

Lymphedema Treatment Act S.1315 / H.R.3630

Supporters Include:

- American Cancer Society
- Susan G. Komen
- American Medical Association
- American Acad. Of Physical Medicine and Rehabilitation
- American Nurses Association
- Oncology Nursing Society
- Wound Ostomy and Continence Nurses Society
- American Physical Therapy Association
- American Occupational Therapy Association
- Association of American Cancer Institutes
- National Comprehensive Cancer Network

Original Sponsors:

Senator Maria Cantwell (D-WA) Senator Chuck Grassley (R-IA)

Rep Jan Schakowsky (D-IL-9) Rep Buddy Carter (R-GA-1) Rep Earl Blumenauer (D-OR-3) Rep Mike Kelly (R-PA-16)

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ABOUT LYMPHEDEMA:

Lymphedema (chronic lymphatic system failure) has a multitude of causes and is the end result of *any* significant impairment to all or part of the lymphatic organ system. It is marked by an accumulation of lymph fluid (swelling) in parts of the body where lymph nodes or lymphatic vessels are damaged or inadequate.

An estimated 3-5 million¹ Americans are affected by this chronic but treatable condition, most commonly from cancer, with 1.5-3 million being Medicare beneficiaries. A growing number of men, women, and children are affected by lymphedema as cancer survivorship increases.

Untreated or inadequately treated lymphedema is progressive, leading to complications, comorbidities, loss of function, disability, and in some cases death. Compression therapy is the essential cornerstone of treatment, without which patients cannot effectively manage this chronic condition.

WHY THIS LEGISLATION IS NEEDED:

Starting in 2001, the Medicare program issued an advisory on the importance of compression garments. A year later, a National Coverage Determination was published highlighting such garments as part of a conservative treatment regimen intended to reduce and control lymphedema-related swelling. To date, HHS acknowledges the importance of compression supplies and indicates that **legislative authority is needed**.

Please note: The Lymphedema Treatment Act was passed in the House during the 116th Congress as part of H.R.3.

WHAT THIS LEGISLATION WILL DO:

- Provide for Medicare coverage of prescribed medical compression garments used in the treatment and management of lymphedema.
- ✓ Enable lymphedema patients to maintain their overall health, activities of daily living, and quality of life.
- Reduce the total healthcare costs associated with this disease by decreasing the incidence of complications, comorbidities, disabilities, and hospitalizations.
- ✓ Align Medicare coverage with existing Federal precedent established by TriCare, Veterans Affairs, and Federal BCBS, all of which provide coverage for these supplies.



More information is available at: LymphedemaTreatmentAct.org

Savings Estimate for the Lymphedema Treatment Act (S.1315/H.R.3630)

The Lymphedema Treatment Act is projected to save the Medicare program at least \$1.3 to \$1.5 billion during the first 10 years, with additional savings likely.

The Lymphedema Advocacy Group commissioned Avalere to estimate the one-year savings potential associated with the coverage of lymphedema compression treatment items as proposed in the Lymphedema Treatment Act (S.1315/H.R.3630). The estimated savings in key areas are presented on the table below.

The full report states: "In addition, patients with lymphedema may not be comprehensively captured in the observational studies and/or claims data due to lack of reported diagnosis, misdiagnosis, or because they are not accessing care, thereby not allowing for more accurate estimates and resulting in **an underestimation of the actual savings potential**."¹

Further, expert opinion and considerable clinical evidence support the expectation that <u>additional savings</u> would also occur in the following areas due to reduced disease progression and fewer complications, but these categories were not included in the savings estimate. In 2019, the lymphedema-related Medicare fee-for-service (FFS) costs were:

- \$50.7 million for evaluation and management services at a physician's office
- \$19.8 million for physical and occupational therapy services
- **\$20.7 million** for emergency department services
- \$49.9 million for compression pump use

Per the below table, with an annual savings of \$126.9 million in hospitalizations and post-acute care, and up to an additional \$18.5 million in VLU-related treatment costs, enactment of the Lymphedema Treatment Act will save the Medicare program at least \$1.3 to \$1.5 billion over the 10-year scoring window from these savings categories alone.

Potential Annual Savings Associated with Coverage of Lymphedema Compression Treatment Items, CY 2021\$

	Medicare		Medicaid		Private Insurance	
Savings Category	Aggregate	Per Person*	Aggregate	Per Person*	Aggregate	Per Person*
Hospitalizations	\$81.0m	\$6,800	\$2.7m	\$4,000	\$13.4m	\$10,500
Post-Acute Care (Skilled Nursing Facility and Home	\$46.0m	\$13,700	\$0.8m	\$8,100	\$5.9m	\$21,200
TOTAL	<mark>\$126.9m</mark>	\$20,400	\$3.5m	\$12,100	\$19.3m	\$31,700
Treatment of Venous Leg Ulcers (VLUs)	<mark>\$18.5m</mark>	\$800	Data not available	Data not available	Data not available	Data not available

Note: The inpatient and post-acute savings estimates can be added together since they are mutually exclusive; savings associated with the treatment of VLUs are across all settings of care and therefore there might be some level of overlap with the first two savings categories. (*Rounded to the nearest \$100.

¹ <u>https://lymphedematreatmentact.org/wp-content/uploads/2021/06/Lymphedema-Treatment-Act-Savings-Estimate.pdf</u>

LYMPHEDEMA: NOT ONE DISEASE

Chronic lymphatic-system failure (lymphedema) occurs in 3-5 million Americans across a wide spectrum of diseases.



Over 40 rare diseases are associated with primary lymphedema including:

- Aagenaes Syndrome
- · Adams-Oliver Syndrome
- · C.H.A.R.G.E. Syndrome
- · C.L.O.V.E.S. Syndrome
- · Carbohydrate Deficient Glycoprotein (types 1a, 1b, 1h)
- · ardio-facial-cutaneous Syndrome
- · Choanalatresia-lymphedema Syndrome
- · Congenital Lymphedema (non-Milroy's)
- · Ectodermal Dysplasia Anhidrotic
- Immunodeficiency Osteopetrosis
- · Lymphedema Syndrome
- · Fabray's Disease
- · Gorham's Disease
- · Hennekam Syndrome
- · Hypotrichosis Lymphedema Telangiectasia
- Klippel Trenaunay Syndrome
- · Klippel-Trenaunay-Weber Syndrome
- · Lipedema
- · Lymphedema Distichiasis Syndrome
- · Lymphedema Myelodysplasia (Emberger Syndrome)
- · Lymphedema Praecox
- · Lymphedema Tarda
- · Lymphedema-Distichiasis
- Macrocephaly-Capillary Malformation
- Maffucci Syndrome

- Meige Syndrome
- · Microcephaly-Chorioretinopathy-Lymphedema-Mental Retardation Syndrome
- · Milroy's Disease
- Mucke Syndrome
- Neurofibromatosis
- Nonne-Milroy Disease
- Noonan's Syndrome
- Oculo-Dento-Digital Syndrome
- · Parkes-Weber Syndrome
- · Phelan McDermid Syndrome
- · Prader Willi Syndrome
- Progressive Encephalopathy-Hypsar -rhythmia-Optic Atrophy Syndrome
- · Protein Losing Enteropathy (associated with numerous forms of congenital heart disease)
- Proteus Syndrome
- Spina bifida
- · Thrombocytopenia with Absent Radius Syndrome
- Trisomy 13,18,21
- Turner's Syndrome
- Velocardiofacial Syndrome
- · W.I.L.D. Syndrome



Secondary cases can be broken into two categories:

22% of all cases are **non-cancer** related.

Any significant damage to the lymphatic organ system can result in lymphedema. Causes include:

- Burns Ilio-femoral bypass
 - · Rheumatoid arthritis

Radiation

Surgery

- Infection
 - Trauma

of all cases are **cancer** related. The overall cancer-related incidence rate is 15.5%. Specific rates include:

- Breast 40%
- Melanoma 16%
- Sarcoma 30%
- · Genital-urinary 10% Head and neck 4%
- Gynecological 20%

1. Journal of the American College of Cardiology. 2008: 52 (10): 799-806

- 2. Vascular Medicine. 1998: (3): 145-156 3. Clinical Genetics. 2010: 77: 438-452
- 4. Cancer. 2010: 116: 5138-49
- 5. Journal of Clinical Oncology. 2009: 27:(3): 390-7 6. Annals of the New York Academy of Sciences. 2008: 1131: 147-154
- 7. European Journal of Cancer Care. (Engl.) 1996: 5: 56-59



For more information visit our website LymphedemaTreatmentAct.org



CHAINS YOU MAY NOT KNOW ABOUT

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

> Damaged vessels blocking the normal = flow of lymphatic fluid

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

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

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

The Lymphedema Treatment Act is a bill, currently in Congress, that aims to improve insurance coverage for compression supplies, allowing lymphedema patients to maintain a healthy and productive life. An estimated 3-5 million Americans suffer from lymphedema — including many that are undiagnosed or undertreated. That is more than ALS, Cystic Fibrosis, Multiple Sclerosis, Muscular Dystrophy, and Parkinson's Disease combined.

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

> > Swollen tissue due to buildup of lymphatic fluid

Causes of Lymphatic Dysfunction

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



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

LymphedemaTreatmentAct.org

Estimated Number of Constituents in Each State Who Would Directly Benefit from Passage of the Lymphedema Treatment Act



The **Avalere Health**¹ **cost analysis for the Lymphedema Treatment Act** demonstrated that nationally, 0.57% of all Medicare patients are diagnosed with lymphedema. Based on this and state Medicare data², here are the estimates of affected Medicare beneficiaries in each state. **Every state Medicaid plan provides coverage for lymphedema compression garments except for GA, MS, ND, OK, SD and WA.*

Alabama 6,037 Montana 1,342 Alaska 556 Nebraska 2,005 Arizona 7,732 Nevada 3,102 Arkansas 3,673 New Hampshire 1,739 California 36,323 New Jersey 9,325 Colorado 5,308 New Mexico 2,449 Connecticut 3,931 New York 20,947 Delaware 1,218 North Carolina 11,523 DC 539 North Dakota 761 Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky	State	2020 Estimate of Medicare Patients with Lymphedema	State	2020 Estimate of Medicare Patients with Lymphedema
Alaska 556 Nebraska 2,005 Arizona 7,732 Nevada 3,102 Arkansas 3,673 New Hampshire 1,739 California 36,323 New Jersey 9,325 Colorado 5,308 New Mexico 2,449 Connecticut 3,931 New York 20,947 Delaware 1,218 North Carolina 11,523 DC 539 North Dakota 761 Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana	Alabama	6,037	Montana	1,342
Arizona 7,732 Nevada 3,102 Arkansas 3,673 New Hampshire 1,739 California 36,323 New Jersey 9,325 Colorado 5,308 New Mexico 2,449 Connecticut 3,931 New York 20,947 Delaware 1,218 North Carolina 11,523 DC 539 North Dakota 761 Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine	Alaska	556	Nebraska	2,005
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California36,323New Jersey9,325Colorado5,308New Mexico2,449Connecticut3,931New York20,947Delaware1,218North Carolina11,523DC539North Dakota761Florida26,440Ohio13,516Georgia10,038Oklahoma4,272Hawaii1,588Oregon5,015Idaho1,964Pennsylvania15,769Illinois12,881Puerto Rico4,274Indiana7,285Rhode Island1,276Iowa3,614South Carolina6,257Kansas3,094South Dakota1,012Kentucky5,356Tennessee7,852Louisiana5,035Texas24,234Maine1,968Utah2,340	Arkansas	3,673	New Hampshire	1,739
Colorado 5,308 New Mexico 2,449 Connecticut 3,931 New York 20,947 Delaware 1,218 North Carolina 11,523 DC 539 North Dakota 761 Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	California	36,323	New Jersey	9,325
Connecticut 3,931 New York 20,947 Delaware 1,218 North Carolina 11,523 DC 539 North Dakota 761 Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	Colorado	5,308	New Mexico	2,449
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DC 539 North Dakota 761 Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	Delaware	1,218	North Carolina	11,523
Florida 26,440 Ohio 13,516 Georgia 10,038 Oklahoma 4,272 Hawaii 1,588 Oregon 5,015 Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	DC	539	North Dakota	761
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Hawaii1,588Oregon5,015Idaho1,964Pennsylvania15,769Illinois12,881Puerto Rico4,274Indiana7,285Rhode Island1,276Iowa3,614South Carolina6,257Kansas3,094South Dakota1,012Kentucky5,356Tennessee7,852Louisiana5,035Texas24,234Maine1,968Utah2,340	Georgia	10,038	Oklahoma	4,272
Idaho 1,964 Pennsylvania 15,769 Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	Hawaii	1,588	Oregon	5,015
Illinois 12,881 Puerto Rico 4,274 Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	Idaho	1,964	Pennsylvania	15,769
Indiana 7,285 Rhode Island 1,276 Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340	Illinois	12,881	Puerto Rico	4,274
Iowa 3,614 South Carolina 6,257 Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340 Maryland 6,004 Vermont 856	Indiana	7,285	Rhode Island	1,276
Kansas 3,094 South Dakota 1,012 Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340 Maryland 6,004 Vermont 856	lowa	3,614	South Carolina	6,257
Kentucky 5,356 Tennessee 7,852 Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340 Maryland 6,004 Vermont 856	Kansas	3,094	South Dakota	1,012
Louisiana 5,035 Texas 24,234 Maine 1,968 Utah 2,340 Maryland 6,004 Vermont 856	Kentucky	5,356	Tennessee	7,852
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Manyland 6 004 Vermont 856	Maine	1,968	Utah	2,340
	Maryland	6,004	Vermont	856
Massachusetts7,692Virginia8,753	Massachusetts	7,692	Virginia	8,753
Michigan 11,933 Washington 7,913	Michigan	11,933	Washington	7,913
Minnesota 5,928 West Virginia 2,519	Minnesota	5,928	West Virginia	2,519
Mississippi 3,470 Wisconsin 6,800	Mississippi	3,470	Wisconsin	6,800
Missouri 7,085 Wyoming 643	Missouri	7,085	Wyoming	643

1. <u>http://lymphedematreatmentact.org/wp-content/uploads/2016/05/Avalere-Score.pdf</u>

2. https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/

The Function of Compression and Why Current Medicare Coverage of Lymphedema Treatment is Inadequate



As stated by the National Cancer Institute, "The goal of lymphedema treatment centers on controlling limb swelling and minimizing complications."²

Under current Medicare policy, lymphedema patients have coverage for Manual Lymphatic Drainage (MLD), performed by a qualified Medicare provider such as a physical or occupational therapist, and, when certain conditions are satisfied, a pneumatic compression pump. The function of both of these treatment modalities is to reduce the volume of stagnant lymph fluid in the affected body part or parts.

The function of a compression garments is to maintain the affected body part in its reduced state and prevent it from swelling further. Without the use of compression garments, MLD and lymphedema pumps provide no lasting benefit and do not enable the patient to maintain their condition.

Medicare does recognize and acknowledge the necessary role compression garments play in the treatment of lymphedema.

Lymphedema pumps, if prescribed, may be covered by Medicare (per National Coverage Determination 280.6³) after "a four-week trial of conservative therapy" has shown little or no benefit. This "conservative therapy" must include the "use of an appropriate compression bandage system or compression garment". The Decision Summary of the Decision Memo for Lymphedema Pumps (CAG 00016N⁴) states providers should, "Encourage patients to use compression garments between pump sessions to prevent reaccumulation of fluid."

Pumps are generally used for an hour a day. A person cannot perform most any activity of daily living while using the pump. As demonstrated by the images below, the pump (seen left) is far different from the compression garments that must be worn continuously to prevent fluid reaccumulation. The Lymphedema Treatment Act will close the unintended gap in coverage that prevents Medicare beneficiaries from accessing medically necessary, prescribed compression garments.



² http://www.cancer.gov/about-cancer/treatment/side-effects/lymphedema/lymphedema-hp-pdq#section/all

³ <u>https://www.cms.gov/medicare-coverage-database/details/ncd-</u>

details.aspx?NCDId=225&ncdver=1&DocID=280.6&SearchType=Advanced&bc=IAAAABAAAAA&

⁴ <u>https://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=50&ver=6&NcaName=Lymphedema+Pumps&DocID=CAG-00016N&bc=gAAAABAAAAAA&</u>

Cost and Utilization of Lymphedema Compression Garments



Garment Type	Standard-Fit, per piece (current average retail price)	Custom-Fit, per piece (current average retail price)	
Arm Sleeve	\$81	\$202	
Hand/Finger Glove	\$132	\$354	
Hand/Forearm Gauntlet	\$67	\$161	
Knee High Stocking	\$64	\$228	
Thigh High Stocking	\$87	\$347	
Waist High Stockings	\$159	\$960	

Chronic Lymphatic System Failure (Lymphedema) most commonly manifests in the extremities.

• The above six types of compression garments constitute 90% of all prescribed compression garments:¹

Typically, patients utilize four compression garments per year for each affected body part.

- Compression garments have a lifespan of six months.
- Patients must have two garments for each affected body part at all times one is worn while the other is laundered.

A preponderance of lymphedema occurs in the upper extremities (less expensive garments).

- Due to the high prevalence of breast cancer-related lymphedema, upper extremity lymphedema accounts for an estimated 85-87% of all cases.^{2 3 4}
- When diagnosed and treated promptly, breast-cancer-related lymphedema patients are likely to be able to use a standard-fit garment, and often only need a sleeve.⁵

Currently, more than 50% of all lymphedema patients are able to use standard-fit garments, as prescribed by a physician, to treat and manage their condition.⁶

 An analysis performed by Avalere Health estimated utilization of standard-fit versus custom-fit to be evenly split, but this assumption was based on utilization data collected only from suppliers who carry both types of products. Since there are many other suppliers who only carry standard-fit products that were not accounted for in their analysis, the actual utilization of standard-fit garments is greater than 50%.

Coverage of lymphedema compression garments would, in time, enable an even greater proportion of patients to utilize standard-fit garments by preventing the disease progression that necessitates the use of custom-fit products.^{7 8}

¹ Based on pricing and utilization data collected from the four largest US manufacturers of both standard-fit and custom-fit compression garments: <u>jobst-usa.com</u>, <u>mediusa.com</u>, <u>lohmann-rauscher.us</u>, <u>juzousa.com</u>

² <u>https://seer.cancer.gov/statfacts/</u>

³ Rockson SG, Ann. N.Y. Acad. Sci. 1131:147-154 (2008)

⁴ Franks PJ, Palliative Medicine 2005: 19: 300-313; Lymphedema: estimating the size of the problem

⁵ http://www.lympho.org/portfolio/best-practice-for-the-management-of-lymphoedema/

⁶ http://lymphedematreatmentact.org/wp-content/uploads/2016/05/Avalere-Score.pdf

⁷ Lymphoedema Framework. Template for Practice: compression hosiery in lymphoedema. London: MEP Ltd, 2006.

⁸ International Lymphoedema Framework - Best Practice for the Management of Lymphedema 2nd Edition 2012.

Medical-Grade Lymphedema Compression Garments are not the same as Over-the-Counter Products



Compression garments sold at pharmacies and through other retailers are not indicated for the management of lymphedema.

Over-the-counter products are almost exclusively for the lower extremities and are used for minor fluid retention or venous stasis.

The medical-grade lymphedema compression garments that would be coverable by Medicare through passage of the Lymphedema Treatment Act also have a number of other distinguishing features including:

- True gradient compression (rather than localized areas of higher compression)
- Higher overall levels of compression and a much wider array of compression strengths
- Superior durability and longevity
- Available for any part of the body that could be affected by lymphedema, not just the lower extremities
- Able to be fit to limbs of any size or shape lymphedema can cause irregularly proportioned and/or extremely enlarged limb size (see below photos)
- Suitable for use in patients with wounds or those predisposed to infection
- Sold by Medicare Accredited DMEPOS suppliers¹
- Require specially trained and certified fitters for custom garments

The compression garments outlined in the Lymphedema Treatment Act, both custom and standard fit, will require a physician's prescription.



¹ <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/DMEPOSAccreditation.html</u>

Disease Progression and Complications for Lymphedema Patients without Access to Care



Untreated or undertreated lymphedema is progressive. Prescribed medical compression garments are essential for maintaining and managing this condition.



Advanced stages of lymphedema can become disfiguring and disabling. The patient pictured here is now receiving treatment and offered these photos to our group in the hope that, through passage of this bill, they will help others access care.



Without treatment patients suffer from more infections, wounds, and other complications.



With treatment many complications can be prevented!

Reducing Lymphedema-Related Infections and Hospitalizations Through the Use of Compression Therapy



The Lymphedema Treatment Act will would provide for Medicare coverage of prescribed medical compression garments, which will improve patient health and quality of life while reducing healthcare costs for our governmental programs.

The first study outlined quantifies the economic burden of lymphedema-related hospitalizations in the US, followed by four studies showing compression therapy's effectiveness in reducing lymphedema-related infections and hospitalizations.

Epidemiology of Lymphedema-Related Admissions in the United States: 2012-2017, *Surgical Oncology*, 2020¹

- Lymphedema is a debilitating chronic condition that has no cure. The primary treatment for these patients are therapies consisting of compression, manual lymphatic drainage, meticulous skin care, and exercise.
- Lymphedema-related hospitalizations are a significant burden to the US healthcare system.
- In the period between 2012 and 2017, there were 165,055 Lymphedema-related hospital admissions with the median age of 62 years representing a total cost of \$5.1 billion during that period. (Note: the study does break out the Medicare and Medicaid populations by both number of patients and total costs.)
- A significant rise in the number of lymphedema hospitalizations were reported over the course of the 7 years of the study, while all-cause hospitalizations declined. The increasing lymphedema hospitalizations is likely due to the improved survival after cancer treatment, which has led to increasing prevalence of patients who have had nodal treatment.
- Nearly half of all lymphedema-related hospitalizations required ongoing care after discharge, at either another facility or through home health care, and these costs are not captured in this study.
- Potential missing diagnosis codes for lymphedema may have resulted in the incorrect exclusion of hospitalizations from the study analysis, which means the overall burden of lymphedema and cellulitis on the US healthcare system was likely underestimated.

¹ https://www.sciencedirect.com/science/article/abs/pii/S0960740420303868

Compression Therapy to Prevent Recurrent Cellulitis of the Leg, New England Journal of Medicine, 2020²

Roughly 80 patients with chronic edema of the leg and a history of cellulitis were randomized to receive compression therapy plus education about cellulitis prevention, or education alone.

- In the control group not receiving compression therapy the rate of cellulitis recurrence was three times greater, and the rate of hospitalization for cellulitis infection was double.
- For patients with chronic leg edema and recurrent cellulitis, the risk for future cellulitis was
 <u>reduced by 77%</u> through the use of compression stockings or other compression therapy supplies.
- The effect was so profound the trial was stopped early, and all patients were given compression therapy.³
- "In a climate of increasing antibiotic resistance, we are delighted to have discovered a nondrug management strategy that has such a dramatic impact on the risk of cellulitis," senior author Bernie Bissett, PhD, Discipline of Physiotherapy, Faculty of Health, University of Canberra.

A Ten-Year Review of Compression Coverage in the Commonwealth of Virginia, *Health Economics Review*, 2016⁴

The following highlights the findings of a ten-year review of Virginia's experience with their state mandate for compression supplies. The mandate applied to private insurance, and later to Medicaid and state employees.

- Visits to providers (physician or therapist) dropped by over 40% (figure 3 page 5).
- Hospital days <u>dropped by over 50%</u> to nearly zero (figure 3, page 6) over the last 5 years.
 Note: Medicare patients would be expected to benefit even more from the mandate as they have a higher risk for hospitalization at baseline.
- "The Virginia data confirmed previous clinical data that the treatment of lymphedema by management of swelling results in <u>lower medical costs and fewer hospitalizations.</u>"

² https://www.nejm.org/doi/full/10.1056/NEJMoa1917197

³ https://www.medscape.com/viewarticle/935845

⁴ <u>https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-016-0117-3</u>

Effects of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema, *Rehabilitation Oncology Journal*, 2011 ⁵

- Lymphedema was recognized as one of the most potent risk factors for the development of recurrent cellulitis, which frequently requires hospitalization.
- The authors remarked that enrollment in the study removed a significant barrier to idealized treatment by covering the cost of bandages and garments through the study's funding.
- The study revealed that treatment, primarily consisting of compression including bandaging and compression garments, reduced the average annual hospitalizations among the study participants from 8.5/year down to 0.67/year, a decrease of 12-fold.

Cellulitis in Chronic Oedema of the Lower Leg: An international crosssectional study. *British Journal of Dermatology, Accepted for Publication,* 2021 ⁶

- The authors investigated the prevalence and risk factors of cellulitis in 7,477 patients at 40 healthcare sites in nine countries between June 2014 and August 2017. Statistical ranges may reflect differences between sites for the type of clinical setting and patients served.
- 5 to 78% of patients with chronic edema were diagnosed with cellulitis within the last 12 months, with a lifetime prevalence of 37 to 47%. Of those patients, 31.2% were hospitalized for treatment.
- Clinicians evaluated a subgroup of 996 patients for the severity of lymphedema. Control of swelling was associated with a significantly lower risk of cellulitis during the previous 12 months while advanced stages of chronic edema were strong risk factors for cellulitis. For stage I, the authors reported cellulitis incidence of 9 70%; stage II, 18 40%; and stage III, 41 67%.
- Based on these findings, the authors conclude compression therapy to control swelling and halt progression into advanced stages of lymphedema may have a significant effect on reducing the risk of cellulitis, thereby reducing healthcare costs. They assert that compression therapy should be mandatory

⁵ https://journals.lww.com/rehabonc/Abstract/2011/29030/Effects of Complete Decongestive Therapy on the.3.aspx

⁶ https://onlinelibrary.wiley.com/doi/10.1111/bjd.19803

Risk Factors for More Severe Cases of COVID-19 in Lymphedema Patients



"The current pandemic of COVID-19 and the risk of SARS-CoV-2 poses a particular risk to people living with preexisting conditions that impair immune response or amplify pro-inflammatory response." ¹

Permanently Impaired Immune Systems – 100% of patients Additional Cancer-Related Immunosuppression – up to 66% of patients

Lymphedema patients have permanently impaired immune function.^{2 3 4} The lymphatic system directly and indirectly regulates immune response. Even in secondary lymphedema, abnormal lymphatic function is systemic.^{5 6 7} Cancer patients and survivors, who comprise two-thirds of all lymphedema patients, often have additional long-term or even permanent immunosuppression.^{8 9 10 11}

Obesity – at least 65% of patients

The prevalence of obesity within the lymphedema population is more than double that of the general population. Obesity is both a cause of lymphedema and can also be the result of lymphedema.^{12 13} Informal assessments in the US have estimated that 50-80% of American lymphedema patients are obese.¹⁴ A formal study in the United Kingdom found 64.6% of lymphedema patients to be obese, 2.32 times higher than the prevalence of obesity in their general population.¹⁵

Age 60 or Older – more than 50% of patients

Half of all lymphedema patients are seniors on Medicare, an estimated 1.5-3 million Americans.¹⁶

Additional Risk Factors – 100% of patients

Lymphedema patients carry excess fluid loads and suffer from chronic inflammation. Lymphedema is characterized by persistent swelling in one or more parts of the body due to impaired lymph transport,¹⁷ and also results in localized as well systemic inflammation.¹⁸ ¹⁹

¹⁰ Lymphocyte depletion and repopulation after chemotherapy for primary breast cancer -

¹ COVID-19 and the role of chronic inflammation in patients with obesity - <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7224343/</u>

² Regulation of Immune Function by the Lymphatic System in Lymphedema - <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6431610/</u>

³ Modulation of Immunity by Lymphatic Dysfunction in Lymphedema - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6361763/

⁴ T-regulatory cells mediate local immunosuppression in lymphedema - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5794510/

⁵ Lymphatic dysfunction in the apparently clinically normal contralateral limbs of patients with unilateral lower limb swelling. https://www.ncbi.nlm.nih.gov/pubmed/22

⁶ Lymphatic abnormalities in the normal contralateral arms of subjects with breast cancer-related lymphedema as assessed by near-infrared fluorescent imaging. - https://www.ncbi.nlm.nih.gov/pubmed/22741072

⁷ Local vascular access of radioprotein injected subcutaneously in healthy subjects and patients with breast cancer-related lymphedema. https://www.ncbi.nlm.nih.gov/pubmed/15136628/

Lymphedema: Not One Disease - https://lymphedematreatmentact.org/wp-content/uploads/2020/05/Lymphedema-Not-One-Disease-full-bleed.pdf

⁹ Significant Impairment in Immune Recovery Following Cancer Treatment - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2777669/

https://breast-cancer-research.biomedcentral.com/articles/10.1186/s13058-015-0669-x ¹¹ Why People with Cancer are More Likely to Get Infections - <a href="https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/p effects/low-blood-counts/infections/why-people-with-cancer-are-at-risk.html

¹³ IL-6 Regulates Adipose Deposition and Homeostasis in Lymphedema - <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4024716/</u>

¹⁴ A New Look at Lymphedema and Obesity: Breaking the Cycle - <u>https://klosetraining.com/2014/09/02/lymphedema-and-obesity-part-i/</u>

¹⁵ LIMPRINT in Specialist Lymphedema Services - <u>https://www.liebertpub.com/doi/pdf/10.1089/lrb.2019.0021</u>

¹⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3652571/#R1

¹⁷ Lymphedema diagnosis, treatment, and follow-up from the view point of physical medicine and rehabilitation specialists https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6657795/ ¹⁸ Inflammatory Manifestation of Lymphedema - <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5297803/</u>

¹⁹ Cytokines are Systemic Effectors of Lymphatic Function in Acute Inflammation - <u>https://www.ncbi.nlm.nih.gov/pubmed/23764549</u>