



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-	2016-
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2020	2025	
Medicare Coverage Costs	50	70	80	80	90	90	100	100	110	120	360	890	
Hospitalization Reduction Savings	*	*	*	*	*	*	*	*	50	50	170	410	
Total change in federal spending	*	*	*	*	50	50	50	60	60	60	190	480	

* 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.¹ 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.² Further, the health care cost burden of the life-long treatment of lymphedema and related complications has not been adequately researched.^{3,4}

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:⁵

- 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 phases⁶:

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

¹ 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>

² 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>

³ Ibid.

⁴ 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>

⁵ "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>

⁶ 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.⁷

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.⁸

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), 2013⁹
- Projected Consumer Price Index for Urban Consumers (CPI-U) and Prospective Payment System (PPS) Factor Update, Congressional Budget Office (CBO) March 2015 Baseline: Medicare¹⁰

⁷ Virginia: <http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+HB383>.

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

⁸ 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.

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

¹⁰ <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 Baseline¹¹
- Historical CPI-U: U.S. city average, the U.S. Bureau of Labor Statistics¹²
- Annual DEMPOS Fee Schedule Update Factors 1990-2014: individual CMS' releases
- Innovators' Guide to Navigating Medicare, Version 2.0, 2010¹³
- Proprietary price and utilization information received from six suppliers currently selling compression items¹⁴
- 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 , 2011¹⁵
- 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. 05-03¹⁶
- 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 2010¹⁷
- 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*¹⁸

¹¹ Files received by Avalere from the CMS' Office of the Actuary.

¹² <http://www.bls.gov/cpi/#tables>

¹³ http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf.

¹⁴ 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

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

¹⁶ http://chbrp.org/documents/ab_213final.pdf

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

¹⁸ <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.¹⁹ 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 pumps²⁰ – 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.²¹ 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 65.²² 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

¹⁹ 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

²⁰ 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

²¹ The HCPCS codes for a compression stocking available under DMEPOS: A6531 and A6532

²² 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.²³ 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.²⁴ 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 2003.²⁵

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.²⁶

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)

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

²⁴ http://chbrp.org/documents/ab_213final.pdf

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

²⁶ 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.²⁷

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

²⁷ 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.²⁸

- **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 CDT²⁹. 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.³⁰ 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.^{31 32} Further, the analysis in California concluded that the lymphedema treatment mandate could have a favorable impact on patients' health via improved lymphedema control.³³ 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.

²⁸ 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)

²⁹ 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

³⁰ We used MS-DRGs and to identify the relevant hospitalizations.

³¹ 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

³² 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.

³³ 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

- **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.