January 13, 2016

The Honorable Orrin Hatch
Chairman
Senate Finance Committee
Room 219 Senate Dirksen Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
Room 219 Senate Dirksen Building
Washington, DC 20510

The Honorable Johnny Isakson
Room 131 Senate Russell Building
Washington, DC 20510

The Honorable Mark R. Warner
Room 475 Senate Russell Building
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden and Senators Isakson and Warner:

Pursuant to the Senate Finance Committee's release of the Chronic Care Working Group (CCWG) Options Document, we are pleased to submit comments from the Lymphedema Advocacy Group. We applaud your efforts in examining the Medicare fee-for-service program. We are especially interested in working with you on policy changes aimed at better serving beneficiaries suffering from chronic medical conditions. Our nation's health care delivery system is transforming rapidly. Engaging health care stakeholders in such a campaign is vital, particularly as new trends and cost effective therapies become available.

Currently, Medicare beneficiaries diagnosed with lymphedema contend with a set of fragmented rules and regulations. In a 2001 Centers for Medicare and Medicaid Services (CMS) memo related to lymphedema pumps (CAG-00016N),[1] the agency states: "The keystones of lymphedema treatment are elevation, compression and exercise. Encourage patients to use compression garments between pump sessions to prevent re-accumulation of fluid." One year later, the agency also issued a National Coverage Determination notice recognizing the importance of compression garment therapy in conjunction with pneumatic pumps.[2] Yet, despite the announcement and repeated inquiries by Congress to the Secretary of Health and Human Services, compression supplies remain uncovered under the Medicare Durable Medical Equipment program or another benefit category.

Lymphedema afflicts millions of Americans including men, women, and children who can be born with a primary form. The majority of cases, however, are secondary, caused most often by cancer treatments that damage the body's lymph transport and immune functions. Other causes include trauma / injury, chronic venous insufficiency, lymphatic infection, congenital malformations and

[1] http://www.cms.gov/medicare-coverage-database/%28S%283iepps3hnwcrz5es0ppyu045%29%29/details/nca-decision-memo.aspx?NCAId=50&ver=6&NcaName=Lymphedema+Pumps&NCDId=190&ncdver=2&IsPopup=y&bc=AAAAAAAAEAAA&

[2] CMS Decision Memo: National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6); January 14, 2002. Link: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&NCAId=63&IsPopup=y&bc=AAAAAAAAAgAAAA%3D%3D&

obesity.[3] The end result is an accumulation of protein-rich lymph fluid in parts of the body where lymph nodes or lymphatic vessels are damaged or inadequate.

A 2010 peer-reviewed study in the American Cancer Society's *Cancer* journal, states that ''lymphedema is a common post-treatment condition [and] has been described as one of the most significant survivorship issues.'' The study found an overall cancer-related lymphedema incidence rate of 15.5 percent, with specific rates as follows: sarcoma 30 percent, breast 20 percent, gynecological 20 percent, melanoma 16 percent, genital-urinary 10 percent, and head and neck 4 percent. Risk increased by 22 percent after pelvic lymph node removal and 31 percent after radiation therapy. Lymphedema is progressive when left untreated or under-treated, and it can put patients at greater risk for serious infections or other costly complications.

The only exception in coverage is for those beneficiaries diagnosed with breast cancer-related lymphedema post mastectomy and reconstruction surgery. This was included under the Women's Health and Cancer Rights Act of 1998, which requires group health plans, insurance companies, and health maintenance organizations to cover comprehensive lymphedema treatment regimens. This coverage does not extend to Medicare beneficiaries with breast cancer-related lymphedema.

Given the rising number of Medicare beneficiaries living with lymphedema – approximately 1.5 million with projections as high as 3 million – legislation has been introduced providing coverage of compression garment therapy when prescribed by a physician. Recently, Senators Maria Cantwell, Chuck Grassley, Chuck Schumer and Mark Kirk introduced S. 2373, the *Lymphedema Treatment Act*. Similarly, Representatives Reichert, Blumenauer, Lance and Schakowsky introduced H.R. 1608, which as of press time boasts 176 bipartisan cosponsors.

As seniors live longer and cancer survivorship increases, compression therapy will become an even more essential component to managing this chronic disease. Many lymphedema patients cannot maintain their condition and experience an unnecessary loss of health and of function in the activities of daily living.

We encourage you to include lymphedema treatment in the CCWG's review process. As the Senate Finance Committee seeks comments to improve outcomes for Medicare patients with chronic conditions, the Lymphedema Advocacy Group and its stakeholders look forward to working with you on closing the Medicare coverage gap for lymphedema. Enclosed please find additional clinical evidence demonstrating the effectiveness and reduced hospitalization attributed to compression therapy. If you have any questions or need additional information, please feel free to contact me or visit www.LymphedemaTreatmentAct.org.

Sincerely,

Heather Ferguson

Heather Ferguson
Executive Director, **Lymphedema Advocacy Group**
Heather@LymphedemaTreatmentAct.org
704-965-0620

Enclosures: Compilation of Medical Literature and Chronic Care Management

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

Compression in the Treatment of Lymphedema:
Evidence for Effectiveness and Reduced Healthcare Expenditure

Compression is an integral component of the standard of care for the treatment of lymphedema known as **Complete Decongestive Therapy (CDT)**. The first six documents outlined below summarize several position papers, reviews, and consensus documents, all of which recognize the necessity of compression for patients with lymphedema. The remaining documents reveal the fact that lymphedema, especially in *preventable* advanced stages, is costly, and that compression therapy reduces disease progression, complications, and the associated cost of care.

1. International Lymphedema Framework (2010): *Compression Hosiery (Garments) in Lymphedema*[1]

The authors reviewed the published evidence for efficacy of compression garments and concluded the following:

- Studies with follow-up periods of six months to five years indicate that compression garments are effective in reducing and/or maintaining lymphedema of the arm and leg both in primary and secondary lymphedema.
- Compression hosiery (garments and arm sleeves) are an integral part of lymphedema management with strong evidence to support their use.
- Outcomes are less optimal in lymphedema management when compression therapy is not used.

2. MEDCAC Meeting on Lymphedema Treatment Protocols (2009)[2]

A Medicare Evidence Development Coverage Advisory Committee (MEDCAC) meeting was held on November 18, 2009. The committee reviewed the Agency for Healthcare Research and Quality's (AHRQ) technology assessment of the efficacies of lymphedema diagnosis and treatment protocols. They also heard scheduled testimony of 15 leading experts on lymphedema as well as a number of unscheduled stakeholders and experts.

- The committee reports that the greatest confidence, for the best outcome, was in Complete Decongestive Therapy[7], of which compression is an integral component (page 14 of meeting transcript)[8].

- When isolating individual modalities of treatment, the committee reports the highest level of confidence was found in compression (page 5 of meeting tables)[7].

3. International Lymphedema Framework (2012): *Compression Management, A Position Document on Compression Bandaging* [3]

The authors note the following regarding compression bandaging and garments:

- Lymphedema requires constant compression, if discontinued edema will recur rapidly.
- Compression removes edema by a reduction in capillary filtration, an increase in lymphatic drainage, a shift of fluid to non-compressed areas, and via a breakdown of fibrosclerotic tissue.
- Patient understanding and adherence are critical to sustained outcomes.
- Once swelling is maximally reduced, long term compression garments are required.

4. National Lymphedema Network Position Statement on The Diagnosis and Treatment of Lymphedema[4]

- The gold standard for the treatment of lymphedema is known as Complete Decongestive Therapy.
- Compression Bandaging is always a requisite part of Complete Decongestive Therapy.
- Following achievement of maximal volume reduction with Complete Decongestive Therapy, patients should be fitted with a compression garment.

5. Cochrane Review of the Effectiveness of Various Lymphedema Therapies[5] **(2008)**

The review concluded that the use of compression bandaging *and* garments was more effective than garments alone. Additionally, they noted that when comparing no treatment to the use of compression garments alone, the garments were deemed beneficial.

6. CMS Decision Memo on Pneumatic Pumps[6]

The decision memo notes the following:

- Standard management of lymphedema typically includes positioning (elevation), manual lymphatic drainage, exercise, and compression garments or wraps.
- A pump may be an appropriate therapy for certain patients that have not been able to reduce limb swelling by conservative treatment. Such conservative treatment must include the use of a compression garment.

- Patients should use compression garments between pump sessions to prevent re-accumulation of fluid.

7. Journal of The American Physical Therapy Association ~ *Breast Cancer Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Care Model (2012)*[9]

- Modeled the direct costs of caring for patients identified in the early stages of lymphedema (using primarily compression garments) through a prospective surveillance program vs. caring for them in the later stages of the disease.
- Determined that the annual direct cost to manage early stage lymphedema with compression garments and minimal therapy was $636.19 vs. $3,124.92 in the more advanced stages requiring intensive therapy and compression.
- Thus, early identification and initiation of compression was calculated to significantly reduce healthcare costs.

8. Journal of Clinical Oncology ~ *Incidence, Treatment Costs, and Complications of Lymphedema After Breast Cancer Among Women of Working Age: A 2-Year Follow-Up Study*[10]

- This study evaluated the economic burden of managing breast cancer related lymphedema via analysis of insurance claims data on a total population of 550,000 insured, nearly 2000 of which had been diagnosed with breast cancer and 180 with breast cancer related lymphedema.
- The two year medical cost differential between breast cancer survivors with and without lymphedema was $22,153 more spent on patients with lymphedema.
- Only 3.4% of the added cost was spent on therapy or compression supplies which are known to prevent disease progression. The remaining 96.6% was spent on the cost of evaluating and treating complications.
- The authors noted:
    - “Breast cancer related lymphedema patients are likely to incur high medical costs as a result of frequent visits to physicians and/or physical therapists to seek symptom control.”
    - “Poorly managed lymphedema may lead to complications needing medical attention, which increases the costs of care.”

9. Rehabilitation Oncology Journal ~ *Effect of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema*[11] (and The American Journal of Infection Control ~ *Outcomes and management costs in patients hospitalized for skin and skin-structure infections)*[12]

- Lymphedema was recognized as one of the most potent risk factors for the development of recurrent cellulitis, which frequently requires hospitalization.
- The authors remarked that the study removed a significant barrier to idealized treatment by covering the cost of bandages and garments (not covered by Medicare) through the study's funding. The item costs ranged from $120–$1000 and items were replaced every 6 months per standard of care.
- The study revealed that 18 months of treatment, primarily consisting of compression including bandaging and custom garments, reduced the cumulative average annual number of hospitalizations among the study participants from 8.5/year down to 0.67/year.
- In 2011, the American Journal of Infection Control published an evaluation of multihospital insurance data which reviewed the cost of over 5,000 admissions between 2002 and 2006 for complicated cellulitis[12]. This population included patients with an underlying condition, such as lymphedema, which complicates the response to treatment. The study found that the length of stay per episode was 9.5–17.2 days and cost ranged from $40,046–$80,093 per hospital stay. Costs are expected to have risen modestly since that time.
- Thus, even at the lower end of cost, 8.5 hospitalizations per year would be expected to cost at least $340,391 whereas, after receiving compression therapy, 0.67 hospitalizations per year would be expected to cost well over **12 fold less** at $26,830.

References:
1.http://www.lympho.org/mod_turbolead/upload/file/Lympho/Template_for_Practice_-_Compression_hosiery.pdf
2.http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=51&fromdb=true
3.http://www.lympho.org/mod_turbolead/upload//file/Resources/Compression%20bandaging%20-%20final.pdf
4.http://lymphnet.org/pdfDocs/nlntreatment.pdf
5.http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0011841/
CAId=50&ver=6&NcaName=Lymphedema+Pumps&NCDId=190&ncdver=2&IsPopup=y&bc=AAAAAAAAEAAA&
6.http://www.cms.gov/medicare-coverage-database/(S(3iepps3hnwcrz5es0ppyu045))/details/nca-decision-memo.aspx?N
7.http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id51a.pdf
8.http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id51b.pdf
9.http://ptjournal.apta.org/content/92/1/152.full.pdf+html
10.http://jco.ascopubs.org/content/27/12/2007.full.pdf+html
11.http://www.oncologypt.org/publications/rehabilitation-oncology-journal/volumes/29/29-3-Rehabilitation-Oncology-Journal.pdf
12.http://www.ajicjournal.org/article/S0196-6553(10)00600-0/abstract