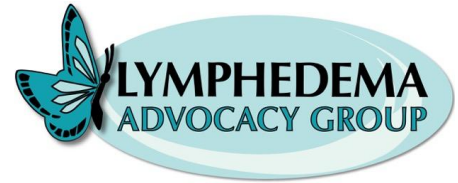


February 13, 2023

Division of DMEPOS Policy
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244



Dear Director Kaiser,

Thank you for the opportunity to provide comments regarding rulemaking related to the implementation of the Lymphedema Treatment Act. This law enables Medicare coverage for compression garments and supplies used in treating and managing lymphedema through the creation of a new benefit category.

About the Lymphedema Advocacy Group

The Lymphedema Advocacy Group is a grassroots, all-volunteer organization founded in 2010 to improve patient care. Since its inception, our primary focus has been improving insurance coverage for compression garments and supplies through the passage of the Lymphedema Treatment Act.

Intent of the Lymphedema Treatment Act

The intent of the law is to ensure that all Medicare beneficiaries with diagnosed lymphedema receive coverage for the prescribed compression supplies necessary to treat and manage their condition in accordance with the standard of care.

As such, it is imperative that beneficiaries have equitable access to care, regardless of:

- the cause of their lymphedema,
- the extent and/or severity of their condition,
- or the location in which they live (i.e. LCD/MAC determinations).

Now that the statutory limitations have been removed, the rules must ensure that beneficiaries with lymphedema have comprehensive and accessible coverage that allows for individualized, patient-centered care.

Background on Lymphedema, its Causes, and the Standard of Care

Lymphedema is a chronic disease, marked by the increased collection of lymphatic fluid, that results in swelling of a region or regions of the body, including but not limited to the arms, legs, genitals, face, neck, chest wall, abdomen, and oral cavity. The progressive accumulation of protein-rich fluid and the development of fibro-adipose tissue within the interstitium exceeds the capacity of the lymphatic system to transport the fluid. If inadequately managed, the affected region(s) can reach disabling proportions and cause disfiguring changes in the skin of the affected region(s).

Consequences can include loss of function and restricted movement, physical discomfort/pain, and the risk of repeated, even life-threatening infection.¹ For more information on the epidemiology, pathophysiology, and presentation of lymphedema and treatment options, see Sleigh and Manna (2022).²

Lymphedema has two classifications. Primary lymphedema is the result of a congenital malformation in the lymphatic system. Secondary lymphedema is an acquired disease, resulting from damage done to the lymphatic system. The most common cause of secondary lymphedema in the United States is cancer treatments that remove or damage lymph nodes and vessels.³

The standard of care for lymphedema treatment and management for both classifications is a multidisciplinary approach known as Complete Decongestive Therapy (CDT).⁴ CDT includes:

1. manual lymphatic drainage (MLD)
2. skincare to optimize skin health and reduce infection risk
3. the use of compression bandages, garments, and supplies
4. exercises that enhance lymphatic flow
5. education regarding risk reduction practices

Typically, patients undergo an intensive phase of initial decongestion that includes services provided by a qualified physical or occupational therapist, to reduce the accumulated swelling to the greatest extent possible, followed by a life-long maintenance phase. All elements of CDT are utilized in both phases, though the frequency, intensity, and/or compression supplies used will vary. The critical component of both phases of treatment is compression.

Physicians can accurately diagnose patients with lymphedema in most instances through a combination of physical examination, evaluation of the patient's history, and understanding the risk factors for lymphedema. Blood, urine, or tissue studies are not needed to make the diagnosis, however, these tests might help to define the underlying causes of lower extremity edema when the etiology is unclear. Imaging (lymphoscintigraphy, 3-dimensional magnetic resonance imaging, computerized tomography, ultrasound) and bioelectrical impedance analysis can be utilized to make or confirm a diagnosis when necessary, or to assess the extent of involvement and help determine therapeutic interventions.⁵

Types of Compression Garments and Supplies

If permitted, we will send you a box of compression garments and supplies in the coming weeks to supplement this text. Each item will be labeled to correspond with the following:

- A. All items marked **EXHIBIT A** are examples of standard-fit daytime compression garments.

¹ <https://pubmed.ncbi.nlm.nih.gov/29636648/>

² <https://www.ncbi.nlm.nih.gov/books/NBK537239/>

³ <https://www.ncbi.nlm.nih.gov/books/NBK537239/>

⁴ International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology. *Lymphology* 2016, 49(4): 170-84.

⁵ <https://www.ncbi.nlm.nih.gov/books/NBK537239/>

- B. All items marked **EXHIBIT B** are examples of custom-fit daytime compression garments.
- C. All items marked **EXHIBIT C** are examples of standard-fit nighttime compression garments.
- D. All items marked **EXHIBIT D** are examples of custom-fit nighttime compression garments.
- E. All items marked **EXHIBIT E** are examples of standard-fit inelastic adjustable compression wraps, which are suitable for daytime or nighttime use.
- F. All items marked **EXHIBIT F** are examples of custom-fit inelastic adjustable compression wraps, which are suitable for daytime or nighttime use.
- G. All items marked **EXHIBIT G** are examples of standard-fit foam compression garments suitable for nighttime use.
- H. All items marked **EXHIBIT H** are examples of custom-fit foam compression garments suitable for nighttime use.
- I. All items marked **EXHIBIT I** are examples of compression bandaging supplies.
- J. All items marked **EXHIBIT J** are examples of ancillary supplies used in combination with other compression garments, wraps, or bandaging supplies.

Note that compression garments are manufactured using one of two knitting processes, resulting in different attributes that must be considered when determining which type or types of garments are prescribed for a patient. Most standard-fit garments are manufactured using a circular-knit process and most custom-fit garments are manufactured using a flat-knit process, however, there are also custom-fit circular-knit and standard-fit flat-knit garments.

The treatment and management of lymphedema can be complex and vary significantly between patients. Each of these types of supplies serves a precise and unique function. Although most patients only require a few of these supplies, it is necessary that all of them be covered when medically necessary, to ensure that every patient has safe, effective, and equitable access to care.

Improving Patient Outcomes: The Role of Compression Therapy in Reducing Complications, Hospitalization, Comorbidities, and Disability.

Numerous studies and real-world data have demonstrated that compression therapy significantly improves patient outcomes while reducing the need for other healthcare services.

The Commonwealth of Virginia began mandating private insurance coverage for lymphedema compression supplies in 2004, and five years later, that coverage was added to their Medicaid plan. An analysis published in *Health Economic Review* in 2016, which analyzed the required annual reporting data from the first ten years of the coverage, showed that the increased access to care resulted in a more than 40% reduction in physician and therapy visits, and a more than 50% reduction in hospitalizations.⁶

A study published in the *New England Journal of Medicine* in 2020 found that 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.⁷ For patients with chronic leg edema and recurrent cellulitis, the risk for future cellulitis was reduced by 77% through the use of compression

⁶ <https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-016-0117-3>

⁷ <https://www.nejm.org/doi/full/10.1056/NEJMoa1917197>

stockings or other compression therapy supplies. The effect was so profound the trial was stopped early, and all patients were given compression therapy. The study's senior author was quoted as saying, "*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.*"⁸

A study published in *Rehabilitation Oncology Journal* in 2011 recognized lymphedema 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 treatment by covering the cost of bandages and garments through the study's funding. The study revealed that treatment consisting of compression, including bandaging and compression garments, reduced the average annual hospitalizations among the study participants by 92%.⁹

A study published in *Surgical Oncology* in 2020 found that lymphedema-related hospitalizations significantly burden the US healthcare system. Between 2012 and 2017, there were 165,055 lymphedema-related hospital admissions with a 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 was reported over the course of the seven years of the study, while all-cause hospitalizations declined. The increasing lymphedema hospitalizations were attributed to improved survival after cancer treatment, which has led to an 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. Further, the study notes that 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.¹⁰

An analysis performed by Avalere in 2021 estimated that Medicare would save \$130-\$150 million dollars annually through a reduction in lymphedema-related hospitalizations and related expenses if beneficiaries had coverage for their prescribed compression garments. The analysis also noted that additional savings would be incurred through fewer physician and therapy visits, lessened need for pneumatic compression pumps, and in other categories where they lacked the data to calculate these savings.¹¹

The evidence suggests that patients with under-treated lymphedema do not see the full therapeutic benefit and a corresponding reduction in other healthcare services. Consequently, it is critically important that they receive comprehensive coverage for compression supplies in accordance with standards of care.

⁸ <https://www.medscape.com/viewarticle/935845>

⁹ https://journals.lww.com/rehabonc/Abstract/2011/29030/Effects_of_Complete_Decongestive_Therapy_on_the.3.aspx

¹⁰ <https://www.sciencedirect.com/science/article/abs/pii/S0960740420303868>

¹¹ <https://lymphedematreatmentact.org/wp-content/uploads/2021/07/Lymphedema-Treatment-Act-Savings-Estimate.pdf>

Recommendations regarding the Scope of the Coverage

1. Allowable Quantities

It is imperative that the allowable quantity not be a fixed number per patient, as this will result in inequitable access to care. Patients with more affected body parts, and/or more severe or complex cases, require more pieces to treat and manage their condition effectively. Just as a double amputee needs more prostheses at one time than a single amputee, or a person with heart disease may need multiple medications at dosages appropriate for them to manage their condition optimally, compression coverage for each lymphedema patient must be commensurate with their medical needs. Regarding standard-fit or custom-fit daytime compression garments, at least two items per affected body part are always necessary. This constitutes one “set” of garments. One set is being worn, while the other is being laundered. Some compression supplies do not require daily laundering, and therefore the patient only requires one such item or set of items at a time.

2. Replacement Frequency and Exceptions

As with any medical device or supply, compression items must be replaced when they have reached the end of their functional lifespan. Using compression supplies that are no longer effective in managing the patient's swelling puts them at increased risk for infections and other complications that can result in costly hospitalization and/or disease progression. Additionally, it is important that protocol be in place for patients to seek exceptions when a compression item requires replacement sooner than the usual frequency. Causes could include but are not limited to changes in health status, changes to body shape or size causing the current compression garment to no longer fit properly, or wear and tear. For example, compression gloves frequently experience greater wear and tear because the patient's hands are exposed and constantly in use, whereas garments on other body parts are often covered and less mobile.

3. Access to Custom-Fit Supplies and/or Flat-Knit Compression Garments

We understand that criteria will be necessary to ensure that each patient uses the most cost-effective compression supply or supplies to treat and manage their condition effectively. However, patients who require custom-fit compression garments and/or flat-knit compression garments must have access to and be afforded coverage for these supplies, without undue burden or delays. The appropriate garment for each patient is based on many factors, including but not limited to the stage of the disease, limb size and shape, and the physical capability to don and doff compression garments. Just as with medications, compression garments are prescribed in accordance with each patient's medical needs, and two patients who look the same on the outside may need different prescriptions to treat and manage their condition effectively. We emphasize that lymphedema patients' compression needs are varied. The most appropriate compression garment(s) for each patient are best determined by their healthcare providers, and all medically necessary compression garments and supplies must be covered to ensure that each patient can treat and manage this chronic disease effectively.

4. Vendors and Existing Reimbursement Rates

Current reimbursement rates for lymphedema compression supplies vary widely amongst the private, state, and federal plans already offering coverage for these supplies. Consequently, some patients who currently have coverage for compression supplies do not have access to a vendor who provides custom garments. It is important that all patients have access to the full range of lymphedema compression supplies needed to treat and manage their condition. Note that we have enclosed the materials that were provided to the Congressional Budget Office, many of which have already been cited above.

5. Additional Codes

We believe that implementing this new coverage necessitates the addition of more billing codes for lymphedema compression supplies in order to differentiate between specific types of supplies. Additionally, while the Lymphedema Treatment Act does not make any changes with regard to physician or therapy services, it is worth considering if additional lymphedema-related diagnosis codes and/or therapy codes would also be beneficial.

6. Coordination of Care with other Medicare Services

Lymphedema patients can receive initial treatment and maintenance treatments in various settings, including outpatient clinics, home health, skilled nursing facilities, long term acute care, or inpatient rehabilitation — anywhere physical and occupational therapy services are provided. It is important that these patients have the ability to obtain medically necessary compression supplies in coordination with these services and circumstances, without the burden being placed on the provider.

Thank you for your consideration of these materials. You may also find the [Committee Report](#) for the Lymphedema Treatment Act helpful to review, particularly pages 3 and 4, which cover the background and need for the legislation.

Please contact me if you have any questions about our comments. We look forward to additional opportunities to provide feedback on this issue in advance of any finalized policies.

Sincerely,



Heather Ferguson
Founder & Executive Director
Lymphedema Advocacy Group
Heather@LymphedemaTreatmentAct.org
704-965-0620

Enclosure:
Materials shared with the Congressional Budget Office



One-Year Savings of Insurance Coverage of Lymphedema Compression Treatment Items

Summary

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 (LTA) (S. 1315/H.R. 3630 of the 117th Congress). Avalere leveraged Medicare claims data and literature findings to estimate potential annual savings associated with the coverage and utilization of compression treatment items by patients with lymphedema across Medicare, Medicaid, and private insurance markets. Although the LTA relates specifically to Medicare coverage, it may set a precedent for other payers to follow. Avalere developed per person as well as aggregate savings estimates, where feasible.

Overall, Avalere estimated at least \$126.9 million potential annual savings to Medicare, at least \$3.5 million to Medicaid, and at least \$19.3 million to commercial payers. Notably, all savings estimates could be understated given limitations in data reporting and available research.

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

Savings Category	Medicare		Medicaid		Private Insurance	
	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	\$126.9m	\$20,400	\$3.5m	\$12,100	\$19.3m	\$31,700
Treatment of Venous Leg Ulcers (VLUs)	\$18.5m	\$800	Data not available	Data not available	Data not available	Data not available

* Rounded to the nearest \$100.

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.

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Methodology

Avalere analyzed the 2019 Standard Analytic Files (SAFs)¹ of Medicare fee-for-service (FFS) claims data for a nationally representative sample of 5% beneficiaries to identify persons diagnosed with lymphedema.² Avalere then determined the portion of beneficiaries who sought treatment³, for lymphedema as a proxy for the future compression treatment items utilization rate. Avalere then extrapolated the 5% sample results to the whole Medicare FFS population, made adjustments to reflect the patients enrolled in Medicare Advantage⁴, and applied the total Medicare enrollment growth rate⁵ to arrive at the estimated 175,000 total beneficiaries with diagnosed lymphedema in 2021, who will directly benefit from the coverage of the lymphedema compression treatment items. Notably, the assessments of the state mandates of lymphedema treatment coverage for patients with private insurance indicate potential increase in compression treatment items utilization once coverage is expanded. For example, the analysis of the California mandate estimated overall 2 percent increase in utilization of lymphedema treatment due to increased awareness the mandate would provide; the utilization specific to compression garments was assumed to increase by nearly 6 percent.⁶

Using SAF claims data, Avalere identified lymphedema-related hospitalizations for beneficiaries who currently receive lymphedema treatment for the average Medicare FFS cost of approximately \$11,300 per hospitalization. Avalere also identified average costs of the skilled nursing facility (about \$17,200) and home health (about \$5,600) stays for those patients. Avalere adjusted Medicare FFS costs to reflect MA, Medicaid, and private insurance costs based on rate differences assumptions.⁷ Avalere then used the estimated number of lymphedema-related hospitalizations identified for Medicaid and private insurance payers as well as discharge status⁸ to estimate inpatient and post-acute care cost savings across payers due to an assumed 46% reduction in hospitalizations for beneficiaries with lymphedema who utilize compression treatment items. The 46% assumption is based on the study that found a 92% reduction in the number of hospitalizations for the management of cellulitis among a cross-payer patient population with lymphedema who undertook compression treatment.⁹ Given that the study had a small sample size

¹ <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/StandardAnalyticalFiles.html>

² Avalere used the following ICD-10 diagnosis codes to identify lymphedema across physician, durable medical equipment, outpatient and inpatient hospital claims: B74.0, B74.1, B74.8, B74.9, I89.0, I89.8, I89.9, I97.2, N90.7, N90.89, Q82.0.

³ Defined as claims for physical therapy (PT) and occupational therapy (OT) visits and for compression pumps (currently covered by Medicare) as well as for select compression treatment items (not covered by Medicare except for the compression stocking intended for wound care). Healthcare Common Procedure Coding System (HCPCS) codes for compression pumps: E0650 thru E0676 and for PT and OT therapy services: 97001, 97002, 97003, 97004, 97161, 97162, 97163, 97164, 97165, 97166, 97167, 97186, 97140, 97110, 97535, 97150, 97124, 97530. The HCPCS codes for compression treatment items: A4466, A6530, A6531, A6532, A6533, A6534, A6535, A6536, A6537, A6538, A6539, A6540, A6541, A6544, A6545, A6549, S8010, S8420 thru S8428.

⁴ In 2019, Medicare FFS was 63% of the total Medicare population, 2020 Medicare Trustees Report.

⁵ 2020 Medicare Trustees Report. <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>

⁶ California Health Benefits Review Program (CHBRP). (2005). *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*. Report to Calif. State Legislature. Oakland, CA: CHBRP. 05-03. http://chbrp.org/documents/ab_213final.pdf

⁷ MA plans are assumed to reimburse in line with Medicare FFS rates and private payers are assumed to reimburse at 189% of Medicare FFS rates: <https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/52819-presentation.pdf>. Medicaid is assumed to reimburse at 72% of Medicare FFS: <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

⁸ Epidemiology of Lymphedema-Related Admissions in the United States: 2012-2017, Surgical Oncology, 2020.

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

⁹ Kathryn Arsenault, Lee Rielly, Helen Wise. "Effects of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema". *Rehabilitation Oncology*, Vol. 29. No.3, 2011. <https://journals.lww.com/rehabonc/pages/articleviewer.aspx?year=2011&issue=29030&article=00003&type=abstract>



and therefore the findings may be inconclusive, Avalere estimated that the real impact on hospitalizations for patients with lymphedema who use compression treatment items could be smaller and have conservatively reduced the study findings by half. This assumption aligns with the recent evidence on compression treatment being associated with the reduction in hospitalizations, where the study found that in the control group not receiving compression therapy the rate of hospitalization for cellulitis infection was double.¹⁰

Finally, Avalere used the SAF claims data to estimate reduction in Medicare costs for beneficiaries with lymphedema who develop venous leg ulcers (VLUs).¹¹ About 10% of beneficiaries with lymphedema are also diagnosed with VLUs costing Medicare over \$3,000 annually per person in VLU-related treatment costs. A study found close to 25% decrease in reoccurrence of VLU due to the use of the compression treatment items¹², which would result in direct savings to Medicare.

Discussion

Expert opinion and considerable clinical evidence support the expectation that proper compression therapy slows disease progression and reduces complications.^{13 14} Further, the analysis in California concluded that the lymphedema treatment mandate could have a favorable impact on patients' health via improved lymphedema control.¹⁵ As such, the improvement in access to compression items due to the Medicare coverage may result in additional reductions in healthcare spending such as disability payments and outpatient therapy, emergency department and physician visits costs, which Avalere did not estimate. In 2019, the estimated Medicare FFS costs for beneficiaries diagnosed with lymphedema 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

Overall healthcare savings resulting from the treatment with lymphedema compression items are likely underestimated since people with lymphedema experience complications and comorbidities associated with healthcare costs, which could be alleviated due to compression treatment. 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.

¹⁰ Compression Therapy to Prevent Recurrent Cellulitis of the Leg, New England Journal of Medicine, 2020. <https://www.nejm.org/doi/full/10.1056/NEJMoa1917197>

¹¹ Avalere used the following ICD-10 diagnosis codes to identify VLU: Varicose veins of lower extremities I83.xxx, Other disorders of veins I87.xxx, Pressure ulcer L89.xxx, Non-pressure chronic ulcer of lower limb, not elsewhere classified L97.xxx

¹² Nelson, E Andrea, and Sally E M Bell-Syer. "Compression for preventing recurrence of venous ulcers." The Cochrane database of systematic reviews vol. 2014,9 CD002303. 9 Sep. 2014. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7138196/>

¹³ N.L. Stout, R. Weiss, J.L. Feldman, B.R. Stewart, J.M. Armer, J.N. Cormier, Y.- C.T. Shih. "A systematic review of care delivery models and economic analyses in lymphedema: health policy impact (2004-2011)". *Lymphology*. 2013 Mar ;46(1):27-41. <https://www.alfp.org/docs/27-41.Mar%202013.STOUT.PDF>

¹⁴ Nicole L. Stout, Lucinda A. Pfalzer, Barbara Springer, Ellen Levy, Charles L. McGarvey, Jerome V. Danoff, Lynn H. Gerber, Peter W. Soballe. "Breast Cancer-Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Model of Care". *Phys Ther*. January 2012; 92(1): 152-163.

¹⁵ http://chbrp.org/documents/ab_213final.pdf





To: Lymphedema Advocacy Group

From: Avalere Health

Date: August 12, 2014

Re: Estimated Federal Costs of H.R. 3877 - The Lymphedema Treatment Act

Summary

The Lymphedema Advocacy Group asked Avalere Health to estimate the cost or savings to the federal government of the Lymphedema Treatment Act (H.R. 3877). This proposed legislation would create a new category of durable medical equipment, prosthetics and orthotics supplies (DMEPOS) for compression items used in the treatment of patients with lymphedema. The compression items would be covered by Medicare Part B with coverage proposed to take effect January 1, 2015.

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

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

	Outlays, by Fiscal Year, in Billions of Dollars										2015- 2019	2015- 2024
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024		
Total change in federal spending	*	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.3	0.8

* represents less than \$50 million

Note: Numbers may not add due to rounding.

Background

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

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

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

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

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

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

³ Ibid.

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

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

CDT involves two phases⁶:

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

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

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

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

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

Data Sources

We used the following data sources to develop our estimate:

- CMS' Medicare 5% Physician, Hospital Outpatient, and Durable Medical Equipment Standard Analytical Files (SAFs), 2012⁹

⁶ Ibid.

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

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

⁸ http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf

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

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

- Projected Consumer Price Index for Urban Consumers (CPI-U), Congressional Budget Office (CBO) March 2014 Baseline: Medicare¹⁰
- Medicare population growth, CMS' Office of the Actuary (OACT) Part B February 2014 Baseline¹¹
- Historical CPI-U: U.S. city average, the U.S. Bureau of Labor Statistics¹²
- Annual DEMPOS Fee Schedule Update Factors 1990-2014: individual CMS' releases
- Innovators' Guide to Navigating Medicare, Version 2.0, 2010¹³
- Proprietary price and utilization information received from six suppliers currently selling compression items¹⁴
- Information gathered during discussions with the clinical experts:
 - Julie F. Hanson MD, FAAP, CLT-LANA, Board Member and Medical Advisor, Lymphedema Advocacy Group
 - Carol L. Johnson OTR/L, CLT-LANA, Board Member and Medical Advisor, Lymphedema Advocacy Group
 - Nicole L. Stout, DPT, CLT-LANA, Board Member and Medical Advisor, Lymphedema Advocacy Group
 - Jane M. Armer, PhD, RN, FAAN, Professor, MU Sinclair School of Nursing, Director, American Lymphedema Framework Project
- California Health Benefits Review Program (CHBRP). (2005). *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*. Report to Calif. State Legislature. Oakland, CA: CHBRP. 05-03¹⁵
- Commonwealth of Massachusetts, Division of Health Care Finance and Policy. *Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Women's Health and Cancer Recovery Senate Bill 896*. Prepared for the Joint Committee on Public Health. December 2010¹⁶
- Report of the State Corporation Commission to the Governor and the General Assembly of Virginia: *The Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2004-2012 Reporting Periods*¹⁷

Assumptions and Methodology

- **Number of Medicare fee-for-service (FFS) beneficiaries with lymphedema:** Avalere analyzed Medicare 5% Standard Analytic Files with physician, durable medical equipment (DME), and outpatient hospital claims data to identify beneficiaries with

¹⁰ <http://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2014-04-Medicare.pdf>

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

¹² <http://www.bls.gov/cpi/#tables>

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

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

¹⁵ http://chbrp.org/documents/ab_213final.pdf

¹⁶ <http://www.mass.gov/chia/docs/r/pubs/10/womens-health-and-cancer-recovery-mb-report.pdf>

¹⁷ <http://leg2.state.va.us/DLS/H&SDocs.NSF/Search%20options?OpenForm>

lymphedema. We used diagnosis codes developed during discussions with clinical experts to identify these patients.¹⁸ We extrapolated our results to the whole Medicare population to estimate that there were 291,900 beneficiaries with lymphedema in 2012.

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

- **Number of beneficiaries who will use compression items.** We assessed the current treatment patterns among the Medicare beneficiaries we identified with lymphedema. Specifically, we determined the proportion of beneficiaries who had claims for physical and occupational therapy (PT and OT) visits and compression pumps¹⁹ – services currently covered by Medicare – as a proxy for the treatment rate among the lymphedema population. We estimate 26 percent of Medicare beneficiaries with lymphedema currently seek therapy treatment. We assume these beneficiaries will use compression items once Medicare coverage is in place.

The California mandate assessment report found underutilization of the treatment among privately insured lymphedema patients under age 65.²⁰ Specifically, the analysis found around 12 percent of lymphedema patients utilizing PT or OT, 20 percent using compression garments, and fewer than 10 percent using MLD. On the other hand, some of the beneficiaries who are currently paying out-of-pocket for compression items are able to manage their lymphedema well on their own and may not need annual therapy visits or compression pumps (the services we used to estimate the treatment utilization rate). However, given the results from the California study, we feel our estimate that over one-quarter of the Medicare population with lymphedema will receive compression items accounts for most of these “unidentified” patients.

We also assumed the percentage of beneficiaries with lymphedema using compression items will increase slightly once Medicare coverage is expanded based on the findings from the assessment of the state mandates of lymphedema treatment coverage for patients with private insurance. The impact analysis of the Massachusetts mandate assumed an increase in the utilization of treatments for lymphedema but did not specify the magnitude of that increase.²¹ The analysis of the California mandate estimated overall 2 percent increase in utilization of services for DME, compression garments, manual lymph drainage, and PT due to increased awareness that lymphedema

¹⁸ We used the following ICD-9 diagnosis codes to identify patients with lymphedema:

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

¹⁹ We used the following Healthcare Common Procedure Coding System (HCPCS) codes for compression pumps: E0650 thru E0676 and for PT and OT therapy services: 97001, 97002, 97003, 97004, 97110, 97140, 97535

²⁰ http://chbrp.org/documents/ab_213final.pdf

²¹ <http://www.mass.gov/chia/docs/r/pubs/10/womens-health-and-cancer-recovery-mb-report.pdf>

treatment mandate would provide; the utilization specific to compression garments was assumed to increase by nearly 6 percent due to the removal of the coverage limits.²² We note that no increase in utilization trends were observed over multiple years of data since the lymphedema treatment coverage mandate was implemented in Virginia in 2003.²³

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

- **Current prices of compression items:** The cost of compression items varies greatly depending on the body part (lower vs. upper extremity) and whether the item has a custom or standard fit. The type and complexity, and thus cost, of compression items required by a patient depend on disease severity. For instance, a large portion of lymphedema patients are breast cancer survivors with the upper extremity lymphedema, which usually requires standard fit items on the lower end of the cost spectrum.²⁴

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

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

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

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

²² http://chbrp.org/documents/ab_213final.pdf

²³ <http://leg2.state.va.us/DLS/H&SDocs.NSF/Search%20options?OpenForm>

²⁴ Based on the information gathered during the discussions with the clinical experts.

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

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

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

- **Medicare reimbursement for compression items under the DMEPOS fee schedule:** For new items, CMS uses the gap-fill methodology based on the payments made under the reasonable charge methodology in the historic base period (1986/87) to determine the DMEPOS fee schedule reimbursement rates. If an item has been available in the base period, CMS will use the average historic price inflated to the current date using the percentage increases from the DMEPOS-covered item annual updates set in law. Since the DMEPOS fee schedule was implemented in 1989, the first annual update is available for 1990. If an item did not exist back in the base period, CMS will use the current retail price, deflate it to an estimated price for the base period using the Consumer Price Index for All Urban Consumers (CPI-U), and then re-inflate it to current date using the percentage increases from the DMEPOS-covered item annual updates set in law.²⁵

Since there is no pricing information available for compression items in the base period, Avalere applied the gap-fill method to the estimated current compression item prices to determine DMEPOS fee schedule payments. It is important to note that CMS updates the DMEPOS fee schedule on a quarterly basis to allow for corrections to any fee schedule amounts, if necessary, based on the market assessment such as product changes or prices other payers pay.

Since these items will be covered on the DMEPOS fee schedule, we inflated the prices for each compression item annually by the expected growth in the CPI-U. Of note, our analysis assumed these newly covered compression items will not be part of the DMEPOS competitive bidding process.

- **Federal financing adjustments:** After estimating the overall Medicare cost for covering compression items, we calculated the federal share of the spending by removing the impact of beneficiary copays and Part B premiums. We then estimated the impact this change in Part B costs would have on Medicare Advantage (MA) plans by calculating the effect on MA benchmarks and payments. We assumed that MA plans would continue to be paid at the same percentage of local FFS costs as they would have been paid under the current policy; since FFS costs will increase under the proposed policy,

²⁵ http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads/InnovatorsGuide5_10_10.pdf

payments to MA plans will go up at the same rate. We also accounted for the federal costs associated with state Medicaid payment of dual-eligible beneficiaries' Part B copays and premiums. We estimate in FY 2015, the first year of Medicare coverage of compression items, the cost to federal government will be slightly under \$50 million.

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

²⁶ N.L. Stout, R. Weiss, J.L. Feldman, B.R. Stewart, J.M. Armer, J.N. Cormier, Y.-C.T. Shih. "A systematic review of care delivery models and economic analyses in lymphedema: health policy impact (2004-2011)". *Lymphology*. 2013 Mar ;46(1):27-41. <https://www.alfp.org/docs/27-41.Mar%202013.STOUT.PDF>

²⁷ Nicole L. Stout, Lucinda A. Pfalzer, Barbara Springer, Ellen Levy, Charles L. McGarvey, Jerome V. Danoff, Lynn H. Gerber, Peter W. Soballe. "Breast Cancer-Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Model of Care". *Phys Ther*. January 2012; 92(1): 152-163.

²⁸ California Health Benefits Review Program (CHBRP). (2005). *Analysis of Assembly Bill 213: Health Care Coverage for Lymphedema*. Report to Calif. State Legislature. Oakland, CA: CHBRP. 05-03. http://chbrp.org/documents/ab_213final.pdf

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



The Lymphedema Treatment Act will 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*, 2020 ¹

- **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*, 2020 ²

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 reduced by 77%** 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*, 2016 ⁴

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 **dropped by over 50%** 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 lower medical costs and fewer hospitalizations."*

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

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

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

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 cross-sectional 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>