
    - Derives from §1861(s)(8)
  - (3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.
    - Derives from § 1861(s)(9)

# Flow Down of Statutory Requirements

	STATUTORY DMEPOS BENEFIT CATEGORIES			
<b>BENEFIT CATEGORY</b>  <b>AUTHORITY</b>	<b>SURGICAL DRESSINGS, SPLINTS, CASTS</b>	<b>DURABLE MEDICAL EQUIPMENT</b>	<b>PROSTHETIC DEVICES</b>	<b>BRACES &amp; ARTIFICIAL LIMBS &amp; EYES (P&amp;O)</b>
<b>Title XVIII Social Security Act</b>	§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)
<b>Code of Federal Regulations 42 CFR</b>	§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)
<b>Benefit Policy Manual Pub. 100-02, Ch. 15</b>	§100	§110 §110.1	§120	§130
<b>NCD Manual Pub. 100-03</b>	§270	§280.1	§§20, 50, 80, 160, 180, 230	
<b>Claims Process. Man. Pub. 100-04, Ch. 20</b>		§10.1.1	§10.1.2	§10.1.3
<b>Example Local Cover- age Determinations (LCDs)</b>	L33831	L33829 L33739	L33317 L33798	L33318 L33686 L33737
<b>HCPCS Code Group</b>	A-Code, S-Code	E-Code	L-Code, S-Code	L-Code

# Examples of LCDs and LCAs Traceable to the Social Security Act

<b>BENEFIT CATEGORY</b>	<b>SSA §</b>	<b>Brief Title</b>	<b>LCD</b>	<b>LCA</b>	<b>CODE</b>
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

Examples from Noridian Administrative Services (DME MAC D)

# 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.



# 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-10-CM: S81.80]
  - Covered as a *burn dressing* (Axxxx) [ICD-10-CM: T24.009]
  - Covered as part of *lymphedema pump* (Exxxx) [ICD-10-CM: I89.0]
- 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-10-CM: I89.0; I97.2]
- 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)

# 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

# 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)**

# 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.

# 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.

# Unintended Consequences of 2006 Administrative Change of HCPCS Code

- Compression stockings have been listed in the HCPCS Code Book as “prosthetic services” (L8100-L8239).
- Use of compression stockings as secondary dressings 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 Jan 1, 2006 to “secondary dressings” (A6530-A6549).
- 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).

# 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...”
- 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...”
- 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.”

# 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
  - Serving as a physical barrier protecting skin from further trauma.



# Mechanisms & Effects of Compression Therapy in Lymphedema

## Mechanism

- Increased interstitial pressure
- Shift of fluid into uncompressed areas
- Increased lymph reabsorption and stimulation of lymphatic contractions
- Breakdown of fibrosclerotic tissue
- Improvement of venous pump in patients with venolymphatic dysfunction

## Effect

- Reduced capillary filtration<sup>6-8</sup> and production of lymph; limb volume decrease
- Proximal volume increase accommodated by normally working lymphatics in that region and assisted by manual lymphatic drainage<sup>9</sup>
- Improvement of lymph kinetics as shown by lymphoscintigraphy<sup>10</sup> and intra lymphatic measurement of flow and pressure<sup>11,12</sup>
- Softening of tissue as shown by ultrasound<sup>13</sup> and durometer<sup>14</sup>
- Increased expelled blood volume; reduction of venous reflux and ambulatory venous hypertension<sup>15</sup>

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

# 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.
- Since 2006, the majority of the ALJs who read and understood the medico-legal logic made favorable determinations for the Appellants, and reversed DME MAC denials.

# 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

# 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)

# 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.”

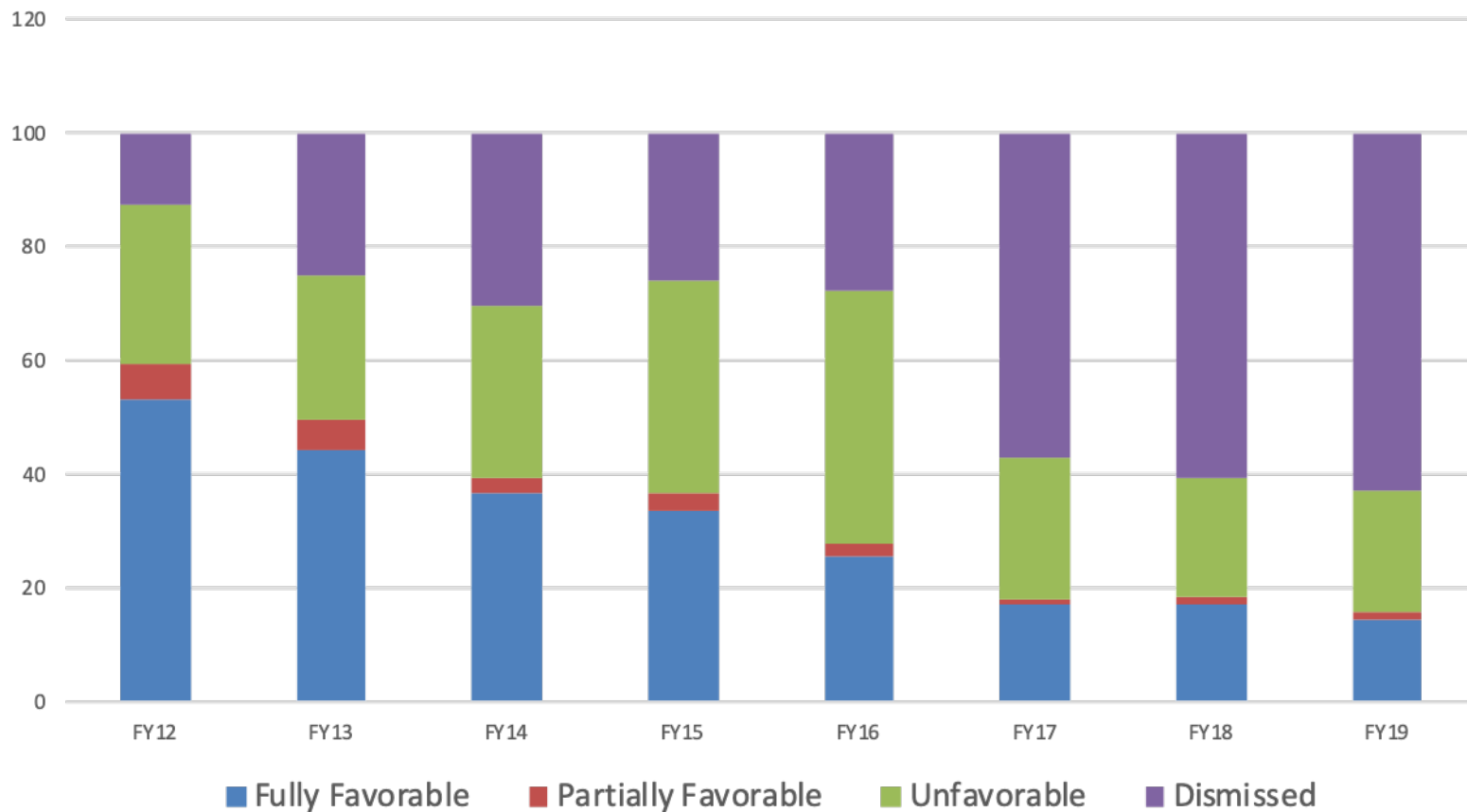
# Feb 20, 2008 Medicare Appeals Council Decision Re: ALJ Decision of Mar 14, 2007

- 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"

# Stealth Level Appeals

- Alarmed that the ALJ claim denial reversal rate was too high, CMS took a number of steps to reduce payments to Medicare beneficiaries. These steps have reduced the lymphedema patients' reimbursement in the last two years.
  - “Stealth Level Appeals” by Administrative Quality Independent Contractor (AdQIC)
  - CMS “training” of Administrative Law Judges (ALJs)
  - Provision of outdated and illogical arguments to Medicare Appeals Council (MAC)
- The majority of ALJs still return FAVORABLE decisions for Beneficiaries
- All FAVORABLE decisions are appealed to the MAC by the AdQIC
- FAVORABLE ALJ decisions are reversed by the MAC based on outdated and illogical scientific arguments and lack of knowledge of Medicare law

# U.S. Department of Health & Human Services ALJ Decision Statistics



Includes appeals decided in the listed fiscal year

Run Date: January 31, 2019

Content created by Office of Medicare Hearings and Appeals (OMHA), last reviewed on February 1, 2019  
U.S. Department of Health & Human Services HHS.gov



# 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

# Caveat

The preceding material is the opinion of an unpaid patient advocate and may not reflect the positions of any organization or governmental agency. Nor does it reflect the current stated position of the Centers for Medicare and Medicaid Services. The statements made herein are based on personal experience and research, and the writer's interpretation of relevant statutes and determinations of selected Administrative Law Judges in relevant appeal hearings. Citations are made to primary sources whenever possible. The author is not a physician or a lawyer, and the foregoing material should not be taken as medical or legal advice.

# Attempts to Change CMS Policy

- 2000 Submitted **Formal Request for a National Coverage Decision: Treatment of Lymphedema**
  - 2001 Response: "... they do not meet any of the statutorily defined benefit categories outlined in the Social Security Act."
- 2004 Submitted inquiry to NIH. Referred to CAG
  - 2004 Response from CAG: 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.
- 2016 Submitted **Formal Request for a National Coverage Determination—Coverage of Lymphedema Compression Treatment Items as Prosthetic Device Benefits**
  - 2018 Response: There is no appropriate benefit category
- 2020 Resubmitted request for NCD
  - 2021 Referred to Technology Coding and Pricing Group to determine benefit category. Awaiting response.

# 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.**