Please describe the submitting organization’s interaction with the Medicare program:
The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as “Appendix [insert label]”

In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description: Coverage of medically prescribed compression supplies for the treatment of lymphedema

Summary: Currently, 1.5 million Medicare beneficiaries suffer from chronic lymphedema system failure (Appendix A).

Related Statute/Regulation:
CMS Decision Memo (CAG-00016N); NCD for Pneumatic Compressional Devices (280.6); Sec. 1861(n) of the Social Security Act.

Proposed Solution:
Cover lymphedema compression supplies under DME or other sub-benefit category. Amend Medicare statute per H.R. 930/S. 497, the Lymphedema Treatment Act (Appendix B).
Appendix A – Summary:
Lymphedema is the accumulation of lymph fluid that obstructs the flow of the lymphatic system, causing persistent swelling of the affected body part. In the oncology setting, the most common causes of lymphedema are radiation therapy and lymph node dissection. Lymphedema can occur in one or more extremities and can involve the corresponding quadrant of the trunk. It can affect the head and neck, breast, genitalia, and lower limbs, depending upon surgeries and radiation therapy performed; however, it is most often reported in the upper extremities of women with breast cancer associated with axillary lymph node dissection and fibrosis after radiation therapy. Upper-extremity lymphedema occurs in 15%–28% of breast cancer survivors, is most common in those who had axillary lymph node dissection, and can present a few days or six to eight weeks after surgery or radiation therapy. Lower-extremity lymphedema occurs in as many as 80% of those who had lymph node dissection in the groin or those who have compression of pelvic or inguinal lymph nodes.

A compression garment is a knit, two-way stretch sleeve or stocking that is worn to assist in controlling swelling and to aid in moving lymph fluid from the affected area. It should be worn only while the patient is awake and active and should be custom fitted. Compression bandaging (CB) is a specialized form of compression used in the treatment of lymphedema. Bandages are the most effective and flexible form of compression, particularly in the early stages of treatment, and they provide proper compression when the patient is active or resting. They also can be easily adjusted to fit changing limb size and compression needs. Multiple layers of short-stretch bandages are applied to the lymphedematous area(s). Short-stretch bandages have limited extensibility under tension (50%), in contrast to Ace® bandages (300%). To achieve an effective compression gradient, bandages must be strategically applied with low-to-moderate tension using more layers in the distal portions of the affected limb(s). Pressure within the short-stretch bandages is low when the patient is inactive (resting pressure). Muscle contractions increase interstitial pressure (working pressure) as muscles expand within the limited volume of the semi-rigid bandages. Interstitial cycling between low-resting and high-working pressures creates an internal pump that encourages movement of congested lymph along the distal to proximal gradient created by bandaging. The non-elastic bandage sheath also counters refilling of fluid and reduces tissue fibrosis, further reducing volume.

Appendix B – Proposed Solution: Cover lymphedema compression supplies under DME or other sub-benefit category.

Lymphedema is a chronic condition affecting millions of Americans that is most often caused by cancer treatments that damage the body’s lymph system or immune functions. Due to the painful swelling that results from lymphedema, compression therapy is an essential component of treatment. Despite being an ongoing necessity, compression supplies are not covered by Medicare. This coverage gap should be closed by requiring Medicare to cover the doctor-prescribed lymphedema compression items that are the cornerstone of lymphedema treatment.
In addition to providing cancer treatment, oncology nurses maintain principal responsibility for managing treatment side effects. Maximizing quality of life and minimizing treatment side effects such as lymphedema are central goals of oncology nurses. Improving insurance coverage for lymphedema treatment will afford our nurses the opportunity to be more effective caregivers and ultimately will result in more successful outcomes for cancer patients nationwide.

ONS specifically recommends compression supplies as part of our “Putting Evidence into Practice” resources for the most effective way to treat lymphedema. ONS has identified evidence that is recommended for practice as well as evidence that is not effective for treatment. In the ONS “Putting Evidence into Practice (PEP)” resources for treating lymphedema, ONS specifically recommends Compression Garments and Bandages for Practice.

A statutory solution has also been proposed in H.R. 930/S. 497, the Lymphedema Treatment Act. This legislation would amend title XVIII (Medicare) of the Social Security Act to cover certain lymphedema compression treatment items as durable medical equipment under Medicare. The bill currently has 277 bipartisan cosponsors in the House and 34 bipartisan cosponsors in the Senate.

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Please describe the submitting organization’s interaction with the Medicare program:

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Short Description: Application of the MIPS payment adjustment on Part B drugs

Summary:

In its 2018 Quality Payment Program (QPP) proposed rule, CMS clarified that it intends to apply the Merit-Based Incentive Payment System (MIPS) payment adjustment to Part B drugs, which it believes it is required to do based on its legislative interpretation of Section 1848(q)(6)(E) as revised by the Medicare Access and CHIP Reauthorization Act (MACRA). This policy is a significant departure from how CMS has applied payment adjustments in prior programs (e.g., the Physician Quality Reporting System (PQRS), the EHR Incentive Program, and the Value-Based Payment Modifier (VM)), where the statute was clear that adjustments should be limited to professional services.

Oncology nurses are deeply concerned about the significant impact of this policy on patient access to important chemotherapy medications used in cancer care and treatment. Oncology practices that fail in MIPS or do not properly “test” the program will not be able to absorb a staggering -4 percent cut, in addition to the -2 percent reduction due to sequestration, to the medications they “buy and bill” and administer to Medicare beneficiaries in their offices. Reductions of this magnitude could potentially force practices, particularly those that are small and/or rural, to send patients to hospital outpatient departments (HOPD) for care, which will significantly increase Medicare spending. Worse
yet, it could force these practices to close their doors permanently, leaving countless beneficiaries with limited or no access to life-saving cancer care and treatment.

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<th>Related Statute/Regulation:</th>
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<td>Section 1848(q)(6)(E)</td>
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<th>Proposed Solution:</th>
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<td>ONS urges Congress to modify the statute so that MIPS adjustments apply only to covered professional services, as it did in prior quality improvement programs. Part B drugs must be excluded from upward and downward payment adjustments under MIPS, just as they are excluded from the Alternative Payment Model (APM) incentive under the same Quality Payment Program (QPP).</td>
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