

Creating a Policy for Coverage of Lymphatic Surgery: Addressing a Critical Unmet Need

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Summary: This article describes the key stakeholders and process involved in developing an insurance policy in the United States to establish medical necessity criteria for lymphatic surgery procedures. Lymphedema is a chronic health issue that impacts over 1.2 million patients and is associated with lifelong health, economic, and psychosocial costs. Patients affected have been described as “medical nomads,” as they often interface with multiple providers before receiving an accurate diagnosis and treatment. This underscores the lack of attention and understanding about this disease across all sectors of the medical system. Unlike nations including Sweden and the United Kingdom, which provide insurance coverage for treatment, the United States has lagged behind. As a country, we have neglected to fully recognize the consequences of inadequate treatment of lymphedema, including chronic morbidities such as loss of mobility, psychosocial sequelae, recurrent infections, and even death. Recently, the authors’ lymphatic center had the unique opportunity to help develop a policy that merged their clinical experience, recently established lymphatic care center of excellence criteria, and third-party payer policy expertise. This experience spanned 1 year from June of 2018 to June of 2019. The authors identify how key partnerships helped fill evidentiary gaps that ultimately resulted in policy change. (*Plast. Reconstr. Surg.* 152: 222, 2023.)

Lymphedema, a disease characterized by chronic swelling of limbs or tissue, is estimated to impact 250 million people worldwide¹ (Fig. 1). On a global scale, it most often occurs because of parasitic infection (filariasis). However, in the United States, it most often occurs after damage to the lymphatic system during oncologic surgical treatment. Lymphedema affects 20% to 40% of the 3.8 million breast cancer survivors living in the United States.²⁻⁵ Despite it being characterized as one of the largest cancer-survivorship burdens, there remains no definitive cure.⁶ Following the onset of swelling, patients are faced with a lifelong predisposition to recurrent episodes of cellulitis, lymphangitis, and life-threatening septicemia. The current cornerstone for disease management includes conservative therapy such as manual lymphatic drainage,

compression wrapping, physiotherapy, and the pneumatic pump, among others. Lifelong adherence to therapies for disease management are considered a requisite to prevent clinical progression. Beyond its profound effect on physical health, it also imposes a significant financial burden and impacts psychosocial and quality-of-life domains.^{7,8}

Current literature has attempted to quantify the economic impact of the disease. The financial burden of breast cancer survivors with lymphedema is steep and ranges from two to seven times that of those without lymphedema.^{4,9-11} This is largely because of costs spent on physical therapy sessions, compression garments, and treatment for infections, including hospitalization.¹¹ These estimates often do not capture costs that

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Fig. 1. Patient with left upper extremity breast cancer–related lymphedema.

are indirectly associated with the disease, such as productivity losses at work or in the household. Patients with lymphedema have been described as “medical nomads” who often encounter multiple different providers until they are properly diagnosed.¹² There is a significant chasm between the high incidence of the disease and underrecognition by both the medical and public domains.¹³ Furthermore, existing gaps in our health care system serve to hinder patient ability to participate in or obtain the indicated therapy for disease management.⁴ Limitations in coverage can result in disease progression, which only serves to increase use of services and health care costs for management of acute disease exacerbation.^{14–16}

The surgical treatment of lymphedema can be traced to the early twentieth century with the advent of the Charles procedure. Surgical care has progressed to include vascularized lymph node transplant (VLNT), lymphovenous bypass (LVB), and debulking operations (Figs. 2 and 3).¹⁷ These procedures are now offered across the United States and have been associated with significant reductions in extremity girth and improvements in quality of life. In a meta-analysis that included 1619 patients, 78% and 56% of patients were able to discontinue conservative therapy after VLNT and LVB, respectively.¹⁸ Moreover, these procedures result in postoperative reductions of infection rates.^{19,20} This would imply a significant economic benefit associated with surgical intervention compared with lifelong conservative management. A study evaluating the cost-savings

associated with LVB found that the surgical costs of the procedure are mitigated by discontinuation of conservative therapy.²¹ Similar postoperative benefits are seen after debulking procedures.^{19,20,22,23} One meta-analysis found a mean postoperative excess limb volume reduction of 96.63% in the affected extremity.²⁴ Quality-of-life benefits were seen across studies and included increases in well-being, mental health, and daily functioning. Furthermore, there are differences in objective criteria used to diagnose and evaluate progression of lymphedema; complicating the ability to group and analyze data in aggregate form.

In this article, we describe the process of developing a policy that provides medical necessity criteria for lymphatic surgery procedures in Massachusetts. Specifically, after reviewing the history of insurance coverage for lymphedema, we detail the individual accomplishments of and partnerships between our institutional lymphatic center, the Lymphatic Education & Research Network (LE&RN), and Blue Cross Blue Shield of Massachusetts that ultimately led to a new medical policy.

TRACING THE HISTORY OF COVERAGE FOR LYMPHEDEMA

Our pathway to policy requires a familiarity with international, domestic, statewide, and local organizational efforts and experiences. Historically, the United States lags behind other industrialized nations in coverage for the surgical treatment of

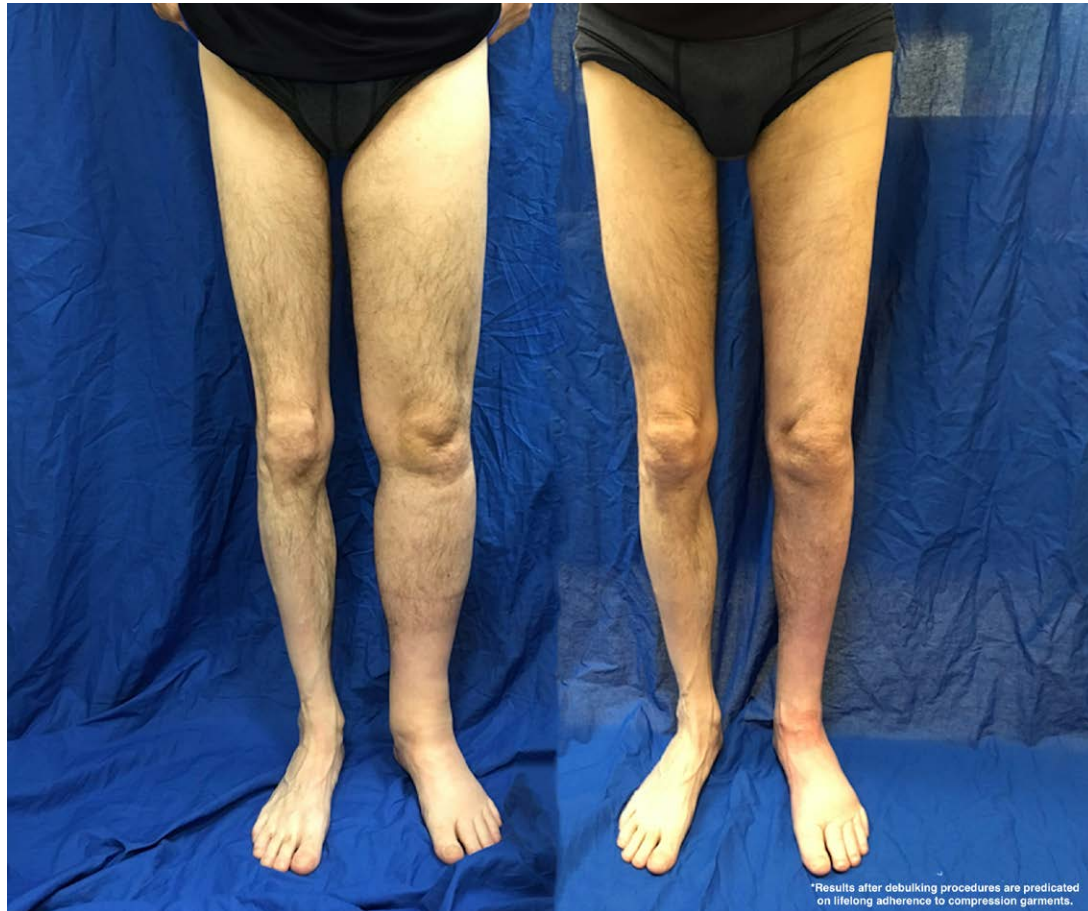


Fig. 2. Predebulking and postdebulking outcomes. (Left) Patient with left lower extremity lymphedema following a pancreatic transplantation before a debulking procedure. (Right) One year after a debulking procedure of the left lower extremity. (Reprinted with permission from Granoff MD, Johnson AR, Shillue K, et al. A single institution multi-disciplinary approach to power-assisted liposuction for the management of lymphedema. *Ann Surg.* 2022;276:e613–e621.)

lymphedema. In the United Kingdom, surgical procedures such as debulking and lymphaticovenous bypass are covered by the National Health Service.²⁵ In Sweden, surgical treatments including debulking are also covered.²⁶ In Austria, coverage for physiologic lymphatic surgery procedures was instituted in 2020. In the Austrian experience, the authors detail how successful lobbying for lymphatic surgery coverage required standardizing diagnosis, evaluation, and treatment. This overall standardized approach demonstrated significant improvement in several patient outcomes, including quality of life.²⁷

Meanwhile, in the United States, insurance coverage has traditionally focused on conservative management of chronic lymphedema. In 1998, the Women's Breast Cancer and Reconstruction Act was enacted to provide across-the-board coverage for breast cancer patients who experienced

any complication, including lymphedema, after an index oncologic operation.²⁸ However, comprehensive coverage has been variable.⁹ For example, Medicare covers certain therapies for lymphedema management (ie, manual lymphatic therapy, physical therapy, lymphatic decongestive exercises), but does not reimburse for a critical component of lymphedema treatment (ie, compression garments and bandages, as they do not meet specified criteria for durable medical equipment).²⁹ Despite passage of the Affordable Care Act in 2010, there was no significant expansion of lymphedema services for patients after oncologic treatment.⁹ Although national policy was not uniform and was generally lacking, individual states had varying success in implementing mandates for lymphedema care. In Virginia, for example, conservative management such as supplies, equipment, complete decongestive therapy,



Fig. 3. Debulking aspirate. Typical aspirate from debulking procedures of lymphedematous extremities. (Reprinted with permission from Granoff MD, Johnson AR, Shillue K, et al. A single institution multi-disciplinary approach to power-assisted liposuction for the management of lymphedema. *Ann Surg.* 2022;276:e613–e621.)

and outpatient self-management and education services are covered.³⁰

The recognized lack of a comprehensive care model at the local, regional, and national levels has catalyzed momentum for policy change. The Lymphedema Treatment Act (LTA) is one example of the coalescence of organizational efforts to facilitate more comprehensive coverage for lymphedema treatment. This bill was a result of a grassroots effort initiated by Heather Ferguson, who struggled to obtain coverage for compression for her own son with lymphedema because of the existing gaps in Medicare guidelines for durable medical equipment. Organized efforts worked toward policy change and resulted in the introduction of the LTA in the one hundred eleventh Congress in 2010.³¹ Subsequently, this legislation received increased bipartisan support and recognition from third-party payers. The LTA was finally passed by the House in 2019 and is currently awaiting approval by the Senate.³²

Despite these exciting advancements, our enthusiasm is tempered by the lack of progress for coverage of surgical interventions for lymphedema. The operative treatment of lymphedema

has been universally relegated as “investigational” by private and public insurance payers. Without a medical policy, independent surgeons were forced to negotiate with private payers for coverage despite evidence of improved overall health and quality of life.^{18,23,24} This process has had the pernicious impact of limiting patient access to surgical care. In addition, with a lack of policy in place, there is a potential for “cash pay” lymphatic surgery to bias those with the financial means to pay out-of-pocket for coverage, further limiting the subset of individuals who could afford treatment.

PARTNER 1: THE BOSTON LYMPHATIC CENTER

The factors that have been identified as obstacles to legislation for lymphatic surgery are multifactorial. One critical hurdle was the existing heterogeneity in modalities used for disease diagnosis and management, lack of a uniform vocabulary among treating providers to characterize lymphedema (disease severity, grading schema used³³), and insufficient outcomes data to establish procedure coverage protocols. In 2009, the

Boston Lymphatic Center REDCap Database

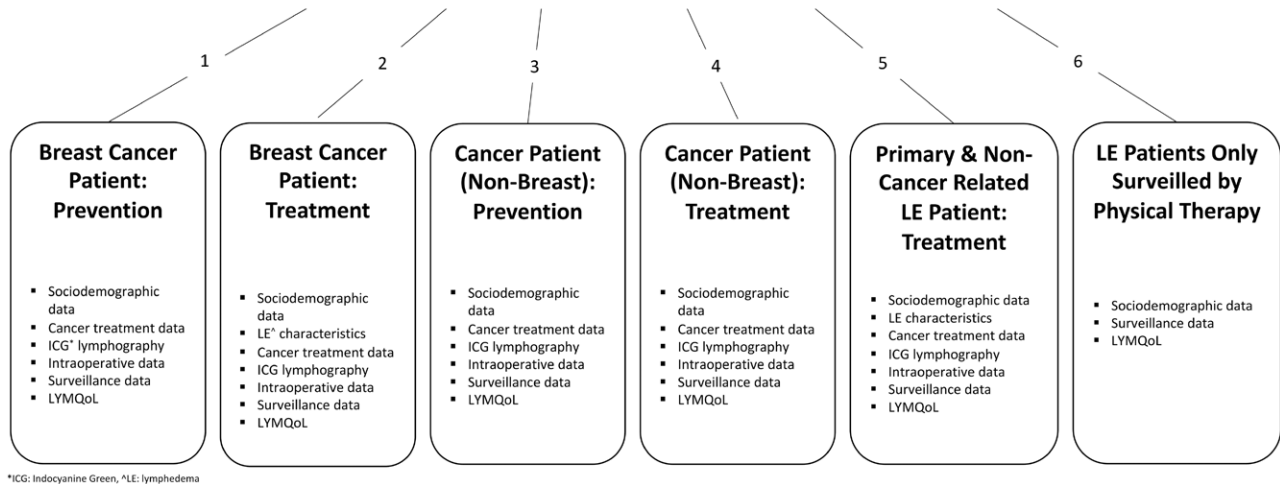


Fig. 4. Institutional Research Electronic Data Capture database: the Boston Lymphatic Center maintains a quality improvement Research Electronic Data Capture database. There are six arms to the database. Arms 1 through 5 are for any patient evaluated in the lymphatic medicine and/or lymphatic surgery clinics. Arm 6 is dedicated to patients who are solely followed up in our lymphatic treatment clinic (physical therapy).

American Lymphedema Framework Project published a report that echoed these concerns. They identified a lack of evidence-based practices for lymphedema as a standardized treatment in the United States.³⁴

Accounting for these concerns, our lymphatic center established standardized protocols for patient evaluation, workup, and treatment using a shared vocabulary and uniform measurement modalities for diagnosis and outcome assessment. We created an institutional Research Electronic Data Capture³⁵ quality improvement database to track all patients (Fig. 4). This robust quality improvement database captures comprehensive clinical data including surgical outcome metrics. The ability to readily access deidentified patient data for different lymphatic operations (ie, LVB, debulking, VLNT) not only allowed us to analyze subjective and objective outcomes data, but also provided contouring of developing protocols. Our blueprint for patient workup, evaluation, and management had already been institutionalized³⁶ (Fig. 5). In this blueprint, we discuss efforts to initiate referrals for immediate lymphatic reconstruction. These were made by visiting centers and by providing grand/divisional rounds and educating them on the program. Furthermore, the use of uniform metrics

for diagnosis and outcomes evaluation improved the statistical rigor of analyses performed. This objectivity would play a critical role in the eventual path to policy.

PARTNER 2: LR&RN

Apart from lobbying for changes in lymphedema coverage on both state and national levels, lymphatic-disease-focused organizations have played a fundamental role in the promotion of educational efforts and support of quality research.³⁷ In this article, we focus on the efforts of one national organization, the Lymphatic Education and Research Network.

On the national level, LE&RN has been very active. The organization supports the LTA and actively engages with the highest levels of government. The organization's national spokesperson, Kathy Bates, testified before Congress in April of 2019 to advocate for National Institutes of Health funding of lymphatic research. LE&RN and Kathy Bates have improved the dialogue of this underrecognized disease by interfacing with the Centers for Disease Control and Prevention. Kathy Bates's personal experience with lymphedema is shared in a video on the Centers for Disease Control and Prevention website.

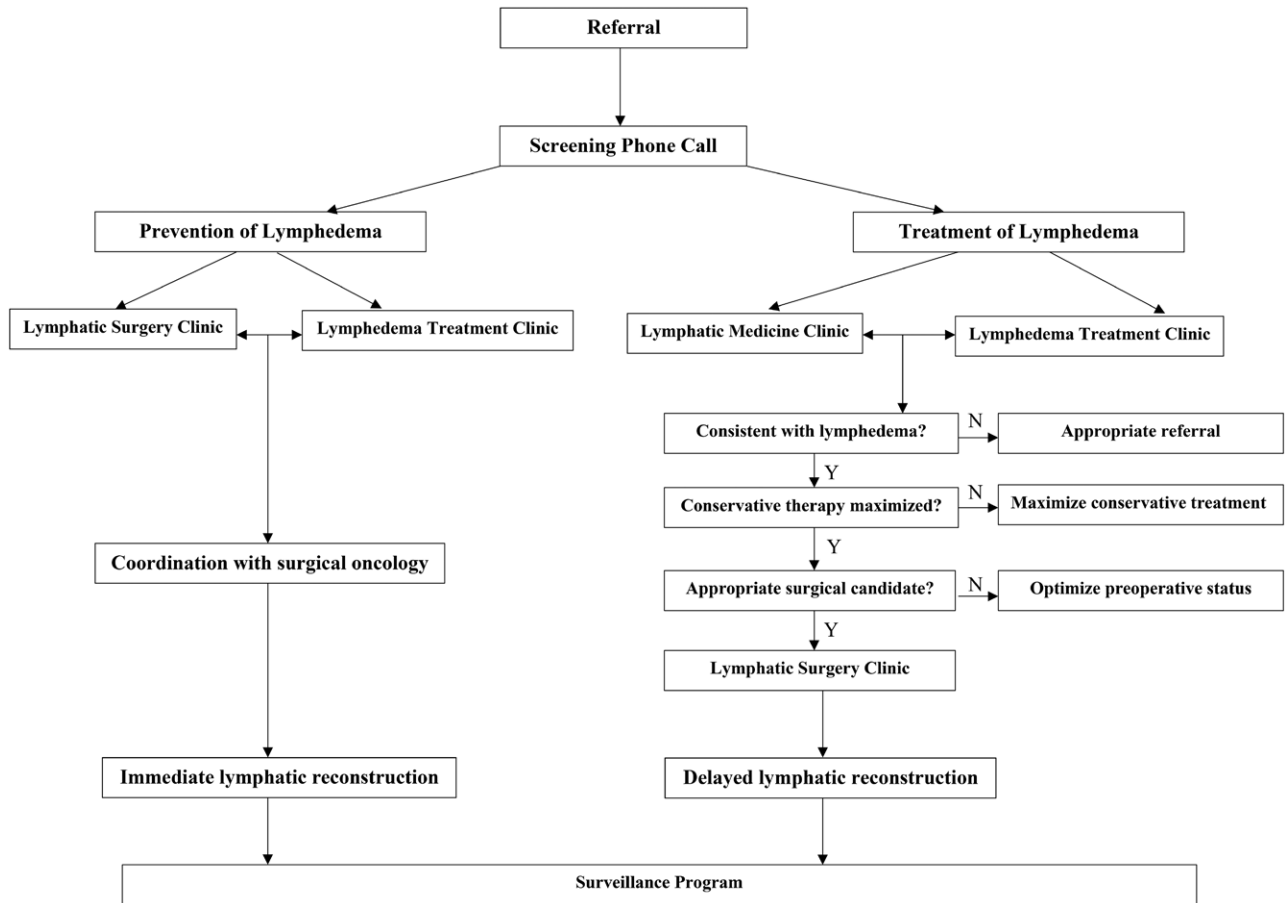


Fig. 5. Our institutional flow chart for adult patients presenting to the Boston Lymphatic Center. (Reprinted with permission from Johnson AR, Fleishman A, Tran BNN, et al. Developing a lymphatic surgery program: a first-year review. *Plast Reconstr Surg.* 2019;144:975e–985e.)

Furthermore, LE&RN spearheaded efforts to improve awareness of lymphedema and lymphatic diseases by initiating World Lymphedema Day,³⁸ which achieved national-level recognition by Congress in 2016 and is now recognized in 19 countries worldwide.

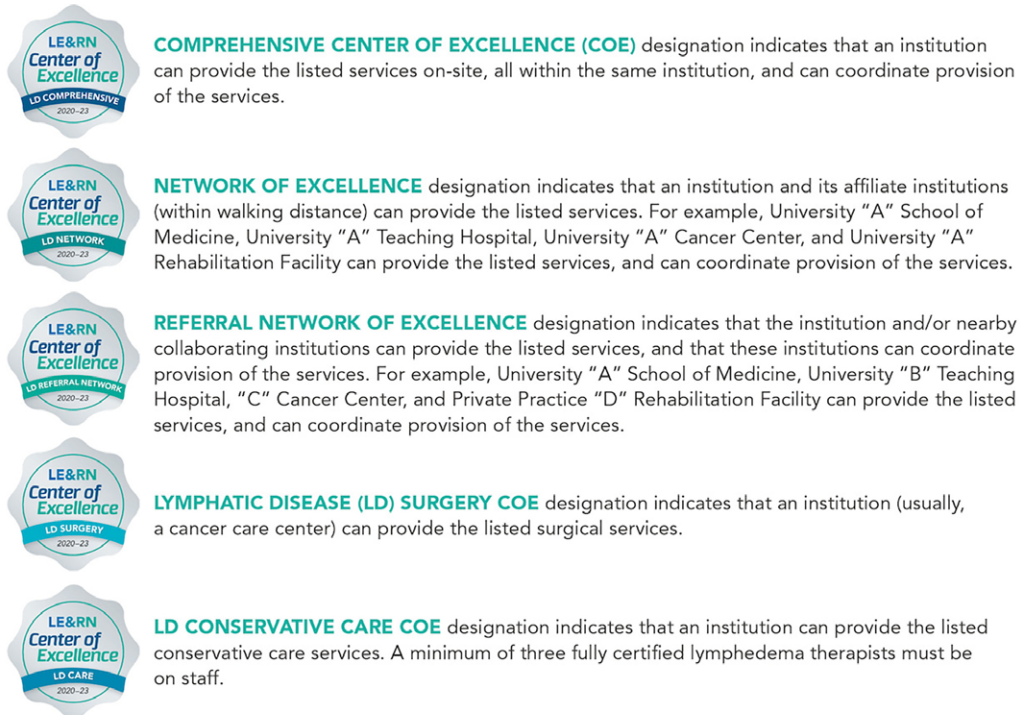
LE&RN has also been influential at the state level. In Massachusetts, for example, the LE&RN chapter, run by Cathy Holly and Lisa Palin, two cancer survivors with lymphedema, hold monthly patient-focused meetings. The chapter holds an annual walk to bring local and regional awareness to lymphatic disorders and leads the celebration of World Lymphedema Day which is now formally recognized by our state legislature because of their efforts. On March 6, the Zakim Bridge in Boston is lit teal (official color for lymphedema) in honor of World Lymphedema Day. The chapter also sponsors and supports events at local hospitals and outpatient treatment centers. In 2017, the Boston Lymphatic Center hosted the first

annual symposium on lymphatic diseases in partnership with LE&RN and the LE&RN-MA chapter (www.bostonlymphaticsymposium.org). This symposium included both clinical and patient-specific forums with the latter chaired by our patient representative and Chair of the Patient Symposium Theresa Whiting. Since its inception, world-renowned experts in the field (surgeons, physical therapists, lymphatic medicine physicians) have met annually to discuss the state of the art in lymphedema and lymphatic disease diagnosis, management, and treatment. During these forums, selected institutional and LE&RN-MA chapter members have collaborated to coordinate an agenda that blends both clinical topics and patient-specific concerns.

Ultimately, these international, national, and state-level initiatives culminated in an effort by LE&RN to develop center of excellence (COE) criteria for institutions committed to treating lymphatic disorders including lymphedema. The



There are five categories for LE&RN Center of Excellence designation



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Fig. 6. LE&RN offers five tiers of COE, with the comprehensive designation being the highest.

COE criteria were initially established by a panel of U.S. lymphatic experts³⁹ and then vetted and modified by an international panel of lymphatic experts (Fig. 6). The COE criteria legitimized the delivery of lymphatic care by setting important benchmarks that were needed for each institution. This designation would ensure that member institutions provide a broad range of services for lymphedema diagnosis and management that included both conservative and surgical treatment approaches. Supported by objective data, COE designation would require an institutional commitment to promoting education and awareness of lymphedema and lymphatic diseases for both the lay public and allied health professionals (Fig. 7). These standards not only serve as a guiding framework to optimize care for the patient with lymphedema and lymphatic disease, but also address the exigent need in uniformly operationalizing important benchmarks in care delivery.

The COE criteria would become another key in the path to policy.

PARTNER 3: BLUE CROSS BLUE SHIELD MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is one of the largest third-party payers in the state, having over 2.9 million members and spending more than \$16 billion in member care in 2019. The organization brought a wealth of experience in medical policy development to the table. In 2018, when we first approached this third-party payer regarding lymphatic procedures, a medical policy was already in place relegating these procedures as investigational. To change this designation, we needed to address three key questions: (1) Do lymphatic surgery procedures actually provide the expected outcomes? (2) Is there a recognized existing shared vocabulary to define the disease and assess its



Fig. 7. As of 2021, there are 11 comprehensive LE&RN COEs worldwide. Eight of these centers are located in the United States.

severity and improvement? and (3) Are there any existing criteria that would hold institutions to high standards in the provision of lymphedema care?

THE PATH TO POLICY

In August of 2018, when we first presented to Blue Cross Blue Shield of Massachusetts, our institutional lymphatic center was approaching its second year, including evaluation of over 400 new patients with lymphatic disorders. Our presentation included our center's standardized protocols for patient evaluation, workup, and treatment. At this time, our shared vocabulary and uniform measurement modalities for diagnosis and surveillance of lymphedema outcomes had been instituted (Fig. 8). Blue Cross Blue Shield of Massachusetts would ultimately visit our center in late 2018 and meet with all key clinical division leaders of the center (lymphatic medicine, lymphatic therapy, lymphatic imaging, and lymphatic surgery) to see first-hand how we delivered care. Moreover, as our center was also actively engaged with LE&RN for the establishment of COE criteria, we shared with them the anticipated

upcoming LE&RN COE criteria and designations. With this exchange of information, we had adequately answered the second and third questions posed above. Finally, we worked together to take on the first question: Do lymphatic surgery procedures actually provide the expected outcomes?

The greatest challenge in demonstrating efficacy of lymphatic surgery procedures was that an independent comprehensive literature review by Blue Cross Blue Shield of Massachusetts before our presentation concluded that lymphatic surgery remained investigational. At this time, there were no ongoing, large randomized controlled trials for lymphovenous bypass, vascularized lymph node transplant, or debulking procedures. Furthermore, we noticed that outcomes cited grouped both upper and lower limbs in outcomes analyses, making it difficult to appreciate true limb-specific volumetric outcomes. In the absence of any randomized controlled trial data and a paucity of grouped outcome metrics, we were forced to acknowledge the difficult task ahead. Using data from our Research Electronic Data Capture database as a model, together with Blue Cross Blue Shield of Massachusetts, we were



Lymphatic Education
& Research Network

UNDERSTANDING LYMPHEDEMA:



KEEPING THE TRAIN ON TRACK

By Dhruv Singhal, MD

Illustrated by Megan Belanger, LMT, CLT

Foreword by Kathy Bates

Fig. 8. *Understanding Lymphedema: Keeping the Train on Track* book cover (by Dhruv Singhal and illustrated by Meghan Belanger). In our initial presentation to Blue Cross Blue Shield of Massachusetts, we used the train analogy to guide our colleagues through the complex nature of lymphatic disease. In retrospect, our colleagues at Blue Cross Blue Shield of Massachusetts noted that our ability to relay these ideas effectively in our first meeting was an important step forward.

able to pool our outcomes data to fill in evidentiary gaps in available literature.

Specifically, we performed a comprehensive literature search and identified studies that reported diagnostic and assessment criteria, and surgical outcomes in a manner that facilitated aggregate analyses. We first grouped outcomes by the extremity affected, and then stratified by lymphedema stage for each study demographic. If available, we reported complications and specifically evaluated continuation/discontinuation of postoperative management modalities. Although the total

number of studies that ultimately met this criterion was small, our analyses were strengthened by our rigorous inclusion criteria. These data could then fill the evidentiary gaps and demonstrate the efficacy of lymphatic surgery procedures. These efforts now permitted a cooperative effort to create an evidence-based policy for coverage.

THE POLICY

Using the highest quality evidence available, criteria were developed to better define a

population that would best benefit from surgical intervention. Our goal was to create an evidence-based policy that would standardize approvals and denials for the surgical treatment of lymphedema. With an understanding that there was still existing heterogeneity in lymphedema diagnosis and assessment (eg, volumetry, bioimpedance, lymphoscintigraphy), we intended to make the criteria nondiscriminatory against institutions that lacked certain testing capabilities. However, we were careful to not kill objectivity and were cautious to use a uniform vocabulary for diagnostic, workup, and intervention criteria. The policy for each procedure can be found online.⁴⁰

In more detail regarding the policy itself, we outlined clear diagnostic criteria for lymphedema. This was developed from our institutional criteria for diagnosis, which required both (1) the presence of signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist and (2) a positive quantitative measurement consistent with the diagnosis (Tables 1 and 2). Furthermore, we wanted to ensure that patients were medically optimized and compliant with compression before initiating surgical workup. For all surgical procedures, patients were required to meet the following criteria: a body mass index of less than or equal to 35 kg/m², compliance with a 6-month course of conservative management,

and the ability to adhere to postoperative care including prolonged use of compression (20 hours per week).

We used the International Society of Lymphology guidelines for lymphedema staging as outlined in the 2016 Consensus Document.⁴¹ The criteria rely on a tiered classification system to classify lymphedema from latent/subclinical (stage 0) through severe (stage III) (Table 3). Patients with differing disease severities and findings on workup/imaging may receive the most benefit from lymphatic surgery procedures that have been shown to be most effective for their specific phenotype. For example, patients with early stage lymphedema with linear channels present on indocyanine green lymphography may best benefit from a lymphovenous bypass procedure. However, we recognize that success in patients with more severe disease has been described; thus, it remains an option for patients with stages II or greater who otherwise meet criteria. Patients with at least stage II lymphedema may also be eligible for VLNT or debulking based on their specific disease phenotype (Fig. 9).

Of significant note, despite our center's concerted efforts and objective data favoring immediate lymphatic reconstruction, we ultimately acknowledged the need for more data to fill these evidentiary gaps before tackling coverage for these procedures.

Table 1. Lymphedema Signs and Symptoms

Signs/Symptoms
Swelling
Heaviness
Tightness
Inability to fit into clothing
Achiness
Numbness and/or tingling
Pain
Fatigue
Infection involving affected extremity

Table 2. Objective Diagnostic Criteria

	Unilateral Disease of Dominant Extremity	Unilateral Disease of Nondominant Extremity	Bilateral Disease (Both Extremities Affected)
Volumetry	≥10% differential	≥7% differential	
Bioimpedance spectroscopy (L-Dex)	≥10 U differential		
Lymphoscintigraphy			
1. 1-hour delayed transit time to first-level lymph nodes	Axillary lymph nodes (upper extremity disease)		
	Inguinal lymph nodes (lower extremity disease)		
OR			
2. Presence of dermal back-flow			

CONCLUSIONS

In this article, we describe a unique experience where policy change was successful through combined clinical and organizational efforts for streamlined care delivery that were ultimately recognized by insurers as a pathway forward for lymphedema coverage. By harnessing objectivity, a comprehensive policy to secure a pathway that provided coverage for the surgical treatment of chronic lymphedema was created. We believe this insurance policy, implemented nationwide,

Table 3. ISL Stages^a

ISL Stage	Description
0	Latent/subclinical disease; swelling not evident despite impaired lymph transport and/or alterations in tissue composition; subjective symptoms may be present (may persist for months/years before overt disease)
1	Early fluid and protein accumulation in tissue that resolves with limb elevation
2	Tissue swelling that does not resolve with limb elevation; presence of pitting because of adipose tissue hypertrophy and fibrosis
3	Severe swelling; lymphostatic elephantiasis; characterized by presence of fibrotic tissue (fibrosclerosis) with or without pitting; trophic skin changes including acanthosis and alterations in skin quality (ie, thickness) may be present

ISL, International Society of Lymphology.

^aAdapted from Executive Committee. The diagnosis and treatment of peripheral lymphedema: 2016 consensus document of the International Society of Lymphology. *Lymphology* 2016;49:170–184.

Developing a Medical Policy for Lymphatic Surgery Procedures

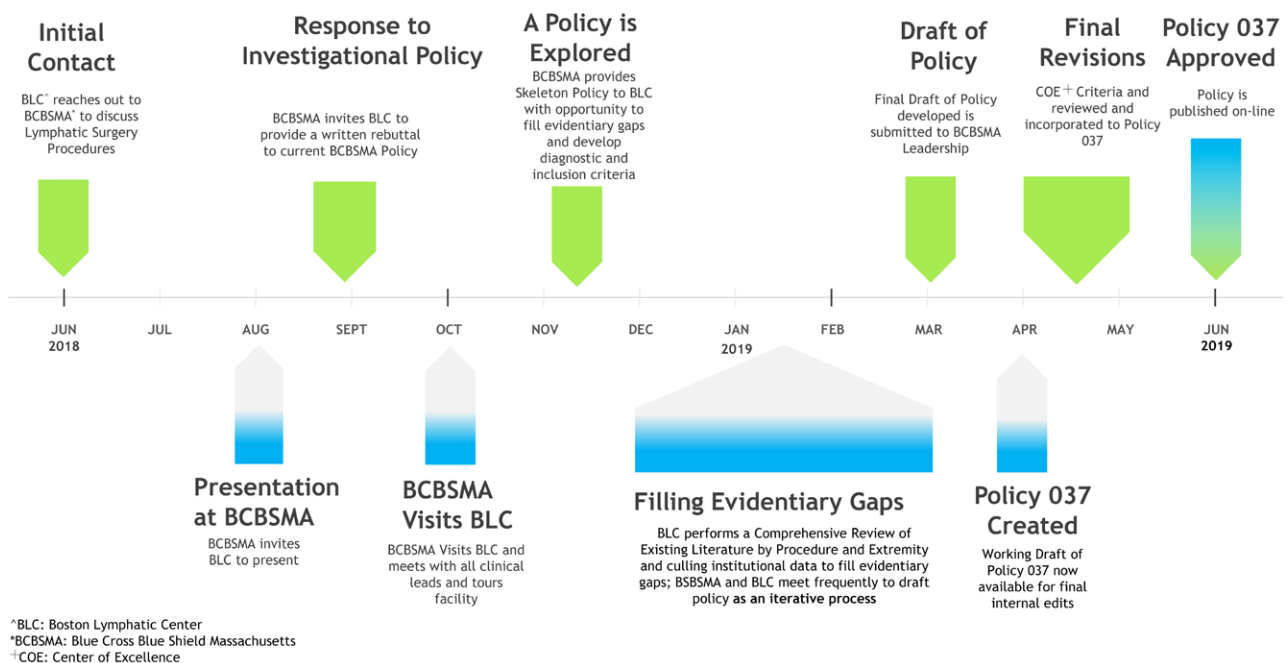


Fig. 9. Major milestones and timeline of policy development.

is a crucial step on the pathway to broadening coverage for lymphatic surgery. The field of lymphedema has been criticized for its subjectivity in assessment, diagnosis, and treatment. The importance of developing a uniform vocabulary to help promote standardization of workup, diagnosis, and management cannot be overestimated. Furthermore, with an established policy, increased acceptance of lymphatic surgery procedures by more insurance providers will possibly lead to the establishment of designated CPT codes. As lymphatic surgery continues to evolve and be offered in a growing number of centers in the United States, the COE criteria will gain in adaptation

and serve as a critical benchmark to not only standardize and optimize care delivery for patients, but also provide a critical path to policy.

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DISCLOSURE

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