October 19, 2009

Medical Evidence Development and Coverage Advisory Committee (MEDCAC)
Centers for Medicare & Medicaid Services (CMS)
Office of Clinical Standards and Quality, Coverage & Analysis Group
C1–09–06, 7500 Security Boulevard
Baltimore, MD 21244

Dear Sir or Madam:

On behalf of the members of the American Physical Therapy Association (APTA), I would like to thank the MEDCAC for the opportunity to comment on the treatment of secondary lymphedema. APTA is a professional association representing 72,000 physical therapists, physical therapist assistants, and students of physical therapy. Physical therapists treat Medicare beneficiaries in a variety of practice settings including private practices, hospitals, skilled nursing facilities, home health agencies, rehabilitation agencies and comprehensive outpatient rehabilitation facilities. It has been noted that the diverse etiology of lymphedema means that patients at risk of developing the disease can be encountered in a wide variety of primary and secondary care settings. As a result, a national coverage decision governing the coverage of lymphedema treatment would impact our members greatly. We look forward to an opportunity to work with the MEDCAC to ensure any policy regarding the coverage of lymphedema reflects best practices and is in the best interest of Medicare beneficiaries.

**Role of Physical Therapists in the Treatment of Lymphedema**

Lymphedema is a debilitating progressive condition for which there is no known cure. It requires that the patient, in collaboration with his or her health care providers, manage the condition to prevent disabling side effects and potentially lethal complications such as infection. Lymphedema affects people regardless of age, gender, economic status, and co-morbid conditions. While primary lymphedema is a result of a hereditary or congenital condition, secondary lymphedema is typically related to cancer treatment. It is caused by lymphatic system dysfunction which results in an abnormal protein rich swelling of the tissue. Patients with lymphedema experience pain associated with

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swelling of the affected limb(s) as well as with additional pressure placed on the joints. These patients also suffer from the psychological impact of having a large or abnormal limb.

The occurrence of secondary lymphedema varies based on the type of cancer and treatment provided. For instance, as many as 49% of patients develop breast cancer-related lymphedema after mastectomy. Approximately 4-17% of patients developed secondary lymphedema after sentinel lymph node biopsy with radiation. The incidence of lower limb lymphedema related to gynecological or urogenital cancer ranges from 50-80%. The American Cancer Society projected 1.5 million new cancer cases in 2008 alone with an estimated annual cost of $206.3 billion. Approximately 10.5 million Americans have a past history of cancer and all cancer survivors who have surgery to remove lymph nodes and/or have radiation therapy are at risk of developing lymphedema. In fact, some estimates place the incidence of lymphedema at 30% among cancer survivors. As a result, secondary lymphedema has the potential to have significant personal, societal, and economic impacts.

Of primary importance to the treatment of this chronic condition is early diagnosis and intervention. Physical therapists play a crucial role in the early detection, treatment, and long-term management of lymphedema. Physical therapists play an important role in detecting the onset of limb swelling at the earliest onset, when the condition can be reversed and even prevented from progressing to a manifest condition. Additionally, interventions provided by physical therapists can diminish limb swelling for patients who have clinically apparent lymphedema. In both early and late stage lymphedema treatment, physical therapy interventions aimed at treating and managing lymphedema potentiate functional gains. Patients with a cancer diagnosis typically receive primary care services including surgery, chemotherapy, and radiation therapy. The medical providers focus on ridding the patient’s body of the cancer, however, there is particularly limited attention to the frequent co-morbidities associated with these therapies. As a result, patients who develop secondary lymphedema often are not diagnosed until the disease

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has advanced to the point where the condition is visibly apparent or the degree of impairment is such that the patient cannot carry out activities of daily living. Physical therapists, as a result of their education and training, are prepared to serve as the provider of choice for the surveillance, early detection, and management of lymphedema at any stage.

Early detection is vital to preventing the progression of the disease. Pre-operative assessments conducted by physical therapists provide a baseline from which to monitor the development of lymphedema. Ongoing interval prospective surveillance by a physical therapist enables diagnosis of lymphedema at the earliest presentation, and with conservative compression interventions, may prevent the condition from becoming manifest in the limb and therefore preventing a lifetime of intensive management of a chronic condition. Further, randomized controlled trials have demonstrated that with proper patient education for activity and exercise, along with ongoing monitoring by a physical therapist, lymphedema may be prevented from occurring. If lymphedema is not diagnosed early and the limb reaches an intermediate stage of swelling, physical therapists have a variety of tools available to them to treat and alleviate the condition. For example, physical therapists provide complete decongestive therapy for patients with lymphedema. Complete decongestive therapy, also known as complex physical therapy, is considered the “gold standard” of care for patients with lymphedema. This includes manual lymphatic drainage, compression bandaging, exercise, education regarding skin and nail care and hygiene, and custom compression garments in an effort to restore near-normal limb girth. Patients undergoing complete decongestive therapy achieve significant reduction in limb volume (between 60% and 80%), improved cosmesis, softening of tissue and a return to near normal function.

In addition to the interventions provided by physical therapists to decongest the swollen limb, lymphedema requires ongoing self-management whereby the patient must adhere to a life-long arduous maintenance routine. The role of the physical therapist is important in educating the patient and caregiver in proper self-care. Additional intermittent episodes of follow-up care with the physical therapist ensure appropriate self-care and comprehensive disease management. This model of care is consistent with the chronic disease management models espoused in the literature as efficacious for long-term disease management. It stands as reasonable to expect that the physical therapist, as a front-line provider for lymphedema management and care, should be engaged as the


provider of choice for ongoing surveillance of those who are at high risk for developing lymphedema and for those with lymphedema to assure disease management.

Patients who develop lymphedema and the providers, such as physical therapists, who care for them, face many obstacles. Lymphedema is often not diagnosed early enough and results in initial treatment being undertaken at an advanced stage when more intensive, costly therapy is required. There are several factors that can contribute to a delayed diagnosis. For instance, the physician may not recognize the signs or symptoms of lymphedema because his or her focus is treating the cancer, not its co-morbidities. In addition, lymphedema may be misdiagnosed as deep vein thrombosis or another condition. Coverage for services related to the treatment of lymphedema is limited as well, preventing timely or appropriate care. Delays in receiving care not only have implications for the patient’s quality of life, but also take a financial toll on the overall health care system.

As CMS and MEDCAC move forward with a potentially revised coverage decision for Medicare related to lymphedema, we respectfully request they consider the role of the physical therapist in the treatment of lymphedema. In this comment letter, we provide information in response to the questions developed in preparation for the MEDCAC meeting. Our responses focus specifically on the questions that relate to the efficacy of lymphedema treatment by physical therapists. We believe it is important that CMS and the MEDCAC consider all the evidence, including studies and expert clinical consensus, when determining whether sufficient evidence exists to provide coverage for lymphedema services.

Of note is the extensive work done in the United Kingdom to develop consensus guidelines for the treatment of lymphedema. The consensus process commenced in 2002 and involved national patient support groups, patients with lymphedema, national professional lymphedema groups, clinical experts, and industry. The standards of practice recommended were made with several key concepts in mind including identification of people at risk for or with lymphedema and the provision of services that deliver high quality clinical care that is subject to continuous improvement and integrates community, hospital, and hospice based services. 14 This consensus document and best practice standard have been accepted in the UK by the National Health Service’s National Institute for Health and Clinical Excellence (NICE) and represents the standard of care for practice and reimbursement. The recommendations made in the consensus document are referenced throughout our comments as they related to the specific areas of concern identified by CMS to be addressed by MEDCAC.

**Diagnosis of Lymphedema**

The first question posed to the MEDCAC panel is whether certain diagnostic strategies can reliably identify and stratify the severity of secondary lymphedema. Appropriate diagnosis relies on standardized methodology and a diagnostic criteria that is sensitive to

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identify the condition at its initial onset. One method identified to effectively diagnose lymphedema is pre- and post-operative measurements of both limbs (arms or legs as appropriate). A pre-operative limb volume measurement enables quantification of normal limb variance in volume. Interval surveillance, often in the absence of swelling, is recommended in order to identify and treat lymphedema at the earliest onset. The initial onset of swelling may be sub-clinical in nature so the methodology for taking repeated measures is important. Without a methodology that involves pre-operative measurement and prospective surveillance the earliest onset of volume change will be missed.

Validated clinical tools for diagnosing lymphedema include: circumferential measurements taken at consistent intervals along the length of the limb, water displacement, optoelectronic perometry, and bioelectrical impedance. Each technique is valid to assess limb volume associated with lymphedema; however the principle of consistent, repeated measures of both limbs through a surveillance program is necessary for these tools to effectively diagnose lymphedema. We encourage MEDCAC to recognize that pre-operative assessment and prospective surveillance by a physical therapist is a diagnostic strategy that can reliably identify and stratify the severity of lymphedema. This methodology also potentiates prevention of disease progression and cost savings.

**Staging of Lymphedema**

One of the questions posed to the MEDCAC panel relates to whether secondary lymphedema can be classified into prognostic stages of severity that are useful to guide choice of therapy or response to therapy. There is some consensus in the staging of lymphedema. According to the International Society of Lymphology classification of lymphedema staging, there are four main stages, Stage 0-Stage III. Stage II is further subdivided to provide additional clarity. Stage 0 is the earliest stage of lymphedema where swelling is not evident but lymph transport is impaired. Stage I signifies the accumulation of tissue that is reduced with elevation of the affected limb. In the early period of Stage II, limb elevation alone is rarely effective and pitting is apparent. In the later phase of Stage II, pitting is less apparent as fibrous tissue is more evident. The final stage, Stage III, is defined as the stage in which tissue hardens and pitting is absent. The skin changes and becomes thicker, and skin folds, fat deposits, and warty overgrowths develop. While the consensus document provides an increased level of detail when compared to other staging schemas, clear similarities exist in the classification of lymphedema into a system identified by stages.

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One study categorized lymphedema according to three stages. Stage I was defined as the early accumulation of fluid relatively high in protein content which could subside with elevation of the limb. In Stage I, pitting may occur and an increase in proliferating cells may also be seen. Once lymphedema progresses to Stage II, elevation alone rarely reduces the tissue swelling and pitting is more pronounced. As Stage II progresses, pitting is less pronounced as excess fat and fibrosis become the dominant symptoms. By Stage III, pitting is largely absent and trophic skin changes such as acanthosis, further deposition of fat and fibrosis, and warty overgrowth have developed.\textsuperscript{19} Although three stages were used in this study, similar characteristics appear to be attributed to the stages as those used in other studies and derived through consensus.

CMS is also interested in determining if specific interventions are best suited for a particular stage of lymphedema. Again, there is some evidence and consensus on this topic. While details about the specific interventions are discussed in greater detail below, it is important to note what interventions are typically used for each stage of this disease. A standardized approach to education and risk reduction by a physical therapist may decrease the risk of developing lymphedema.\textsuperscript{11, 15} Utilizing basic principles of skin care, infection prevention and appropriate exercise precautions, the physical therapist is the optimal provider to guide patients in reducing risk associated with the development of lymphedema. When lymphedema is diagnosed at its earliest stage, a conservative compression intervention along with education and ongoing surveillance and education effectively manages the swelling and may prevent the condition from progressing to an advanced stage. Later stage (II and III) lymphedema requires intensive complex decongestive therapy.\textsuperscript{20}

**Assessment of Measures of Improved Health Outcomes**

The panel is being asked whether an improvement in certain measures (e.g. affected limb circumference, affected limb volume) is associated with an improvement in health outcomes for the patient. As stated in one study by Kristiana Gordon and Peter Mortimer:

“A number of key issues need to be addressed for each patient: reduction in limb swelling, prevention of skin changes (such as brawny texture, prominent skin creases, hyperkeratosis, papillomatosis), prevent of infection and treatment of specific problems like lymphorrhea. These can be addressed through the four cornerstones of physical therapy. Treatment regimens should be considered as twofold: an initial intensive treatment phase aiming for limb- volume reduction, often combining external compression, exercise and massage therapies; followed by the long-term maintenance phase of utilizing compression hosiery to sustain manageable limb volume.” \textsuperscript{21}

\textsuperscript{19} The Diagnosis and Treatment of Peripheral Lymphedema: 2009 Consensus Document of the International Society of Lymphedema. 2009; 42.


Patients with lymphedema often suffer from skin infections or a break down in skin integrity. This is a result of reduced local immunity in the affected part of the body. As a result, an improvement in skin integrity and reduction in such infections could be seen as improving health outcomes in a patient. In fact, lymphedema can cause ulceration, contact dermatitis, venous exczema, and fungal infections among other skin infections or conditions. Control of lymphedema is important to preventing these co-morbid skin conditions.

Lymphedema can also result in reduced limb function including strength, endurance, and range of motion. Assessment of limb function is considered a standard component of treatment of this condition. Included in an assessment of limb function as it pertains to lymphedema are the use of aides, range of joint motion, and the ability to carry out activities of daily living such as walking and dressing.

**Effectiveness of Lymphedema Interventions**

CMS has asked MEDCAC to consider the evidence demonstrating the effectiveness and outcomes of the various treatment options for patients with secondary lymphedema, including compression bandaging and/or compression garments, pneumatic compression devices, exercise-based treatments, and massage-based treatment. The use of these interventions for the treatment of lymphedema has been analyzed in several studies, which have indicated the interventions are effective.

Specifically, several studies have stated that a combination of these treatments, rather than a particular intervention provided in isolation, is often most effective in treating lymphedema. For example, elevation alone is rarely able to minimize the symptoms of lymphedema. According to a report published by the Cochrane Collaboration in 2009, the standard treatment approach in Europe has involved a two-phased approach. In the first phase, multi-layer bandaging, care of the skin, manual lymph drainage, exercise, and pneumatic compression is employed. In the second phase, patients are required to wear strong compression hosiery to maintain the reduction in swelling, carry out regular daily exercise, and continue with regular manual lymph drainage whenever possible. Current consensus literature also supports a multidisciplinary approach involving many services currently provided within the scope of practice of physical therapists. The exact

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interventions are also determined by the site, stage, severity, and complexity of lymphedema.\textsuperscript{27}

**Compression Bandaging/Compression Garments**

Several studies discuss the use, importance, and efficacy of compression garments and/or bandages. One such study stated that physical therapists had a responsibility to encourage their patients to consistently use compression garments over the long-term.\textsuperscript{28} It is important to note that compression garments may be prefabricated or custom-made and are of varying degrees of elasticity. They lessen the amount of excess fluid that can enter an affected extremity by increasing interstitial hydrostatic pressure within the limb.\textsuperscript{29} In fact, graded compression garments have been cited by some studies as a “mainstay” of lymphedema therapy.\textsuperscript{30} In a study that used CT scanning to assess the effect of compression garment therapy, a significant decrease in the cross-sectional area of subcutaneous compartments was found. The mean decrease was 9\% in the proximal portion and 26\% in the distal portion of the limb.\textsuperscript{31}

The type of bandaging or garment used can vary based on the presentation of the patient and severity of the disease. When lymphedema is diagnosed at an early, sub-clinical stage, compression garments have been shown to be effective at reducing limb volume, possibly preventing the progression to a more advanced stage of lymphedema. Additionally, these authors found that with regular use of compression garments during exertional activities, patients were able to maintain their limb volume suggesting that this form of early compression intervention may have a long-term preventive effect. For patients with Stage II and more advanced lymphedema, one study recommended the use of elastic compression hosiery garments. This study also found that for patients with more advanced lymphedema, hosiery garments should be followed by the use of multilayer compression bandaging (CB). A randomized, controlled trial found that multiple-layer short stretch bandages were a “superior” initial treatment for Stage II and III lymphedema.\textsuperscript{32} Regardless of the exact form of bandage or garment, many studies outline the efficacy of their use in the treatment of lymphedema.\textsuperscript{33}

While compression bandages have been determined to lead to reduction in lymphedema, those involved in developing consensus guidelines note the importance of coupling compression garment interventions with exercise, skin care, and elevation for early stage


lymphedema. When treating advanced stage lymphedema in the lower and upper limbs, strategies include compression bandaging, manual lymphatic drainage and therapeutic interventions including exercise, skin care, and elevation. Once limb decongestion has occurred, compression garments are the main compression intervention recommended for ongoing long-term care. Regular assessment of the patient using a compression garment should be conducted by the physical therapist at specified intervals. Garments should be replaced every three to six months depending on the needs of the patient and the elasticity of the garment. Compression garments have been found most effective for the treatment of patients with Stage I lymphedema while those in Stage II seem to garner best results with CB. Patients in Stages II and III benefit from a combination of skin care, exercise, elevation, and CB.34

Multilayer compression bandaging is an important element of therapy related to the treatment of lymphedema. CB uses inelastic bandages that have low extensibility and produce high working pressures and lower resting pressures. CB restores shape to the limb and/or affected area, reduces skin changes, supports overstretched skin, and softens subcutaneous tissues. It is indicated when skin changes are marked or limb distortion and skin folds preclude compression garments.35

Pneumatic Compression Devices

Pneumatic compression consists of an electrical air compression pump attached to an inflatable garment that is placed over the affected limb. The garment is inflated and deflated over a set period of time. Pneumatic compression works by decreasing capillary function, and therefore lymph formation, rather than accelerating lymph return. Evidence suggests that it is most effective in non-obstructive edemas.36

Studies have shown that pneumatic compression devices demonstrate promise in the treatment of lymphedema. Specifically, a study has found that sequential intermittent pneumatic compression has been shown to be beneficial in the treatment of lymphedema. This same study found that outcomes were improved when pneumatic compression devices were used in conjunction with compression therapy and comprehensive decongestive therapy.37 A second study found that the reduction in lymphedema volume in patients treated with a pneumatic compression device was 18% greater than the

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reduction produced by elastic compression. Pneumatic compression devices are widely used in the treatment of lymphedema.

**Manual Lymphatic Drainage**

Manual lymphatic drainage is a technique that causes lymph conduits to contract more often and siphons lymphatic fluid away from congested regions and subsequently toward nearby functioning lymph basins. In other words it is designed to reduce swelling by encouraging lymph flow. It is often used in the early, intensive phase of lymphedema therapy. The use and effectiveness of manual lymphatic drainage is supported by expert clinical opinion. However, many believe that with few exceptions this intervention is not an effective treatment on its own and should be used in conjunction with compression therapy.

Manual lymphatic drainage is a specialized intervention involving specific hand placement and directionality of the treatment. Usually the therapist conducting MLD has specialty training in these techniques to facilitate improved fluid flow.

**Exercise-based Treatment**

Studies have shown that exercise is beneficial due to skeletal muscle activity aiding the extrinsic pumping mechanism of the lymphatic system. Aerobic exercise increases intra-abdominal pressure which facilitates pumping of the thoracic duct. In a document developed to provide clinical practice guidelines for the treatment of lymphedema related to breast cancer, exercise is reported as beneficial to controlling lymphedema. A recent study in the New England Journal of Medicine touts the benefits of resistive exercise in over 200 women with lymphedema. The study found that women with breast cancer related lymphedema performed exercise safely when they used compression garments during their exercise program.

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Conclusion

In conclusion, I would like to again thank CMS and MEDCAC for the opportunity to comment on this important coverage issue. If you have additional questions, please contact Sarah Nicholls-Sharp, Assistant Director for Federal Payment and Regulatory Affairs at 703-706-3189 or sarahnicholls-sharp@apta.org.

Sincerely,

R. Scott Ward, PT, PhD
President