



# Lymphedema Treatment Act HR 1608 / S 2373

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- Oncology Nursing Society
- American Acad. of Physical Medicine and Rehabilitation
- American Occupational Therapy Association
- American Physical Therapy Association
- Wound, Ostomy and Continence Nurses Society
- LIVESTRONG
- Colon Cancer Alliance
- Susan G. Komen
- Ovarian Cancer National Alliance
- Lymphatic Education and Research Network
- National Lymphedema Network

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## ABOUT LYMPHEDEMA:

Lymphedema, which encompasses a variety of diseases, is marked by an accumulation of lymph fluid (swelling) in parts of the body where lymph nodes or lymphatic vessels are damaged or inadequate. This chronic but treatable condition affects millions of Americans. Among the many causes, damage from cancer treatment is the most common.

Untreated or inadequately treated lymphedema is progressive, leading to complications, comorbidities, loss of function, disability, and in some cases even death. Compression therapy is the time-proven cornerstone of lymphedema treatment, without which patients cannot maintain their condition. Coverage for compression will enable patients to effectively manage this disease, thereby greatly improving their overall health and quality of life.

## WHY THIS LEGISLATION IS NEEDED:

Medicare does not cover the medically necessary compression supplies used daily in lymphedema treatment, citing they do not fit under any benefit category. This issue has been thoroughly vetted, with the Center for Medicare Services (CMS) maintaining that coverage for these items cannot be brought about through policy change. The Health and Human Services Secretary has confirmed that a change in statute is necessary (see page 2 for statement).

## WHAT THIS LEGISLATION WILL DO:

- Provide for Medicare coverage of the doctor-prescribed compression supplies that are essential to the effective treatment of lymphedema;
- Reduce the total healthcare costs associated with this disease by decreasing the incidence of complications, co-morbidities and disabilities resulting from this medical condition.

This is not a disease specific bill; it covers all currently known forms of lymphedema (for which there are presently 12 different CPT diagnosis codes), and, as distinct etiologies are continuing to be discovered, would encompass those diseases as well.

The Lymphedema Treatment Act will enable coverage of compression supplies under Durable Medical Equipment. No other proposed revision or reform of Medicare will rectify this unintended gap in coverage.

Please visit our website to learn more.



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

## **WHY MEDICARE BENEFICIARIES ARE NOT CURRENTLY RECEIVING THE STANDARD OF CARE FOR LYMPHEDEMA:**

Congressman Dave Reichert submitted official queries to each of the last two Health and Human Services Secretaries. He inquired whether Medicare could provide coverage for the compression supplies needed for every day self-management of lymphedema.

In 2012 (Secretary Sebelius) and again in 2015 (Secretary Burwell), the official responses indicated a lack of an appropriate benefit category.

*“Although Medicare does cover certain compression garments in the treatment of venous stasis ulcers as a secondary surgical dressing, CMS has not identified any other Medicare part B benefit category that could be used to cover everyday self-care garments for lymphedema patients. A statutory change could provide for Medicare coverage and financing for these items”.*

*~Secretary Burwell 9/2015*

## **ADDITIONAL INFORMATION ABOUT LYMPHEDEMA CAN BE FOUND AT:**

### **The National Lymphedema Network**

<http://www.lymphnet.org/resources/nln-position-paper-the-diagnosis-and-treatment-of-lymphedema>

### **The Lymphatic Education and Research Network**

<http://lymphaticnetwork.org/living-with-lymphedema/lymphedema/>

### **The National Cancer Institute at the National Institutes of Health**

[www.cancer.gov/cancertopics/pdq/supportivecare/lymphedema/healthprofessional/page1](http://www.cancer.gov/cancertopics/pdq/supportivecare/lymphedema/healthprofessional/page1)

## **WASHINGTON POST ARTICLE:**

**A story chronicling one family’s struggle to obtain a diagnosis and treatment for their child’s lymphedema, and the origins of the Lymphedema Treatment Act -**

[https://www.washingtonpost.com/national/health-science/what-caused-a-newborn-twins-badly-swollen-legs/2015/09/28/684919e0-315a-11e5-8353-1215475949f4\\_story.html](https://www.washingtonpost.com/national/health-science/what-caused-a-newborn-twins-badly-swollen-legs/2015/09/28/684919e0-315a-11e5-8353-1215475949f4_story.html)

## **PUBLIC SERVICE ANNOUNCEMENT:**

**This 13-minute video about Lymphedema and the Lymphedema Treatment Act provides excellent foundational information, and includes interviews with doctors, researchers, therapists, and patients -** <https://youtu.be/GQZuvWs4-Pc>

## **AVALERE HEALTH COST ANALYSIS OF THE LYMPHEDEMA TREATMENT ACT:**

**To obtain a copy please contact our House or Senate bill sponsor’s office, or go to** <http://lymphedematreatmentact.org/about-the-bill/ta-info-packet-for-congress/>.

## **LIBRARY OF CONGRESS LINKS:**

**House Bill, HR 1608 -** <https://www.congress.gov/bill/114th-congress/house-bill/1608>

**Senate Bill, S 2373 -** <https://www.congress.gov/bill/114th-congress/senate-bill/2373>

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Please visit our website to learn more.



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

# 6 THINGS YOU MAY NOT KNOW ABOUT LYMPHEDEMA

**1** Lymphedema is chronic swelling caused by a build-up of fluid that occurs when the lymphatic system is either faulty or damaged.

Damaged vessels blocking the normal flow of lymphatic fluid

**3** Most physicians in the United States are taught about the lymphatic system for **1 hour** or less during their 4 years of medical school training.

**4** There is no known cure for lymphedema, but it can be effectively treated. **Compression therapy** is the most critical component of treatment. Without it, patients are at increased risk for complications and disability.

**5** Medicare, and many private insurance policies do NOT cover compression garments, wraps, or bandages — the supplies needed for compression therapy.

**6** The **Lymphedema Treatment Act** is a bill, currently in Congress, that aims to improve insurance coverage for compression supplies, allowing lymphedema patients to maintain a healthy and productive life.

**2** An estimated 3-5 million Americans suffer from lymphedema — including many that are undiagnosed or undertreated. *That is more than ALS, Cystic Fibrosis, Multiple Sclerosis, Muscular Dystrophy, and Parkinson's Disease combined.*



2 out of 5 breast cancer patients will develop lymphedema within 5 years of surgery.\*

Swollen tissue due to buildup of lymphatic fluid

## Causes of Lymphatic Dysfunction

- A. Lymph node removal for cancer treatment
- B. Injury to lymphatic vessels due to trauma or infection
- C. Venous insufficiency, causing overload of lymphatic vessels
- D. Congenital malformation of lymphatics



Visit our website to learn more about lymphedema and how to support this bill.

[LymphedemaTreatmentAct.org](http://LymphedemaTreatmentAct.org)

**Estimated number of constituents in each state who would directly benefit from passage of the Lymphedema Treatment Act.**



The Avalere Health cost analysis for the Lymphedema Treatment Act demonstrated that nationally, 0.57% of all Medicare patients have diagnosed lymphedema. Published totals of Medicare beneficiaries as of March 2012 are shown below<sup>1</sup>. When extrapolating 0.57% of those state totals, we arrive at 2012 estimates of Medicare beneficiaries diagnosed with lymphedema. Published estimates of growth in Medicare beneficiaries suggest an 8% rise between 2012 and 2015<sup>2</sup>. When extrapolating 8% more total (and 8% more with lymphedema) in each state, we arrive at 2015 estimates of Medicare beneficiaries diagnosed with lymphedema.

<b>United States</b>	<b>Total Medicare Beneficiaries by State As of March 2012</b>	<b>2012 Estimate of Medicare Patients with Lymphedema by State</b>	<b>2015 Estimate of Medicare Patients with Lymphedema by State</b>
Alabama	881686	5025	5427
Alaska	69301	395	426
Arizona	977447	5571	6016
Arkansas	552375	3149	3400
California	5000198	28,508	30,788
Colorado	667277	3803	4107
Connecticut	586545	3343	3610
Delaware	157289	896	967
DC	81260	463	500
Florida	3527830	20108	21716
Georgia	1318733	7516	8117
Hawaii	217678	1240	1339
Idaho	242889	1384	1494
Illinois	1907859	10874	11743
Indiana	1048499	5976	6454
Iowa	531209	3027	3269
Kansas	448215	2554	2758
Kentucky	793271	4521	4882
Louisiana	718037	4092	4419
Maine	276467	1575	1701
Maryland	827426	4716	5093
Massachusetts	1104483	6295	6798
Michigan	1728338	9851	10639
Minnesota	819803	4672	5045
Mississippi	516809	2945	3180

Missouri	1040491	5930	6404
Montana	177835	1013	1094
Nebraska	287565	1639	1770
Nevada	379860	2165	2338
New Hampshire	231444	1319	1424
New Jersey	1378274	7856	8484
New Mexico	329994	1880	2030
New York	3093591	17633	19043
North Carolina	1568429	8940	9655
North Dakota	110827	631	807
Ohio	1971260	11236	12135
Oklahoma	625924	3567	3852
Oregon	653905	3727	4025
Pennsylvania	2350558	13398	14469
Rhode Island	188502	1074	1159
South Carolina	820947	4679	5053
South Dakota	141079	804	868
Tennessee	1109791	6325	6831
Texas	3187332	18167	19620
Utah	299427	1706	1842
Vermont	117393	669	722
Virginia	1203462	6859	7407
Washington	1029529	5868	6337
West Virginia	392021	2234	2412
Wisconsin	948489	5406	5838
Wyoming	84076	479	517
Guam	12873	73	78
Puerto Rico	693652	3953	5059
Virgin Islands	17241	98	105

1. <http://kff.org/medicare/state-indicator/total-medicare-beneficiaries/#>

2. <http://www.intellectualltakeout.org/library/chart-graph/projected-number-medicare-beneficiaries-2001-2030>



## **Compression in the Treatment of Lymphedema: Evidence for Effectiveness and Reduced Healthcare Expenditure**

The Lymphedema Treatment Act seeks coverage for compression bandages, supplies, and garments used to reduce lymphedema related swelling, and to prevent its recurrence. **Compression is an integral component** of the standard of care for the treatment of lymphedema known as **Complete Decongestive Therapy (CDT)**. The first six documents outlined below summarize several position papers, reviews, and consensus documents, all of which recognize the necessity of compression for patients with lymphedema. The remaining documents reveal the fact that lymphedema, especially in *preventable* advanced stages, is costly, and that compression therapy reduces disease progression, complications, and the associated cost of care.

### **1. International Lymphedema Framework (2010): *Compression Hosiery (Garments) in Lymphedema*<sup>1</sup>**

The authors reviewed the published evidence for efficacy of compression garments and concluded the following:

- Studies with follow-up periods of six months to five years indicate that compression garments are effective in reducing and/or maintaining lymphedema of the arm and leg both in primary and secondary lymphedema.
- Compression hosiery (garments and arm sleeves) are an integral part of lymphedema management with strong evidence to support their use.
- Outcomes are less optimal in lymphedema management when compression therapy is not used.

### **2. MEDCAC Meeting on Lymphedema Treatment Protocols (2009)<sup>2</sup>**

A Medicare Evidence Development Coverage Advisory Committee (MEDCAC) meeting was held on November 18, 2009. The committee reviewed the Agency for Healthcare Research and Quality's (AHRQ) technology assessment of the efficacies of lymphedema diagnosis and treatment protocols. They also heard scheduled testimony of 15 leading experts on lymphedema as well as a number of unscheduled stakeholders and experts.

- The committee reports that the greatest confidence, for the best outcome, was in Complete Decongestive Therapy<sup>7</sup>, of which compression is an integral component (page 14 of meeting transcript)<sup>8</sup>.
- When isolating individual modalities of treatment, the committee reports the highest level of confidence was found in compression (page 5 of meeting tables)<sup>7</sup>.

### **3. International Lymphedema Framework (2012): *Compression Management, A Position Document on Compression Bandaging***<sup>3</sup>

The authors note the following regarding compression bandaging and garments:

- Lymphedema requires constant compression, if discontinued edema will recur rapidly.
- Compression removes edema by a reduction in capillary filtration, an increase in lymphatic drainage, a shift of fluid to non-compressed areas, and via a breakdown of fibrosclerotic tissue.
- Patient understanding and adherence are critical to sustained outcomes.
- Once swelling is maximally reduced, long term compression garments are required.

### **4. National Lymphedema Network Position Statement on The Diagnosis and Treatment of Lymphedema**<sup>4</sup>

- The gold standard for the treatment of lymphedema is known as Complete Decongestive Therapy.
- Compression Bandaging is always a requisite part of Complete Decongestive Therapy.
- Following achievement of maximal volume reduction with Complete Decongestive Therapy, patients should be fitted with a compression garment.

### **5. Cochrane Review of the Effectiveness of Various Lymphedema Therapies**<sup>5</sup> (2008)

The review concluded that the use of compression bandaging *and* garments was more effective than garments alone. Additionally, they noted that when comparing no treatment to the use of compression garments alone, the garments were deemed beneficial.

### **6. CMS Decision Memo on Pneumatic Pumps**<sup>6</sup>

The decision memo notes the following:

- Standard management of lymphedema typically includes positioning (elevation), manual lymphatic drainage, exercise, and compression garments or wraps.

- A pump may be an appropriate therapy for certain patients that have not been able to reduce limb swelling by conservative treatment. Such conservative treatment must include the use of a compression garment.
- Patients should use compression garments between pump sessions to prevent re-accumulation of fluid.

**7. Journal of The American Physical Therapy Association ~ *Breast Cancer Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Care Model (2012)*<sup>9</sup>**

- Modeled the direct costs of caring for patients identified in the early stages of lymphedema (using primarily compression garments) through a prospective surveillance program vs. caring for them in the later stages of the disease.
- Determined that the annual direct cost to manage early stage lymphedema with compression garments and minimal therapy was \$636.19 vs. \$3,124.92 in the more advanced stages requiring intensive therapy and compression.
- Thus, early identification and initiation of compression was calculated to significantly reduce healthcare costs.

**8. Journal of Clinical Oncology ~ *Incidence, Treatment Costs, and Complications of Lymphedema After Breast Cancer Among Women of Working Age: A 2-Year Follow-Up Study*<sup>10</sup>**

- This study evaluated the economic burden of managing breast cancer related lymphedema via analysis of insurance claims data on a total population of 550,000 insured, nearly 2000 of which had been diagnosed with breast cancer and 180 with breast cancer related lymphedema.
- The two year medical cost differential between breast cancer survivors with and without lymphedema was \$22,153 more spent on patients with lymphedema.
- Only 3.4% of the added cost was spent on therapy or compression supplies which are known to prevent disease progression. The remaining 96.6% was spent on the cost of evaluating and treating complications.
- The authors noted:
  - “Breast cancer related lymphedema patients are likely to incur high medical costs as a result of frequent visits to physicians and/or physical therapists to seek symptom control”.
  - “Poorly managed lymphedema may lead to complications needing medical attention, which increases the costs of care”.

## 9. Rehabilitation Oncology Journal ~ *Effect of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema*<sup>11</sup>

(and The American Journal of Infection Control ~ *Outcomes and management costs in patients hospitalized for skin and skin-structure infections*)<sup>12</sup>

- Lymphedema was recognized as one of the most potent risk factors for the development of recurrent cellulitis, which frequently requires hospitalization.
- The authors remarked that the study removed a significant barrier to idealized treatment by covering the cost of bandages and garments (not covered by Medicare) through the study's funding. The item costs ranged from \$120 - \$1000 and items were replaced every 6 months per standard of care.
- The study revealed that 18 months of treatment, primarily consisting of compression including bandaging and custom garments, reduced the cumulative average annual number of hospitalizations among the study participants from 8.5/year down to 0.67/year.
- In 2011, the American Journal of Infection Control published an evaluation of multihospital insurance data which reviewed the cost of over 5,000 admissions between 2002 and 2006 for complicated cellulitis<sup>12</sup>. This population included patients with an underlying condition, such as lymphedema, which complicates the response to treatment. The study found that the length of stay per episode was 9.5-17.2 days and cost ranged from \$40,046 - \$80,093 per hospital stay. Costs are expected to have risen modestly since that time.
- Thus, even at the lower end of cost, 8.5 hospitalizations per year would be expected to cost at least \$340,391 whereas, after receiving compression therapy, 0.67 hospitalizations per year would be expected to cost well over **12 fold less** at \$26,830.

### References:

- 1.[http://www.lympho.org/mod\\_turbolead/upload/file/Lympho/Template\\_for\\_Practice\\_-\\_Compression\\_hosiery.pdf](http://www.lympho.org/mod_turbolead/upload/file/Lympho/Template_for_Practice_-_Compression_hosiery.pdf)
- 2.<http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=51&fromdb=true>
- 3.[http://www.lympho.org/mod\\_turbolead/upload//file/Resources/Compression%20bandaging%20-%20final.pdf](http://www.lympho.org/mod_turbolead/upload//file/Resources/Compression%20bandaging%20-%20final.pdf)
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- 11.<http://www.oncologypt.org/publications/rehabilitation-oncology-journal/volumes/29/29-3-Rehabilitation-Oncology-Journal.pdf>
- 12.[http://www.ajicjournal.org/article/S0196-6553\(10\)00600-0/abstract](http://www.ajicjournal.org/article/S0196-6553(10)00600-0/abstract)





**To:** Lymphedema Advocacy Group

**From:** Avalere Health

**Date:** July 29, 2015

**Re:** Estimated Federal Costs of H.R.1608 - The Lymphedema Treatment Act

**Summary**

The Lymphedema Advocacy Group asked Avalere Health to estimate the cost or savings to the federal government of the Lymphedema Treatment Act (H.R. 1608). This proposed legislation would create a new category of durable medical equipment, prosthetics and orthotics supplies (DMEPOS) for compression items used in the treatment of patients with lymphedema. The compression items would be covered by Medicare Part B with coverage proposed to take effect January 1, 2016.

Avalere’s analysis estimates that the proposed legislation would increase federal spending by \$475 million over the FY2016 – FY2025 federal budget window. Our estimate reflects a cost of \$886 million associated with Medicare coverage of the compression items used to treat beneficiaries with lymphedema, including some beneficiaries who may already be paying for these items out-of-pocket. The estimate also includes \$411 million in potential savings associated with a reduction in hospitalizations among beneficiaries with lymphedema utilizing compression items as a part of their therapy.

**Table 2: Estimated Change in Federal Spending due to the Lymphedema Treatment Act**

	Outlays, by Fiscal Year, in Millions of Dollars											2016-2020	2016-2025
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025			
Medicare Coverage Costs	50	70	80	80	90	90	100	100	110	120	<b>360</b>	<b>890</b>	
Hospitalization Reduction Savings	*	*	*	*	*	*	*	*	50	50	<b>170</b>	<b>410</b>	
Total change in federal spending	*	*	*	*	50	50	50	60	60	60	<b>190</b>	<b>480</b>	

\* represents less than \$50 million  
 Note: Numbers may not add due to rounding.

## Background

Lymphedema is a complex, chronic condition manifested by the swelling of the affected body part due to the insufficient function of the lymphatic system. Lymphedema is commonly developed by patients who have undergone cancer treatment, particularly related to breast cancer. Less common causes of lymphedema are trauma/injury, chronic venous insufficiency, lymphatic infection, congenital malformations, and obesity.<sup>1</sup> Lymphedema requires lifelong compression therapy to continuously minimize the swelling. Untreated or inadequately treated lymphedema is progressive, resulting in complications such as cellulitis and deterioration of the patient's health status, and in some cases, can cause disability.

Lymphedema is prevalent, yet due to limited awareness among patients and health care providers combined with the lack of the epidemiological evidence, the disease has not been properly tracked and documented.<sup>2</sup> Further, the health care cost burden of the life-long treatment of lymphedema and related complications has not been adequately researched.<sup>3 4</sup>

The current, clinically recognized, nonsurgical standard of care for treatment of the patients with lymphedema is complete decongestive therapy (CDT) that includes the following four components:<sup>5</sup>

- Manual Lymph Drainage (MLD): A specialized rehabilitation therapy used to manually move stagnant lymph fluid out of the affected areas of the body.
- Compression Therapy: Any combination of compression garments, devices or multi-layer bandaging systems used to lessen or prevent re-accumulation of swelling after affected areas have been decongested.
- Lymph Drainage Exercises: Exercises that stimulate lymph pumping and flow, which should be performed while the affected areas of the body are under compression therapy described above.
- Skin Care: Meticulous skin care and hygiene in order to minimize the risk of infection and other complications.

CDT involves two phases<sup>6</sup>:

1. **Intensive Rehabilitation**: In this phase, a rehabilitation therapist (specializing in physical or occupational therapy) works to reduce the swelling (decongestion), using MLD and

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<sup>1</sup> McMaster University Evidence-based Practice Center. "Diagnosis and Treatment of Secondary Lymphedema, Technology Assessment Report". Prepared for Agency For Healthcare Research and Quality (AHRQ). May 28, 2010.  
<http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id66aTA.pdf>

<sup>2</sup> N.L. Stout, R. Weiss, J.L. Feldman, B.R. Stewart, J.M. Armer, J.N. Cormier, Y.- C.T. Shih . "A systematic review of care delivery models and economic analyses in lymphedema: health policy impact (2004-2011)". *Lymphology*. 2013 Mar ;46(1):27-41.  
<https://www.afp.org/docs/27-41.Mar%202013.STOUT.PDF>

<sup>3</sup> Ibid.

<sup>4</sup> McMaster University Evidence-based Practice Center. "Diagnosis and Treatment of Secondary Lymphedema, Technology Assessment Report". Prepared for Agency For Healthcare Research and Quality (AHRQ). May 28, 2010.  
<http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id66aTA.pdf>

<sup>5</sup> "The diagnosis and treatment of peripheral lymphedema". 2013 Consensus Document of the International Society of Lymphology. *Lymphology* 46 (2013) 1-11. <http://www.u.arizona.edu/~witte/2013consensus.pdf>  
Poage E, Singer M, Armer J, Poundall M, Shellabarger MJ. "Demystifying lymphedema: development of the lymphedema putting evidence into practice card". *Clin J Oncol Nurs*. 2008 Dec;12(6):951-64. <http://www.guideline.gov/content.aspx?id=15699>  
Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on lymphedema, November 18, 2009. <http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=51&fromdb=true>

<sup>6</sup> Ibid.

compression therapy combined with multi-layer bandaging. The patient is educated to perform lymph drainage exercises and to apply proper skin care. This phase usually lasts 4-6 weeks.

2. Ongoing Self-Maintenance: In this home-care phase, the patient is responsible for maintaining the results achieved in the intensive phase by continuing proper skin care, exercises, and compression therapy by using appropriate items such as limb-specific compression garments.

Currently, Medicare and many private insurance plans do not cover compression items, which are considered a necessary part of CDT. Patients with lymphedema often pay out-of-pocket for compression items and the prices vary greatly among types of supplies and suppliers. Notably, individual states either have passed (Virginia, California, and North Carolina) or have a proposed legislation (e.g. Massachusetts) that mandates private insurers to provide coverage of the lymphedema treatment, including compression items.<sup>7</sup>

H.R. 1608, titled the Lymphedema Treatment Act would create a new category under the existing DMEPOS benefit to provide Medicare Part B coverage for the following prescribed compression items:

- Multi-layer compression bandaging systems
- Custom or standard fit gradient compression garments
- Non-elastic and low-elastic compression garments and compression wraps and directional flow pads
- Any other compression items as determined by the Secretary of HHS

Once covered, compression items would be assigned billing codes under the Healthcare Common Procedure Coding System (HCPCS) and would be reimbursed by Medicare under the DMEPOS fee schedule. The Centers for Medicare & Medicaid Services (CMS) would likely determine the reimbursement rates for these newly covered items using its existing gap-fill methodology.<sup>8</sup>

## Data Sources

We used the following data sources to develop our estimate:

- CMS' Medicare 5% Physician, Hospital Outpatient, Hospital Inpatient, and Durable Medical Equipment Standard Analytical Files (SAFs), 2013<sup>9</sup>
- Projected Consumer Price Index for Urban Consumers (CPI-U) and Prospective Payment System (PPS) Factor Update, Congressional Budget Office (CBO) March 2015 Baseline: Medicare<sup>10</sup>

<sup>7</sup> Virginia: <http://leg1.state.va.us/cgi-bin/legp504.exe?2021+ful+HB383>;

Massachusetts: <https://malegislature.gov/Bills/188/Senate/S493>

<sup>8</sup> [http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5\\_10\\_10.pdf](http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf).

See also Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §60.3 - Gap-filling DMEPOS Fees.

<sup>9</sup> <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/StandardAnalyticalFiles.html>

<sup>10</sup> <https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf>

- Medicare population growth and Admissions per Capita growth, CMS' Office of the Actuary (OACT) Part B January 2015 Baseline<sup>11</sup>
- Historical CPI-U: U.S. city average, the U.S. Bureau of Labor Statistics<sup>12</sup>
- Annual DEMPOS Fee Schedule Update Factors 1990-2014: individual CMS' releases
- Innovators' Guide to Navigating Medicare, Version 2.0, 2010<sup>13</sup>
- Proprietary price and utilization information received from six suppliers currently selling compression items<sup>14</sup>
- Information gathered during discussions with the clinical experts:
  - Julie F. Hanson MD, FAAP, CLT-LANA, Board Member and Medical Advisor, Lymphedema Advocacy Group
  - Carol L. Johnson OTR/L, CLT-LANA, Board Member and Medical Advisor, Lymphedema Advocacy Group
  - Nicole L. Stout, DPT, CLT-LANA, Board Member and Medical Advisor, Lymphedema Advocacy Group
  - Jane M. Armer, PhD, RN, FAAN, Professor, MU Sinclair School of Nursing, Director, American Lymphedema Framework Project
- Kathryn Arsenault, Lee Rielly, Helen Wise, *Effects of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema*, Rehabilitation Oncology, Vol. 29. No.3 , 2011<sup>15</sup>
- California Health Benefits Review Program (CHBRP). (2005). *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*. Report to Calif. State Legislature. Oakland, CA: CHBRP. 05-03<sup>16</sup>
- Commonwealth of Massachusetts, Division of Health Care Finance and Policy. *Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Women's Health and Cancer Recovery Senate Bill 896*. Prepared for the Joint Committee on Public Health. December 2010<sup>17</sup>
- Report of the State Corporation Commission to the Governor and the General Assembly of Virginia: *The Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2004-2012 Reporting Periods*<sup>18</sup>

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<sup>11</sup> Files received by Avalere from the CMS' Office of the Actuary.

<sup>12</sup> <http://www.bls.gov/cpi/#tables>

<sup>13</sup> [http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5\\_10\\_10.pdf](http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf).

<sup>14</sup> The following suppliers provided Avalere Health with the data: Academy Bandages (Academy of Lymphatic Studies); Bandages Plus; Graybeal Orthopedics; Luna Medical, Inc.; Lymphedema Products, LLC; SunMed Medical Systems, LLC

<sup>15</sup> <http://www.oncologypt.org/publications/rehabilitation-oncology-journal/volumes/29/29-3-Rehabilitation-Oncology-Journal.pdf>

<sup>16</sup> [http://chbrp.org/documents/ab\\_213final.pdf](http://chbrp.org/documents/ab_213final.pdf)

<sup>17</sup> <http://www.mass.gov/chia/docs/r/pubs/10/womens-health-and-cancer-recovery-mb-report.pdf>

<sup>18</sup> <http://leg2.state.va.us/DLS/H&SDocs.NSF/Search%20options?OpenForm>

## Assumptions and Methodology

- **Number of Medicare fee-for-service (FFS) beneficiaries with lymphedema:** Avalere analyzed Medicare 5% Standard Analytic Files with physician, durable medical equipment (DME), and outpatient hospital claims data to identify beneficiaries with lymphedema. We used diagnosis codes developed during discussions with clinical experts to identify these patients.<sup>19</sup> We extrapolated our results to the whole Medicare population to estimate that there were 316,640 beneficiaries with diagnosed lymphedema in 2013.

We assume the prevalence of lymphedema in the Medicare population will remain constant over the next 10 years. We therefore increased the number of patients with lymphedema by the growth rate of the overall Medicare FFS population.

- **Estimated number of beneficiaries who will use compression items.** We assessed the current treatment patterns among the Medicare beneficiaries we identified with lymphedema. Specifically, we determined the proportion of beneficiaries who had claims for physical and occupational therapy (PT and OT) visits and compression pumps<sup>20</sup> – services currently covered by Medicare – as a proxy for the treatment rate among the lymphedema population. We estimate 27 percent of Medicare beneficiaries with lymphedema currently seek therapy treatment. In addition, we identified a group of beneficiaries with lymphedema who had Medicare claims for a compression stocking – the only compression items currently covered by Medicare under DME surgical supplies category and intended for wound care.<sup>21</sup> Beneficiaries are eligible for this coverage only when an open wound is present. We found that approximately 4 percent of beneficiaries with lymphedema had claims for a compression stocking. We removed these patients from the “treatment” group to the extent there were overlaps. As a result, we estimate 24 percent of Medicare beneficiaries with lymphedema currently seek therapy treatment and do not use compression stockings.

The California mandate assessment report found underutilization of the treatment among privately insured lymphedema patients under age 65.<sup>22</sup> Specifically, the analysis found around 12 percent of lymphedema patients utilizing PT or OT, 20 percent using compression garments, and fewer than 10 percent using MLD. On the other hand, some of the beneficiaries who are currently paying out-of-pocket for compression items are able to manage their lymphedema well on their own and may not need annual therapy visits or compression pumps (the services we used to estimate the treatment utilization

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<sup>19</sup> We used the following ICD-9 diagnosis codes to identify beneficiaries with lymphedema:

457.0 Post Mastectomy Lymphedema Syndrome  
457.1 Lymphedema Other  
757.0 Congenital Lymphedema or Hereditary Edema of the Legs  
624.8 Vulvar Lymphedema  
457.8 Other Non-Infectious Disorder of Lymphatic Channels  
125.0 Bancroftian Filariasis  
125.1 Malayan Filariasis  
125.6 Other Specified Filariasis  
125.9 Unspecified Filariasis

<sup>20</sup> We used the following Healthcare Common Procedure Coding System (HCPCS) codes for compression pumps: E0650 thru E0676 and for PT and OT therapy services: 97001, 97002, 97003, 97004, 97110, 97140, 97535

<sup>21</sup> The HCPCS codes for a compression stocking available under DMEPOS: A6531 and A6532

<sup>22</sup> [http://chbrp.org/documents/ab\\_213final.pdf](http://chbrp.org/documents/ab_213final.pdf)

rate). However, given the results from the California study, we feel our estimate that little less than one-quarter of the Medicare population with lymphedema will receive compression items accounts for most of these “unidentified” patients.

We also assumed the percentage of beneficiaries with lymphedema using compression items will increase slightly once Medicare coverage is expanded based on the findings from the assessment of the state mandates of lymphedema treatment coverage for patients with private insurance. The impact analysis of the Massachusetts mandate assumed an increase in the utilization of treatments for lymphedema but did not specify the magnitude of that increase.<sup>23</sup> The analysis of the California mandate estimated overall 2 percent increase in utilization of services for DME, compression garments, manual lymph drainage, and PT due to increased awareness that lymphedema treatment mandate would provide; the utilization specific to compression garments was assumed to increase by nearly 6 percent due to the removal of the coverage limits.<sup>24</sup> We note that no increase in utilization trends were observed over multiple years of data since the lymphedema treatment coverage mandate was implemented in Virginia in 2003.<sup>25</sup>

Based on the assessment of the state mandates related to private insurance coverage, we assumed that the percentage of beneficiaries using compression items would increase by 2 percent once the Medicare coverage begins. We based this assumption on the notion that lymphedema patients do not receive adequate treatment for many different reasons such as lack of disease awareness or poor access to care, and therefore Medicare coverage of compression items is not going to drastically increase the utilization of these products.

- **Current prices of compression items:** The cost of compression items varies greatly depending on the body part (lower vs. upper extremity) and whether the item has a custom or standard fit. The type and complexity, and thus cost, of compression items required by a patient depend on disease severity. For instance, a large portion of lymphedema patients are breast cancer survivors with the upper extremity lymphedema, which usually requires standard fit items on the lower end of the cost spectrum.<sup>26</sup>

Avalere obtained proprietary 2013 price and sales volume data from five national and one regional supplier who provide compression items to lymphedema patients, including Medicare beneficiaries who pay out-of-pocket. Specifically, Avalere asked suppliers to provide data for the following categories of compression items broken down by the body part, when applicable:

- Compression bandaging systems
- Compression garments (standard and custom fit)
- Compression alternatives/devices (standard and custom fit)

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<sup>23</sup> <http://www.mass.gov/chia/docs/r/pubs/10/womens-health-and-cancer-recovery-mb-report.pdf>

<sup>24</sup> [http://chbrp.org/documents/ab\\_213final.pdf](http://chbrp.org/documents/ab_213final.pdf)

<sup>25</sup> <http://leg2.state.va.us/DLS/H&SDocs.NSF/Search%20options?OpenForm>

<sup>26</sup> Based on the information gathered during the discussions with the clinical experts.

We assessed the utilization of each compression item type (reflected by units sold and customers served) and calculated the weighted average price points associated with each of the categories. We averaged retail/self-pay prices and contracted insurance rates reported by suppliers to estimate the overall compression item pricing in the market.

- **Utilization patterns of compression items after Medicare coverage expansion:**

Avalere determined utilization patterns for each compression item type after the coverage expansion based on the current lymphedema treatment standards and the analysis of the supplier data. Specifically, we assumed all treatment-receiving Medicare beneficiaries with lymphedema will use compression bandages and garments as required by a proper course of CDT:

- Compression bandaging systems: 2 bandaging sets, replaced every 6 months; 4 annually
- Compression garments: 2 items, replaced every 6 months; 4 annually

This is the quantity standard already used by private insurers who cover compression items and what we assumed Medicare will cover as well. Beyond those quantities, beneficiaries would have to prove medical necessity to receive additional items.

To estimate the percentage of beneficiaries who will use custom fit compression garments as opposed to standard fit, we assessed the supplier utilization data. Based on the data patterns we assumed 50 percent of beneficiaries will use standard fit garments and another 50 percent will use custom fit garments. Similarly, we used the supplier data to determine the portion of beneficiaries who will use more durable items from the compression alternatives/device category. We assumed 50 percent of beneficiaries who use bandages and garments will also use an alternative item (either standard or custom fit) replaced annually.

- **Medicare reimbursement for compression items under the DMEPOS fee schedule:**

For new items, CMS uses the gap-fill methodology based on the payments made under the reasonable charge methodology in the historic base period (1986/87) to determine the DMEPOS fee schedule reimbursement rates. If an item has been available in the base period, CMS will use the average historic price inflated to the current date using the percentage increases from the DMEPOS-covered item annual updates set in law. Since the DMEPOS fee schedule was implemented in 1989, the first annual update is available for 1990. If an item did not exist back in the base period, CMS will use the current retail price, deflate it to an estimated price for the base period using the Consumer Price Index for All Urban Consumers (CPI-U), and then re-inflate it to current date using the percentage increases from the DMEPOS-covered item annual updates set in law.<sup>27</sup>

Since there is no pricing information available for compression items in the base period, Avalere applied the gap-fill method to the estimated current compression item prices to determine DMEPOS fee schedule payments. It is important to note that CMS updates the DMEPOS fee schedule on a quarterly basis to allow for corrections to any fee

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<sup>27</sup> [http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5\\_10\\_10.pdf](http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf)

schedule amounts, if necessary, based on the market assessment such as product changes or prices other payers pay.

As compression items will be covered on the DMEPOS fee schedule, we inflated the prices for each item annually by the expected growth in the CPI-U. Of note, our analysis assumed these newly covered compression items will not be part of the DMEPOS competitive bidding process. Were these items to be competitively bid, there will likely be a resulting reduction in cost to the Medicare program. For the DME items in Round 2 of the DMEPOS Competitive Bidding Program (July 1, 2013 - June 30, 2016) Medicare payment amounts were reduced by 45 percent, on average.<sup>28</sup>

- **Potential savings:** A 2011 study found a 92 percent reduction in the number of hospitalizations for the management of cellulitis among patients with lymphedema who undertook CDT<sup>29</sup>. We adjusted the study results to determine the 73 percent reduction in hospitalizations for patients 65 and over as a more accurate proxy of the impact on the Medicare population. However, given that the study had a small sample size and reflected optimal treatment conditions, we estimate that the real impact on hospitalizations among the Medicare beneficiaries who use CDT could be smaller by 50 percent resulting in the 37 percent reduction in hospitalizations. This estimation also reflects lower level of severity among the patients 65 and over in the study compared to the actual Medicare beneficiaries. Patients 65 and over in the study had on average 0.8 admissions for the cellulitis treatment. Using the 2013 Medicare inpatient claims data, we determined that about 6 percent of beneficiaries with lymphedema had hospital admissions related to the cellulitis treatment.<sup>30</sup> We then calculated an average of 1.3 hospitalizations per patient at an average Medicare cost of \$9,939. We next estimated the reduction in the 2016-2025 Medicare spending due to the 37 percent reduction in hospitalizations for beneficiaries with lymphedema who will use compression items.

Expert opinion and considerable clinical evidence support the expectation that proper compression therapy slows disease progression and reduces complications.<sup>31 32</sup> Further, the analysis in California concluded that the lymphedema treatment mandate could have a favorable impact on patients' health via improved lymphedema control.<sup>33</sup> As such, the improvement in access to compression items due to the Medicare coverage may result in additional ameliorating effects on federal spending such as reductions in disability payments, outpatient physical or occupational therapy, and physician visits.

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<sup>28</sup> Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) , Competitive Bidding Program, Round 2 Weighted Average Savings. Available at:

[http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2\\_Weighted\\_Average\\_Savings.pdf/\\$File/R2\\_Weighted\\_Average\\_Savings.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/$File/R2_Weighted_Average_Savings.pdf)

<sup>29</sup> Kathryn Arsenault, Lee Rielly, Helen Wise, Effects of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema, *Rehabilitation Oncology*, Vol. 29. No.3 , 2011

<sup>30</sup> We used MS-DRGs and to identify the relevant hospitalizations.

<sup>31</sup> N.L. Stout, R. Weiss, J.L. Feldman, B.R. Stewart, J.M. Armer, J.N. Cormier, Y.- C.T. Shih . "A systematic review of care delivery models and economic analyses in lymphedema: health policy impact (2004-2011)". *Lymphology*. 2013 Mar ;46(1):27-41.

<https://www.alfp.org/docs/27-41.Mar%202013.STOUT.PDF>

<sup>32</sup> Nicole L. Stout, Lucinda A. Pfalzer, Barbara Springer, Ellen Levy, Charles L. McGarvey, Jerome V. Danoff, Lynn H. Gerber, Peter W. Soballe. "Breast Cancer-Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Model of Care". *Phys Ther*. January 2012; 92(1): 152-163.

<sup>33</sup> California Health Benefits Review Program (CHBRP). (2005). *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*. Report to Calif. State Legislature. Oakland, CA: CHBRP. 05-03. [http://chbrp.org/documents/ab\\_213final.pdf](http://chbrp.org/documents/ab_213final.pdf)

- **Federal financing adjustments:** After estimating the overall Medicare cost for covering compression items, we calculated the federal share of the spending by removing the impact of beneficiary copays and Part B premiums. We then estimated the impact this change in Part B costs would have on Medicare Advantage (MA) plans by calculating the effect on MA benchmarks and payments. We assumed that MA plans would continue to be paid at the same percentage of local FFS costs as they would have been paid under the current policy; since FFS costs will increase under the proposed policy, payments to MA plans will go up at the same rate. We also accounted for the federal costs associated with state Medicaid payment of dual-eligible beneficiaries' Part B copays and premiums. We estimate in FY 2016, the first year of Medicare coverage of compression items, the cost to federal government will be \$51 million before savings.

Congress of the United States  
Washington, DC 20515

**Cosponsor the Lymphedema Treatment Act to Help Millions of Medicare Beneficiaries Currently Lacking Treatment for Lymphedema**

Dear Colleague:

Lymphedema has been called “cancer treatment’s dirty little secret” and afflicts millions of Americans, yet Medicare beneficiaries currently lack coverage of compression supplies needed to effectively treat the condition. Lymphedema is progressive when left untreated and can put patients at greater risk for serious infection and disability. **To help patients successfully treat lymphedema and manage their symptoms, we urge you to join us in cosponsoring H.R. 1608, the *Lymphedema Treatment Act*.** This legislation will provide Medicare coverage of doctor-prescribed compression supplies while also helping to reduce total Medicare spending by decreasing the incidence of costly complications, co-morbidities and disabilities associated with the disease.

Lymphedema is a chronic condition resulting from the accumulation of lymph fluid which causes tissue swelling, most often in the arms or legs. It is estimated to afflict 1.5 to 3 million Medicare beneficiaries and 3 to 5 million Americans as a whole. While individuals can be born with a primary form of lymphedema, the majority of cases are secondary forms of lymphedema most often caused by cancer treatments that damage the body’s lymph system and immune functions. For cancer patients, lymphedema is one of the most significant survivorship issues. Breast cancer, in particular, is one of the most common causes of secondary lymphedema with an incidence rate of 20 to 40 percent.

Fortunately, there is hope for lymphedema patients as the risks and complications associated with the disorder can be mitigated through Complete Decongestive Therapy (CDT), which is considered the gold standard for treating lymphedema. In addition to manual lymph drainage and decongestive exercises, an essential component of CDT is compression therapy. Unfortunately, Medicare does not currently cover compression supplies. As a result, many Medicare patients cannot maintain their condition and experience an unnecessary loss of health and of function in the activities of daily living.

In order to improve the health care for lymphedema patients and decrease the rate of costly complications for cancer survivors, H.R. 1608 would provide Medicare coverage of medically necessary compression supplies. If you would like more information about the bill or to cosponsor, please contact Lindsay Manson in Rep. Reichert’s office (5-7761), Kristen Donheffner in Rep. Blumenauer’s office (5-4811), Molly McDonnell in Rep. Lance’s office (5-5361) or Amy Kelbick in Rep. Schakowsky’s office (5-2111).

Sincerely,



DAVE REICHERT  
Member of Congress



EARL BLUMENAUER  
Member of Congress



LEONARD LANCE  
Member of Congress



JAN SCHAKOWSKY  
Member of Congress

114TH CONGRESS  
1ST SESSION

# H. R. 1608

To amend title XVIII of the Social Security Act to provide for Medicare coverage of certain lymphedema compression treatment items as items of durable medical equipment.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 25, 2015

Mr. REICHERT (for himself, Mr. BLUMENAUER, Mr. LANCE, and Ms. SCHAKOWSKY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to provide for Medicare coverage of certain lymphedema compression treatment items as items of durable medical equipment.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lymphedema Treat-  
5 ment Act”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Lymphedema is a chronic disease that re-  
4 sults in an accumulation of protein-rich lymph fluid  
5 in parts of the body where lymph nodes or lymphatic  
6 vessels are damaged or inadequate.

7 (2) Lymphedema afflicts millions of Americans,  
8 including men, women, and children who can be  
9 born with a primary form of lymphedema. The ma-  
10 jority of cases, however, are secondary forms of  
11 lymphedema most often caused by cancer treatments  
12 that damage the body's lymph transport and im-  
13 mune functions.

14 (3) A 2010 peer-reviewed study in the Amer-  
15 ican Cancer Society's Cancer journal stated  
16 "lymphedema is a common post-treatment condition  
17 [and] has been described as one of the most signifi-  
18 cant survivorship issues". The study reported an  
19 overall cancer-related lymphedema incidence rate of  
20 15.5 percent, with specific rates as follows: sarcoma  
21 30 percent, breast 20 percent, gynecological 20 per-  
22 cent, melanoma 16 percent, genital-urinary 10 per-  
23 cent, and head and neck 4 percent. Risk increased  
24 22 percent after pelvic lymph node removal and 31  
25 percent after radiation therapy.

1           (4) Lymphedema is progressive when left un-  
2           treated or under-treated and can put patients at  
3           greater risk for serious infections or other costly  
4           complications.

5           (5) Congress acknowledged the importance of  
6           comprehensive lymphedema treatment coverage with  
7           passage of the Women’s Health and Cancer Rights  
8           Act of 1998, which requires group health plans, in-  
9           surance companies, and health maintenance organi-  
10          zations to cover breast cancer-related lymphedema  
11          treatment post mastectomy and reconstruction.

12          (6) Medicare beneficiaries with lymphedema  
13          currently lack coverage for compression therapy, an  
14          essential component of care they must use to man-  
15          age their chronic disease. As a result, many patients  
16          cannot maintain their condition and experience an  
17          unnecessary loss of health and of function in the ac-  
18          tivities of daily living.

19          (7) This Medicare coverage gap should be  
20          closed to help provide improved health care for  
21          lymphedema patients and in turn decrease the inci-  
22          dence of costly complications, co-morbidities and re-  
23          lated disabilities.



1           “(C) which would not, other than under  
2 subsection (s)(6), be included as medical and  
3 other health services under this title; and

4           “(2) includes—

5                 “(A) multilayer compression bandaging  
6 systems;

7                 “(B) custom or standard fit gradient com-  
8 pression garments;

9                 “(C) non-elastic and low-elastic compres-  
10 sion garments and compression wraps and di-  
11 rectional flow pads; and

12                 “(D) any other compression garments,  
13 bandaging systems, devices, and aids deter-  
14 mined by the Secretary to be effective in the  
15 prevention or treatment of lymphedema.”.

16           (b) EFFECTIVE DATE.—The amendment made by  
17 subsection (a) shall apply to lymphedema compression  
18 treatment items furnished on or after 180 days after the  
19 date of the enactment of this Act.

○