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

Congressman Dave Reichert’s question to the Health and Human Services Secretary (2/2012)

“Lymphedema affects an estimated 1.5 to 3 million Medicare beneficiaries. Individuals often need constant care to avoid recurrent infections. While Medicare does cover and pay for statutorily limited therapy and sequential compression pumps, many patients suffer from recurrent infections, progressive degradation in their condition and eventual disability because they cannot afford the compression bandages and garments required for everyday self-care. I have heard from patients and providers that state compression garments are a necessary form of treatment for patients with Lymphedema. They state compression garments help to improve the quality of life and stave off reoccurring infections for patients. Why does CMS not cover these treatments? Does CMS need a statutory change in order to provide coverage for these garments?”

The Health and Human Services Secretary’s response (8/2012)

“Currently, Medicare covers durable pneumatic compressors, referred to as lymphedema pumps, and appliances used in conjunction with these pumps under the Part B benefit for durable medical equipment. These equipment and accessories are used to treat lymphedema and are covered because they fall under a defined Medicare benefit category. In order for items to be covered by Medicare, they must meet the definition of a Medicare-covered benefit defined in the statute. However, it is important to note that although Medicare provides coverage for certain items, it does not provide coverage for every item with potential use for a person with a medical problem even if a physician prescribes the item. Other devices used to treat lymphedema, such as sleeves and stockings, are not covered by Medicare because they do not meet the definition of durable medical equipment or any other Medicare benefit category established by law.”

ADDITIONAL INFORMATION ABOUT LYMPHEDEMA CAN BE FOUND AT:

The National Lymphedema Network

The National Cancer Institute at the National Institutes of Health
www.cancer.gov/cancertopics/pdq/supportivecare/lymphedema/healthprofessional/page1
www.cancer.gov/cancertopics/pdq/supportivecare/lymphedema/Patient

A COST IMPACT ANALYSIS OF THE LYMPHEDEMA TREATMENT ACT IS AVAILABLE:

To obtain a copy contact Lindsay Manson in Representative Dave Reichert’s office at:
lindsay.manson@mail.house.gov or 202-225-7761

Please visit our website to learn more. www.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 (which follows) demonstrated that nationally, 0.57% of all Medicare patients have diagnosed lymphedema. Published totals of Medicare beneficiaries as of March 2012 are shown below. 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. When extrapolating 8% more total (and 8% more with lymphedema) in each state, we arrive at 2015 estimates of Medicare beneficiaries diagnosed with lymphedema.

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<th>United States</th>
<th>Total Medicare Beneficiaries by State As of March 2012</th>
<th>2012 Estimate of Medicare Patients with Lymphedema by State</th>
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To: Lymphedema Advocacy Group
From: Avalere Health
Date: August 12, 2014
Re: Estimated Federal Costs of H.R. 3877 - 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. 3877). 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, 2015.

Avalere’s analysis estimates that the proposed legislation would increase federal spending by $818 million over the FY2015 – FY2024 federal budget window. Our estimate reflects the costs associated with Medicare coverage of the compression items used to treat patients with lymphedema, including some patients who may already be paying for these items out-of-pocket. The spending increase does not include any estimate of potential savings associated with improved health of patients with lymphedema utilizing compression items as a part of their therapy.

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

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* 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, and obesity. 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. Further, the health care cost burden of the life-long treatment of lymphedema and related complications has not been adequately researched.

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:

- **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.

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3 Ibid.
CDT involves two phases:

1. **Intensive Rehabilitation:** In this phase, a rehabilitation therapist (specializing in physical or occupational therapy) works to reduce the swelling (decongestion), using MLD and 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 suppliers. Notably, individual states either have passed (Virginia) or have a proposed legislation (e.g. Massachusetts) that mandates private insurers to provide coverage of the lymphedema treatment, including compression items.

H.R. 3877, titled the Lymphedema Treatment Act would create a new category under the existing DMEPOS benefit to provide Medicare Part B coverage for the following 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.

**Data Sources**

We used the following data sources to develop our estimate:

- CMS' Medicare 5% Physician, Hospital Outpatient, and Durable Medical Equipment Standard Analytical Files (SAFs), 2012

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6 Ibid.
Massachusetts: [https://malegislature.gov/Bills/188/Senate/S493](https://malegislature.gov/Bills/188/Senate/S493)
See also Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §60.3 - Gap-filling DMEPOS Fees.
*Projected Consumer Price Index for Urban Consumers (CPI-U), Congressional Budget Office (CBO) March 2014 Baseline: Medicare*¹⁰

*Medicare population growth, CMS’ Office of the Actuary (OACT) Part B February 2014 Baseline*¹¹

*Historical CPI-U: U.S. city average, the U.S. Bureau of Labor Statistics*¹²

*Annual DEMPOS Fee Schedule Update Factors 1990-2014: individual CMS' releases*¹³

*Innovators’ Guide to Navigating Medicare, Version 2.0, 2010*¹³

*Proprietary price and utilization information received from six suppliers currently selling compression items*¹⁴

*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


### 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.\textsuperscript{18} We extrapolated our results to the whole Medicare population to estimate that there were 291,900 beneficiaries with lymphedema in 2012. 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.

- **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\textsuperscript{19} – services currently covered by Medicare – as a proxy for the treatment rate among the lymphedema population. We estimate 26 percent of Medicare beneficiaries with lymphedema currently seek therapy treatment. We assume these beneficiaries will use compression items once Medicare coverage is in place.

The California mandate assessment report found underutilization of the treatment among privately insured lymphedema patients under age 65.\textsuperscript{20} 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 rate). However, given the results from the California study, we feel our estimate that over 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.\textsuperscript{21} 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

\textsuperscript{18} We used the following ICD-9 diagnosis codes to identify patients 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

\textsuperscript{19} 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

\textsuperscript{20} http://chbrp.org/documents/ab_213final.pdf

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.\textsuperscript{22} 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.\textsuperscript{23}

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.\textsuperscript{24}

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)

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:

\textsuperscript{22} http://chbrp.org/documents/ab_213final.pdf
\textsuperscript{23} http://leg2.state.va.us/DLS/H%20SDocs.NSF/Search%20options?OpenForm
\textsuperscript{24} Based on the information gathered during the discussions with the clinical experts.
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.\(^{25}\)

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

  Since these items will be covered on the DMEPOS fee schedule, we inflated the prices for each compression 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.

- **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 2015, the first year of Medicare coverage of compression items, the cost to federal government will be slightly under $50 million.

- **Potential savings:** Our estimate of costs to the federal government from extending Medicare coverage to compression items does not include any potential savings associated with the improved health of the patients with lymphedema utilizing compression items as a part of their therapy. We were unable to quantify the impact of the appropriate treatment of lymphedema on better health outcomes and lower health care utilization resulting in the potential reduction in federal spending. Nevertheless, expert opinion and considerable clinical evidence supports the expectation that proper compression slows disease progression and reduces complications.\(^{26} \)\(^{27} \) Further, the analysis in California concluded that the lymphedema treatment mandate could have a favorable impact on patients’ health.\(^{28} \) As such, the improvement in access to compression items via Medicare coverage may have an ameliorating effect on federal spending.


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.

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Lymphedema Treatment Act”.

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SEC. 2. FINDINGS.

Congress makes the following findings:

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

(2) Lymphedema afflicts millions of Americans, including men, women, and children who can be born with a primary form of lymphedema. The majority of cases, however, are secondary forms of lymphedema most often caused by cancer treatments that damage the body’s lymph transport and immune functions.

(3) A 2010 peer-reviewed study in the American Cancer Society’s Cancer journal stated “lymphedema is a common post-treatment condition [and] has been described as one of the most significant survivorship issues”. The study reported an overall cancer-related lymphedema incidence rate of 15.5 percent, with specific rates as follows: sarcoma 30 percent, breast 20 percent, gynecological 20 percent, melanoma 16 percent, genital-urinary 10 percent, and head and neck 4 percent. Risk increased 22 percent after pelvic lymph node removal and 31 percent after radiation therapy.
(4) Lymphedema is progressive when left untreated or under-treated and can put patients at greater risk for serious infections or other costly complications.

(5) Congress acknowledged the importance of comprehensive lymphedema treatment coverage with passage of the Women’s Health and Cancer Rights Act of 1998, which requires group health plans, insurance companies, and health maintenance organizations to cover breast cancer-related lymphedema treatment post mastectomy and reconstruction.

(6) Medicare beneficiaries with lymphedema currently lack coverage for compression therapy, an essential component of care they must use to manage their chronic disease. As a result, many patients cannot maintain their condition and experience an unnecessary loss of health and of function in the activities of daily living.

(7) This Medicare coverage gap should be closed to help provide improved health care for lymphedema patients and in turn decrease the incidence of costly complications, co-morbidities and related disabilities.
SEC. 3. MEDICARE COVERAGE OF CERTAIN LYMPHEDEMA COMPRESSION TREATMENT ITEMS AS ITEMS OF DURABLE MEDICAL EQUIPMENT.

(a) **IN GENERAL.**—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (n), in the first sentence, by inserting before the semicolon the following: “and includes lymphedema compression treatment items (as defined in subsection (iii))”; and

(2) by adding at the end the following new subsection:

“(iii) **LYMPHEDEMA COMPRESSION TREATMENT ITEMS.**—The term ‘lymphedema compression treatment items’—

“(1) means, with respect to an individual, compression garments, devices, bandaging systems, components, and supplies—

“(A) that are primarily and customarily used in the medical treatment of lymphedema;

“(B) as prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) to the extent authorized under State law); and
“(C) which would not, other than under subsection (s)(6), be included as medical and other health services under this title; and

“(2) includes—

“(A) multilayer compression bandaging systems;

“(B) custom or standard fit gradient compression garments;

“(C) non-elastic and low-elastic compression garments and compression wraps and directional flow pads; and

“(D) any other compression garments, bandaging systems, devices, and aids determined by the Secretary to be effective in the prevention or treatment of lymphedema.”.

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