



LYMPHEDEMA DIAGNOSIS AND TREATMENT COST SAVING ACT

H.R. 4662

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111TH CONGRESS, 2ND SESSION**



***LYMPHEDEMA TREATMENT IS
GOOD BUSINESS AS WELL AS GOOD MEDICINE***

2010 Congressional Package H.R. 4662 Kissell

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EXECUTIVE SUMMARY

The **Lymphedema Diagnosis and Treatment Cost Saving Act of 2010** would provide coverage for Medicare Beneficiaries diagnosed with lymphedema from any cause in accordance with evidence-based medically recommended protocols, and reduce the incidence of lymphedema-related infection.

The Challenge

LYMPHEDEMA is a medical condition affecting an estimated 1.5 to 3 million Medicare Beneficiaries who are not currently receiving treatment from Medicare according to the current medical standard of care. Medicare is spending **billions of dollars every year** treating **largely preventable** lymphedema-related **CELLULITIS**.

Over time, untreated lymphedema results in disfigurement, disability and even death. The recognized standard of treatment of lymphedema is Complete Decongestive Therapy (CDT). CDT comprises four interacting protocols applied in two phases (acute and ongoing): manual lymph drainage (MLD); compression therapy; lymph drainage exercises; and skin care. [Refs: ACS 1998, ISL 2003, NLN 2006]. A recent technology assessment by the MEDCAC has determined that there is moderate to good evidence that these protocols, with and without adjuvant sequential pneumatic compression, will result in an improvement in the health of lymphedema patients. The initial intensive phase is performed by specially trained medical professionals, but ongoing care is patient self-provided at home using techniques taught the patient by the healthcare provider.

Medicare does not currently cover lymphedema treatment materials or treatment by lymphedema-qualified professionals other than Physical Therapists and Occupational Therapists, nor does Medicare require that the provider of lymphedema treatment services be qualified in the specialized treatment techniques. While Medicare does cover and pay for statutorily-limited therapy and sequential compression pumps, many patients suffer recurrent infections, progressive degradation in their condition and eventual disability because they cannot afford the compression bandages and garments required for their everyday self-care.

What this Legislation Would Do

This legislation would provide coverage for the compression bandages, garments and supplies used daily in the treatment and management of lymphedema, would require that lymphedema treatment providers have adequate training and demonstrated competence in the specialized lymphedema treatment protocols, would allow treatment by qualified health care providers not currently reimbursed by Medicare, and coordinate the covered elements of lymphedema treatment.

This is NOT a new health mandate. The staff, equipment and facilities are already in place in most medical providers. Most providers already cover lymphedema treatment, and there are no exclusions in any medical policies. **The Women's Health and Cancer Rights Act of 1998 already mandates the treatment of lymphedema resulting from breast cancer treatment.**

Lymphedema treatment can be shown to result in medical savings which exceed ongoing costs by factors of 2-5. A lymphedema coverage mandate has been in effect in Virginia since 2004, and a similar law was passed in North Carolina this year, which became effective in 2010. Data from the first five years of operation in Virginia show claim costs of \$1.12-2.82 per year per contract (0.04-0.09% of total claims) **not accounting for the expected savings due to reduced cellulitis rates.**



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**MEDICARE LYMPHEDEMA TREATMENT COVERAGE PROBLEMS ADDRESSED BY
“LYMPHEDEMA DIAGNOSIS AND TREATMENT COST SAVING ACT OF 2010”**

The recognized standard of treatment of lymphedema is Complete Decongestive Therapy (CDT). CDT comprises four interacting protocols applied in two phases (acute and management): Manual Lymph Drainage (MLD); Compression Therapy; Lymph Drainage Exercises; and Skin Care. (References: ACS 1998, ISL 2003, NLN 2006, MEP 2006)

Medicare does not cover lymphedema treatment materials, nor treatment by lymphedema-qualified professionals other than PTs and OTs. While they do cover and pay for statutorily-limited therapy and DME, many patients suffer progressive degradation in their condition, frequent infections and eventual disability due to under- or non-treatment. This proposed bill attempts to correct this condition and save millions of Medicare dollars in the process.

Treatment Item	Medicare Coverage	Effect of Proposed Bill
Manual lymph drainage Therapists LE competency As medically required	Physical therapy & rehab PTs and OTs only No competency standard \$1860/year	Makes medical procedure Certified LTs (PTs, OTs, RNs, DOs, MTs) Trained to LANA certification level As medically required, per treatment plan
Compression therapy C. bandage system C. garments Certified Fitters C. devices C. pumps	Not a defined benefit Not covered Not covered Not required Sometimes as DME Simple models covered after 4 weeks of ineffective treatment fails	Adds compression therapy benefit category Adds bandages for LE treatment at home Adds compression garments for LE Tx Adds requirement for certified fitters Adds as compression items for LE Tx Models appropriate for LE Tx covered only in conjunction with MLD and after 6 months of CDT fails (not in bill-requires CMS NCD)
Lymph Drainage Exercise	(Only done with compression, which is not covered) No PT/OT competency standard	Adds patient education on decongestive exercise program. Requires PT and OT training on specialized LE exercises
Skin Care		Adds patient education on skin care

In addition to the changes to bring Medicare into conformance with practice in Europe for the last four decades and at lymphedema treatment clinics in the U.S. for the last 15 years, the proposed bill adds two important patient protection items: differential diagnosis of lymphedema and lymphedema informed consent.

Practice Item	Current Practice	Effect of Proposed Bill
Differential Diagnosis of Lymphedema	Sporadic, usually by elimination	Covers differential diagnosis, lymphoscintigraphic analysis in difficult cases
Informed Consent (Removed from Bill)	Patient seldom informed of relative risk of LE with alternative curative procedures	Requires disclosure of relative risk of LE for alternative surgical and radiative procedures

The projected result of these changes is dramatic reduction (variously reported as 50-100%), in the incidence of infection in lymphedema patients, improvement of quality of life and reduction of disabilities caused by this “hidden epidemic” lymphedema.



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LYMPHEDEMA TREATMENT FACT SHEET

(a) NATURE OF LYMPHEDEMA—Lymphedema is a swelling of a limb and/or other part of the body because of a functional inability of the lymphatic system to transport intercellular lymphatic fluid back to the circulatory system. Lymphatic fluid becomes stagnant, leaving the patient prone to infection. When infection occurs it progresses with uncommon rapidity, many patients requiring immediate emergency treatment with antibiotics and costly hospitalization. Lymphedema can affect arms, legs, breast, back, side, face, neck, abdomen, groin and genitalia as well as internal organs.

- (1) Congenital (primary) lymphedema, caused by a malformed or underdeveloped lymphatic system, can be present at birth, develop at puberty (lymphedema praecox), or occur at older ages (lymphedema tarda).
- (2) Secondary lymphedema can result from blunt trauma, surgical procedure, radiation, infection, parasites or disease involving the lymphatic system. The greatest incidence of secondary lymphedema in the United States occurs in cancer treatment survivors (breast, melanoma, sarcoma, gynecological, prostate).
- (3) Other common non-cancer-related causes of lymphedema are vein-harvesting surgery associated with coronary artery by-pass procedures and abdominal, hip and knee replacements.
- (4) If left untreated, the swollen area can become fibrous and prone to serious, debilitating infections. Over time, untreated lymphedema results in disfigurement, disability and even death.

(b) PREVALENCE OF LYMPHEDEMA IN MEDICARE

- (1) There are more than 9,600,000 individuals in the United States today who are cancer survivors (living with, through, and beyond cancer).
- (2) 61 percent of cancer survivors are 65 years of age and older.
- (3) 10 to 40 percent of all breast cancer axillary node dissection and inguinal node dissection patients will develop lymphedema over their lifetime.
- (4) Add to this number an estimate of how many persons underwent surgeries known to lead to lymphedema such as coronary artery by-pass grafts (277,000 over 65 in 2002), hip and knee replacements (314,000 over 65 in 2002), and cellulitis (374,000 over 65 in 2002).
- (5) An assumed 20% incidence of lymphedema yields a potential of 1.36 Million cases of lymphedema of the upper limbs, lower limbs, head and neck, breast and torso in this Medicare population.

(c) CURRENT STANDARD OF TREATMENT OF LYMPHEDEMA—Treatment procedures have been developed in Europe over the last 30 years, and have been accepted by American medicine for the last 10 years.

- (1) The current standard of treatment for lymphedema is called complex (or complete) decongestive therapy (CDT) and has been the recommended lymphedema treatment protocol in Europe since 1995 (International Society of Lymphology) and in the U.S. since 1998 (American Cancer Society Lymphedema Workshop, Cancer Supplement December 15, 1998, Volume 83, Number 12.) CDT comprises a number of interrelated treatment modalities that are most efficacious when utilized in an interdependent fashion. In a meeting on November 18, 2009 the Medicare Evidence Development Coverage Advisory Committee affirmed that there is adequate evidence available to support CDT with or without adjuvant pneumatic sequential compression as being beneficial in the treatment of lymphedema.



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(2) Complex decongestive therapy for the acute treatment program (Phase 1) consists of manual lymph drainage, short-stretch bandaging, remedial exercise, skin care, and instruction on self massage and home maintenance, including the fitting and procurement of compression garments, bandages and devices. Pneumatic sequential compression may be beneficial as an adjunct to CDT but should never be used in its absence. Treatment duration and frequency for the acute treatment program (Phase 1) as well as follow-up treatments shall be dictated by medical necessity, as determined by a licensed physician knowledgeable in diagnosis and current management standards of the treatment of lymphedema.

(3) After effective volume reduction has been accomplished through the combined effects of these modalities, Phase 2 of the treatment program, the home treatment phase, continues for the life of the patient according to an individual medical treatment plan, and comprises, as directed by a licensed physician knowledgeable in diagnosis and current management standards of the treatment of lymphedema: self-manual lymph drainage; day-time use of well-fitted compressive garments, night-time bandaging with multi-layer low-stretch bandages or manually-adjustable compression devices; skin care; and exercise while under compression. It is generally not helpful to fit compressive garments prior to the institution of volume-reducing techniques. The compressive garment should be fitted to apply an appropriate range of external pressure, generally between 20 and 60 mmHg. It is recommended that garments be replaced every 3-6 months to maintain maximal therapeutic benefit.

(4) There are numerous accredited schools that teach the CDT protocols for lymphedema treatment to licensed physical therapists, occupational therapists, massage therapists and nurse practitioners. The Lymphology Association of North America (LANA) provides national certification of lymphedema therapists who meet stringent academic and experiential requirements and who are qualified to perform the medical protocols involved in lymphedema treatment.

(d) THE NEED FOR INSURANCE COVERAGE-- Medicare has no national medical policy for the treatment of lymphedema, currently covers procedures and equipment not medically accepted for primary treatment of lymphedema and routinely denies coverage for components of the currently accepted conservative treatment. Attempts to change this policy over the past 10 years have been resisted by CMS on the basis that there must be a change in federal regulations to initiate a policy change.

(1) Many patients have had Medicare denials for compression bandage systems and compression garments reversed by Medicare Administrative Law Judges, but only after many expensive appeals. These reversals are applicable to the case on hand and are not translated into policy change.

(2) Procedures for patients and patient advocates to appeal adverse decisions and medically unsound national coverage determinations have been severely limited by new appeal procedures implemented by DHHS in August and November 2002.

(3) Only half of the states have implemented legislation requiring private health insurers to provide lymphedema coverage for breast cancer survivors in conformance with the Women's Health and Cancer Rights Act of 1998, and Medicare coverage is not in compliance with this Act.

(4) Some states have lymphedema treatment policies and will cover manual lymph drainage, but only as rehabilitative physical therapy and not medical treatment, and are therefore subject to Medicare annual limits.

(5) Many medical providers fail to provide medical treatment in accordance with the current recommended standard of care partly because of lack of knowledge of the current medical standard of treatment for lymphedema, and partly because they do not understand the favorable economics of lymphedema treatment.

(6) There is currently no state law except in Virginia and North Carolina mandating treatment of lymphedema from causes other than breast cancer, and patients suffering from lymphedema and its disabling and life-



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threatening sequela are routinely denied diagnosis and treatment according to current standards.

(7) Patient compliance is essential to the efficacy of the management of lymphedema. Medicare does not cover compression garments, bandages, and devices or provide replacements of these prosthetic devices to enable patient compliance with their lymphedema treatment plan.

(8) Medicare provides coverage for expensive pneumatic sequential pumps for the treatment of lymphedema. Current medical standards for lymphedema treatment recommend use of pumps only in conjunction with manual lymph drainage, compression therapy and exercise, but these conservative treatments are not covered.

(e) **THE COST SAVINGS OF LYMPHEDEMA TREATMENT**—Treatment of lymphedema can be shown to save significant amounts of money for the medical provider, the Government and the patient.

(1) Treatment of lymphedema has been shown to reduce and/or eliminate the incidence of infection (cellulitis and lymphangitis) encouraged by stagnant lymph. The benefit of lymphedema treatment has been estimated as a 50-85% reduction in the incidence of infection (Boris 1997, Campisi 2001, Földi 1996, Ko 1998, O'Brien 1990). With average hospital inpatient rates averaging \$1696 per patient day (2007 AHA Annual Survey), and average stays ranging from 5.6 days for arms and 10.4 days for legs (2003 California Hospital Discharge Database), treatment of a case of cellulitis might cost between \$9,500-17,600.

(2) By reducing the number of hospital admissions and doctor visits, providers will experience reduced cost. It can be demonstrated that proper treatment of lymphedema and compliance by patients with daily protocols is not only good medicine, but it is good business and a cost saving tool for insurance companies. For example, savings in medical expenses over a forty-year survival lifetime for treating a woman diagnosed with breast cancer at age 40 has been estimated at close to \$400,000 (Weiss Model Case Study).

(3) Proper treatment and management of lymphedema can enable patients living with lymphedema to continue to live productive lives, require less disability assistance, and eliminate pain medication for the pain of untreated lymphedema.

(4) This is not a new healthcare mandate. The staff, facilities and support services required to provide the medically recommended treatment already exist at most providers. Most providers surveyed in Virginia, where a lymphedema treatment statute went into effect in 2004, claim to provide treatment for lymphedema, and it is not excluded in most medical coverage contracts. The projected savings in avoided emergency medical treatment of cellulitis and lymphangitis are in excess of the cost of medically indicated manual lymph drainage and compression bandages, garments and devices.

(5) With the implementation of the current conservative standard for treatment of lymphedema, CDT, there may be a significant cost saving in not requiring the often un-needed and sometime harmful compression pumps currently provided by Medicare to treat lymphedema. Use instead of more effective pneumatic sequential compression devices specifically designed for treatment of lymphedema could enable greater treatment effectiveness for the home treatment phase of lymphedema.

(6) With a law that clearly defines the current standard of treatment of lymphedema, providers will be less likely to deny necessary treatment and be required to engage in lengthy and expensive beneficiary appeals.



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THE NATIONAL BURDEN OF LYMPHEDEMA

CURRENT STUDIES

Although lymphedema has been receiving an increasing amount of scientific attention in recent years, the extents of its impact on the quality of patient's lives and its burden on society have not been appreciated. The impact of lymphedema is felt immediately by the patient, who suffers from a debilitating swelling of an arm, leg, breast or torso, the pain that accompanies the swelling, impairment of physical activities, psychological and social problems and frequent infections requiring emergency treatment. The burden on society is felt immediately by increased cost of treating preventable infections and long term by having to support the disabled patient who may no longer be able to make a living.

Treatment of lymphedema has been shown to reduce the incidence of recurrent cellulitis, and to retard the progression of lymphedema to harder-to-treat stages. It is therefore a very effective way to reduce the burden of lymphedema on the patient as well as the nation.

1. Incidence of Lymphedema (Weiss 2004-5)

Onset of lymphedema is shown to vary as a function of the method of measurement and the causative therapeutic procedure. Toxic effects of radiotherapy do not become fully evident until many years after treatment. Using sensitive lymphoscintigraphic measures of lymphedema, Campisi 2003 shows early effects of breast cancer treatment at 3-6 months (range <1 to 24 months). The delayed effects of radiotherapy are demonstrated [Pierquin 1986] with median onset at 7 (range 2-37) months with surgery alone, 12 (1-52) months with surgery and radiation and 25 (6-156) months with radiation alone. Other researchers demonstrate medians between 1 and 2 years, with maximum times of onset of 3 to 10 years for mixed cohorts.

Swelling after breast cancer treatment can occur at a number of sites, and the restriction of measurements to one particular site such as the forearm, upper arm or entire arm and hand results in an underestimation of the incidence of lymphedema. Arm swelling may account for only about half of the patient-reported swelling [Bosompra et al 2002]. Other reported sites include the breast, chest, underarm and back. But measurement of these sites is very difficult, and so remains largely unreported. Breast lymphedema incidences of 70% using measurement of dermal swelling have been demonstrated [Rönkä 2004] while clinical examination detects only 35% in the same cohort.

Changes in the mix of breast cancer surgery and radiotherapy over the last 50 years have resulted in a change in the incidence of lymphedema, since each therapy has a different associated morbidity. Halsted Radical Mastectomies with and without radiotherapy, the standard until the 1970's, resulted in upper limb lymphedema rates of 22-44% without and with radiotherapy. With the ascendancy of the less radical Modified Radical Mastectomy in the 1970's and 1980's lymphedema rates fell to 19-29% without and with radiotherapy [Schünemann & Willich 1997]. The 1990's brought Breast Conserving Surgery from a small percentage to approximately half of the surgeries performed [Yoshimoto et al 2004] with a further drop in upper limb lymphedema rates to 7-10% without and with radiotherapy [Schünemann & Willich 1997].

Breast lymphedema started to receive attention in 1982 with Kissin reporting clinical rates of 8% and Clarke reporting rates of 41% using skin measurements. Recent reports estimate the rates 1-9% based on subjective reporting [Fehlauer 2003][Højris 2000], 10-19% based on clinical examination [Fehlauer 2003][Goffman 2004] 20-48% [Rönkä 2004] [Senofsky 1991] and 30-70% based on skin thickness measurement [Rönkä 2004].

Lower limb lymphedema rates are likewise a strong function of the extent of the surgery and radiation used for treatment of reproductive and pelvic cancers, as well as lower limb melanomas. Whereas there are many different



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methods commonly used to evaluate upper limb swelling, there are very few methods reported to measure lower limb swelling. Lower limb lymphedema is reported in medical records only when it is severe enough that compression is not adequate, or causes disablement. Reported lower limb lymphedema ranges from zero [Coblentz 2002] to 60-80% [Balzer 1993][James 1982][Papachristou 1977] with many reports between these extremes.

Lymphedema of the genitals has been reported as 2-5% [Gaarenstroom 2003][Nelson 2004] and 18% (combined with lower limb) [Lieskovsky 1980]. Genital lymphedema among users of pneumatic pumps on the lower limb has been reported at 43% [Boris 1998].

Prevalence of primary lymphedema has been estimated as 1.15/100,000 persons under 20 years [Smeltzer 1985]

2. Time Course of Lymphedema (Bar Ad 2009)

In a study cohort of 1,713 consecutive Stage I or II breast cancer patients who underwent breast conservation therapy, including axillary staging followed by radiation, arm lymphedema was documented in 266 (16%) of the patients. One hundred nine patients, 6% of the overall group and 40% of the patients with arm lymphedema, presented with mild arm lymphedema, defined as a difference of 2 cm or less between the measured circumferences of the affected and unaffected arms. Among the 109 patients with mild arm lymphedema at the time of arm lymphedema diagnosis, the rate of freedom from progression to more severe lymphedema was 79% at 1 year, 66% at 3 years, and 52% at 5 years. The patients who were morbidly obese, had positive axillary lymph nodes, or received supraclavicular irradiation at the time of breast cancer treatment were at higher risk of progression from mild arm lymphedema to more severe edema. Mild arm lymphedema, generally considered to be a minor complication after breast conservation treatment for breast cancer, was associated with a risk of progression to a more severe grade of arm lymphedema in a substantial fraction of patients.

3. Cellulitis-Lymphedema Cycle (Damstra 2008)

Infection of the skin and lymphatic system (cellulitis/lymphangitis) is a major cause of lymphedema. It is also a major result of lymphedema. (Stoberl & Partsch 1987). There is evidence that there is suppression of immune competence in a lymphedematous limb (Mallon 1997). Some 10-15% of lymphedema patients experience infections each year (Swenson et. al. 2002, Kasseroller 1998). Research described by Dr. Kitamura at the 2010 meeting of the International Lymphoedema Framework in Brighton, Eng on the incidence of cellulitis in Japan among her breast cancer patients showed that 135/656 (20.6%) breast cancer survivors developed lymphedema, and of these 135 lymphedema patients 72 (53.3%) experienced recurrent cellulitis. The Kitamura figure of 11% falls within the earlier figures of Swenson and Kasseroller. Treatment of lymphedema has been shown to decrease the frequency of infections (Földi 1996, Boris 1997, Ko 1998). In a 2008 study Damstra concluded: Erysipelas (cellulitis) is often presumed to be purely infectious in origin, with a high rate of recurrence and a risk of persistent swelling due to secondary lymphoedema. In this study, we show that patients presenting with a first episode of erysipelas often have signs of pre-existing lymphatic impairment in the other, clinically non-affected, leg. This means that sub-clinical lymphatic dysfunction of both legs may be an important predisposing factor. Therefore, we recommend that treatment of erysipelas should focus not only on the infection but also on the lymphological aspects, and long-standing treatment for lymphoedema is essential in order to prevent recurrence of erysipelas and aggravation of the pre-existing lymphatic impairment. A similar conclusion is described by Berdette in 2008 “The Investigators concluded that these data suggested that lymphedema was a predisposing factor in the cellulitis and was not caused by the infection. In another study the lymphatic drainage of 30 patients with recurrent cellulitis was studied via lymphoscintigraphy. Seventy-seven percent (23 out of 30) were found to have significant lymphatic abnormalities correlating well with the aforementioned data that show the major role of lymphedema in recurrent disease.”

4. Case Study (Weiss 2007)



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A number of separate approaches have been taken to arrive at a credible estimate of the potential savings to be achieved. One approach was to postulate two lymphedema treatment scenarios for a woman diagnosed with and treated for breast cancer. The first scenario postulates that she receives early and continued treatment of her lymphedema according to the recommended guidelines. The second scenario postulates that she receives no treatment for her lymphedema, but does receive medical treatment for her recurrent lymphedema-related infections. Data to support both scenarios are derived from statistics taken from recent scientific journals. The cost of lymphedema treatment over 40-year Breast Cancer Survivor's survival lifetime was \$95,250 while the cost of medical treatment when the lymphedema was not treated was \$340,000 which amounts to a saving of \$244,750 over the 40 year lifetime of the illustrative patient (Cost Ratio = 3.57 no LE treatment / LE treatment).

5. Burden of Lymphedema (Shih 2009)

A recent published study estimated the economic burden of breast cancer–related lymphedema (BCRL) among working-age women, the incidence of lymphedema, and associated risk factors. Claims data were used to study an incident cohort of breast cancer patients for the 2 years after the initiation of cancer treatment. Medical costs and rate of infections likely associated with lymphedema were compared between a woman with BCRL and a matched control. Approximately 10% of the 1,877 patients had claims indicating treatment of lymphedema. The matched cohort analysis demonstrated that the BCRL group had significantly higher medical costs (\$14,877 to \$23,167) and was twice as likely to have lymphangitis or cellulitis (OR= 2.02, P= .009). Outpatient care, especially mental health services, diagnostic imaging, and visits with moderate or high complexity, accounted for the majority of the difference.

6. Reducing the Burden with Early Intervention with Compression Garments (Stout 2008)

In this prospective study, the authors demonstrated the effectiveness of a surveillance program that included preoperative limb volume measurement and interval postoperative follow-up to detect and treat sub-clinical LE. LE was identified in 43 of 196 (21.9%) women who participated in a prospective BC morbidity trial. Limb volume was measured preoperatively and at 3- month intervals after surgery. If an increase >3% in upper limb (UL) volume developed compared with the preoperative volume, then a diagnosis of LE was made, and a compression garment intervention was prescribed for 4 weeks. Upon reduction of LE, garment wear was continued only during strenuous activity, with symptoms of heaviness, or with visible swelling. Women returned to the 3-month interval surveillance pathway. Statistical analysis was a repeated-measures analysis of variance by time and limb (P < .001) comparing the LE cohort with an age-matched control group. The time to onset of LE averaged 6.9 months postoperatively. The mean (±standard deviation) affected limb volume increase was 83 mL (±119 mL; 6.5% ±9.9%) at LE onset (P = .005) compared with baseline. After the intervention, a statistically significant mean 48 mL (±103 mL; 4.1% ±8.8%) volume decrease was realized (P < .0001). The mean duration of the intervention was 4.4 weeks (±2.9 weeks). Volume reduction was maintained at an average follow-up of 4.8 months (±4.1 months) after the intervention.

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MEDCAC MEETING OF 11/18/09 AND H.R. 4662

The Medicare Evidence Development Coverage Advisory Committee (MEDCAC) meeting held November 18, 2009 was a watershed for the Medicare treatment of lymphedema. It was the first time that an authoritative U.S. government agency studied current lymphedema diagnosis and treatment protocols to determine whether there is enough “evidence” of its efficacy in the treatment of lymphedema to warrant Medicare coverage.

On November 18 the MEDCAC conducted a full-day forum on the evidence basis of lymphedema measurement and treatment at their quarterly meeting, the first time in their ten-year existence that this subject was discussed.

The National Lymphedema Network (NLN) took a leading position in organizing lymphedema medical experts from around the country to “focus on the quality of evidence surrounding the diagnosis and treatment of secondary lymphedema”. Evidence was submitted to the Lymphedema Panel supporting commonly used lymphedema diagnosis and treatment protocols.

The open meeting featured a presentation of the Technology Assessment HHS/AHRQ commissioned from McMaster University Evidence-based Practice Center, Hamilton ONT Canada, followed by assessments by invited national lymphedema experts Stanley Rockson, MD and Jane Armer, PhD, RN, FAAN. This was followed by scheduled public comments from 13 lymphedema experts from lymphedema and venous organizations.

NLN Medical Advisory Committee members Kathleen Francis, MD, Sheila Ridner RN, PhD, and Paula Stewart MD, CLT-LANA provided scheduled public comments as did Robert Weiss, MS. Jane Armer RN, PhD was one of two guest speakers, and Janice Cormier, MD was a guest member of the MEDCAC Lymphedema Panel. The NLN was well represented at this meeting and provided valuable inputs to CMS.

In the afternoon the Panel questioned the presenters and discussed the evidence with the goal of eventually voting on a number of issues concerning their confidence in the adequacy of the evidence to support coverage of individual measurement and treatment modalities.

The original list of items to be voted on included only the individual modalities and not the combined modalities that comprise CDT. It was only at the request of two of the volunteer guest speakers that CDT and CDT plus adjunct pneumatic compression were added to the list. These items rightly received higher scores than the individual modalities in recognition of the complementary effects of the combined therapies.

The interpretation of the scoring is that 3 is “intermediate confidence that the treatment method produces clinically meaningful improved health outcomes for patients with secondary lymphedema.” A score of 5.00 signifies high confidence of that outcome. The threshold for consideration is 2.5. The final result was that CDT received the highest score (3.64), CDT with pneumatic compression devices, compression bandaging/compression garments and pneumatic compression devices following with scores of 3.45, 3.27 and 3.00 respectively. Note that all of the top three treatment options involve compression bandaging, garments and devices which are currently not covered by Medicare.

The MEDCAC Lymphedema Panel was to have published their final assessment, with all supporting evidence, on the CMS MEDCAC web site, within 30 days. It has been five months and no final report has been posted. It is my belief that the evidence, references and analyses sent in prior to the meeting by lymphedema experts around the country, plus the invited and voluntary testimony at the meeting and the comments solicited after the meeting, have caused a reassessment to be necessary, and the Technology Assessment to be redone based on the clinical expertise lacking in the original assessment, and subsequently brought to the meeting.

Once published, the assessment will presumably be used by the CMS Coverage & Analysis Group in future discussions of Medicare coverage of lymphedema diagnosis and treatment. There will be future opportunities



for public and expert inputs into proposed Medicare coverage changes and we must continue to take advantage of these opportunities.

With respect to the relationship of the MEDCAC meeting and H.R. 4662, the results of the MEDCAC meeting, i.e. the conclusion that there is sufficient evidence to support complex decongestive therapy, with or without sequential pneumatic compression, as effective treatment of lymphedema, supports the inclusion of those modalities in the bill. The bill mandates coverage of these protocols, while the on-going Coverage & Analysis Group activities will develop the policies and procedures to implement the law.

Please note that the National Lymphedema Network and the undersigned lymphedema advocate have been urging CMS for ten years to change their lymphedema treatment coverage provisions, but have been told repeatedly that there is not enough evidence, and that the law must be changed in order to make the requested policy changes. The November 2009 MEDCAC meeting and the February 2010 introduction of H.R. 4662 brought a historic confluence in these two necessary steps to providing quality diagnosis and treatment to lymphedema sufferers!

Note also that the recently passed health reform bills [the Patient Protection and Affordable Care Act (PPACA; P.L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (HCERA; P.L. 111-152)], were predominantly healthcare ACCESS acts while H.R. 4662 is a QUALITY OF CARE act. The healthcare system accessed must provide complete medical care of lymphedema or else suffer the expense of billions of dollars each year in treating preventable lymphedema-related cellulitis. These ACCESS and QUALITY OF CARE acts are complementary.

[Adapted from legislation columns in National Lymphedema Network *LYMPHLink* issues of January-March 2010 and April-June 2010 by Robert Weiss, M.S. NLN Lymphedema Legislative Advocate]



LYMPHEDEMA TREATMENT ACT | H.R. 4662 KISSELL

LYMPHEDEMA TREATMENT IS GOOD BUSINESS AS WELL AS GOOD MEDICINE

Lymphedema Diagnosis and Treatment Cost Saving Act of 2010 (Introduced in House) H.R. 4662 IH

111th CONGRESS

2d Session

H. R. 4662

To amend title XVIII of the Social Security Act to improve the diagnosis and treatment of lymphedema under the Medicare Program and to reduce costs under such program related to the treatment of complications of lymphedema, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

February 23, 2010

Mr. KISSELL introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

A BILL

To amend title XVIII of the Social Security Act to improve the diagnosis and treatment of lymphedema under the Medicare Program and to reduce costs under such program related to the treatment of complications of lymphedema, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Lymphedema Diagnosis and Treatment Cost Saving Act of 2010'.

SEC. 2. COVERAGE OF LYMPHEDEMA DIAGNOSIS AND TREATMENT SERVICES UNDER MEDICARE.

(a) Coverage of Services- Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) in subparagraph (DD), by striking 'and' at the end;

(B) in subparagraph (EE), by adding 'and' at the end; and

(C) by adding at the end the following new subparagraph:

'(FF) lymphedema compression treatment items (as described in subsection (iii)) and lymphedema diagnosis and treatment services (as described in subsection (hhh)) if such services are prescribed by and reviewed by a treating physician and performed by such physician or—

'(i) a physical therapist or an occupational therapist who meets the quality requirements of subsection (hhh)(2)(C);

'(ii) a qualified professional, such as a physician, nurse practitioner, clinical nurse specialist, chiropractor, or physician's assistant who is licensed or certified by the State in which the services are performed to perform therapy services and who meets the quality requirements of (hhh)(2)(C); or

'(iii) a qualified person, such as a physical therapist assistant, occupational therapy assistant, licensed massage therapist, licensed practical nurse, or licensed home health practitioner who meets the quality requirements of (hhh)(2)(C) providing such services are rendered under the direct supervision of a physical therapist or occupational therapist qualified in lymphedema treatment and management who meets the quality requirements of (hhh)(2)(C); and



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(2) by adding at the end the following new subsections:

(hhh) Lymphedema Diagnosis and Treatment Services- (1) The term 'lymphedema diagnosis and treatment services' means, with respect to an individual and consistent with paragraph (3), differential diagnosis and treatment of lymphedema (regardless of cause) according to the current standard of lymphedema diagnosis and treatment described in paragraph (2)(A) by, or under the direction of, a health care professional that is a certified provider as described in paragraph (2)(B) in an outpatient setting and that meets the quality standards described in paragraph (2)(C), but only if the physician who is managing the individual's lymphedema certifies that such services are needed under a comprehensive plan of care related to the individual's diagnosed lymphedema.

(2) For purposes of paragraph (1):

(A) The current standard of lymphedema diagnosis and treatment described in this subparagraph is such standard as defined by the American Cancer Society and the International Society of Lymphology and called 'complex decongestive therapy', a multi-modal therapy comprising manual lymph drainage, compression therapy, exercise, and skin care. Such standard consists of the initial phase of treatment which is performed by qualified health care professionals on an outpatient basis (Phase 1 treatment) and the continuing maintenance phase (Phase 2 treatment) which is performed in a home setting by the patient, patient's family, or patient's aide after receiving instruction described in paragraph (5).

(B) A qualified provider is a physician or lymphedema therapist knowledgeable of the diagnosis and current medical standard of treatment of lymphedema, or any other individual or entity designated by the Secretary, that, in addition to providing lymphedema outpatient self-management training services (as defined in paragraph (3)(C)(iii)), provides other items or services for which payment may be made under this title.

(C)(i) Subject to clause (ii), the quality standards described in this subparagraph are quality standards established by the Secretary equivalent to the practice standards established by the Lymphology Association of North America.

(ii) In applying this subsection during the 3-year period beginning on the date of the enactment of this subsection, a therapist who has completed at least 135 hours of lymphedema treatment training and is certified by the training school is deemed to have met the requirement of clause (i), and may practice under a certified provider within a plan of care developed by the certified provider; regardless of whether the therapist meets the experience standards established by the Lymphology Association of North America.

(D) The term 'lymphedema diagnosis' means the differential diagnosis of the source of the patient's edema and the identification of the specific etiology in order to develop the lymphedema treatment plan. Such term shall include diagnostic tools such as the lymphoscintigraphic functional test or other test the Secretary determines to be efficacious to directly observe lymphatic system function may be indicated if medical history or tests to rule out other causes are not adequate to provide a clear positive diagnosis of lymphedema.

(3) Coverage- With respect to lymphedema diagnosis and treatment services coverage under this part, the following shall apply:

(A) MANUAL LYMPH DRAINAGE-

(i) Lymphedema diagnosis and treatment services coverage under this part shall include an initial course of manual lymph drainage as part of complete decongestive therapy (Phase 1) when medically required by the qualified provider described in paragraph (2)(B).

(ii) The schedule and number of manual lymph drainage treatment sessions shall be determined by the treating physician or lymphedema therapist as required by medical necessity, and not the limits governing rehabilitation therapy described in section 1833(g).

(B) COMPRESSION BINDING SYSTEMS, GARMENTS AND DEVICES-

(i) For purposes of this part, the materials and aids used in lymphedema compression therapy-



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`(I) while physically resembling items in other benefit categories such as surgical dressings, durable medical equipment, splints and braces, orthotics and prosthetics described in subsections (s)(5), (s)(6), and (s)(9), do not serve the same medical function as such items in such other categories and have significantly different therapeutic characteristics and uses; and

`(II) are specified in subsection (iii) as a separate benefit category.

`(ii) Such coverage shall include any compression garments, binding systems and devices described in subsection (iii) deemed by the patient's qualified caregiver to be medically necessary as part of the treatment of lymphedema.

`(iii) Such coverage shall include replacements when required to maintain their medically required compressive function or to accommodate changes in the patient's dimensions or medical condition.

`(C) LYMPHEDEMA SELF-MANAGEMENT TRAINING-

`(i) IN GENERAL-

`(I) The initial course of treatment (phase 1) described in paragraph (2)(A), with respect to such services, shall include training of the patient and an aide or family member as required to perform self-treatment in a home setting, including any of the following home treatment modalities which are determined by the qualified provider to be medically required and are a part of the continuing maintenance phase (phase 2) home treatment plan described in paragraph (2)(A):

`(aa) Self-manual lymph drainage (simple lymph drainage).

`(bb) Compression bandaging.

`(cc) Donning and care of compression garments.

`(dd) Performance of an appropriate decongestive exercise program.

`(ee) Use of specialized manually adjustable compression devices, donning aids, and other required ancillary equipment; and if medically indicated.

`(ff) Use of sequential gradient compression pneumatic pump.

`(II) As part of such treatment, patient training shall include instruction on periodic self-measurements, skin care, indications of infection, and the steps to be taken if infection occurs.

`(III) The term 'lymphedema outpatient self-management training services' means educational and training services furnished to an individual diagnosed with lymphedema by a certified provider (as described in paragraph (2)(B)) in an outpatient setting but only if the physician who is managing the individual's lymphedema condition certifies that such services are needed under a comprehensive plan of care related to the individual's lymphedema condition.

`(ii) CONSULTATION WITH ORGANIZATIONS IN ESTABLISHING PAYMENT AMOUNTS FOR SERVICES PROVIDED BY PHYSICIANS – In establishing payment amounts under section 1848 for physicians' services consisting of lymphedema outpatient self-management training services, the Secretary shall consult with appropriate organizations, including such organizations representing individuals or Medicare beneficiaries with lymphedema, in determining the relative value for such services under section 1848(c)(2).

`(D) MEASUREMENTS TO DEFINE TREATMENT EFFICACY- Periodic measurements shall be made to enable evaluation of the efficacy of the treatment plan and patient adherence, to modify the treatment plan or to determine the need for follow-up courses of treatment.

`(E) FOLLOW-UP TREATMENT- Such coverage shall provide for follow-up treatments whenever medically



required to periodically validate home techniques, to monitor progress against the written treatment plan, and to modify the treatment plan as required.

`(F) DENIAL- No individual other than a licensed physician or certified lymphedema therapist competent to evaluate the specific clinical issues involved in the care requested, may deny or modify requests for authorization of health care services or materials described in subsection (iii) pursuant to this subsection.

`(G) PROHIBITION OF ADDITIONAL TREATMENT FEES- No additional fees or deductibles may be assessed, with respect to such treatment, for compliance with this title other than assessed for similar medical services.

`(iii) Lymphedema Compression Treatment Items-

`(1) DEFINITION- The term `lymphedema compression treatment item` means compression therapy materials and supplies used daily in the medical treatment of lymphedema upon prescription of the treating physician or therapist, including-

`(A) compression binding systems comprising, as medically required, short-stretch and medium-stretch compression bandages; cotton, synthetic, or foam padding; gauze or elastic finger and toe bandages; foam pads; and tubular bandages;

`(B) compression garments and compression pads for compression treatment of lymphedematous arms, legs, torso, face and neck, breast and chest, abdomen, and genitalia;

`(C) manually-adjustable compression sleeves and padded directional flow sleeves for use on upper and lower limbs;

`(D) orthotic shoes; and

`(E) donning aids, bandage rollers, and other specialized items used with the items described in subparagraphs (A) through (D).

`(2) SPECIAL REQUIREMENT ON LYMPHEDEMA PUMPS- Such term shall include a pneumatic pump for the treatment of lymphedema only if the treating physician or therapist's prescription for such pump is accompanied by a certificate of medical necessity which specifies as a minimum-

`(A) the differential diagnosis of lymphedema and any related co-conditions such as venous insufficiency, peripheral arterial disease, lipedema, morbid obesity, myxedema, and any other condition which may be significant in the selection of a type, specification, and usage of the pump; and

`(B) the physician's or therapist's judgement of the type and specifications of the pump based on the patient's medical necessity.'.

(b) Payment-

(1) LYMPHEDEMA OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES INCLUDED AS PHYSICIANS' SERVICES- Section 1861(s) (2)(S) of such Act (42 U.S.C. 1395x(s)(2)(S)) is amended by inserting `and lymphedema outpatient self-management training services under subsection (hhh)(3)(C)' after `subsection (qq)'.`

(2) LYMPHEDEMA COMPRESSION TREATMENT ITEMS-

(A) IN GENERAL- Section 1833(a) of such Act (42 U.S.C. 1395l(a)) is amended-

(i) in paragraph (8), by striking at the end `and`;

(ii) in paragraph (9), by striking at the end the period and inserting a semi-colon; and

(iii) by adding at the end the following new paragraph:

`(10) in the case of lymphedema compression treatment items described in section 1861(iii), the amount determined under section 1834(n); and'.



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(B) PAYMENT DETERMINED- Section 1834 of such Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

(n) Payment for Lymphedema Compression Treatment Items-

(1) GENERAL RULE FOR PAYMENT-

(A) IN GENERAL- With respect to a lymphedema compression treatment item described in section 1861(iii) for which payment is determined under this subsection, subject to subparagraph (D), payment shall be made in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS- The payment basis described in this subparagraph, with respect to a lymphedema compression treatment item described in section 1861(iii), is the actual charge for the item.

(C) EXCLUSIVE PAYMENT RULE FOR HOME HEALTH AGENCIES- This subsection shall constitute the exclusive provision of this title for payment for lymphedema compression treatment items described in section 1861(iii) under this part or under part A to a home health agency.

(D) EXCEPTIONS-

(i) Subparagraph (B) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(ii) Subparagraph (B) shall not apply to items that are furnished as an incident to a physician's professional service.

(2) SPECIAL PAYMENT RULES-

(A) ALLOWABLE ITEMS- To be eligible for payment under this subsection, an item described in section 1861(iii) must-

(i) be ordered by a qualified physician or lymphedema therapist for treatment of diagnosed lymphedema;

(ii) primarily and customarily be used to serve a medical purpose;

(iii) generally not be useful to a person in the absence of an illness or injury; and

(iv) be appropriate for use in the home.

(B) ALLOWABLE QUANTITIES- In the case it is determined by the qualified physician or qualified lymphedema therapist involved that compression therapy demands daily compression as part of lymphedema treatment according to section 1861(hhh)(1), then payment may be made in accordance with this subsection for the following quantities -

(i) in the case of compression binding systems described in section 1861(iii)(1)(A), 2 sets for each affected body part;

(ii) in the case of compression garments described in section 1861(iii)(1)(B), 2 garments for each affected body part;

(iii) in the case of compression devices described in section 1861(iii)(1)(C), 1 each for each affected body part; and

(iv) in the case of compression therapy aids described in section 1861(iii)(1)(D), as determined by the qualified physician or qualified lymphedema therapist.

(C) ALLOWABLE USE- Payment may be made under this subsection for a lymphedema compression treatment item described in section 1861(iii) only if such item -

(i) is prescribed by a certified provider as defined in section 1861(hhh)(2)(B);



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(C), the greater of 3 years or per manufacturer's warrantee.

(iv) AIDS- In the case of compression therapy aids described in section 1861(iii)(1)(D), as required to maintain functional usefulness.

(C) SUPPLIER REQUIREMENTS- Section 1834(j)(5) of such Act (42 U.S.C. 1395m(j)(5)) is amended- (i) in subparagraph (E), by striking at the end `and`;

(ii) in subparagraph (F), by striking at the end the period and inserting `; and`; and

(iii) by adding at the end the following new subparagraph:

(G) lymphedema compression treatment items (as described in section 1861(iii)).

(3) LYMPHEDEMA DIAGNOSIS AND TREATMENT SERVICES-

(A) IN GENERAL- Section 1833(a) of such Act, as amended by paragraph (2)(A), is further amended by adding at the end the following new paragraph:

(11) with respect to lymphedema diagnosis and treatment services (as defined in subsection (hhh)(1))-

(A) furnished by a qualified physical therapist or qualified occupational therapist, as defined in section 1834(o)(2)(A), the amounts described in section 1834(k); or

(B) furnished by a lymphedema therapist, as defined by 1834(o)(2)(B), under direction of a qualified physical therapist or qualified occupational therapist, the amounts described in section 1834(o).

(B) PAYMENT METHOD- Section 1834 of such Act, as amended by paragraph (2)(B), is further amended by adding at the end the following new subsection:

(o) Payment for Outpatient Lymphedema Diagnosis and Treatment Services-

(1) IN GENERAL- For purposes of section 1833(a)(11)(B), in the case of lymphedema diagnosis and treatment services described in section 1861(hhh) for which payment is determined under this subsection and that are performed by a qualified lymphedema therapist (as defined in paragraph (2)) under the direction of a qualified physician therapist or qualified occupational therapist, the payment basis shall be 80 percent of the lesser of-

(A) the actual charge for the service; or

(B) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) QUALIFIED THERAPISTS- For purposes of this subsection:

(A) IN GENERAL- The term `qualified`, with respect to a physical therapist, occupational therapist, or lymphedema therapist, means that the physical therapist, occupational therapist, or lymphedema therapist meets the quality requirements described in section 1861(hhh)(2)(C).

(B) LYMPHEDEMA THERAPIST- The term `lymphedema therapist` means any of the following individuals so long as such individual is legally authorized to practice by the State in which the lymphedema diagnosis and treatment service involved is performed and meets the quality requirements described in subparagraph (A):

(i) A registered nurse, nurse practitioner, family nurse practitioner or clinical nurse specialist (as described in section 1861(aa)(5)).

(ii) A doctor of medicine or doctor of osteopathy (as described in section 1861(r)(1)).

(iii) A physician assistant (as described in section 1861(aa)(5)).

(iv) A chiropractor.



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`(v) A licensed massage therapist.

`(vi) A licensed home health practitioner.

`(3) APPLICABLE FEE SCHEDULE AMOUNT- In this subsection, the term `applicable fee schedule amount' means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

`(4) UNIFORM CODING- For claims for services for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

`(5) RESTRAINT ON BILLING- The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to lymphedema diagnosis and treatment services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C), except that in applying such subparagraphs the practitioner described shall be any practitioner described in paragraph (2)(B).

(C) EXCLUSION FROM CERTAIN THERAPY SERVICES- Section 1833(g)(4) of such Act (42 U.S.C. 1395l(g)(4)) is amended by inserting `or to expenses incurred with respect to lymphedema diagnosis and treatment services (as defined in subsection (hhh)(1))' before the period at the end.

(c) Effective Date- The amendments made by this section shall apply to items and services furnished on or after the date that is 90 days from the date of the enactment of this Act.



For Immediate Release: March 4, 2010
Contact: Haven Kerchner, 704.786.1612
Haven.kerchner@mail.house.gov

Congressman Kissell Introduces Bill Requiring Fair Treatment of Lymphedema Patients

WASHINGTON – Congressman Larry Kissell (NC-08) has introduced legislation which would require Medicare to offer fair treatment coverage for Americans afflicted with primary and secondary lymphedema.

The Lymphedema Diagnosis and Treatment Cost Saving Act of 2010, HR 4662, is designed to improve patient care and reduce costs associated with complications related to lymphedema. Lymphedema, also known as lymphatic obstruction, is a condition of localized fluid retention and tissue swelling caused by a compromised lymphatic system.

Kissell introduced the legislation after meeting with constituent Heather Ferguson, whose son Dylan, suffers from primary lymphedema. Ferguson, who lives in Charlotte, has been active in working to raise awareness of the disease and to help alleviate the troubles lymphedema sufferers have getting insurance to cover treatment.

“I was moved by Heather’s story, and all she has gone through to ensure that her son receives this important treatment. Her dedication to helping others in the same situation has inspired me to help her in her quest to make sure lymphedema patients have an opportunity to receive treatment,” Kissell said. “This preventative treatment will help improve life for many people throughout this country.”

Ferguson has worked with North Carolina Representative Tricia Cotham to get legislation through the North Carolina General Assembly to help patients in the state. But Ferguson wanted to help all patients suffering from lymphedema. She contacted Kissell, whom she’d met before he was elected, and asked him to help her bring the fight national.

“When my insurance company agreed to cover my son’s treatment for a year, I was shocked and so discouraged. I asked if they would offer this opportunity to other policy holders and they said no. I realized that I would be fighting with insurance companies to ensure Dylan could receive treatment for my entire life and then, for Dylan’s entire life. It wasn’t enough to get our insurance company to cover it, I wanted to fix the problem,” Ferguson said. “I am so lucky that my own representatives, both state and national, have been so responsive to my efforts. I never expected this to happen so quickly, and am so thankful to Congressman Kissell for his quick response to this. It has renewed my faith in the political system to know that my representatives are there to listen to their constituents.”

The treatment for lymphedema is known as complex decongestive therapy. The treatment is used world-wide, is not experimental, and has been used for decades with proven success. Not all components of the treatment fall under the categories for which Medicare typically provide coverage. With treatment, patients can live long, healthy and virtually normal lives. However, without treatment, the disease can progressively worsen, causing severe disfigurement, disability, pain and in some cases, even death.

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LYMPHEDEMA TREATMENT ACT | H.R. 4662 KISSELL

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For Immediate Release: May 3, 2010
Contact: Haven Kerchner, 704.786.1612
Haven.kerchner@mail.house.gov

Lance Armstrong's LIVESTRONG Throws Support Behind Congressman Kissell's Lymphedema Bill

CONCORD – LIVESTRONG, the foundation started by seven-time Tour de France winner Lance Armstrong, has announced its endorsement of H.R. 4662, the Lymphedema Diagnosis and Treatment Cost Saving Act of 2010 introduced by Congressman Larry Kissell (NC-08). This bill will require Medicare to offer fair treatment coverage for Americans afflicted with primary and secondary lymphedema.

Lymphedema is a condition caused by a compromised lymphatic system or lymphatic obstruction which results in localized fluid retention and tissue swelling. It is a common side effect of cancer treatments. If left untreated, lymphedema can cause serious complications including severe disfigurement, disability, pain, and in some cases, even death.

Kissell, a cycling enthusiast, is a fan of Armstrong and has continually worn a LIVESTRONG wristband for more than five years. The bright yellow wristband is sold through LIVESTRONG with 100 percent of the proceeds used to support the foundation's survivor services and programs.

"Lance Armstrong is an incredible champion in cycling, but it is his work through LIVESTRONG to improve the lives of those affected by cancer that makes him a true champion," Kissell said. "I have tremendous respect for his dedication to this cause, and am so proud to announce that LIVESTRONG has endorsed the lymphedema legislation. This bill will have such a positive impact on the lives of so many sufferers of this condition."

LIVESTRONG, founded by Armstrong after his own cancer diagnosis, focuses on preventing cancer, ensuring access to screening and care, improving the quality of life for people affected by cancer and investing in needed research.

Doug Ulman, president and CEO of LIVESTRONG said, "Improving the lives of people fighting cancer and its effects must be a greater priority in Washington. This legislation will have a direct and positive impact on people throughout the nation. LIVESTRONG applauds Representative Kissell for sponsoring this very important bill."



Support Medicare Coverage for Lymphedema



Dear Colleague:

I am writing to ask your support for a bill I recently introduced, H.R. 4662, the Lymphedema Diagnosis and Treatment Cost Saving Act of 2010. Lymphedema, also known as lymphatic obstruction, is a condition of localized fluid retention and tissue swelling caused by a compromised lymphatic system. While the exact cause of primary lymphedema is still unknown, it generally occurs due to poorly-developed or missing lymph nodes and/or channels in the body.

Currently, Medicare and some private insurance companies do not offer complete coverage for this disease, which afflicts millions of Americans, and is most commonly caused by treatment for cancer. These policies only cover the expensive, difficult to treat and often chronic complications which are the inevitable result of patients having not received the proper medical care in the earlier stages. Such policies are falling short of providing these individuals treatment in accordance with established standards of care. Current policies lead to the expenditure of precious healthcare resources to treat preventable lymphedema-related cellulitis.

Treatment for lymphedema is a medical necessity critical to the health and well-being of those who suffer from the disease. The clinically-proven treatment of lymphedema is called “complex decongestive therapy.” It is used world-wide by the medical community, is not experimental, and has decades of proven success. Unfortunately, not all components of this treatment fall under categories for which Medicare or private insurance companies typically provide coverage. With treatment, a patient lives a long, healthy and virtually normal life. But without treatment, the disease can grow progressively worse, causing severe disfigurement, disability and pain, and in some cases even results in death. This bill would offer an immense step forward by requiring Medicare coverage of complex decongestive therapy. Providing coverage for successful early treatment is essential. A lymphedema treatment mandate went in to effect in North Carolina January 1, 2010, and one has been in effect in Virginia since 2004. This is a preventative treatment bill that will reduce Medicare costs while improving patient care and quality of life.

Please support H.R. 4662, which will improve patient care while reducing Medicare costs. If you are interested in signing on as a co-sponsor of this bill, contact Zach Pfister in my office at zach.pfister@mail.house.gov or 202-225-3715.

Sincerely,

Larry Kissell
Member of Congress



LYMPHEDEMA TREATMENT ACT | H.R. 4662 KISSELL

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SUPPORTING ORGANIZATIONS

(List current as of July 7, 2010)

FOUNDATIONS AND NON-PROFITS

Breast Cancer Network of Strength
Colon Cancer Alliance
Komen Advocacy Alliance
Lighthouse Lymphedema Network
LiveStrong - the Lance Armstrong Foundation
Living Beyond Breast Cancer
Lymphedema Awareness Foundation (LAF)
National Lymphedema Network



INTERNET LISTS, ADVOCACY ORGANIZATIONS

Elymphnotes
Lymphedema Community
Lymphedema People
Lymphland
Lymph Notes
Stand Up - Speak Out



TRAINING SCHOOLS

Academy of Lymphatic Studies (ACOLS)
The Chikly Health Institute (C.H.I.)
The Dr. Vodder School of North America
Finger Lakes Massage School
Klose Training & Consulting
Norton School of Lymphatic Therapy



TREATMENT CLINICS

Carolinas Rehabilitation
James Cancer Hospital & Solove Research Institute
Northwest Lymphedema Center
Rivertown Lymphedema Clinic and Rehab, LLC.



MANUFACTURERS

BiaCare
BSN Medical Inc. (Jobst)
CircAid Medical Products, Inc.
Farrow Medical Innovations
ImpediMed
JoViPak Corporation
Lohmann & Rauscher
LymphedIVAs
MediUSA
Solaris
Torbot Group, Inc, Jobskin Div



SUPPLIERS

Alala, LLC
Brown Medical Industries
Lymphedema Products, LLC.



LYMPHEDEMA TREATMENT ACT | H.R. 4662 KISSELL

LYMPHEDEMA TREATMENT IS GOOD BUSINESS AS WELL AS GOOD MEDICINE

FREQUENTLY ASKED QUESTIONS ABOUT H.R. 4662

How Many Medicare Beneficiaries Have Lymphedema?

- *How many patients are estimated to have lymphedema in the US?*

Estimates of lymphedema patients in the U.S. range from 3 million (primary and secondary lymphedema) to 6 million (including mixed lymphedema and venous insufficiency), with an estimate of 1.6 million lymphedema cases in Medicare.

- *How much does it cost to treat lymphedema?*

Five years of actual claim costs in Virginia, which has had a lymphedema mandate since 2004, show claim costs of between \$1.12 and \$2.82 per insured per year which represented 0.04-0.09% of total claims.

- *If it costs money to treat lymphedema, where do the savings come from?*

Many clinical studies have shown that when the swelling of lymphedema is controlled, the risk of infection of the lymphedematous limb is reduced by 50-100%. It is essential to look at the “big picture” where the costs of CDT (lymphatic drainage and compression materials) are more than compensated by the avoidance of costs for treating lymphedema-related infections (cellulitis, lymphangitis, erysipelas).

- *What is the estimated cost of treating lymphedema-related hospitalizations?*

An estimate made using a special retrieval from California hospital discharge records for 2003 showed that it cost \$80 million for hospitalizations in California in 2003 to treat lymphedema-related cellulitis. This estimate did not consider the additional office visits, physical therapy and drug costs for the cases not serious enough to result in hospitalizations.

- *What is the estimated reduction in costs with this program?*

Based on a hypothetical model study of two treatment scenarios for a 40-year old breast cancer survivor, a 3.5 Return on Investment was calculated. Other theoretical studies using this hypothetical scenario for an assumed distribution of lymphedema severities yields an estimated Medicare saving of several hundred million dollars per year in avoided costs of treatment of lymphedema-related cellulitis.

Who is Behind This Bill?

- *Do you have partners in this effort?*

Our primary partners are the National Lymphedema Network and LiveStrong – the Lance Armstrong Foundation, and we are actively seeking participation by the American Cancer Society and Susan B. Komen Foundation. Organizations which have agreed to endorse the bill include: foundations and non-profits; patient advocacy groups and support groups; lymphedema therapist training schools; treatment clinics and lymphedema therapists; manufacturers, and suppliers.

Doesn't Medicare Cover Lymphedema Treatment?

- *Doesn't Medicare already cover the treatment of lymphedema?*

Medicare covers up to \$1860 per year of physical or occupational therapy and the cost of simple pneumatic pumps which may or may not be appropriate in the treatment of lymphedema.

- *What is not currently covered that would be covered?*

1. Materials involved with the compression treatment of lymphedema, including: compression bandage systems (the assembly of finger and toe bandages, tubular sleeves, padding, foam pieces, non-elastic bandages, tape);



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compression garments (for arms, legs, torso, breast, genitalia, hands, feet, head and neck); directional flow pads; compression devices (strapped, elastic, bandaged); donning aids and bandage rollers, etc.

2. Treatment by lymphedema-trained medical professionals such as nurses (RNs, NPs, APNs, CNSs), physicians, physician's assistants (PAs), Physical Therapists (PTs), Occupational Therapists (OTs) and Speech-Language Pathologists (SLPs) and treatment by lymphedema-trained medical personnel such as therapy assistants (PTAs, OTAs) under the direct supervision of a lymphedema-trained PT or OT.
3. Sequential pneumatic compression devices designed specifically for the treatment of lymphedema if deemed to be appropriate and medically necessary and prescribed by a physician

• *Why do we need a new law to cover compression items when used in the treatment of lymphedema?*

Proposals for a national coverage determination submitted in 2000 to HCFA by Robert Weiss and by the National Lymphedema Network were rejected. A proposal submitted in August 2000 to include in Medicare coverage the compression wraps and garments, was verbally rejected with no analysis of the legal or medical arguments. We have repeatedly been told that there is no benefit category in the Social Security Act that covers these items, and that the law would have to be changed.

On September 27, 2001 we were told by Sean R. Tunis M.D., M.Sc., Director Coverage and Analysis Group, Office of Clinical Standards and Quality "Compression garments are not covered, as they do not meet any of the statutorily defined benefit categories outlined in the Social Security Act,"

On November 9, 2004 we were told by Steve Phurrough, MD, MPA, Director Coverage and Analysis Group, Office of Clinical Standards and Quality "The lack of coverage in these situations stems from limitations in the law. Unless authorized under a provision of the Medicare law, compression sleeves or stockings cannot be covered under the Medicare program."

• *How does the November 2009 MEDCAC meeting relate to the bill?*

The MEDCAC meeting provided us with expert opinion that existing evidence gives reasonable confidence that the following lymphedema treatment modalities are effective and beneficial in the treatment of lymphedema patients:

- a. Complete decongestive therapy (CDT) including MLD, compression bandaging and garments, exercises and skin care;
- b. CDT in conjunction with a sequential pump;
- c. Compression bandage systems and compression garments;
- and d. Sequential pumps.

What Does H.R. 4662 Do For Medicare Beneficiaries?

• *Just what exactly does the bill do, and how does it change Medicare statutes?*

This Act amends Title XVIII of the Social Security Act (Medicare), specifically to:

1. define a new benefit category "lymphedema diagnosis and treatment services" in new section 1861(hhh) [42 U.S.C. 1395x] comprising manual lymph drainage, compression binding systems, garments and devices, lymphedema self-management training, measurements to define treatment efficacy and follow-up treatment when medically required.
2. add patient lymphedema education as a physicians' service in section 1861(s)(2)(S) [42 U.S.C. 1395x];
3. add a new benefit category for compression therapy medical items in section 1861(iii) [42 U.S.C. 1395x] and define special requirements for prescribing and coordinating the use of adjuvant pneumatic sequential compression devices;



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4. provide payment rules for compression therapy items to Section 1834 [42 U.S.C. 1395m] and for therapist services to Section 1833 [42 U.S.C. 1395l];
5. define the qualification requirements for professionals who may prescribe for and treat lymphedema patients in 1861(s)(2)(FF) and by reference to 1861(hhh)(2) [42 U.S.C. 1395x]
6. add requirement that garment fitters be specially qualified in section 1834(n)(2)(E) [42 U.S.C. 1395m]
7. provide for replacement of compression items under defined conditions in 1834(n)(3)(A) [42 U.S.C. 1395m]

• ***Why is the bill in the Energy and Commerce and Ways and Means Committees? Is there a time frame?***

These two Committees have Health Subcommittees that are responsible for Medicare oversight. They will determine the timeframe for consideration and recommendation to the floor of the House for vote.

The number of co-sponsors and the existence of a Senate twin will be the biggest factors in moving the bill along, so I suggest that you work on those tasks. We have already made contact with all of the Health Subcommittee members, and Zach coordinates with the health legislative aides (HLAs) of interested legislators.

• ***What can I do in my own state to help pass this bill?***

There are two things YOU can do: Ask your Senators to introduce a companion bill in the Senate, and ask your elected Representative to sign up as a co-sponsor of H.R. 4662. We have ten Democratic and five Republican Co-Sponsors today. The bill is bipartisan, self supporting, and has no budgetary impact according to healthcare mandate impact studies made on similar lymphedema bills in California, Massachusetts, New York, Virginia and North Carolina.

This is truly a “revolution” by lymphedema patients who have been trying to obtain the quality treatment for their condition which has been used in Europe and Australia for decades, and for which they have been fighting in the U.S. over the last ten years.

• **Whom do I contact for further information?**

• ***Do you have a lobbyist in Washington?***

No. We have no paid lobbyists – only the volunteer efforts of a team of unpaid lymphedema patients, family members and industry representatives who understand the great need for coverage of lymphedema treatment and the tremendous benefits to patients, therapists, businesses, insurers and Medicare that can result from this coverage.

• ***Is there a main staff aide shepherding this process?***

We are working with Zach Pfister, Congressman Larry Kissell’s Senior Legislative Assistant <Zach.Pfister@mail.house.gov>, who is coordinating requests to co-sponsor from other legislators.

• ***Does Congressman Kissell’s aide have the particulars I would need, or should we talk on the phone?***

Contact NLN at NLN@lymphnet.org or at 1.800.541.3259 for information on lymphedema. Please talk to Bob Weiss LymphActivist@aol.com if you need any particulars on the bill, its need and goals, wording, etc. Contact Heather Ferguson hmff@earthlink.net for current information on organizations or individuals supporting the bill, sample letters, or grassroots activities.

Limit your contact with Zach to matters concerning co-sponsors, contacts with other legislative offices, committee schedules, etc.



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Measuring the Cost of a Lymphedema Treatment Mandate - 5 Years of Experience in the Commonwealth of Virginia (Revised December 2009)

BACKGROUND: One of the most urgent of problems today is our inability to afford quality healthcare. Lymphedema, once acquired, is a lifelong disease with no currently known cure. However, the quality of that treatment is greatly to be questioned, and often does not meet the recommended standards of knowledgeable lymphedema specialty groups. These standards include the treatment by specially qualified therapists, a course of treatment limited only by medical necessity, patient instruction in self treatment and the provision and daily use of compression bandages, garments and devices. It can be shown that lymphedema treatment in accordance with these protocols, with high patient adherence, is **an effective way to REDUCE healthcare costs** by reducing the periodic infections for which the lymphedema patient is at risk.

Lymphedema mandates are being considered in a number of states similar to the lymphedema treatment mandate passed by the Commonwealth of Virginia in 2003. Virginia also has in place a rule that requires every insurer, health services plan and health maintenance organization (HMO) to report to the State Corporation Commissioner the yearly cost and utilization information for each of the 30 mandates currently in effect.

This document is an abstract of the costs of the Virginia lymphedema treatment mandate for the years 2004 through 2008, the first 5 years the mandate has been in effect. It contains claims and utilization data, and estimates by the healthcare providers of the insurance premium impact of each mandate. These impacts are spending impacts only, and do not consider the beneficial effects of lymphedema treatment on reducing medical and hospital costs by the inevitable reduction of lymphedema-related cellulitis.

DATA SOURCE: The source of data for this document is the series of “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: 20066, 7 & 8 Reporting Period” Reports RD191, RD289, RD246, RD322 and RD294, available at the Virginia Department of Insurance website at URL: <http://leg2.state.va.us/DLS/H&SDocs.NSF/Published%20by%20Year?>

The cost data for the lymphedema mandate is abstracted and presented with a discussion of other states’ lymphedema mandate analyses. This Virginia report is the only comprehensive and authoritative report to date of the cost of lymphedema care, and covers 26-28 major insurance companies and 14-16 HMOs representing 77-80% of the Virginia insurance market, and 1.3 to 1.7 million units of coverage.

VIRGINIA LYMPHEDEMA MANDATE: Section 38.2-3418.14 of the Code of Virginia requires that insurers, health service plans and HMOs provide coverage that shall include benefits for equipment, supplies, complex decongestive therapy, and outpatient self-management training and education for the treatment of lymphedema.

CPT AND ICD-9-CM CODES COLLECTED: The codes collected and costed in the company claims reports included ICD Codes 457.0 Postmastectomy lymphedema syndrome, 457.1 Other lymphedema, 757.0 Hereditary edema of legs, CPT Codes, 97124 Massage, compression, 97140 Manual therapy techniques, manipulation, 97535 Self-care/home management training

CLAIM EXPERIENCE: Claim experience provides the most direct measure of the cost of a lymphedema treatment mandate. The lymphedema claims filed as a percentage of the total claims for individual contracts was 0.04-.06%, and for group contracts was 0.06-0.09%. The average lymphedema claim cost per individual contract was \$1.12-1.79 and for group contract \$2.16-2.82. [Tables 5 & 6]. Since most insurance contracts included lymphedema treatment prior to the mandate and separate claim data for lymphedema treatment were not required to be reported, it is not possible to determine what portion of these claim costs result from the mandate.



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UTILIZATION OF SERVICE: Data are provided on the number of visits and the number of days attributable to each mandated benefit for the year. The group data was held to be more reliable than the individual contract data. The average number of visits per contract for lymphedema treatment was 0.09, and the average number of days per contract was 0.01. [Table 7]

PREMIUM IMPACT: Companies are required to use actual claim experience and other relevant actuarial information to determine the premium impact of each mandated benefit. The estimated premium impact of the lymphedema mandate ranged 0.27% to 0.56% of the overall average contract premium on individual contracts, and 0.12% to 0.25% on HMO contracts. It is not possible to explain why the estimated premium impacts are so much greater than the actual claims experience.

MANDATE ANALYSES IN OTHER STATES: A 2004 analysis of a similar Massachusetts bill estimated per member per month costs of \$0.03 for coverage of lymphedema treatment. In 2005 the California Health Benefits Review Program estimated an increase of 0.0003% or \$0.01 per person per year for implementing AB-213 Liu. None of these analyses accounted for significant avoided costs due to reduced infection that could be passed on to the customer as REDUCED premiums.

CONCLUSIONS: An upper bound on the costs of implementing a lymphedema treatment mandate can be estimated using the actual claims data in Virginia, where a lymphedema mandate has been law since January 1, 2004. It is an upper bound since: 1) the estimated premium increases are many times the actual claims experience for the years analyzed; 2) the reported claims experience represents the total lymphedema treatment claims instead of the incremental increase due to the mandate, and; 3) the reduction in total claim costs due to resulting lower cellulitis rates are not used to reduce estimated premiums.

REFERENCES

1. "Report of the State Corporation Commission on The Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2006 Reporting Period to the Governor and the General Assembly of Virginia" Report RD289, October 25, 2007 available at the Virginia Department of Insurance website at URL: <http://leg2.state.va.us/DLS/H&SDocs.NSF/Published%20by%20Year?>
2. California Health Benefits Review Program, "Analysis of Assembly Bill 213 Health Care Coverage for Lymphedema" A Report to the 2005-2006 California Legislature, April 7, 2005.
3. Commonwealth of Massachusetts Mandated Benefit Review - "Review and Evaluation of Proposed Legislation Entitled: "An Act Providing Coverage for Lymphedema Treatments" Companion bills: Senate Bill No. 848 & House Bill No. 1309, Provided for: The Joint Committee on Insurance Division of Health Care Finance and Policy Commonwealth of Massachusetts.



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An Estimate of Healthcare Savings which could be achieved through Proper Lymphedema Management

The underlying principle behind the analysis is the assumption that management of lymphedema results in an immediate and significant reduction in the incidence of lymphedema-related infection. The ongoing cost of treatment of lymphedema is balanced out by the savings due to avoidance of the necessity of treating recurring cellulitis, frequently on an emergency basis.

A number of separate approaches have been taken to arrive at a credible estimate of the potential savings to be achieved. The first approach (Appendix A) was to postulate two lymphedema treatment scenarios for a woman diagnosed with and treated for breast cancer. The first scenario postulates that she receives early and continued treatment of her lymphedema according to the recommended guidelines. The second scenario postulates that she receives no treatment for her lymphedema, but does receive medical treatment for her recurrent lymphedema-related infections. Data to support both scenarios are derived from statistics taken from recent scientific journals. The results of this study establishes, for this hypothetical case, a significant saving to her medical provider when the lymphedema is treated and managed.

Infection of the skin and lymphatic system (cellulitis/lymphangitis) is a major cause of lymphedema. It is also a major result of lymphedema. (Stoberl & Partsch 1987). Some 10-15% of lymphedema patients experience infections each year (Swenson et. al. 2002, Kasseroller 1998). Therefore one might expect 30,000-45,000 cellulitis cases yearly from 300,000 lymphedema patients in California (Appendix C). Hospital discharges for 2003 involving cellulitis of all sites and from all causes were 111,438. The average hospital stay for cellulitis was 5 days (Hospital Discharge Data 2002). At an average hospital stay cost per patient per day in California of \$1763 (2003 AHA Annual Survey) this places the yearly burden for treatment of cellulitis in California at almost 1 Billion dollars, with \$264-397 million estimated as related to lymphedema. If the incidence of cellulitis is reduced by 50% through the treatment of lymphedema (Ko et. al. 1998, Foeldi 1996) a \$132-200 million saving would result, not accounting for medication cost savings or savings due to reduced disability.

Another approach taken was an attempt to extend this principle to a large population by examining actual hospital admissions data to attempt to size the burden of unmanaged lymphedema and the savings to be achieved for a larger population by treating the lymphedema. This study utilized the Patient Discharge Data for Calendar Year 2003 maintained by the California Office of Statewide Health Planning and Development. Total number of patient discharges in 2003 involving cellulitis of the arm or hand (ICD-9-CM Codes 682.3 and 682.4) were 18,876. Of this total, 307 cases involved upper limb lymphedema or swelling. These 307 cases involved an average hospital stay of 5.6 days for a total cost of \$8,271,398. The total number of patient discharges in 2003 involving cellulitis of the leg and foot (ICD-9-CM Codes 682.6 and 682.7) were 62,056. Of this total, 1851 cases involved lower limb lymphedema or swelling. These 1851 cases involved an average hospital stay of 10.4 days for a total cost of \$62,814,399. Similar relationships are shown between discharges with cellulitis of the lower limbs and various surgical procedures e.g.: hip and knee replacement and hysterectomy 224 cases at \$25,262,301 cost; and coronary artery by-pass grafts 265 cases at \$66,224,482 cost. Each of these infections is a lymphedema risk factor. Adding up the costs of only the cases of cellulitis documented as being related to lymphedema or swelling, yields a total of \$162,571,000 in treatment of lymphedema-related cellulitis, well within the \$132-200 million range of savings calculated using a different analysis using different data sets.

An estimate was made as to the cost of providing lymphedema treatment to the estimated lymphedema patients in California. Hinrichs found that the distribution of severities was 75% mild (Stage 1), 22% moderate (Stage 2) and 3% severe (Stage 3). Yearly costs of treatment developed in the hypothetical breast cancer scenario (Appendix A) were \$200 for Stage 1, \$1550 for Stage 2 and \$5500 for Stage 3. Applying the observed distribution of severity of lymphedema



[Hinrichs 2004] to the estimated 300,000 California lymphedema patients and using the estimated costs of treatment, yields an annual cost of lymphedema treatment if all patients were to be diagnosed and treated of \$197 million. These estimated costs are in the range of estimated savings using statistics in scientific journals and hospital databases.

So the bottom line is that treatment of lymphedema is cost neutral and has the potential of saving money, providing a significantly improved quality of life for lymphedema patients and reducing the burden of disabilities resulting from late-stage lymphedema. Further references to the cost-efficacy of lymphedema treatment are found in the annotated references of Appendix B.

[The work described here was adapted from the Paper “Three Methods for the Cost-Efficacy Analysis of Lymphedema Treatment”, Robert Weiss, M.S. Presented at the American Society of Lymphology 2007 Annual Conference, Kansas City, MO, Nvember 26-8, 2007.]

APPENDIX A
STRUCTURE FOR A COST-EFFICACY STUDY OF LYMPHEDEMA TREATMENT

ASSUMPTIONS:

- Patient diagnosed and treated for breast cancer at 40 years of age
- Patient lives to 80 years of age
- Assume two different scenarios for post-mastectomy lymphedema treatment:
 - Patient receives early and continual lymphedema treatment
 - Patient does not treat lymphedema, but treats lymphedema-related infections

DEVELOPMENT OF TREATMENT COSTS:

- Costs postulated for Phase I (clinical) and Phase II (home) Treatment.
 - Phase I costs include 2-week course of CDT @ \$1000, 1 compression sleeve @ \$100, 1 bandaging kit @ \$150 = \$1250.
 - Phase II annual costs depend on Stage of LE.
 - +Stage 1 (less than 2cm) costs include 4 Medi or Juzo compression sleeves per year @ \$50 = \$200/year.
 - +Stage 2 (between 2-10cm) costs include 4 Elvarex compression sleeves @ \$150, 1-week CDT course @ \$500, 3 bandaging kits @ \$150 = \$600+500+450= \$1550/year.
 - +Stage 3 (greater than 10cm) costs include 6 Elvarex compression sleeves @ \$150, 6-weeks of CDT @ \$500 / week, 4 bandaging kits @ \$150, Pneumatic compression pump \$5000/5 years = \$900+3000+600+1000=\$5500/year.
- Assumed cost of treatment of an infection in emergency room setting including intravenous antibiotic, 2-week course of oral antibiotic, followup office visits, physical therapist = \$5000.

LYMPHEDEMA PROGRESSION SCENARIOS:

- Incidence of infection (cellulitis/lymphangitis) depends on stage and treatment. Each infection further scars the lymphatic system and advances the stage of the lymphedema.
 - Untreated
 - +Stage 1: 1 infection which ends Stage 1 and initiates Stage 2;
 - +Stage 2: 1 infection every 2 years;
 - +Stage 3: 2 infections per year.
 - Treated
 - +Stage 1: 1 infection which ends Stage 1 and initiates Stage 2;
 - +Stage 2: 1 infection every 5 years;
 - +Stage 3: 1 infection every 2 years

SCENARIOS COSTED FOR 40 YEARS OF SURVIVAL:

- SCENARIO #1- Lymphedema after breast cancer is NOT TREATED:
 - Stage 1 (less than 2cm) for 2 years, followed by;
 - Stage 2 (between 2-10cm) for 6 years, followed by;
 - Stage 3 (greater than 10cm) for remaining 32 years.



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- SCENARIO #2- Lymphedema after breast cancer IS TREATED:
 - Stage 1 (less than 2cm) for 5 years, followed by;
 - Stage 2 (between 2-10cm) for remaining 35 years.

COST SUMMATIONS

- Cost for Scenario #1:
 - 2 years @ Stage 1, 1 infection: $5000 = \$5,000$
 - 6 years @ Stage 2, 3 infections: $3 \times \$5000 = \$15,000$
 - 32 years @ Stage 3, $64 \times \$5000 = \$320,000$
 - Total cost for 40 years $\$340,000$
- Cost for Scenario #2:
 - 5 years @ Stage 1, 1 infection: $5000 + 5 \times \$200 = \$6,000$
 - 35 years @ Stage 2, 7 infections: $7 \times \$5000 + 35 \times \$1,550 = \$89,250$
 - Total cost for 40 years $\$95,250$

- Net Cost of Lymphedema Treatment over 40-year Breast Cancer Survivor’s survival lifetime:
 - $\$95,250$ minus $\$340,000$ equals NEGATIVE $\$244,750$ (Savings for illustrative patient)
 - Cost Ratio = 3.57 (no LE treatment / LE treatment)

The estimates for the cost of treating one infection are low, perhaps by a factor of two or three. The cost differentials would be much more dramatic if these higher figures were to be used. The above analysis does not include the disability and loss of wages or the pharmaceutical costs for pain management due to not treating or under-treating lymphedema.



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LYMPHEDEMA TREATMENT COST-EFFECTIVITY REFERENCES

Boris, MD, M., Weindorf, MD, S., Lasinski, M.A., P.T., B.: “Persistence of Lymphedema Reduction After Complex Lymphedema Therapy”, (1997) *Oncology*, Vol. 11, No. 1, January 1997, pp. 99-109, discussion pp. 110, 113-114. Three case reports document dramatic decreases in incidence of hospitalizations for treatment of cellulitis for three patients treated by CDT.

Brinkman DF, Moore C and Harkins SE: Cost Effectiveness of a lymphedema program in home care” *National Lymphedema Network LYMPHLink* Jan-Mar 2010;22(1):8-9. Study of 30 lymphedema patients treated between August 2002 and April 2004 in a home care setting demonstrated a substantial reduction in average nursing visits (144 to 5.2), average nursing cost (\$13,000 to \$701), Rehabilitation costs (\$2210 to \$206) and total agency cost (\$13,000 to \$533).

Campisi C, Boccardo F, Zilli A, Maccio A, Napoli F: “The use of vein grafts in the treatment of peripheral lymphedemas: long-term results”, *Microsurgery*. 2001;21(4):143-7. Study of 665 patients with microsurgical lymphatic-venous anastomoses for obstructive lymphedema with 446 patients available for long-term follow-up. Average follow-up of greater than 7 years showed average reduction in excess volume of 69%. There was an 87% reduction in the incidence of cellulitis.

Campisi C, Boccardo F, Zilli A, Maccio A, Napoli F: “Long-term results after lymphatic-venous anastomoses for the treatment of obstructive lymphedema”. *Microsurgery* 2001;21(4):135-9. Over the past 25 years, 665 patients with obstructive lymphedema have been treated with microsurgical lymphatic-venous anastomoses; of these, 446 patients were available for long-term follow-up study. Objective assessment was undertaken by water volumetry and lymphoscintigraphy. Lymphangiography, lymphangiography (in patients with gravitational reflux pathology), and echo-Doppler were used preoperatively. Subjective improvement was noted in 578 patients (87%). Objectively, volume changes showed a significant improvement in 552 patients (83%), with an average reduction of 67% of the excess volume. Of those patients followed up, 379 patients (85%) have been able to discontinue the use of conservative measures, with an average follow-up of more than 7 years and average reduction in excess volume of 69%. There was a 87% reduction in the incidence of cellulitis after microsurgery.

Casley-Smith, J. R. PhD, MD, Boris, M., MD, Weindorf, S. MD, Lasinski, B. MA, PT: “Treatment for Lymphedema of the Arm—The Casley-Smith Method, A Noninvasive Method Produces Continued Reduction”, (1998) *Cancer (Supplement)* Vol. 83, No. 12, Dec 15, 1998, pp. 2843-2860. Costs per year and effectivities of a 4-week course of CDT treatment was presented, including costs of bandages and garments (Figure 9). Average costs for different treatments ranged from \$2000-3000 per year with 40% to over 100% reductions of initial edema. Cost ranges from savings (negative costs) to \$7000 per year for various alternative treatment protocols.

Daane, S. MD, Poltoratszy, P. RPT, CPT, Rockwell, W. B. MD: “Post-mastectomy Lymphedema Management: Evolution of the Complex Decongestive Therapy Technique”, *Ann Plast Surg*, Feb 1998, Vol 40, No. 2, pp. 128-134. Treatment was an average of 15.3 visits per patient over a period of 3-4 weeks, with an average cost of \$1513. The duration of each treatment session was from 45 minutes to 1 hour. The goals of therapy are to control edema, to prevent infection and to improve function. Each inflammatory episode can exacerbate lymphatic fibrosis.

Földi MD, E.: “Prevention of Dermatolymphangioadenitis by Combined Physiotherapy of the Swollen Arm after Treatment of Breast Cancer”, *Lymphology*, 1996, Vol. 29, pp. 91-94. Study of medical records of 150 breast cancer patients with arm lymphedema in the years 1990-1994. Conclusion were that in women with arm lymphedema after treatment of breast cancer, recurrent Dermatolymphangioadenitis (DLA) attacks [cellulitis/lymphangitis infections] can nearly be eliminated by improvement in arm swelling by combined physiotherapy (CPT) Phase I. If these women are free of skin risk factors [unrelated to the lymphedema] such as psoriasis, neurodermatitis, varicose lymphatics, lymph fistulae and/or fungal overgrowth, continued CPT (Phase II) maintains reduction of edema and prevents further DLA episodes.



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Ko, MD, D. S. C., Lerner, MD, R., Klose, CCDPI, G.; Cosimi, MD, A. B.: "Effective Treatment of Lymphedema of the Extremities"; Arch of Surgery, April 1998; Vol. 133, pp. 452-458. 299 patients referred for evaluation of lymphedema of the upper or lower extremities were treated with CDT for an average duration of 15.7 days. Lymphedema reduction was measured following treatment and at 6- and 12-month follow-up visits. The incidence of infections decreased from 1.10 infections per patient year to 0.65 infections per patient year after a complete course of CDP [Phase I and Phase II] (Table 2).

Krishnamoorthy K: "Estimated costs of acute adenolymphangitis to patients with chronic manifestations of bancroftian filariasis in India." Indian J Public Health 1999 Apr-Jun;43(2):58-63.

In India, lymphatic filariasis persists as a major cause of clinical morbidity and as an impediment to socio-economic development. The direct costs incurred for the treatment of adeno-lymphangitis (ADL) episodes and the consequent indirect costs due to loss of income were determined from selected agricultural labour-intensive rural endemic pockets in Tamil Nadu. Information on the occurrence of ADL, its frequency and duration were collected using semi-structured questionnaire from randomly selected patients afflicted with chronic manifestations of bancroftian filariasis. Direct (treatment) cost per year per patient was found to range from Rs. 30 to 101 among patients with different manifestations. Income foregone (indirect cost) annually by each patient, which is a function of frequency and duration of ADL ranged from Rs. 182 to 702. ADL episodes among filarial patients alone cost a minimum of Rs. 4515 million for the nation every year. Cost benefit analysis of filariasis control programme in India showed that the benefits in terms of savings on treatment and work lost due ADL alone exceeded the cost by 24%. The per capita cost of the National Filaria Control Programme was calculated to be Rs. 2.6 per annum.

Lerner, R. MD: "Complete Decongestive Pysiotherapy and the Lerner Lymphedema Services Academy of Lymphatic Studies (the Lerner School)", (1998) Cancer (Supplement) Vol. 83, No. 12, Dec 15, 1998, pp. 2861-2863. "By employing [the Foeldi] method of CDP we have been given a treatment modality that achieves a greater than 80% long term success rate without morbidity or mortality and without disfigurement of any kind. We have been able to do this for a reasonable cost, and, by transferring the future care of the lymphedema patient away from the doctor/hospital setting, we have produced a very cost effective method of caring for this long-term, chronic disease."

Miller SR, Mondry T, Reed JS, Findley A, Johnstone PA. Delayed cellulitis associated with conservative therapy for breast cancer. J Surg Oncol. 1998 Apr;67(4):242-5.

Delayed breast cellulitis is an infrequently reported entity after conservation therapy for breast cancer. We describe our experience with this entity at Naval Medical Center, San Diego. Eight patients who presented with delayed cellulitis after wide local excision/axillary dissection and breast radiotherapy (RT) are presented. Their clinical characteristics and therapy are described and possible causative factors are analyzed. The latency of breast cellulitis is variable after breast conservation therapy, although most cases in our experience and in the literature occur within a year post-RT. These infections are frequently refractory to a single course of antibiotics (n = 4 cases in our experience). Some patients suffer multiple episodes separated by months. Breast cancer patients are at risk for delayed cellulitis after conservative surgery and RT. The mechanism of such events probably involves lymph stasis, however, therapy is no different from the more frequently occurring cases of cellulitis presenting perioperatively.

O'Brien BM, Mellow CG, Khazanchi RK, Dvir E, Kumar V, Pederson WC.: "Long-Term Results after Microlymphaticovenous Anastomoses for the Treatment of Obstructive Lymphedema," J Plastic and Reconstr Surg, 1990, Vol. 85, No. 4, pp. 562-72. Over the last 14 years, 134 patients with obstructive lymphedema have been treated with microlymphaticovenous anastomoses. Ninety patients were available for long-term follow-up study. Of these, 52 patients were treated by microlymphatic surgery only and 38 of them also had segmental or radical reduction surgery, either at the same time or secondarily. Objective assessment was undertaken by volume and circumferential measurements. Initially, lymphangiography was used, but a study demonstrated increased edema immediately following the investigation in one-third of the patients and it was abandoned, both preoperatively and postoperatively.



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In the microlymphaticovenous anastomoses only group (N = 52), subjective improvement occurred in 38 patients (73 percent). Objectively, volume changes showed a significant improvement in 22 patients (42 percent), with an average reduction of 44 percent of the excess volume. In the microlymphaticovenous anastomoses and reduction surgery, usually segmental, group (N = 38), subjective improvement occurred in 30 patients (78 percent) and objective improvement occurred in 23 patients (60 percent), with an average reduction of 44 percent of the excess volume. Of those followed up, 67 patients (74 percent) have been able to discontinue the use of conservative measures, with an average follow-up of 4.0 years and average reduction in excess volume of 26 percent. There was a 58 percent reduction in the incidence of cellulitis following surgery. In those patients who were improved, drainage resulted in increased softness of the limbs. Edema of the hand diminished considerably in most patients, although this was difficult to measure. These long-term results indicate that microlymphaticovenous anastomoses have a valuable place in the treatment of obstructive lymphedema and should be the treatment of choice in these patients. Reduction surgery can be used as an adjunct in some of these patients, especially in the posteromedial aspect of the upper arm. Liposuction has been used in failed cases or in patients in whom no lymphatics could be found. Improved results can be expected with earlier operations because patients referred earlier usually have less lymphatic disruption.

Reid T: "Treatment of Lymphedema and Recurrent Cellulitis", Case Report presented at the Second National Lymphedema Network Conference, Sept 1996. 31 year old patient with lymphedema due to multiple knee injuries and surgeries spent 152 days in hospital between May 1994 and November 1995. After 5 months of treatment with Reid manually-adjustable compression sleeve, she had no further events of cellulitis and was able to be taken off antibiotics. Cost effectiveness analysis showed savings over 5 months to exceed \$90,000-\$130,000 based on hospital cost of \$2-3,000/day.

Thiadens SRJ, Rooke TW, Cooke JP: "Lymphedema" in Current Management of Hypertensive and Vascular Diseases (1992) Mosby Yearbeck, Inc., St. Louis, MO. pp. 314-319. In a retrospective study of 304 lymphedema patients, over 25 percent had incurred an episode of cellulitis over a period of 3 years.



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