

Via online submission

October 19, 2009

Ms. Maria Ellis
The Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Office of Clinical Standards and Quality
Coverage and Analysis Group, C1-09-06
Baltimore, MD 21244

Re: **AOTA Comments on Lymphedema for Meeting of the Medicare Evidence
Development and Coverage Advisory Committee on November 18, 2009**

Dear Ms. Ellis,

The American Occupational Therapy Association (AOTA) represents the interests of over 140,000 occupational therapists, occupational therapy assistants, and therapy students, many of whom are covered and reimbursed as practitioners under the Medicare Program. We appreciate the opportunity to provide a submission on behalf of the professional we represent to contribute to the November 18, 2009 discussion of the adequacy of the available evidence that supports the diagnostic and treatment methods used in the management of secondary lymphedema.

I. Role of Occupational Therapy in Lymphedema Treatment

Occupational therapy is a health, wellness, and rehabilitation profession working with people of all ages experiencing stroke, spinal cord injuries, cancers, brain injury, congenital conditions, developmental delay, joint replacements and surgeries, mental illness, and other conditions. Occupational therapists also work to prevent the occurrence of conditions and promote wellness among all client groups. Occupational therapists help people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy professionals have unique expertise in evaluating participation and enabling engagement in meaningful occupations (e.g., activities of daily living (ADLs)) while addressing the context (e.g., the individual's limitations), environment and other factors. Occupational therapy evaluation and treatment is used for individuals with acute and chronic conditions. It includes a multifaceted evaluation of a patient's functional abilities, limitations (sensory, cognitive, motor function, judgment, etc.), home and community needs and roles, social and psychosocial contexts, and other elements.

Occupational therapy strategies for addressing secondary lymphedema are directed at preventing or minimizing the fluid accumulation in the affected body parts, protecting the affected body parts from additional injury or harm, restoring any lost function and providing education to effectively and more easily accomplish activities of daily living (ADLs) and avoid social or mental health complications such as depression or isolation.

Occupational therapy clients receive education about the impact of their cancer treatments on the lymphatic system and are instructed in how to care for their limb and skin in the affected quadrant where the lymph nodes were removed or radiation treatment occurred. Those who are at risk for developing lymphedema, or who already have developed lymphedema, often have anxiety about whether participating in their daily activities will result in the onset of lymphedema or an increase in their swelling, respectively. Activities that tend to exacerbate the condition are discussed in relation to the client's current activities, and the therapist suggests energy conservation techniques and ways to modify daily activities to prevent worsening of swelling.

Occupational therapy clients also are offered the following intervention options:

- Bandaging training with specialized lymphedema bandages and supplies
- Manual lymphatic drainage therapy, a light manual therapy technique that stimulates the lymphatic system and redirects lymph fluid to a functioning drainage area
- Training in a home exercise program
- Self-massage training for the client or massage training for a partner
- Measurement and fitting of compression garments, instruction in donning garments, and determining a schedule for their use
- Adaptation of daily living activities, e.g., dressing, cooking, driving
- Recommendations for changes to the environment to ease mobility and function

Because lymphedema is a chronic condition, the main goal of occupational therapy is to minimize the amount of edema in the affected area, and then to maximize client participation in ADLs and roles with a home management program to facilitate participation in valued daily activities. Lymphedema management can be time consuming, so the therapist tries to help clients incorporate the management program into their daily routines.

Occupational therapists are uniquely qualified because of their broad education to examine the synergy between the physical and psychosocial aspects of lymphedema and other clinical conditions and to understand how both aspects impact one's ability to participate in daily activities and enjoy a positive quality of life. Occupational therapists evaluate activities of daily living (such as dressing and grooming), instrumental activities of daily living (such as homemaking, shopping, medication management, cooking and driving), as well as work, leisure, and social participation to determine the individual's ability to participate in these valued occupations and design ways to enable increased independence in performance of those activities. In addition, the occupational therapist works with family members and caregivers to provide support for the client during both treatment and maintenance phases.

The psychological and social sequelae of secondary lymphedema have been under-recognized and little-researched complications of treatment for lymphedema, in particular those associated with

breast carcinoma. Psychological sequelae include frustration, distress, depression and anxiety. Occupational therapy professionals target interventions to result in amelioration of psychological symptoms accompanied by improvement in functional capacity and the ability to engage in culturally normative daily occupations.

Social sequelae comprise changes in role function, lack of social support and pain and disability. (McWayne & Heiney, 2005). Through the use of real life activities as therapy, occupational therapy practitioners can improve not only functional capacity but also quality of life for people with lymphedema in the areas of employment, education, community living, and home and personal care. Evidence from a randomized controlled trial of a program of preventive occupational therapy in independently dwelling older adults found improvements in quality of life for the following areas: physical functioning, role functioning, vitality, social functioning, and general mental health at 6-month follow-up (Clark, et al., 2001). Occupational therapy practitioners use their educational preparation and practice experience to restore, maintain, and improve function for people with physical and mental illness, injury, or limitations. Core educational elements for occupational therapists include anatomy, neurology, physiology, kinesthesiology, psychology, and developmental and behavioral sciences.

Occupational therapists have the requisite training, credentialing and educational experience to appropriately treat lymphedema. Occupational therapists can receive education and training in interventions for this condition through coursework, laboratory training in practical applications, fieldwork (clinical internships), continuing education, and certification programs. Entry level for occupational therapists is currently a Master's degree or higher post-baccalaureate degree such as a Doctor of Occupational Therapy (OTD) degree. All occupational therapist programs are accredited by the Accreditation Council for Occupational Therapy Education. To practice, occupational therapists must graduate from an accredited school and pass a certification examination in all 50 states, the District of Columbia, Puerto Rico and Guam.

II. Summary of Evidence for Occupational Therapy Interventions in Lymphedema Treatment

Two systematic reviews were located that examine the efficacy of lymphedema treatments (Moseley, Carati, & Piller, 2007; Preston, Seers, & Mortimer, 2004). Thirty-two studies within the scope of occupational therapy practice were included in the Moseley, Carati, & Piller (2007) review. Studies included in the review had the following study designs: randomized controlled trial; parallel and cross-over format; case-control; and cohort studies.

The review examined the following conservative therapies including: manual lymphatic drainage, compression bandaging and garments, complex physical therapy, pneumatic pumps, low level laser therapy, limb exercises and limb elevation.

The results of the review indicate that more intensive therapies and those under the guidance of a health professional, such as manual lymphatic drainage, complex physical therapy, pneumatic pump, and laser therapy generally resulted in greater volume reduction, while those that were self-guided such as compression guided wear, exercises, and limb elevation resulted in smaller volume

reductions. All conservative therapies resulted in improvements in subjective arm symptoms and quality of life for the studies that measured these outcomes.

The Preston, Seers, & Mortimer (2004) review, a Cochrane review, included only randomized controlled trials. Three studies met the inclusion criteria, and the authors of the review indicate that the results of these limited positive results need to be interpreted with caution.

Two more recent studies provide additional evidence for occupational therapy interventions for lymphedema. Mondry, Riffenburgh, & Johnstone (2004) followed twenty lymphedema patients undergoing complex decongestive therapy that included manual lymphatic drainage, multilayer compression bandage, therapeutic exercise, and skin and nail care. Patients completed 2-4 weeks of treatment and were followed for one year.

The results indicated that the number of patients classified as severe decreased over the course of treatment. For the overall patient population, girth and volume were reduced, and decreased limb girth correlated with pain reduction. While limb girth and volume reverted slightly during the follow-up period, measurements stabilized below baseline. Quality of life scores consistently increased throughout treatment and follow-up, to 5% over baseline. According to the Mondry article, quality of life issues include a loss of function of the arm and a feeling of disability.

McClure, McClure, Day and Brufsky (in press) reported on the results of a randomized controlled trial of exercise-based and relaxation recommendations for individuals with lymphedema. The program incorporated low-to-moderate intensity exercise that included muscle shortening, and gravity-resistive arm flexibility exercise, deep diaphragmatic breathing, Progressive Muscle Relaxation, and facial massage. McClure et al, state “[a] healthier physiological state within the affected lymphedematous area may improve lymphatic function, physical and emotional BCRL (breast cancer-related lymphedema) symptoms for the mind, body, and spirit.” At 3-month follow-up of this 5-week program participants demonstrated improvements in both physical and emotional symptoms such as: bioimpedance, arm flexibility, quality of life, mood, and weight loss.

III. Conclusion

The evidence for occupational therapy intervention in the area of lymphedema is positive. It indicates that interventions including manual lymphatic drainage, compression, exercise, and relaxation improve physical function as well as the psychological and social components of mood and quality of life. The occupational therapy practitioner tailors the self-management techniques to the specific lifestyle of each client with the ultimate objective of improving a client’s functional ability to engage in normative daily occupations and roles for both the treatment period and beyond.

Thank you, again, for the opportunity to submit materials for discussion during the meeting of the Medicare Evidence Development and Coverage Advisory Committee on November 18, 2009. AOTA looks forward to a continuing dialogue with CMS and related entities on coverage and payment policies that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Sincerely,



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