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June 21, 2015

Senator Orrin G. Hatch, Chairman  
Senator Ron Wyden, Ranking Member  
Senator Johnny Isakson  
Senator Mark R. Warner  
United States Senate Committee on Finance  
Washington, DC 20510-6200  
Sent to the Senate Finance Committee Chronic Care Reform at [chronic\\_care@finance.senate.gov](mailto:chronic_care@finance.senate.gov)

Esteemed Senators Hatch, Wyden, Isakson and Warner,

We thank you for your efforts to improve health care for patients with chronic conditions.

My wife Pearl and I are in our eighties and have been receiving care from a Medicare Advantage organization for the last 15 years. Mrs. Weiss is a survivor of breast cancer and has chronic lymphedema as a result of the cancer therapy that saved her life 23 years ago. I am a lymphedema patient advocate and I have dedicated my life to assuring that Mrs. Weiss continues to receive the care she needs for her chronic lymphedema, and to help the millions of other lymphedema patients, who have no advocacy, receive quality care according to current medical standards.

Besides being a member of your target population, I am a contributor to the technical literature on healthcare delivery in the United States, having recently published a review of lymphedema care delivery models and economic analyses of the costs and benefits of lymphedema treatment [Stout 2013]. I have assisted in the drafting and passage of lymphedema treatment laws in California, Connecticut, Georgia, Massachusetts, New York and Virginia, and have written a bill for the coverage of lymphedema treatment by Medicare [Lymphedema Diagnosis and Treatment Cost-Saving Acts of 2010 and 2011 [H.R. 4662 and H.R. 2499] And finally, I maintain a web page for the benefit of lymphedema patients and the therapists who treat them. [<http://www.lymphactivist.org>]

Rather than reiterating all of the reasons why lymphedema care delivery is problematic I would like to quote the abstract of a recent peer-reviewed paper dealing with the same problem experienced by Canadian lymphedema stakeholders. I would estimate that the number of lymphedema patients in the U.S. are at least ten times the Canadian lymphedema population.

“Even though it is estimated that at least 300 000 people in Canada may be affected by chronic oedema/lymphoedema, recognition of the seriousness of this chronic disease in health care is scarce. Lymphoedema affects up to 70% of breast and prostate cancer patients, substantially increasing their postoperative medical costs. Adding to this problem are the escalating rates of morbid obesity across North America and the fact that 80% of these individuals are thought to suffer with an element of lymphoedema. The costs related to these patient populations and their consumption of health care resources are alarming.

“Untreated chronic oedema/lymphoedema is progressive and leads to infection, disfigurement, disability and in some cases even death. Thus, prognosis for the

patient is far worse and treatment is more costly when the disease is not identified and treated in the earlier stages. Although the number of individuals coping with chronic oedema/lymphoedema continues to increase, the disparity between diagnosis, treatment and funding across Canada endures. The reasons for this include a lack of public awareness of the condition, insufficient education and knowledge among health care providers regarding aetiology and management and limited financial coverage to support appropriate methods and materials.” [Keast 2015]

Lymphedema is a chronic, progressive condition, often leading to disability if untreated or undertreated. Lymphedema often is caused by damage to the lymphatic system by trauma, surgery, radiotherapy, certain chemotherapeutic agents, or infection. It starts with lymph stasis caused by: an inability of the initial lymphatics to collect tissue fluid; the inability of the lymph vessels to transport adequate fluid; lymphatic valve dysfunction; fibrosis or removal of lymph nodes; fibrosis of surrounding tissue, abnormal lymphatic loads because of venous insufficiency or hypertension; lymphatic scarring due to infection; abnormal deposition of lipid cells or obesity. [Mortimer 2014]

The incidence of lymphedema and the medical cost of treating lymphedema in breast cancer patients was estimated the using claims data [Shih 2009]. The study found that the two-year medical costs are significantly higher for patients with lymphedema (\$23,167) compared to those breast cancer survivors without lymphedema (\$14,877).

Lymphedema, thought of in the past as a “blockage in the lymphatic plumbing” is increasingly found to be a condition intimately related to cardiovascular dysfunction, metabolic disease and diabetes, immune system function, wound healing, fat deposition and obesity. [Mortimer 2014] Patients with lymphedema were twice as likely to have lymphangitis or cellulitis, known to contribute to a more advanced condition and to compound medical costs. Treatment of lymphedema has been found to reduce or eliminate the incidence of cellulitis [Ko 1998, Földi 1996].

Standard treatment for lymphedema includes use of multiple tools depending on the stage, severity, source and duration of the lymphedema. Typically, an intensive phase of treatment is performed in an outpatient clinical setting by a specially-trained therapist involving manual lymph drainage (MLD), compression bandaging, decongesting exercises, patient education and meticulous skin care. The intensive phase is followed by a home care maintenance phase comprising a combination of self-MLD, self-bandaging and/or wearing of compression garments, decongesting exercises and meticulous skin care. [ISL 2013, NLN 2011, etc.]

“Lymphoedema is multi-faceted, each patient is strongly unique in the presentation and often in the combination of symptoms and associated sequelae, each patient responds to an intervention differently and each has different treatment and management preferences either forced on them by finances or the availability of treating staff. Often then there is a gulf between what might be able to be done optimally and what can be done in reality.” [Piller 2003]

For this reason the treating physician and therapists must have a wide selection of tools to use for treating a particular patient at a particular stage of the condition. A grave mistake is made in looking for one “best treatment” (e.g. MLD, bandaging, compression garments, exercise, sequential compression devices) based on a controlled clinical trial on a limited sample of patients. The treating

physician and trained lymphedema therapist are the only judges of what combination of protocols are called for and are likely to lead to the best measured outcome. This parallels treatment of cancer, where the treating medical team decides how much of which modality (surgery, radiotherapy, chemotherapy, hormonal therapy) is required based on the individual patient's condition.

Not all of these elements of the standard of lymphedema care are covered by Medicare in spite of evidence supporting with an intermediate level of confidence that complex decongestive therapy (CDT) alone, CDT with adjuvant compression devices, compression bandaging/compression garments alone, and pneumatic compression devices alone "produce clinically meaningful improved health outcomes for patients with secondary lymphedema" [MEDCAC 2009].

The specialized nature of manual lymph drainage and compression bandaging is not recognized by Medicare and there are no specialized CPT codes to describe these services. Therapy is statutorily limited for lymphedema treatment despite its being a treatment of a diagnosed medical condition and not necessarily rehabilitation. Compression bandages and garments are not covered and the services of measurement and fitting of these necessary medical items is also not covered.

Evidence is emerging in the last few years that early treatment of pre-clinical lymphedema has the potential of preventing or slowing progression to more severe stages and avoiding the permanent tissue changes that result from long-standing lymph stasis (lymphedema). [Box 2002, Stout-Gergich 2008, Boccardo 2009, Torres-Lacomba 2010, Zimmermann 2012]. Methods for measurement of pre-clinical lymphedema (e.g. skin thickness measurement by ultrasound or magnetic resonance imaging, bioelectric impedance, tissue dielectric constant, ultrasonic tonometry, dual beam X-ray absorptiometry, indocyanine green-enhanced lymphography, lymphangioscintigraphy, etc.) are in use in other countries and are not used widely in the U.S.

Hard evidence is also starting to emerge that early treatment of lymphedema reduces adverse clinical outcomes and costs. Using insurance claims data on a population of 1,065 individuals with cancer-related lymphedema, it was shown that introduction of a sequential pneumatic compression device for the treatment of lymphedema decreased annual rate of hospitalization from 45 to 32%, outpatient hospital visits from 95 to 90%, cellulitis diagnoses from 28 to 22%, physical therapy use from 50 to 41%, and annual health care costs from \$62,190 to \$50,856 [Table 3 of Brayton 2014].

A major barrier to quality care for chronic lymphedema patients was removed with the settlement of the *Jimmo v. Sebelius* case. Previously treatment of chronic lymphedema patients required a measured or potential improvement in outcome, but the rules regarding maintenance therapy were changed effective 01-07-14 when the following was added to Chapter 7, §20.1.2 of the Medicare Claims Processing Manual:

“Coverage of skilled nursing care or therapy to perform a maintenance program does not turn on the presence or absence of a patient's potential for improvement from the nursing care or therapy, but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, to prevent or slow further deterioration of the patient's condition.”

It is because of these data on the current burden of chronic lymphedema on the American healthcare system and the demonstrated benefits of early treatment of lymphedema before it becomes disabling,

that we feel that a reform to the current Medicare coverage policies for lymphedema complement and should be a part of your efforts to reduce the staggering costs of treating patients with multiple chronic conditions. Efforts to **reduce the costs of treatment** of chronic disease should include measures to **prevent** chronic disease from becoming disabling.

***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. [Please see the Appendix]***

Our suggestions are grouped to respond to your stated three goals:

1. Increase care coordination among individual providers across care settings;
2. Streamline Medicare's current payment system to incentivize appropriate level of care for patients with chronic conditions; and
3. Facilitate delivery of high quality care, improve outcomes, increase program efficiency, and reduce growth in Medicare spending.

### **Increase Care Coordination**

- Lymphedema should be added to the CMS list of 25 chronic diseases [Ref [https://www.medicalschemes.com/medical\\_schemes\\_pmb/chronic\\_disease\\_list.htm](https://www.medicalschemes.com/medical_schemes_pmb/chronic_disease_list.htm)];
- ICD-10-CM diagnostic codes for lymphedema should be expanded to enable medical recording of site, severity and cause of lymphedema. The 3-6 current diagnostic codes are not adequate to guide development of rational treatment decisions and plans;
- Lymphedema-aware providers should be included in chronic care coordinating teams;
- Lymphedema is included in only 4 of the 24 breast cancer survivorship guidelines reviewed by the IOM in their landmark study on breast cancer survivorship [Table 2-3 in Hewitt 2006]. Lymphedema information must be made a requirement in cancer survivor transition plans;
- The *Jimmo v. Sebelius* Settlement decision must be fully implemented to assure that skilled therapy be covered when there is a medical need even when there is no prospect for improvement as a means of preventing deterioration or worsening of medical conditions such as lymphedema;

### **Streamline Medicare Payment System**

- Cover lymphedema compression bandage systems, garments, devices and supplies as “prosthetic devices” per SSA §1861(s)(8) as defined in the Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, §120 Prosthetic Devices;
- Develop separate policies for the treatment of lymphedema that recognize the uniqueness of treatment for this condition. Policies should reimburse for bandaging, garment measurement and fitting, special decongestive exercises and patient education in home care. They should coordinate the lymph decongestion therapy with the use of sequential pneumatic devices.
- Development and acceptance of objective and subjective outcome measurement instruments be encouraged for measurement of the severity of lymphedema, as opposed to severity of functional disability, for the purpose of ensuring efficacy of lymphedema treatment services for pre-clinical and chronic disease at all body sites where it may occur (breast, trunk, abdomen, external genitalia, head, neck, face as well as upper and lower limbs). Only by measuring lymphedema outcomes, instead of disability, can proper reimbursement schemes be developed that reflect the efficacy of lymphedema treatment.

### **Facilitate High Quality Care**

- Medicare must cover the universally-accepted protocols of complex decongestive therapy (CDT) for lymphedema treatment [NLN 2011, ISL 2013];
- Consider lymphedema treatment the same as treatment of other diagnosed diseases and separate it from rehabilitative services which demand improvement from a limited number of treatments.
- Medicare coverage should include a variety of measurement and treatment services to allow the treating physicians and treating therapists to determine which combination of modalities are indicated for each patient to arrive at a written plan of treatment, and to select the appropriate measurements to measure progress against that plan;
- Lymphedema treatment should be restricted to therapists trained in lymphedema protocols;

### **Technology Advances**

- Encourage development and use of methods for detecting and measuring early, preclinical lymphedema for identification of patients at high risk, with the goal of prevention of lymphedema by early intervention;

### **Epidemiology of Lymphedema**

- Request that the CDC perform a study of the prevalence and severity of lymphedema. The study should answer questions such as:
  - What is the current number of lymphedema sufferers in the U.S.?
  - What is the distribution of lymphedema between primary and secondary?
  - What is the distribution of severities?
  - For primary and secondary what is the distribution between lower limb, upper limb, abdomen, external genitalia, chest and breast, head and neck, facial, whole body lymphedema?

***Lymphedema Treatment is Good Business as well as Good Medicine***

Respectfully submitted,

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Robert Weiss, MS  
Independent Lymphedema Patient Advocate

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Pearl Hiat Weiss, BA, BRE  
Breast Cancer Survivor, Lymphedema Patient

**APPENDIX**  
**An Estimate of Healthcare Savings Achievable Through  
Proper Lymphedema Management**

[http://www.lymphactivist.org/potential\\_savings.php](http://www.lymphactivist.org/potential_savings.php)

The underlying principle behind this 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 cost 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 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 recommended medical 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. 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 1998, Földi 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 California 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) was 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) was 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 a hypothetical breast cancer scenario 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.

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