

STATE OF MARYLAND



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MARYLAND HEALTH CARE COMMISSION

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January 10, 2017

The Honorable Larry Hogan
Governor
State of Maryland
Annapolis MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis MD 21401-1991

Dear Governor Hogan, President Miller, and Speaker Busch:

Pursuant to Insurance Article § 15-1501, Annotated Code of Maryland, the Maryland Health Care Commission is pleased to submit this year's annual mandated health insurance services evaluation on **Coverage for the Diagnosis, Evaluation, and Treatment of Lymphedema.**

The Commission contracted with NovaRest, Inc., an actuarial consulting firm, to conduct the fiscal impact of this proposed mandate (HB 113) that failed to pass during the 2016 legislative session. NovaRest indicates in the enclosed report that the mandate would not have a material impact on the total cost of health care in Maryland. However, the Commission strongly urges the Legislature to proceed with caution when considering the adoption of additional mandated health insurance services given their cumulative deleterious impact on affordability over time despite a minimal impact on premiums at the time of adoption.

The Commission also believes it is important to note that if most carriers in Maryland (as noted in the report, based on those carriers who responded to the mandate survey questions) are already covering these services, when deemed medically necessary, then to mandate such a service does not seem necessary.

Lymphedema Mandate Letter

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Lastly, the Commission would like to stress the importance for the Legislature to define the need for a specific service in proposed mandate legislation in the future. Testimony on this bill revealed that carriers in the regulated insured market in Maryland impacted by the bill currently cover treatment of lymphedema. Other testimony stated that although medical services are covered, the cost of associated durable medical equipment may be unaffordable to some insured members.

Please do not hesitate to contact me at 410-764-3565, if you have any questions.

Sincerely,



Ben Steffen
Executive Director

cc: The Honorable Mac Middleton, Chair, Senate Finance Committee
The Honorable Shane Pendergrass, Chair, House Health and Government Operations Committee
Delegate Alfred C. Carr, Jr.
Linda Stahr
Sarah Albert (5)

Enclosure



December 15, 2016

**Annual Mandate Report:
Coverage for Lymphedema Diagnosis,
Evaluation, and Treatment**

Prepared for the Maryland Health Care Commission
Pursuant to Insurance Article §15-1501
Annotated Code of Maryland

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Evaluation of Proposed Mandated Health Insurance Services

Insurance Article § 15-1501, Annotated Code of Maryland, requires that the Maryland Health Care Commission (MHCC) annually assess the impact of proposed mandated health insurance services that failed to pass during the preceding legislative session or that were submitted to MHCC by a legislator by July 1 of each year. The assessment reports are due to the General Assembly annually by December 31.

NovaRest, Inc. and its subcontractors, (collectively called “NovaRest” in this report) have been contracted as the MHCC’s consulting actuary, and have prepared the following evaluation: coverage for lymphedema diagnosis, evaluation and treatment.

This report includes information from several sources to provide more than one perspective on the proposed mandates with the intention of providing a totally unbiased report. As a result, there may be some conflicting information within the contents. Although we only used sources that we considered credible, we do not offer any opinions regarding whether one source is more credible than another, leaving it to the reader to develop his/her own conclusions.

The Affordable Care Act (ACA) describes a broad set of benefits that must be included in any essential health benefits (EHB) package. In its December 2011 bulletin, the Department of Health and Human Services (HHS) provided guidance on the types of health benefits plans each state could consider when determining a benchmark EHB plan for its residents. Each state had the opportunity to update its benchmark plan effective for 2017. Maryland has chosen the small group CareFirst BlueChoice HMO HSA-HRA \$1,500 plan as its 2017 benchmark plan.¹ It is important to note that ACA requires states to fund the cost of any mandates that are not included in the state-specific EHBs for policies purchased through the Health Exchange Market.²

¹ Center for Consumer Information & Insurance Oversight. “List of Proposed Essential Health Benefit Benchmark Plans for 2017 and Beyond.” <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-Proposed-BMP.pdf>. Accessed November 6, 2016.

² In Maryland this would be the Maryland Health Benefit Exchange.

Process

NovaRest was charged to address the following questions regarding these proposed mandates:

- The extent to which the coverage will increase or decrease the cost of the service;
- The extent to which the coverage will increase the appropriate use of the service;
- The extent to which the mandated service will be a substitute for a more expensive service;
- The extent to which the coverage will increase or decrease the administrative expenses of carriers, including health maintenance organizations, or other organizations authorized to provide health benefit plans in the State, and the premium and administrative expenses of policyholders and contract holders;
- The impact of this coverage on the total cost of health care; and
- The impact of all mandated health insurance services on employers' ability to purchase health benefits policies meeting their employees' needs.

NovaRest reviewed literature (which included reports completed for other states which were either considering or have passed similar legislation), interviewed providers, gathered statistics from public sources regarding the 2015 premium levels for the various markets, and developed an independent estimate of the impact on premiums for each market for each proposed mandate.

To provide as complete a picture as possible regarding the proposed impact of each of these mandates, NovaRest issued a survey to the top six commercial/HMO carriers in the commercial fully insured market in Maryland to ascertain the extent that each of the proposed mandates is currently covered in their policies. The survey responses are included in Appendix I. Data requests quantifying use of the services included in the proposed mandates were part of the surveys. The various claim codes included in these requests are shown in Appendix II. There were very tight time frames for the carriers to respond as well as tight time frames for NovaRest to develop this report. The following chart shows the six major carriers and the degree to which they responded to the surveys.

+Commercial Carriers/HMOs Surveyed and the Degree to Which They Responded

Carrier/HMO	Full Response	Partial Response	Did Not Provide Any Answers
Aetna		X	
CareFirst	X		
CIGNA	X		
Evergreen		X	
Kaiser	X		
United Health Care			X

To determine the extent to which the proposed mandates are currently covered in the Medicaid program, we surveyed the top three Medicaid managed care organizations (MCOs).³ The survey responses from these entities are not included to protect the confidentiality of the sole MCO that responded. The claim codes included in the Medicaid managed care survey are the same claim codes included in the commercial carrier surveys. Similar to the surveys for the commercial carriers, the time frames for the Medicaid managed care providers to respond were very tight. The following chart shows the Medicaid managed care providers and the degree to which they responded to the surveys:

Carrier/HMO	Full Response	Partial Response	Did Not Provide Any Answers
AmeriGroup	X		
Priority Partners			X
Maryland Physician Care			X

Additionally, NovaRest communicated via email with one lymphedema provider to understand the diagnosis of lymphedema and the services provided to lymphedema patients. See the *Discussions with Providers* section for more details on the interviews.

We relied upon the analysis completed by the Department of Legislative Services for quantification of the impact of these mandates on the State Employee and Retiree Health and Welfare Benefits Program.

³ The decision to issue the survey to the top three Medicaid MCOs was based upon input from Department of Health and Mental Hygiene (DHMH), which oversees the Medicaid program.

Prevalence of Lymphedema

The California Health Benefits Review Program cited statistics from national claims data that 0.7% of the population has lymphedema.⁴ Based upon the information received from MHCC from the Medical Care Data Base (MCDB) that showed 12,664,196 member months for calendar year 2014 and a 0.7% incidence rate, there are about 7,400 fully insured Maryland residents that have lymphedema. $(12,664,196 \times .007 \div 12)$.

Anywhere from 6 percent to 63 percent (depending upon the study) of breast cancer patients develop lymphedema, most as a result of radiation and/or the surgical removal of lymph nodes. Based on 2010 data, the overall incidence of lymphedema in other cancers was 30% in sarcomas; 20% in gynecologic cancers; 16% in melanomas; 10% in genitourinary cancers, and 4% in head/neck cancers.⁵

Mandated Coverage for Lymphedema Diagnosis, Evaluation, and Treatment

House Bill 113 (<http://mgaleg.maryland.gov/2016RS/bills/hb/hb0113F.pdf>) would require insurers, nonprofit health service plans, or health maintenance organizations (collectively known as carriers) that provide hospital, medical, or surgical benefits, to provide coverage for the medically necessary diagnosis, evaluation, and treatment of lymphedema. Coverage may be subject to certain deductibles, copayments, and coinsurance required by carriers for similar coverages under the same health insurance policy or contract. The annual deductibles, copayments, or coinsurance requirements may not be greater than those imposed by the carrier for similar coverages.

⁴ California Health Benefits Review Program. "Analysis of Assembly Bill 213, Health Care Coverage for Lymphedema." April 2005, http://chbrp.org/documents/ab_213final.pdf. Accessed November 4, 2016.

⁵ Mapes, Diane. "A Little Known Side Effect with a Huge Impact." Hutch News, September 3, 2015, <https://www.fredhutch.org/en/news/center-news/2015/09/lymphedema-cancer-treatment-side-effect.html>. Accessed November 4, 2016.

Background

According to MedicineNet.com, lymphedema is defined as

“swelling in one or more extremities that results from impaired flow of the lymphatic system. The lymphatic system is a network of specialized vessels (lymph vessels) throughout the body whose purpose is to collect excess lymph fluid with proteins, lipids, and waste products from the tissues. This fluid is then carried to the lymph nodes, which filter waste products and contain infection-fighting cells called lymphocytes. The excess fluid in the lymph vessels is eventually returned to the bloodstream.”⁶

When the lymph vessels are blocked or unable to carry lymph fluid away from the tissues, localized swelling (lymphedema) is the result.

Lymphedema most often affects a single arm or leg, but in uncommon situations, both limbs are affected.

- Primary lymphedema is the result of an anatomical abnormality of the lymph vessels and is a rare, inherited condition.
- Secondary lymphedema results from an identifiable damage to or obstruction of normally-functioning lymph vessels and nodes.

Worldwide, lymphedema is most commonly caused by filariasis (a parasite infection) but in the U.S., lymphedema most commonly occurs in women who have had breast cancer surgery, particularly when followed by radiation treatment. This results in one-sided (unilateral) lymphedema of the arm. However, any surgical procedure that requires removal of regional lymph nodes or lymph vessels, such as vein stripping, lipectomy, burn scar excision and peripheral vascular surgery, can potentially cause lymphedema. Damage to lymph nodes and lymph vessels due to trauma, burns, radiation, infections or compression or invasion of lymph nodes by tumors can also cause lymphedema.⁷

Symptoms of mild lymphedema may be a feeling of heaviness, tingling, tightness, warmth or shooting pains in the affected extremity. These symptoms may be noticed before the presence of obvious swelling. Other symptoms include a decrease in the ability to see or feel veins or tendons in the extremities,

⁶ Stoppler, Melissa C. M.D. “Lymphedema.” MedicineNet.com, <http://www.medicinenet.com/lymphedema/article.htm>. Accessed November 2, 2016.

⁷ Ibid.

tightness of jewelry or clothing, redness of the skin, the asymmetrical appearance of the extremities, tightness or reduced flexibility in the joints and a slight puffiness of the skin. As the condition progresses, these symptoms will become more pronounced.⁸

If not treated, an extremity may swell to several times its normal size. The long-term accumulation of fluid and proteins in the tissues leads to inflammation and eventual scarring of tissues, leading to a firm, taut swelling and the skin in the affected area thickens and may take on a lumpy appearance. The immune system function is also suppressed in the scarred and swollen areas affected which can lead to frequent infections and in some cases a malignant tumor of lymph vessels known as lymphangiosarcoma.⁹

According to Mayo Clinic, if the cause of the lymphedema is not obvious (for example, no recent surgery involving lymph nodes or radiation treatment) then there are four imaging tests that can be used to diagnose lymphedema:¹⁰

- MRI scan. An MRI produces 3-D, high-resolution images using a magnetic field and radio waves.
- CT scan. CT scans produce detailed, cross-sectional images of the body that can reveal blockages in the lymphatic system.
- Doppler ultrasound. Doppler ultrasound is a variation on the conventional ultrasound that may find obstructions by looking at blood flow and pressure by bouncing high-frequency sound waves (ultrasound) off red blood cells.
- Radionuclide imaging of the lymphatic system (lymphoscintigraphy). Radioactive dye is injected and then scanned by a machine to track the dye as it moves through the lymph vessels, highlighting blockages.

Lymphedema is a chronic disease affecting an estimated 3 - 5 million Americans and is a relatively under-recognized condition in both medical and public domains.¹¹ There is no cure for lymphedema.

⁸ Ibid.

⁹ Ibid.

¹⁰ Mayo Clinic Staff. "Lymphedema Tests and Diagnosis." <http://www.mayoclinic.org/diseases-conditions/lymphedema/basics/tests-diagnosis/con-20025603>. Accessed November 1, 2016.

¹¹ Stout, N.L. et al. "A Systematic Review of Care Delivery Models and Economic Analysis in Lymphedema: Health Policy Impact (2004-2011)." *Lymphology* 46 (2013) Mar 46: 27-41, <https://www.alfp.org/docs/27-41.Mar%202013.STOUT.PDF>. Accessed November 1, 2016.

In an article in *Rehabilitation Oncology Journal*, lymphedema was recognized as one of the most potent risk factors for the development of recurrent cellulitis, which frequently requires hospitalization.¹²

The Women’s Health and Cancer Rights Act (WHCRA), signed into law on October 21, 1998, requires health plans that cover mastectomies to provide treatment for any physical complications at all stages of a mastectomy, including lymphedema.¹³ However, a study completed in 2009 found that “insurance coverage of lymphedema may still vary as a result of the differential level of compliance to this federal regulation or different health plan benefits, with economic barriers to care more likely to be observed among patients in plans with higher cost sharing.”¹⁴

Currently, the clinically recognized, nonsurgical standard of care for treatment of lymphedema is complete decongestive therapy (CDT) that includes the following four components:¹⁵

- 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 Exercised: Exercises that stimulate lymph pumping and flow, which should be performed while the affected areas of the body are under compression therapy described above.

¹² Lymphedema Advocacy Group. “Lymphedema Treatment Act HR 1608/S2372.” http://lymphedematreatmentact.org/wp-content/uploads/2016/03/Lymphedema-Treatment-Act-HR1608_S2373.pdf. Accessed November 2, 2016.

¹³ Center for Consumer Information & Insurance Oversight. “Women’s Health and Cancer Rights Act.” https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html. Accessed November 2, 2016. Note that certain plans such as church plans or governmental plans may not be subject to the law.

¹⁴ Shih, Ya-Chen Tina et al. “Incidence, Treatment Costs, and Complications of Lymphedema After Breast Cancer Among Women of Working Age: A 2 Year Follow-up Study.” *Journal of Clinical Oncology*, April 2009, <http://ascopubs.org/doi/full/10.1200/JCO.2008.18.3517>. Accessed November 2, 2016.

¹⁵ Avalere Health. Study for Lymphedema Advocacy Group entitled, “Estimated Federal Costs of H.R. 1608—The Lymphedema Treatment Act.” http://lymphedematreatmentact.org/wp-content/uploads/2016/03/Lymphedema-Treatment-Act-HR1608_S2373.pdf. Accessed October 31, 2016.

- Skin Care: Meticulous skin care and hygiene to minimize the risk of infection and other complications.

CDT involves two phases:¹⁶

- Intensive Rehabilitation: A physical or occupational therapist uses MLD and compression therapy combined with multi-layering bandaging to reduce the swelling. The patient is educated to perform lymph drainage exercises and to apply proper skin care. This phase usually lasts 4 - 6 weeks.
- Ongoing Self-Maintenance: In this home-care phase, the patient is responsible for maintaining the gains achieved in the intensive phase by continuing exercises, compression therapy (using appropriate items such as limb-specific compression garments) and continuing proper skin care.

In severe cases, surgical treatments are used to remove excess fluid and tissue; however, surgery is not able to cure lymphedema. It is extremely important that patients with lymphedema monitor themselves for infection in the affected area to avoid having it spread into the bloodstream resulting in sepsis. Infections need to be treated immediately with antibiotics.¹⁷

“Gradient compression garment” means a garment that (1) is used for the treatment of lymphedema; (2) requires a prescription; and (3) is custom fit for the individual for whom it is prescribed. Gradient compression garment does not include disposable medical supplies, including over-the-counter compression or plastic knee-high or other stocking products.

Required coverage under the proposed bill must include equipment, supplies, complete decongestive therapy, gradient compression garments, and self-management training and education.

Prevalence of Coverage

Medicare

While the scope of this analysis is limited to the fully insured markets in Maryland, we believe providing information regarding other health care programs may assist policymakers in their decision-making process. Currently, Medicare

¹⁶ Ibid.

¹⁷ Op. cit. – Stoppler, Melissa C.



does not cover the medically necessary compression supplies used in lymphedema treatment because they do not fit under any benefit category. CMS maintains that coverage for these items cannot be brought about through policy change, but require a change in the statute as seen from this statement by HHS Secretary Burwell, September 2015:¹⁸

“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”.

Legislation has been introduced at the federal level, (Lymphedema Treatment Act HR 1608/S2372) in the 114th Congress but has not passed.

Maryland Medicaid Managed Care

The only Medicaid MCO that responded our survey indicated that treatment for lymphedema is covered when medically necessary. Criteria have been established for determining if single or multi-chamber non-programmable pneumatic compression devices or single or multi-chamber pneumatic programmable compression devices are appropriate. These devices will be covered if the individual has been compliant with conservative therapy (such as elevation of the affected limb, exercise, massage, use of a compression bandage system or compression garment) and the lymphedema is not improving.

Compression garments are considered medically necessary after a diagnosis of lymphedema with the following exception: the use of chest and trunk compression garments (appliances) with a pneumatic compression device is not considered medically necessary.

Complete decongestive therapy (CDT) is covered under the physical therapy benefits of Medicaid when such services have been deemed to be medically necessary. There are criteria required for all rehabilitative services as well as habilitative services. Any individual with lymphedema would need to satisfy these criteria to be eligible for benefits.

¹⁸ Op. cit. – Lymphedema Advocacy Group.



ACA Benchmark Plan

The 2017 Maryland benchmark plan for ACA compliant plans is the small group CareFirst BlueChoice HMO HSA-HRA \$1,500 plan. This plan has a maximum of 30 visits for physical rehabilitation therapy services per injury/illness per year and 30 visits for physical habilitation therapy services per injury/illness per year.¹⁹ Prior authorization is required for physical habilitation therapy services for adults. Gradient (graduated) compression garments were not specifically mentioned in the benchmark plan.

Maryland Commercial Carriers and HMOs

WHCRA requires that health plans provide services for the treatment of any physical complications at all stages of a mastectomy, including lymphedema. As part of our review, we did ask carriers to include any limitations and treatments they would not cover and the rationale as to why they would not cover.

¹⁹ Center for Consumer Information & Insurance Oversight. "Information on Essential Health Benefits (EHB) Benchmark Plans." <https://www.cms.gov/ccio/resources/data-resources/ehb.html#Maryland>. Accessed November 3, 2016.



All carriers cover lymphedema when medically necessary. For limitations to coverage, refer to the following table.

Coverage Limits and Medical Review Requirements for Treatment of Lymphedema	
	Response
Carrier #1	For short term therapy for the treatment of lymphedema for SG business, would defer to the MD benchmark plan for the benefit limit and for LG business, the benefit would vary but may be between 30 to 90 annual visits.
Carrier #2	If DME or PT is being requested as part of treatment, medical review is required for those services and subject to our current benefit limitations (30 therapy visits per condition, per plan year) and medical necessity review for PT and all DME.
Carrier #3	Lymphedema services are covered under the plan's short term rehab and durable medical equipment benefits and limitations, which vary depending on the plan. Many plans include a maximum allowable benefit or number of visits. When the maximum allowable benefits are exhausted, coverage is no longer provided even if medically necessary.
Coverage of Gradient (graduated) Compression Garments	
	Response
Carrier #1	Covered same as any other diagnosis subject to visit limits and dollar limits of the underlying benefits. DME is an EHB in all states and dollar limits can only apply to grandfathered/exempt plans. However, specifically for coverage of a gradient compression garment for lymphedema, the garment would be considered Durable Medical Equipment (DME) which under the ACA is an Essential Health Benefit (EHB) that can have no annual dollar limit (for Small Group business.) For Large Group business, the carrier would also have no annual dollar limit for DME.
Carrier #2	a. Replacement garments will be covered every six months, up to a maximum of two garments per body part, when existing garments are no longer functional, as determined and documented by the clinician who is treating the patient for the specific diagnoses; or, b. Replacement garments may be covered before the six-month period, if after reevaluation by the therapist a change in garment type or size is needed to improve therapeutic response. c. If a member requires multiple garments for the same body part, to allow variation in size or pressure, only one of each size/type will be issued.
Carrier #3	Lymphedema Therapy benefits are subject to any applicable deductible, coinsurance, copayment or benefit limitation. When benefits are provided in the member's contract, benefits for Lymphedema Therapy (Complex Decongestive Therapy) are provided for the treatment of lymphedema to include equipment, supplies, therapy, self-management training and education.
Carrier #4	If DME or PT is being requested as part of treatment, medical review is required for those services and subject to our current benefit limitations (30 therapy visits per condition, per plan year) and medical necessity review for PT and all DME.
Carrier #5	Lymphedema services are covered under the plan's short term rehab and durable medical equipment benefits and limitations, which vary depending on the plan. Many plans include a maximum allowable benefit or number of visits. When the maximum allowable benefits are exhausted, coverage is no longer provided even if medically necessary.

One carrier considers two pairs of compression sleeves/gloves per affected arm every six months for members with intractable lymphedema of the arms to be

medically necessary. Compression garments for the abdomen, chest, genitals, trunk, head or neck are considered experimental and investigational because of the lack of peer-reviewed published literature evaluating the clinical utility of compression garments for these anatomical sites. Graded compression stockings that have a pressure of 18 mm HG or more, require a physician's prescription and require measurements for fitting are considered medically necessary. No more than four stockings per year are considered medically necessary.

Another carrier will cover graduated compression stockings and other garments that have a pressure of 20 mm HG or more. Replacement garments are covered at a rate of two every six months if the garment is required for continuous, 24-hour use; or one garment every six months if required for partial day or night time use only. Reassessment is required every two years.

One carrier has established criteria for determining whether a pneumatic compression device with and without gradient pressure is medically necessary. The criteria require a diagnosis of lymphedema and:

- Marked hyperkeratosis with hyperplasia and hyperpigmentation;
- Papillomatosis cutis lymphostatica;
- Deformity of elephantiasis;
- Skin breakdown with persisting lymphorrhea; or
- Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology.

In addition to the above criteria, the lymphedema must be documented to have been unresponsive to other clinical treatment over the course of a required four-week trial of conservative therapy including the use of compression garments, regular exercise, and elevation of the limb. When available, manual lymphatic drainage is a key component of conservative treatment and is considered appropriate medication treatment when there is a concurrent congestive failure. An additional requirement for pneumatic compression devices with calibrated gradient pressure is that the lymphedema must be extending onto the chest, trunk and abdomen past the limits of a standard compression sleeve.

Another carrier will cover pneumatic compression devices in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include the use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb.

The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

State Employee and Retiree Health and Welfare Benefits Program

According to an analysis completed by the Maryland Department of Legislative Services, the State Employee and Retiree Health and Welfare Benefits Program currently provides coverage for lymphedema services as required under the bill.²⁰

Self-Funded Plans

The prevalence of this coverage among self-funded plans, which would not otherwise be required to provide state mandated benefits, demonstrates the degree to which the proposed benefits are deemed necessary. To ascertain this, we included questions regarding self-funded plans as part of our surveys to the carriers. The results from 4 carriers are:

1. One carrier indicated that coverage for these benefits is typically the same for non-grandfathered plans; i.e., the same 99 - 100% coverage level.
2. Another carrier indicates coverage would be the same as under fully insured plans.
3. A third carrier indicated that all insured plans and most self-funded plans would have coverage according to the plan's coverage policy and most individual and group medical plans have DME coverage.
4. A fourth carrier indicated the coverage for self-funded plans is typically the same as fully insured plans.

Other States

To date, two states have passed some legislation mandating some coverage for lymphedema: Virginia and North Carolina. Legislation was introduced in California and Massachusetts. The following chart, as shown in the paper, "A Systematic Review of Care Delivery Models and Economic Analyses in Lymphedema: Health Policy Impact (2004 - 2011)" summarizes the benefits either proposed and passed for each of the three states for which studies have been completed, as well as any limits:

²⁰ Department of Legislative Services. "Fiscal and Policy Note HB 113 Health Insurance-Coverage for Lymphedema Diagnosis, Evaluation, and Treatment."
http://mgaleg.maryland.gov/2016RS/fnotes/bil_0003/hb0113.pdf. Accessed October 25, 2016.

State Mandate Analysis of Lymphedema Legislation in the United States of America

Criteria	California*	Massachusetts†	Virginia
Bill	AB 213 (Liu 2007)	S. 0896 (Spilka 2009)	HB 1737 (Wardrup 2003)‡ Section 38.2-3418.14 - Code of Virginia (7 year retrospective Claims Data)§
Coverage required	<ul style="list-style-type: none"> Physician diagnostic services and plan of care Standard of care treatment A supply of medically-required compression garments, compression bandages and associated compression materials Patient education for: <ul style="list-style-type: none"> Self-treatment Compression use Techniques for self-measurement Skin care Recognition of infection 	<ul style="list-style-type: none"> Equipment and supplies Complex decongestive therapy Outpatient self-management training and education for the treatment of lymphedema 	Coverage for the treatment of lymphedema including: <ul style="list-style-type: none"> Supplies Equipment Complex decongestive therapy Outpatient self-management training and education services by health care professionals who are qualified by specific education, experience, and credentials to provide the covered benefits.
Limits of applicability	<ul style="list-style-type: none"> Individuals <65 years with private insurance (group and individual) Public plans including CalPERS HMO, Medi-Cal managed care, or Healthy Families People ≥ 65 enrolled in Medi-Cal managed care plan 	<ul style="list-style-type: none"> Commercial insurers and MassHealth fully-insured market Health Maintenance Organizations (HMOs), and Blue Cross Blue Shield plans, Group Insurance Commission (GIC) 	<ul style="list-style-type: none"> Each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical, coverage on an expense-incurred basis Each corporation providing individual or group accident and sickness subscription contracts Each health maintenance organization providing a health care plan for health care services
<p>* “California Health Benefits Review Program: Analysis of Assembly Bill 213, Health Care Coverage for Lymphedema”, CHBRP 05-03, April 7, 2005. http://chbrp.org/documents/ab_213final.pdf</p> <p>† 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” Provided for The Joint Committee on Public Health, December 2010.</p> <p>‡ Report of the Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 383, Mandated Coverage of Lymphedema, Commonwealth of Virginia, 2003, http://leg2.state.va.us/dls/h&sdocs.nsf/fc86c2b17a1cf388852570f9006f1299/45c3e11e8d10b10485256cfa005258ca/\$FILE/RD15.pdf</p> <p>§ Virginia 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: Reports RD191, RD289, RD246, RD322 and RD294 covering reporting periods 2005-2009.</p>			

Source: A Systematic Review of Care Delivery Models and Economic Analyses in Lymphedema: Health Policy Impact (2004 - 2011), N.L. Stout, et al.



As referenced previously, legislation has been introduced at the federal level, (Lymphedema Treatment Act HR 1608/S2372) but has not passed.

Utilization of Services

MHCC gathered lymphedema data from the MCDB which represents claims from all payers. The following chart shows the utilization and costs for all lymphedema patients for calendar year 2014:²¹

Total Market	Total Lymphedema Diagnosis Evaluation and Treatment, 2014							
	# Services	Allowed Charges	Member Cost Share	Paid	Cost/Service	PMPM		
						Allowed	Member Cost Share	Paid
Fully Insured								
Individual	1,117	\$219,650	\$32,350	\$187,657	\$197	\$0.082	\$0.012	\$0.070
Small Group	1,749	\$289,142	\$49,277	\$238,950	\$165	\$0.084	\$0.014	\$0.069
Large Group	3,082	\$482,061	\$60,302	\$417,879	\$156	\$0.074	\$0.009	\$0.064
Total	5,948	\$990,853	\$141,929	\$844,486	\$167	\$0.078	\$0.011	\$0.067

Using enrollment data provided, we generated utilization rates of 0.0005 services per member per month (PMPM) for fully insured; 0.0007 PMPM for self-funded; and 0.0006 PMPM overall. These reflect all services, including inpatient hospital.

The California study showed the following utilization of services before the implementation of any mandate:²²

Service	# Services/Member/Year
Durable Medical Equipment	0.91
Compression garments	0.52
Therapy Services	5.94
Drugs	0.16
Inpatient Services	0.54
Total Utilization	8.08

²¹ Services from MCDB do not reflect inpatient services.

²² California Health Benefits Review Program. "Analysis of Assembly Bill 213, Health Care Coverage for Lymphedema." April 2005, http://chbrp.org/documents/ab_213final.pdf. Accessed November 4, 2016.

The average treatment costs per year in 2005 dollars was \$963.31.²³

This same study estimated an overall increase in utilization of lymphedema services of about 1.5%.

Virginia enacted a lymphedema mandate in 2004 that was almost identical to the proposed Maryland mandate. In September 2016, a study was completed to analyze the costs for the ten-year period following its effective date. The study, “Cost of a Lymphedema Treatment Mandate - 10 Years of Experience in the Commonwealth of Virginia” shows the following utilization statistics:²⁴

The number of visits for lymphedema treatment averaged 0.1 (Range 0.09–0.11) visits per year for the first four years of the mandate and dropped to 0.06 (0.05–0.07) visits per year for the last six years. Hospitalizations for lymphedema remained at or below 0.02 days per year during the entire 10-year period with a downward trend during the last five years.

The number of provider visits for lymphedema treatment per year per contract for the three State insurers ranged from 0.0007 to 0.0049. Hospitalizations were not reported by the State insurers. (“State insurers” means insurers offered to Commonwealth of Virginia employees, dependents and retirees as well as Medicaid participants).

This report showed that the passage of the mandate did not result in increased utilization of services associated with lymphedema. There is evidence that lymphedema treatment resulted in reduced utilization of physician’s and therapist’s services for lymphedema and a reduction in hospital stays for lymphedema or cellulitis treatment.

Cost of Treatment

The statistics previously shown for the Maryland MCDB show the average cost per service for lymphedema was \$167 in 2014, of which the member paid about \$24, or about 14.3% of allowed costs. The costs varied significantly by type of service ranging from \$27 for equipment and supplies; \$96 for CDT, and \$139 for self-management training, to \$801 for gradient compression garments. The

²³ Ibid.

²⁴ Weiss, Robert. “Cost of a Lymphedema Treatment Mandate - 10 Years of Experience in the Commonwealth of Virginia.” Health Economics Review, September 2016, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5010541/>. Accessed November 1, 2016.



allowed cost for lymphedema claims was \$0.08 per member per month (PMPM); the average paid claims PMPM was \$0.07.

A study showed the use of an advanced pneumatic compression device (APCD) reduced lymphedema-related hospital outpatient and other medical costs per patient in a twelve-month period by 37 percent for cancer patients (from \$2,597 to \$1,642), and 36 percent for non-cancer patients (\$2,937 to \$1,883). These costs do not include the offsetting additional durable medical equipment costs.²⁵

Discussions with Providers

We received an email response from one lymphedema therapist. She emphasized that many lymphedema patients go years without being diagnosed and receiving treatment. Lack of treatment can result in years of suffering, both physical and social.

There is a recognition to prevent the progression of lymphedema by evaluating patients before treatment for cancer, teaching risk reduction tactics and, if the condition develops, minimizing its advance. It is important to note that lymphedema affects more than just cancer patients. Any medical procedure or condition that injures or removes lymph nodes may result in lymphedema. There are several treatment regimens including medication and home-program recommendations. All regimens require education and some require decongestive therapy which usually includes manual lymph drainage and elastic compression bandaging along with exercises. Most patients require compression garments and some require the addition of a vasopneumatic pump for home use. The providers' perceptions of the insurance coverage of garments were different than the responses we received from the carriers. The carriers indicated that they all covered these garments. However, some may have limits on the number and type of garments. The provider impressions are that most insurance coverage is "inadequate" (and nonexistent with Medicare). For patients requiring therapy, the protocol for some is five days a week, 60 to 120 minutes for the first 4 - 6 weeks with periodic follow-up. Therefore, insurance policies that incorporate any limit on the number of therapy visits can be detrimental. If lymphedema is not treated, the condition will worsen and complications such as cellulitis may occur which could result in infections and hospitalization.

²⁵ Karaca-Mandic, Pinar et al. "The Cutaneous, Net Clinical and Health Economic Benefits of Advanced Pneumatic Compression Devices in Patients with Lymphedema." The JAMA Network, November 2015, <http://jamanetwork.com/journals/jamadermatology/fullarticle/2453326>. Accessed November 4, 2016.



Questions Concerning Mandated Coverage for Lymphedema Diagnosis, Evaluation, and Treatment

The extent to which the coverage will increase or decrease the cost of the service.

Mandating a service or product increases the demand for that service and product, which typically increases the cost of the service. Carriers can offset this upward pressure on price by contracting with providers, where allowed. Due to provider contracting and the fact that most plans cover treatment of lymphedema, potential increases in cost are not expected to have a significant impact on PMPM or percentage of premium estimates.

The extent to which the coverage will increase the appropriate use of the service.

The carriers universally indicated that lymphedema services were already being covered. The proposed mandate does not negate any cost sharing provisions, annual limitations on the number of services, or determination of medical necessity. Although the publicity around the mandate may have some impact on patient awareness of the service and provider willingness to prescribe the service, we do not expect any significant increase in the appropriate use of the service.

The extent to which the mandated service will be a substitute for a more expensive service.

This mandate is not a substitute for a more expensive service.

The extent to which the coverage will increase or decrease the administrative expenses of carriers, including health maintenance organizations, or other organizations authorized to provide health benefit plans in the State, and the premium and administrative expenses of policyholders and contract holders.

This mandate would have next to no impact on administrative costs.



Financial Impact on Premiums

Analyses in Other States

The Virginia study showed that lymphedema claims as a percent of total claims varied between 0.012% - 0.100% for individual and group contracts, or less than one one-thousandth of total claims in all types of insurance contracts. The impact on the premium for all contracts was less than 0.2%.²⁶

The analysis for the proposed California lymphedema mandate completed by the California Health Benefits Review Program in 2005 estimated an increase of 0.0003% or \$0.01 per person per year for implementing the bill. This study assumed an increase of between 1.5% and 2.0% for DME, compression garments, and therapy visits.

The Massachusetts analysis estimated a range of impacts from \$0.10 PMPM to \$0.11 PMPM, or 0.002% to 0.03% of premium.²⁷ This estimate is significantly lower since the Massachusetts bill was limited to lymphedema following breast cancer surgery; the California bill did not have this limitation.

In the carrier surveys for this analysis, one carrier in Maryland estimated the premium increase to be 0.02%. Another carrier estimated the premium increase would range from 0.30% to 0.50% depending on the market. Carriers had a concern that only medically necessary services would be required under the mandate. No other carriers provided cost estimates.

NovaRest Estimate

Based on the Virginia experience with a similar mandate, we would not expect a material increase in utilization resulting from the passage of this bill. All of the carriers indicated that they currently provide coverage for lymphedema services and their interpretation, as well as ours, is that the proposed mandate would not preclude the use of medical management in determining the most appropriate level of care for these services. Also, the federal WHCRA which requires lymphedema services for women following breast cancer surgery has been in place for many years. This proposed legislation is essentially for all other lymphedema cases.

²⁶ Op. cit. – Weiss, Robert.

²⁷ Massachusetts Division of Health Care Finance and Policy (DHCFP). “Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Women’s Health and Cancer Recovery.” December 2010, <http://archives.lib.state.ma.us/bitstream/handle/2452/101824/ocn711076017.pdf?sequence=1&isAllowed=y>. Accessed November 4, 2016.



Using the MCDB as the basis for utilization and costs, the 2014 PMPMs by market were:

Market	2014 Paid PMPM
Individual	\$0.07
Small Group	\$0.07
Large Group	\$0.06
Total	\$0.07

We trended the 2014 allowed PMPMs in one year at a 4.0% annual trend, and then applied a paid-to-allowed ratio of 85.2% (2014 ratio provided in the Maryland MCDB) to get 2015 paid PMPMs. We then divided these values by the 2015 average premiums PMPMs by market in Maryland to get the projected percent of premium impact, as shown in the chart below. The average premiums were taken from the Supplemental Health Care Exhibit included in the 2015 NAIC Annual Statement for the six carriers included in the survey.

Market	2015 Avg Premium PMPM	2015 Paid PMPM	Percent of Premium
Individual	\$235.44	\$0.07	0.031%
Small Group	\$360.28	\$0.07	0.020%
Large Group	\$428.29	\$0.07	0.016%
Total	\$373.97	\$0.07	0.019%

The impact on premium is about \$0.07 PMPM. However, this estimate is overstated because it reflects the cost of lymphedema breast cancer claims, which are already covered by the federal mandate

The impact of this coverage on the total cost of health care.

The total cost of health care would only change to the extent that the cost of the service would change or the utilization of the service would change. We do not anticipate any significant change in the cost or utilization of the service. These estimates of already-small gross costs include services already mandated for women who have breast cancer and are, therefore,



overstated. While time and data limitations precluded us from attempting to isolate lymphedema costs between breast cancer patients and all other patients, we can state that the total cost for this proposed mandate is minimal and will not have a material impact on the total cost of health care.

The impact of all mandated health insurance services on employers' ability to purchase health benefits policies meeting their employees' needs.

Any mandate or regulation that results in the increase of costs and administrative complexity to the fully insured premiums will serve as another incentive for employers to consider self-insuring. The Employee Benefit Research Institute (EBRI) released the results of a study it completed examining the trends from 1996 - 2015 in self-insured health plans among private-sector employers. The key findings were:²⁸

- The percentage of private-sector employers offering health plans of which at least one was self-insured increased from 28.5% in 1996 to 49% in 2015, representing a 36.8% increase.
- Between 2013 and 2015, the percentage of employers offering health plans with at least one self-insured plan increased for employers with 100 - 999 employees (mid-size employers) from 25.3% to 30.1%; for small employers (25 - 99 employees) the percent increased from 13.3% to 14.2% and decreased for large employers (>1,000 employees) from 83.9% to 80.4%.
- The percentage of health-covered employees enrolled in self-insured plans increased from 58.2% to 60.0% from 2013 - 2015, with the largest increases occurring with small and mid-size employers.

It is not the cost of any single mandate that drives employers to self-insure, but rather an accumulation of multiple mandates. The ACA has several components that appear to incentivize employers away from fully-insured plans including EHBs, health insurance tax and, in the case of employers with fifty or fewer employees, benchmark plans and metal-level plans. Given the low-cost impact of the proposed mandate, it is unlikely that its passage alone would cause a major shift to self-insurance.

²⁸ Fronstin, Paul PhD. "Self-Insured Health Plans: Recent trends by Firm Size." 199602915, Employee Benefit Research Institute, July 2016, https://www.ebri.org/pdf/notespdf/EBRI_Notes_07-no7-July16.Self-Ins.pdf. Accessed November 6, 2016.

Appendix I: Carrier Survey Responses

1. Please describe any types of treatments for lymphedema that are not covered and the rationale for their exclusions.

	Response
Carrier #1	<p>The carrier's coverage of lymphedema is consistent across all line of businesses. Our policies cover as follows:</p> <p>A. Contraindicated conditions for Compression Therapies</p> <ol style="list-style-type: none"> 1. Suspicion or diagnosis (or treatment) of acute Deep Vein Thrombosis (DVT) or arterial obstruction. 2. Severe peripheral arterial disease 3. Septic phlebitis or other acute limb infections 4. Unhealed irradiated soft tissues 5. Peripheral edema secondary to severe Congestive Heart Failure <p>B. Conditions that are generally not medically appropriate for coverage</p> <ol style="list-style-type: none"> 1. Stasis dermatitis or venous edema 2. Lipodermatosclerosis 3. Prevention of thrombosis in immobilized persons 4. Post thrombotic syndrome 5. Edema following surgery, fracture, burns and other trauma which can be treated with OTC products 6. Postural hypotension 7. Severe edema in pregnancy 8. Edema accompanying paraplegia, quadriplegia, etc. 9. Venous insufficiency 10. Varicose veins 11. Active malignancy, confirmed or suspected local disease 12. Exercise recovery <p>C. Non medical grade stockings and other garments (<20 mmHG of compression) are not covered</p>
Carrier #2	<p>Lymphedema treatment is addressed in two coverage policies (CPs): Pneumatic Compression Devices and Compression Garments (CP 0354), and Complex Lymphedema Therapy (CP) We consider the following treatments to be experimental, investigational or unproven:</p> <ul style="list-style-type: none"> •a chest (HPCPS code E0657) and/or trunk (HPCPS code E0656, E0670) pneumatic appliance for use with a pneumatic compression pump •a compression garment for trunk or chest <p>The pneumatic pumps would be covered under the durable medical equipment (DME) benefits. Coverage for pneumatic compression devices/lymphedema pumps used in the home is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Regarding self-management education and training—typically the health care professional or DME provider who is rendering care and/or equipment would provide instruction on managing the condition and equipment. Standard benefit plans exclude services that are training or educational in nature, so if billed separately this may not be covered, depending on the procedure code used.</p>



Carrier #3	<p>Effective 10/9/2003 Lymphedema Therapy (complex decongestive therapy) Medical Policy 8.01.014 – services for the treatment of lymphedema are considered medically necessary. (Medical Policy attached)</p> <p>Bioimpedance for the assessment of lymphedema has been considered experimental/investigational since 2010 according to Medical Policy 2.01.062 Bioimpedance for Assessment of Lymphedema (Medical Policy attached)</p>
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2. For calendar year 2015, what percent of your fully insured policies provided coverage for lymphedema, as described under the proposed mandate, by market?

	Market	Percent of Members Having Coverage
Carrier #1	Individual	100%
	Small Group	NA
	Large Group	100%
	Total	100%
Carrier #2	Individual	99-100%
	Small Group	100%
	Large Group-fully insured	99-100%
	Total	99-100%
Carrier #3	100% when medically necessary	
Carrier #4	Individual	100%
	Small Group	100%
	Large Group	100%
	Total	100%
Carrier #5	100% of our members have this coverage when medically necessary	

If your current fully-insured policies provide some, but not all, of the coverages described under the proposed mandate, please provide a chart showing the percent of policies that provide coverage for some of the services.

No carriers responded



3. Please describe any limitations on the number of services provided, such as an annual limit for gradient compression garments, number of therapy sessions, etc.

	Response
Carrier #1	<p>Covered same as any other diagnosis subject to visit limits and dollar limits of the underlying benefits. DME is an EHB in all states and dollar limits can only apply to grandfathered /exempt plans. However, specifically for coverage of a gradient compression garment for lymphedema, the garment would be considered Durable Medical Equipment (DME) which under the ACA is an Essential Health Benefit (EHB) that can have no annual dollar limit (for Small Group business.) For Large Group business, the plan would also have no annual dollar limit for DME. For short term therapy for the treatment of lymphedema for SG business, the plan would defer to the MD benchmark plan for the benefit limit and for LG business, the benefit would vary but may be between 30 to 90 annual visits.</p>
Carrier #2	<p>A therapist, wound care specialist, or physician may specify the number of initial bandages and garments, according to patients' treatment regimens, activity levels, and environments. Determining type, amount and frequency of REPLACEMENT compression bandages and garments Reassessment for replacement compression bandages and garments is required every 2 years by the therapist, wound care specialist, or physician to determine continued need.</p> <p>Partial Day or Night Time Use Only 1. Initially, when treatment is for part of the day or only at night, only one (1) bandage or compression garment, for each limb, should be ordered and approved. 2. Replacements of more than 1 set or item per limb, may be ordered, as appropriate, per the lymphedema therapist or physician.</p> <p>Continuous, 24 hour Use 1. Velcro day/night time garments such as Solaris Ready wraps, CircAid, or Juxta-Fit, may have to be cleaned frequently. We will approve two (2) items, for each limb, initially and for each replacement.</p> <p>Bandages and compression garments should be ordered as DME for up to 2 years so that replacements may be approved in the interim without repeated physician order.</p> <p>a. Replacement garments will be covered every six months, up to a maximum of two garments per body part, when existing garments are no longer functional, as determined and documented by the clinician who is treating the patient for the specific diagnoses; or, b. Replacement garments may be covered before the six month period, if after reevaluation by the therapist a change in garment type or size is needed to improve therapeutic response. c. If a member requires multiple garments for the same body part, to allow variation in size or pressure, only one of each size/type will be issued. 4. A reassessment for bandages/compression garments is required every 2 years by the certified lymphedema therapist, physician, or vascular clinic to determine continued need replacement items can be approved.</p> <p>Pneumatic Compression Device (Night time / Intermittent Use) Initial Use Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.</p>

	<p style="text-align: center;">Replacement Garments and Compressors</p> <p>When intermittent use compression devices include pneumatic compression equipment, the garments are generally worn fewer hours over time, and are replaced less frequently than continuous use garments. The attached garments and the compressor devices have separate assessment and replacement requirements.</p> <p>1. Reassessment for both the compression garment and the device is required every 2 years by the lymphedema therapist, treating physician, or vascular clinic to determine continued need before replacements can be approved. The therapists' or physicians' evaluation and documentation of therapeutic results must include measurement of:</p> <p>a. The compression device is effective in maintaining the size of the affected extremity.</p> <p>b. The compression device is effective in reducing hypertrophic scarring and joint contractures of affected extremity.</p> <p>c. The compression device is effective in reducing venous insufficiency with venous stasis ulcers.</p> <p>2. Two night time garment (Reid sleeve or comparable) will be initially provided. Replacements will be issued 1 per year for 2 years, and then reassessment is required.</p> <p>3. Pneumatic compression machines are generally replaced every 3 years per manufacturer's specifications when documentation is provided for the minimum manufacturer's inspection, as in a. below.</p> <p>a. Devices must be inspected per the manufacturer's specifications or, at a minimum every 24 months, to qualify for replacement.</p> <p>b. When the therapist or physician recommend a change in therapy earlier than 3 years, the following criteria apply: i. Excessive change in girth or excessive damage from drainage whereas the garment is no longer effective.</p>
Carrier #3	Lymphedema Therapy benefits are subject to any applicable deductible, coinsurance, copayment or benefit limitation. When benefits are provided in the member's contract, benefits for Lymphedema Therapy (Complex Decongestive Therapy) are provided for the treatment of lymphedema to include equipment, supplies, therapy, self-management training and education.
Carrier #4	If DME or PT is being requested as part of treatment, medical review is required for those services and subject to our current benefit limitations (30 therapy visits per condition, per plan year) and medical necessity review for PT and all DME.
Carrier #5	Lymphedema services are covered under the plan's short term rehab and durable medical equipment benefits and limitations, which vary depending on the plan. As previously stated, many plans include a maximum allowable benefit or number of visits. When the maximum allowable benefits are exhausted, coverage is no longer provided even if medically necessary.



4. Please complete the following table based on calendar year 2015 data*:

	Market	% of Members with Lymphedema	Average Charges for Lymphedema Services	Average Annual Cost Sharing (Out of Pocket) for Services for Lymphedema Services*	Average Annual Cost Sharing for all Members for All Services	Average Cost PMPM for All Members
Carrier #1	Total	0.15%	\$328.83	\$21.56		
Carrier #2	Individual	0%	0	0	\$216	0
	Small Group	NA	NA	NA	NA	NA
	Large Group	100%	\$973.80	\$303.43	\$104.60	\$0.13
	Total	100%	\$973.80	\$303.43	\$320.50	\$0.13
Carrier #3	Total	0.00%	0.05 pmpm	0.01 pmpm	N/A	N/A
Carrier #4	Individual	0.10%	\$1,892.60	\$295.71	\$793.24	\$66.10
	Small Group	0.09%	\$1,943.55	\$290.43	\$695.24	\$57.94
	Large Group	0.07%	\$1,470.08	\$252.63	\$472.86	\$39.41
	Total	0.09%	\$1,802.16	\$282.85	\$659.82	\$54.98

5. If some of the services in the proposed mandate are not currently covered or have some type of service limitation, please provide the following information, using calendar year 2015 data:

	Market	Lymphedema-Related Rejected Claims (in Dollars)	Lymphedema-Related Rejected Claims (PMPM)	Reason for Rejection (if available)
Carrier #1	Individual	0	0	0
	Small Group	0	0	0
	Large Group	\$275.00	\$22.92	59-group plan terminated
	Total	\$275.00	\$22.92	0



6. What would be the impact on premium if this proposed mandate was passed? Please express as a PMPM and as a percentage of premium for each market segment: individual, small group, large group.

	Market	Impact on Premium (PMPM)	Impact on Premium (% of premium)
Carrier #1	Individual	\$0.10	0.02%
	Small Group	\$0.10	0.02%
	Large Group	\$0.10	0.02%
	Total	\$0.10	0.02%
Carrier #2	Individual	\$0.13	0.50%
	Small Group	\$0.12	0.40%
	Large Group	\$0.07	0.30%
	Total	\$0.11	0.40%

7. Please identify any administrative concerns/costs associated with this proposed mandate.

	Response
Carrier #1	Additional mandates, taken collectively, increase the cost of healthcare and health care premiums. As premiums increase, fewer employers are able to afford to offer coverage, which results in fewer citizens having access to employer-sponsored coverage.
Carrier #2	None identified since medical necessity should still be required.

8. Please provide any other comments or suggestions regarding this proposed mandate.

No concerns were raised.

9. How does your coverage typically differ for self-funded plans or, is coverage typically the same as fully insured plans? If coverage for self-funded plans differs, what is your estimate of the proportion of self-funded plans that cover this benefit to the same extent as fully-insured plans?

	Response
Carrier #1	Typically the same
Carrier #2	Coverage would be the same as fully insured plans
Carrier #3	Typically the same for non-grandfathered plans. Expect same 99-100% coverage level.
Carrier #4	All insured plans and most self-funded plans would have coverage according to the carrier's Coverage Policy and most individual and group medical plans have DME coverage.



Appendix II: Claim Codes

Lymphedema CPT/HCPCS Code Table

97001	therapy	initial evaluation by a physical or an occupational therapist, or an Evaluation and Management CPT Code for physicians.
97002	therapy	re-evaluation by a physical or an occupational therapist, or an Evaluation and Management CPT Code for physicians.
97003	therapy	initial evaluation by a physical or an occupational therapist, or an Evaluation and Management CPT Code for physicians.
97004	therapy	re-evaluation by a physical or an occupational therapist, or an Evaluation and Management CPT Code for physicians.
97110	therapy	Therapeutic exercises
97016	dme	Vasopneumatic Pump
97124	therapy	Massage therapy for edema of an extremity
97140	therapy	Manual therapy, manual lymphatic drainage (15 minute units)
97150	therapy	Group therapy
97504	dme	Orthotic training/fitting
97530	therapy	Therapeutic activities, restoration of impaired function
97535	self-management	Self-care home management training, instruction on bandaging, exercises, and self-care
97703	dme	Checkout for orthotic or prosthetic use
A6530	Gradient compression garments	Gradient compression stocking; 18-30 mmHg
A6532	Gradient compression garments	Gradient compression stocking; 40-50 mmhg, each
A6533	Gradient compression garments	Gradient compression stocking, thigh length, 18-30 mmhg, each
A6534	Gradient compression garments	Gradient compression stocking; 30-40 mmhg, each
A6535	Gradient compression garments	Gradient compression stocking, thigh length, 40-50 mmhg, each
A6536	Gradient compression garments	Gradient compression stocking; full length/chap style, 18-30 mmHg, each
A6537	Gradient compression garments	Gradient compression stocking, full length/chap style, 30-40 mmhg, each
A6538	Gradient compression garments	Gradient compression stocking, full length/chap style; 40-50 mmhg, each
A6539	Gradient compression garments	Gradient compression stocking, waist; 18-30 mmHg, each
A6540	Gradient compression garments	Gradient compression stocking, waist; 30-40 mmhg, each
A6541	Gradient compression garments	Gradient compression stocking, waist;40-50 mmhg, each
A6545	Gradient compression garments	Gradient compression stocking, waist;30-50 mmhg, each



A6549	Gradient compression garments	Gradient compression stocking, waist, not otherwise specified
S8420	Gradient compression garments	Gradient pressure aid (sleeve and glove combination), custom made
S8421	Gradient compression garments	Gradient pressure aid (sleeve and glove combination), ready made
S8422	Gradient compression garments	Gradient pressure aid (sleeve), custom made, medium weight
S8423	Gradient compression garments	Gradient pressure aid (sleeve), custom made, heavy weight
S8424	Gradient compression garments	Gradient pressure aid (sleeve), ready made
S8425	Gradient compression garments	Gradient pressure aid (glove), custom made, medium weight
S8426	Gradient compression garments	Gradient pressure aid (glove), custom made, heavy weight
S8427	Gradient compression garments	Gradient pressure aid (glove), ready made
S8428	Gradient compression garments	Gradient pressure aid (gauntlet), ready made
L8239	Gradient compression garments	Gradient Compression Stocking NOS, (Arm Sleeve w/ Shoulder Strap)
S8950	therapy	Complex lymphedema therapy, each 15 mn

ICD-9-CM CODES Used

125.0-125.9	Filarial lymphedema
457.0	Post-mastectomy lymphedema syndrome
457.1	Other lymphedema (praecox, secondary, acquired/chronic, elephantiasis)
457.2	Lymphangitis
457.8	Other noninfectious disorders of lymphatic channels (chylous disorders)
624.8	Vulvar lymphedema
729.81	Swelling of limb
757.0	Congenital lymphedema (of legs), chronic hereditary, <u>ideopathic</u> hereditary
782.3	Edema of Legs-Acute traumatic

Bibliography

- Avalere Health. Study for Lymphedema Advocacy Group entitled, “Estimated Federal Costs of H.R. 1608—The Lymphedema Treatment Act.” http://lymphedematreatmentact.org/wp-content/uploads/2016/03/Lymphedema-Treatment-Act-HR1608_S2373.pdf. Accessed October 31, 2016.
- California Health Benefits Review Program. “Analysis of Assembly Bill 213, Health Care Coverage for Lymphedema.” April 2005, http://chbrp.org/documents/ab_213final.pdf. Accessed November 4, 2016.
- Center for Consumer Information & Insurance Oversight. “Information on Essential Health Benefits (EHB) Benchmark Plans.” <https://www.cms.gov/cciio/resources/data-resources/ehb.html#Maryland>. Accessed November 3, 2016.
- Center for Consumer Information & Insurance Oversight. “List of Proposed Essential Health Benefit Benchmark Plans for 2017 and Beyond.” <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-Proposed-BMP.pdf>. Accessed November 6, 2016.
- Center for Consumer Information & Insurance Oversight. “Women’s Health and Cancer Rights Act.” https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html. Accessed November 2, 2016.
- Department of Legislative Services. “Fiscal and Policy Note HB 113 Health Insurance-Coverage for Lymphedema Diagnosis, Evaluation, and Treatment.” http://mgaleg.maryland.gov/2016RS/fnotes/bil_0003/hb0113.pdf. Accessed October 25, 2016.
- Fronstin, Paul PhD. “Self-Insured Health Plans: Recent trends by Firm Size.” 199602915, Employee Benefit Research Institute, July 2016, https://www.ebri.org/pdf/notespdf/EBRI_Notes_07-no7-July16.Self-Ins.pdf. Accessed November 6, 2016.
- Karaca-Mandic, Pinar et al. “The Cutaneous, Net Clinical and Health Economic Benefits of Advanced Pneumatic Compression Devices in Patients with Lymphedema.” The JAMA Network, November 2015, <http://jamanetwork.com/journals/jamadermatology/fullarticle/2453326>. Accessed November 4, 2016.
- Lymphedema Advocacy Group. “Lymphedema Treatment Act HR 1608/S2372.” http://lymphedematreatmentact.org/wp-content/uploads/2016/03/Lymphedema-Treatment-Act-HR1608_S2373.pdf. Accessed November 2, 2016.
- Mapes, Diane. “A Little Known Side Effect with a Huge Impact.” Hutch News, September 3, 2015, <https://www.fredhutch.org/en/news/center-news/2015/09/lymphedema-cancer-treatment-side-effect.html>. Accessed November 4, 2016.
- Massachusetts Division of Health Care Finance and Policy (DHCFP). “Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Women’s Health and Cancer Recovery.” December 2010, <http://archives.lib.state.ma.us/bitstream/handle/2452/101824/ocn711076017.pdf?sequence=1&isAllowed=y>. Accessed November 4, 2016.



Mayo Clinic Staff. "Lymphedema Tests and Diagnosis." <http://www.mayoclinic.org/diseases-conditions/lymphedema/basics/tests-diagnosis/con-20025603>. Accessed November 1, 2016.

Shih, Ya-Chen Tina et al. "Incidence, Treatment Costs, and Complications of Lymphedema After Breast Cancer Among Women of Working Age: A 2 Year Follow-up Study." *Journal of Clinical Oncology*, April 2009, <http://ascopubs.org/doi/full/10.1200/JCO.2008.18.3517>. Accessed November 2, 2016.

Stoppler, Melissa C. M.D. "Lymphedema." *MedicineNet.com*, <http://www.medicinenet.com/lymphedema/article.htm>. Accessed November 2, 2016.

Stout, N.L. et al. "A Systematic Review of Care Delivery Models and Economic Analysis in Lymphedema: Health Policy Impact (2004-2011)." *Lymphology* 46 (2013) Mar 46: 27-41, <https://www.alfp.org/docs/27-41.Mar%202013.STOUT.PDF>. Accessed November 1, 2016.

Weiss, Robert. "Cost of a Lymphedema Treatment Mandate - 10 Years of Experience in the Commonwealth of Virginia." *Health Economics Review*, September 2016, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5010541/>. Accessed November 1, 2016.