Project Name: Diagnosis and Treatment of Secondary Lymphedema
Project ID: LYMT0908

Table 2: Public Review Comments

Reviewer Name[1]	Reviewer Affiliation[2]	Section[3]	Reviewer Comments	Author Response[4]
Alvarez, Oscar M. PhD	Director, Wound Care Program, Calvary Hospital, Bronx, NY	NA	First of all I would like to thank the MedCAC committee for their service and dedication of their time to study the evidence regarding what we know about the diagnosis and treatment of secondary lymphedema. As an educator and researcher in the field of wound healing and chronic wound pathology for more than 25 years I attended the meeting hoping to learn more about the MedCAC process and current opinion regarding this very difficult and growing clinical condition affecting more than 2 million people. I offer the following comments your kind consideration: 1. The MedCAC committee (as it should) focuses sharply on the technology assessment (review of the literature) to base its conclusion regarding the value of diagnostic techniques and treatment options. The process, in and of itself, undervalues the importance of obvious evidence just because it has not been the subject of a randomized clinical trial (RCT). There are simply some treatments or therapies that do not need to be researched to be proven to be efficacious. Take for example the importance of repositioning to prevent pressure ulcers in the immobile patient. Such is the case with compression therapy, comprehensive decongestive therapy (CDT) and intermittent pneumatic compression (IPC) for the treatment of advanced secondary lymphedema. Just a few of the photographs shown by many of the presenters should be evidence enough. As articulated by MedCAC panelist Dr. Umscheid, "you don't need to review evidence to justify the value of wearing a seat belt or the use of a parachute". Those of us who have experience treating these patients trust in the truth that these modalities (if performed and/or used properly) are simply effective. It is my opinion that in this particular case medical opinion should be considered as valuable as an RCT.	1. EBM includes three prongs: published evidence, clinical expertise, patient preferences. The TA focused on the published evidence. Private and public health insurers will decide how to weight the other two prongs of EBM in their decision making. Photographs are not considered 'evidence' from the standpoint of EBM. For photographs to really demonstrate evidence, they would have to be taken using a well-defined protocol. Too often photographs illustrate extremes that cannot easily be applied to the average case.

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			2. The technology assessment (as performed by the McMaster Evidence-Based Practice Center) is inconclusive and should be repeated using much broader indexing to include foreign publications. Also the indexing should include each of the treatment modalities by generic, trade names and synonyms. Additional indexing should include chronic venous insufficiency, recurring cellulitis, venous ulcers, and lower leg ulceration. Other sources of information such as Medscape and the internet should be included. For example when I indexed: wound healing, venous ulcer, lower leg edema, lymphedema pump, and intermittent compression in medscape, pubmed and the internet, I found 4 comparative studies (that were in agreement) demonstrating that intermittent compression provided by different pneumatic devices decreased edema and enhanced ulcer healing in patients who had been diagnosed with CVI and secondary lymphedema (1-4). 3. Surprisingly, the technology assessment as it was performed (with such narrow guidelines) did not yield much information regarding non-cancer secondary lymphedema. Those of us that see chronic wounds can attest to the overwhelming number of patients with secondary lymphedema who have never been diagnosed. In fact, most of these patients (even with stage III secondary lymphedema) are diagnosed with obesity, edema, or CVI. Such patients are frequently treated with compression bandages and improve as a result of compression alone. 4. I was also surprised that simple compression and IPC therapy only received voting scores of 3.2 and 3.0 respectively. I believe (and think experts agree) that compression is the cornerstone of treatment for patients with secondary lymphedema. CDT would only be marginally effective without the use of compression. Compression is a necessary part of the treatment plan and this is only provided by compression bandages, compression garments and/or IPC. 5. I agree with Dr. Goodman and the MedCAC committee that more research is needed to satisfy the evidence gap that currently exists regarding the diagnosis, staging and treatment of secondary lymphedema. But would like to add, that this is certainly true for sub-clinical to moderate disease and not so for advanced disease. Perhaps it would be good to consider the	2. A foreign language search has been completed with expanded search terms. The conclusions of the original TA did not change. One of the major points of the TA was there was such a dearth of studies in secondary lymphedema, so we could not draw conclusions about specific modalities, sub-populations, etc. 3. The state of the published literature was such that few studies (satisfying our inclusion criteria) have ever been published outside of the cancer population. If these studies existed, then we would have picked them up and included them. 4. The McMaster EPC is not involved with the workings of the MEDCAC panel in any way. 5. We agree that the issue of severity is important and we point out in the TA that the evidence regarding severity was inconclusive in the published literature.

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			severity of the disease when evaluating the merit of the evidence. I think everyone would agree that an accurate clinical diagnosis of secondary lymphedema is easily made in a patient presenting with the signs and symptoms of advanced disease. Likewise there is general agreement (and obvious evidence) that CDT and IPC are effective treatment modalities. 6. I should not be overlooked that the real goal for managing the patient who suffers with advance secondary lymphedema is to promote the quality of life (QOL) by addressing both lymphedema-related symptoms (wounds, massive edema, disfigurement, dermal fibrosis, papillomatosis, cellulitis, and overall appearance) as well as psychosocial reactions (fear, anxiety, depression, anger, denial, guilt, blame and lowered self esteem). Future research should incorporate both physical and QOL parameters in their design. 7. Finally I would like to urge the stakeholders and its leadership to unite in the formation of an unbiased scientific advisory panel to guide future research, develop a patient registry, and guide the development of treatment guidelines for secondary lymphedema. References: 1 McCulloch et al., Advances in Wound Care 1994;7:22 2 Mulder et al., Wounds 1990; 3:111 3 Pekanmaki et al., Clin Exp Derm 1987; 12:350 4 Coleridge-Smith et al., Surgery 1990; 108:87	6. Thank you for the observation. 7. Thank you for the observation.
Anonymous Reviewer 1	NA	see Chapter 1	Under treatment modalities, low level laser is mentioned as a modality, yet it is considered experimental, and currently there is at least one study, at Vanderbilt, to try and assess its efficacy. This is a small, preliminary study that is not double blinded. It was cleared for marketing by the FDA under the 510(K) process--declaring it equivalent to a product on the market (no similar product exists for lymphedema), so no proof of safety or efficacy were required. The National Lymphedema Network published a LymphLinks newsletter reviewing the laser, and the overall consensus was that	Low level laser was mentioned in Chapter 1 because it has been evaluated for use in lymphedema. We do not advocate for or against its use in lymphedema. Our literature search did not find evidence for the efficacy of laser.

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			the existing studies are too small, with too short of a follow up to unequivocally declare it either safe or effective. It's mechanism is unknown. It is not to be used with metastatic cancer, yet it is commonly used in the axilla where there is a statistical possibility of positive nodes that were not found on sentinel node biopsy. It is not listed under treatment guidelines by the National Lymphedema Network. It is experimental, and while able to be sold direct to the consumer, there is no scientific data to support its long-term safety or effectiveness. Its manufacturer states that it has no side effects, which would infer that it is biologically inactive, or that the inadequate studies have not revealed the side effects due to under-powering and lack of long term follow up. The one study with long term follow up, done by Neil Piller, showed little long term benefit.	
Anonymous Reviewer 2	NA	NA	1. The definition of secondary lymphedema is that which results from cancer treatment (among other inciting factors) therefore a study including only patients with lymphedema who have had cancer treatment is inherently a study of secondary lymphedema. This significant flaw is noted in the following studies; Bertalli et al, Brorson et al (Plas Reconstr Surg 1998 & Lymphology 1998) Frischenschlager et al, Gothard et al, Gozza et al, Lette et al, Sander et al and Venturini et al. This glaring oversight must be remedied to validate the technical report. 2. Primary vs. Secondary Lymphedema: The treatment interventions are the same and the modalities used in intervention are likewise the same. It is unreasonable to believe that a modality which demonstrates successful efficacy in on population cannot be extrapolated to the other. Although the pathogenesis of the conditions differs, the mechanism of fluid congestion is the same and therefore the treatment of congestion is the same. These articles should be re-considered for inclusion to the technical report.	1. Frischenschlager has been added to the TA, but the other studies did not meet our inclusion criteria. 2. The pathophysiology of primary and secondary lymphedema is different and one cannot therefore automatically assume that benefits found in one population are transferable to another population. Indeed, there are plenty of examples in medicine where treatment is dependent on the cause of the condition. For example, ankle edema (not lymphedema) can be caused by heart, liver or kidney failure through different mechanisms. Treatments are quite different. Since the scope of the TA was secondary lymphedema,

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				we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup).
			3. Studies investigating risk reduction interventions were considered as prevention studies and excluded from the report. These studies highlight vital information for the clinical interventions necessary to identify lymphedema at the earliest onset and to treat lymphedema at an early stage. Well designed prospective cohort studies illustrating clinical paradigms for prospective surveillance include; patient education interventions, exercise interventions, models for measurement and clinical follow up that are standardized and controlled in the context of these trials. (Box et al, and Cornish et al 2000) The implementation of these models enables the early detection and treatment of lymphedema with minimal cost and intensity of intervention	3. The assigned scope of the review did not include prevention questions. The question of prevention is an excellent topic for future research. The issue of where prevention stops and early detection/treatment begins is insufficiently defined in the literature. Thus, we took a conservative approach and classified studies as 'prevention' if the study authors described their research as 'prevention' or reported features of a prevention study in their methods, e.g., treatment for lymphedema was initiated on all study participants regardless of symptomatology or diagnosis. We did not exclude studies based on the timing of diagnosis or treatment, provided study participants were described as having secondary lymphedema. Therefore, comparative studies undertaken to evaluate diagnostic tests or treatments for early stage secondary lymphedema were within the scope of the technology assessment.
			4."Stakeholders complained that some of the most significant research in the lymphedema field was developed in Europe, and because the tech assessment excluded peer-reviewed studies that were not published in English, some of that research may not have been represented."	4. We have added a foreign language search and the results did not change the original conclusions of the TA. We contacted one MEDCAC presenter who mentioned the existence of non-English-language studies during his presentation at the meeting and asked him if he could suggest a bibliography of non-English-language

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				studies. He did not respond to our query (twice).
Anonymous Reviewer 3	NA	1. see page 2, 20 2. see page 2	Comment 1: In addition to physical therapists, in the US evaluations are also typically done by occupational therapists and treatments are typically done by PT's, OTR's, and PT and OT assistants. It is important to acknowledge Occupational therapy for respect to the profession and for insurance reimbursement. Comment 2: There are many highly regarded training programs in the US for lymphedema management certification. You only mention specialized training outside of the country. Comment 3: For diagnosis, volumetrics are more difficult to perform in the clinic environment. If using circumferential measurement, perhaps a lower percentage of difference between limbs should be considered lymphedema in order to 'catch' it early. Past studies were not consistent in their definitions or ways of measuring. Since new research is showing importance of early diagnosis, perhaps you should re-look at bioimpdence as an acceptable method of measurement for women with breast cancer only. If there is any chance of 'reversing' lymphedema it is in the early stages, otherwise it becomes a lifelong self-management program.	1. We have added a clarification in the text to recognize OT involvement. (see Chapter 2 page 20). 2. We eliminated mention of specific programs to avoid the appearance of endorsement (we do not endorse any specific program). We only mention specific programs if they are cited by name in any of the included studies. 3. We included bioimpedence in the diagnostic testing section of the TA and commented on the current evidence for its use as a test for lymphedema. (Chapter 3 – Results).
Anonymous Reviewer 4	NA	NA	I would like to respectfully request that the literature review published in CA Cancer J Clin 2009 be looked at prior to making any decisions. This is a very comprehensive review of the literature and should shed some light on any research that is currently missing from the Tech Assessment. The link is listed below. Lawenda, BD, Mondry, TE, and Johnstone, PAS. Lymphedema: A primer on the identification and management of a chronic condition in oncologic treatment.? CA Cancer J Clin 2009; 59; 8-24. Available at URL, http://caonline.amcancersoc.org/cgi/content/full/59/1/8	The cited study is a narrative review of lymphedema in general. Many of the diagnostic tests and treatments mentioned in the review were included in our TA. Since the narrative review was not guided by research questions or literature search criteria, it may certainly have included studies that were excluded from the TA (e.g., case series).
Anonymous Reviewer 5	NA	NA	Comment 1: The Technology Assessment is based on a limited review of the body of literature that informs the current treatment of lymphedema. The basis for limiting the search strategy to RCTs	1. The technology assessment was commissioned to evaluate the published evidence for the diagnosis and treatment of secondary lymphedema. Our findings

			and observations studies with a control is understandable from a purist evidence-based perspective and perhaps even necessary for MedCAC purposes, but the shortcoming of this approach is that entities reviewing this TA, including third party payers other than CMS, may use this assessment as a definitive body of literature on which to make decisions for covering various treatment modalities. While this is a remarkable piece of work, it does not come close to encompassing what is known and practiced in the optimal treatment of lymphedema today, and that fact was brought forth in the testimony presented by a renowned group of experts at the MedCAC hearing.	suggest that more high quality studies are needed to advance the lymphedema literature. Future research could be designed to evaluate current knowledge and practice using high quality studies.
			Comment 2: The MedCAC's charge and the purpose of the TA was to review published evidence, not to review pathophysiology. However, when evidence is poor or lacking - and lack of evidence supporting lymphedema treatment was pointedly noted in the TA as well as by the MedCAC, knowledge of underlying physiology must be relied upon to inform treatment choices. Obviously, the fact that the published evidence is poor does not mean that lymphedema patients should not or cannot be treated.	2. We agree that physiology should play a role in treatment choices. The TA shows that there is little published evidence on the efficacy of these choices. The issue of who should be treated is beyond the scope of the TA and it not addressed in the TA.
			Comment 3: Any review of the TA should be combined with a review of the MedCAC hearing testimony as well as review of the tremendous number of scholarly articles, non-English language research, and texts authored by lymphedema experts. This broader view will provide more comprehensive answers to the questions posed in the TA as well as illustrate current practice and the For instance, the TA stated that no studies reported on factors which may increase risk of harms associated with treatment. Yet it is an accepted fact in lymphedema treatment that some limb-only pneumatic devices have been associated with development of a fibrotic ring at the proximal limb and with inducement or exacerbation of genital and/or trunk swelling. A study done by Boris, et al.(1) documented this risk and it is also discussed in numerous texts(2)and articles because it is seen in real-world practice. The TA also reports that "traditional deep massage is not used for lymphedema because it can damage the delicate lymphatic system" yet also reports that pressure from an IPC can be as high as	3.Boris does not have a control group and thus did not meet the inclusion criteria for the TA Foldi is a textbook and thus did not meet the inclusion criteria for the TA Mayrovitz 2007 subjects did not have lymphedema and thus the study did not meet inclusion criteria for the TA

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			300 mmHg. The TA?s statements reflect a disconnect regarding what level and type of pressures are appropriate in lymphedema treatment. Pressures have been discussed in the literature and Rockson in his MedCAC presentation alluded to a study, which was not included in the TA, that discussed pressures necessary for the propagation of lymph flow.(3) The TA triggered a healthy and overdue discussion about the status of evidence supporting lymphedema treatment. It should be viewed in that context, but as noted by the couple of examples above, it is not a complete guide for appropriate lymphedema treatment nor should it be used as a sole basis for decision-making by health insurers. 1 Boris M, Weindorf S, Lasinski BB. The risk of genital edema after external pump compression for lower limb lymphedema. Lymphology 1998; 31: 15-20 2 Foldi M, Foldi E, Kubik S. Textbook of Lymphology for Physicians and Lymphedema Therapists. 1st Ed. 2003 Urban & Fischer; English text revised by Biotext, LLC, San Francisco CA: 112, 282-283 3 Mayrovitz HN. Interface pressures produced by two different types of lymphedema therapy devices. Phys Ther. 2007: 87(10): 1379-88	
Anonymous Reviewer 6	NA	NA	As a physical therapist who specializes in breast cancer rehabilitation, it is morbidly evident that we need to provide adequate means for treatment of secondary lymphedema due to breast cancer. Up to 1/3 women are affected by this disease, and it is one without a cure. The pain and possible deformity affects their daily lives in terms of pain, self esteem, clothing choices ... everyday living. Caring for lymphedema includes massage, compression wrapping, and use of compression garments to control the swelling. Insurance covers slings for rotator cuff repair ... what is the difference between this and covering garments needed for control of lymphedema? Please provide assistance and means for women (and men) who are affected by this debilitating disease.	Thank you for your comments. We have no influence on funding decisions, which are beyond the scope of the TA.

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Ayres, Margaret	Oncology Section APTA	NA	Point 1: Errant classification of primary lymphedema in studies clearly investigating secondary lymphedema Stratification of primary and secondary lymphedema was faulty in the report of excluded studies (Appendix C) and calls into question the entire validity of the tech report. A notable flaw in the review of research reports must be remedied. The reviewers excluded several studies which they classified as ?Primary lymphedema? but were clearly secondary lymphedema studies as noted in their titles or abstracts. The authors of these excluded studies expressly defined their study population as ?breast cancer patients?, ?patients after mastectomy?, ?cancer patients?, however since they did not use the specific words; ?secondary lymphedema? they were incorrectly excluded. The definition of secondary lymphedema is that which results from cancer treatment (among other inciting factors) therefore a study including only patients with lymphedema who have had cancer treatment is inherently a study of secondary lymphedema. This significant flaw is noted in the following studies; Bertalli et al, Brorson et al (Plas Reconstr Surg 1998 & Lymphology 1998) Frischenschlager et al, Gothard et al, Gozza et al, Lette et al, Sander et al and Venturini et al. This glaring oversight must be remedied to validate the technical report. Point 2: Excluded studies that were conducted on patient cohorts that included both primary and secondary lymphedema Many well-designed studies, focused on the efficacy of treatment modalities, were excluded because they included both primary and secondary lymphedema patients. Scientific rigor in randomized controlled trials dictates that if study results are to be extrapolable to the greater population, then like representation of the population should be exhibited in the study design. Excellent studies such as Badger et al, Bergan et al, Damstra et al, Matthews et al, Mayrovitz et al (Lymphology 2005) Mayrovitz et al (Lymphology 2006) and Monnin-Delhom et al, that demonstrate sound efficacy of a	1. A review of the excluded studies list was conducted and only Frischenschlager et al was incorrectly excluded and thus added to the TA. All other articles mentioned did not meet inclusion criteria for the TA 2. The pathophysiology of primary and secondary lymphedema is different and one cannot therefore automatically assume that benefits found in one population are transferable to another population. Indeed, there are plenty of examples in medicine where treatment is dependent on the cause of the condition. For example, ankle edema (not lymphedema) can be caused by heart, liver or kidney failure through different mechanisms. Treatments are quite different. Since the scope of the TA was secondary lymphedema, we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary

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			treatment modality for lymphedema were excluded from consideration because of the integration of primary lymphedema patients into the study. It is unreasonable that these studies would be scientifically valid if they did not explore application in both primary and secondary lymphedema. It is also unreasonable that their results should not be considered extrapolable to secondary lymphedema. A significant limitation exists in constraining the technical review to explore only and exclusively studies that offered treatment for secondary lymphedema. Regardless of the pathogenesis of the condition (primary vs. secondary) the treatment interventions are the same and the modalities used in intervention are likewise the same. It is unreasonable to believe that a modality which demonstrates successful efficacy in on population cannot be extrapolated to the other. The modality impacts the mechanism of fluid exchange and resorption. In both primary and secondary lymphedema conditions, this mechanism is faulty. Although the pathogenesis of the conditions differs, the mechanism of fluid congestion is the same and therefore the treatment of congestion is the same. These articles should be re-considered for inclusion to the technical report. Point 3: Prevention Studies errantly classified Studies investigating risk reduction interventions were considered as prevention studies and excluded from the report. These studies highlight vital information for the clinical interventions necessary to identify lymphedema at the earliest onset and to treat lymphedema at an early stage. Well designed prospective cohort studies illustrating clinical paradigms for prospective surveillance include; patient education interventions, exercise interventions, models for measurement and clinical follow up that are standardized and controlled in the context of these trials. (Box et al, and Cornish et al 2000) The implementation of these models enables the early detection and treatment of lymphedema with minimal cost and intensity of intervention.	and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup). 3. The assigned scope of the review did not include prevention. The question of prevention is an excellent topic for future work. The issue of where prevention stops and early detection/treatment begins is insufficiently defined in the literature. Thus, we took a conservative approach and classified studies as ‘prevention’ if the study authors described their research as ‘prevention’ or reported features of a prevention study in their methods, e.g., treatment for lymphedema was initiated on all study participants regardless of symptomatology or diagnosis. We did not exclude studies based on the timing of

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			The purpose in each of these studies is not presented as a prevention trial. In fact, each highlights that early detection and management of early stage lymphedema is the goal. This challenges us to look beyond the current construct of ?treating an existing impairment? and encourages us to consider a new paradigm of care that focuses on ?early identification and treatment of an impairment?. These methods of intervention are vastly different as the latter takes on a preventive approach in identifying impairments that will present and managing them at an early stage. This is considered a ?Secondary Prevention? approach and is espoused in the realm of public health as an optimal construct for disease morbidity intervention and ultimate cost savings. This construct should be embraced as we investigate the secondary lymphedema literature. Secondary lymphedema is a morbidity directly related to primary cancer disease treatment and secondary prevention approaches such as those espoused in these excluded research studies should be considered by the technical report.	diagnosis or treatment, provided study participants were described as having secondary lymphedema. Therefore, comparative studies undertaken to evaluate diagnostic tests or treatments for early stage secondary lymphedema were within the scope of the technology assessment.
			Point 4: Numerous studies were excluded from Appendix C implying that these studies were not even considered by the reviewers.	4. Appendix C only lists the studies excluded at full text. The reviewers reviewed over 3000 titles and abstracts in the original draft of the TA. We have included a footnote in this Appendix to make this a little clearer.
			Point 5: Definition of Diagnostic Exploratory Studies It is unclear why 'Diagnostic Exploratory Studies' were excluded when a specific charge for the review was to identify studies that offered sufficient evidence of 'Quantitative techniques to determine limb volume/skin elasticity' and 'Patient reported symptomatology'. (MedCAC Question 1, Part b and c) Quantitative techniques were explored in adequately powered and controlled studies by: Balzarini et al, Berard et al, Mayrovitz et al (Lymphology 2007 and Physiol Funct Imaging 2009), and Ward et al. These studies should be reconsidered. Patient reported symptomatology was explored in a substantially	5. The term diagnostic exploratory was used to describe studies that did not examine validity, sensitivity/specificity, reliability or responsiveness of diagnostic tests. The excluded studies list was reviewed and Ward and Stanton were added to the TA.

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			powered cohort study by Armer et al, however was excluded. This study should be reconsidered	
Bonanno, Andrea	Physiotherapist	NA	As a physical therapist who treats patients with secondary lymphedema, I want to acknowledge the importance of patients receiving services for comprehensive decongestive therapy (CDT) for the management of lymphedema. CDT includes both manual lymphatic drainage (MLD) and compression wrapping and bandaging. While there is literature that supports this use of CDT for patients with secondary lymphedema, further research regarding mode, frequency, duration and intensity of different interventions will facilitate refinement of patient interventions. Just as with medical management and the ongoing research which is completed to further refine medications regimes, further research in the area of secondary lymphedema will support refinements in patient management. Lymphedema is an unfortunate side effect of life saving treatment (e.g. treatment for breast cancer) and patients deserve ongoing research to improve their quality of care and outcomes.	Thank you for your comments. We are an evidence based practice center and have no influence on funding decisions
Cohen, Sara OTR/L	Memorial Sloan-Kettering Cancer Center	NA	On page 2 of the technology assessment, the document states: "Treatments are typically administered by physical therapists." Additionally, in the section titled: "Who are the Health Care Professionals That Administer These Treatments?" on page 20, the document further states "Typically, physical therapists administer lymphedema treatments, though massage therapists, nurses, and physicians may also perform certain kinds of lymphedema treatments." Occupational therapy is a separate profession from physical therapy, and many occupational therapists provide lymphedema treatment throughout the United States. All of the training programs accept occupational therapists for training in lymphedema management. Occupational therapists are licensed to provide this therapy, and the therapy provided by occupational therapists is covered by Medicare and most other insurance companies. Please include the profession of occupational therapy in this document.	Thank you for your comment. The profession of OT has been added to the TA.
Decourcy Squire	Complex lymphatic	NA	I am a certified lymphedema therapist who has been treating patients with lymphedema of various etiologies for 15 years. I am	Thank you for your comments. We are an evidence based practice center and have no

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	therapy courses		also a lymphedema instructor and train other therapists. My two major concerns about Medicare coverage for lymphedema treatment are 1. Compression garments and compression wrapping materials are an essential part of the treatment and management of lymphedema. Without them, patients are unable to maintain the results of intensive treatment to keep their lymphedema under control. These items are often imported, are often required to be custom-made, are often subject to hospital or third party markups--and thus are extremely expensive for patients who have to pay out-of-pocket. I think these should be covered by Medicare. 2. The treatment for lymphedema which is internationally acknowledged as currently the most effective treatment is a combination of manual lymph drainage, compression wrapping, specific exercises, skin care, and instruction in self-care and activity modification. This treatment is generally most effective if done 4-6 times a week by a trained therapist until maximum reductions are achieved and the patient is independent in a self-care program to maintain these results. Because the etiology, severity, duration, and extent of lymphedema varies from patient to patient, treatment length may also need to vary. Instead of an arbitrary limit of number of visits, lymphedema visits should be by medical necessity (as such conditions as wounds are). Thank you for considering these points.	influence on funding decisions. While the evidence reviewed in our technology assessment did not point to any particular treatment that could be categorized as "most effective", we would like to point out that a lack of evidence for the effectiveness of a particular therapy should not be equated with evidence for ineffectiveness.
Ehrlichm Abb	Lymph Notes	NA	The following are insights I have gained as a patient and through my involvement as a member of the Lymph Notes website and authoring books to help lymphedema patients. (1) As speakers at the meeting noted, lymphedema is not just arms and legs. A "one-size-fits-all" treatment and reimbursement plan, based on arms and legs, is neither effective, nor fair, to patients. (2) It is essential that the training requirements for lymphedema therapists be clarified and publicized. Unethical individuals claim to be qualified therapists and patients have no way of evaluating their training. (3) Locating a qualified therapist is also a major problem for patients. A central listing, organized by state, would be a great	Thank you for your comments

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			patient service. (4) Early detection of developing lymphedema holds promise in controlling this condition. There should be a way to encourage/require oncologists to educate patients before cancer treatment begins. (5) As cancer survivors with lymphedema age, providing self-care becomes increasingly difficult and the services of a trained caregiver is increasingly important. Organizing appropriate training for caregivers should be considered.	
Elliott, Bettina H.	Private Citizen	NA	I am a 12+ year survivor of Stage 4 Inflammatory Breast Cancer and as such consider myself a very fortunate person. Needless to say, I wouldn't be alive today if I had not had expert care and follow-up care. I owe an enormous amount to my specialty physical therapist, whom I do not need to see so often any more. But she is the person who put me on the right path. Medical doctors still have a lot to learn. I do have a residual reminder lymphedema of the right arm; the fluid extends down into my right rib cage. Medicare does pay for a compression machine, which has helped in the past. However, I have given it up for the last one and one-half years, and my arm is none the worse for that. However, I do wear a compression sleeve every day; this sleeve is not covered at all by Medicare. It is a very curious fact that Medicare pays for a piece of machinery that has been proven to be of doubtful value, and is very expensive. On the other hand, a compression sleeve is not paid for by Medicare; it is relatively inexpensive, and its faithful use bears astonishing results. Nevertheless, the compression sleeve (at approximately $150+) is not so inexpensive that it is beyond many people's means. Considering its great benefits (it doesn't usually take the lymphedema away, but it controls it and keeps the affected limb from getting bigger with fluid build-up), it is astonishing that 'evidence-based research' has not found it to be very worthwhile for women with lymphedema to have. It is necessary to have two at any given time; they do need to be carefully washed and dried. I have spoken with some young women (I am now 75) who have	Thank you for your comments. We have no influence on funding decisions, which are beyond the scope of the TA. Regarding evidence-based research and compression sleeves, we would like to point out that a lack of evidence for the effectiveness of a particular therapy should not be equated with evidence for ineffectiveness. Rather, the type of research needed to assess effectiveness may simply not have been conducted yet.

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			survived breast cancer with ensuing lymphedema. Perhaps because they are young and their bodies more resilient, they have been able to 'cure' their lymphedema by faithful use of the compression sleeve for a period of about two years. They are then free of the lymphedema and the need for the sleeve (which they nevertheless still keep close at hand, for airplane trips, for gardening, and the like). It seems to me that the powers who make some medical decisions need to be conversant with patients' experiences. In the end, this will provide the best care at the lowest cost. I urge you to encourage the CMS to pursue coverage for compression sleeves for breast cancer survivors with arm lymphedema, and for the necessary education to use them properly. The best education probably comes from the specialty physical therapists, who can do manual drainage on a periodic basis while educating their patients about exercise and the proper use of the lymphedema compression sleeve.	
Frost, Ann PT	Queen's Women's Health Center, Honolulu, Hawaii	NA	Thank you for your interest in lymphedema however I believe your report gives insufficient attention to secondary lymphedema, most commonly manifested in the U.S. as breast-cancer related. This type of lymphedema affects approximately 20-30% of this population. If left untreated it can result in infection, hospitalization, disfigurement, and severe functional deficits. Physical therapy/complex decongestive therapy has been shown to provide benefit in people with this condition. It is extremely important that patients be able to receive treatment and that we continue to collect relevant information about this treatment and its outcomes.	We respectfully disagree with your comment that the report gives insufficient attention to secondary lymphedema related to breast cancer. The TA report is primarily about secondary lymphedema from breast cancer (most included articles involved breast cancer lymphedema patients).
Hayes, Sandi M.D.	Queensland University of Technology, Australia	NA	**Comment 1**: It was with interest that I read the diagnosis and treatment of secondary lymphedema report. The authors, I believe, accurately reflect the state of the literature by concluding that "the field of research into secondary lymphoedema is ripe for advancement". **Comment 2**: They also concluded that "the contents of this report may serve as a springboard to guide future scientific endeavors in	1. Thank you 2. The purpose of our TA was to comment on the current literature. Dr. Hayes's final sentence

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			this domain". It is this latter comment that is of concern, since it is noted earlier that limb and volume circumference measures are the de facto 'gold standard' of assessment. While these methods of diagnosing lymphoedema are commonly used, both in research and practice, this in itself does not demonstrate they are the most appropriate or sensitive measures. I would like to direct the authors of the report to a recent publication: Piller N, Keeley V, Ryan T, Hayes S, Ridner S. Early detection ' a strategy to reduce risk and severity' Journal of Lymphology, 2009; 4(1). Many of the questions addressed by the technology assessment report were presented to lymphoedema experts in the compilation of this particular publication. While the publication presents opinions of the experts involved, their comments are backed by science (with references listed). Further, given that the technology assessment report has the potential to influence future research in the area, it is pertinent to highlight that the way we measure lymphoedema influences what we learn from the research, including its prevalence and incidence, associated risk factors, as well as the effectiveness of prevention and treatment strategies. Therefore, careful consideration needs to be given to how lymphoedema is measured, rather than simply replicating how lymphoedema has been 'traditionally' measured.	("…careful consideration needs to be given to how lymphoedema is measured, rather than simply replicating how lymphoedema has been 'traditionally' measured") confirms what we write in the TA (i.e., "the contents of this report may serve as a springboard to guide future scientific endeavors in this domain").
Jacobs, Laura F. MD, PhD	Norma Tec	NA	I wanted to bring to your attention the following important clinical research project comparing several different non-invasive treatments for secondary lymphedema that is currently underway. Because this research project has not yet been completed, it obviously would not have been identified in the AHRQ Technology Assessment review of the literature. Nonetheless, it is a significant step towards the type of evidence-based medicine that is required in the current healthcare landscape. For information regarding the research project, please review the following clinicaltrials.gov link: http://clinicaltrials.gov/ct2/show/NCT00951067 Some brief highlights of the project: - prospective, randomized clinical trial - investigators are blinded to the treatment a subject gets	Thank you for mentioning this important, ongoing study. We look forward to the results.

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			- population = adult patients with upper extremity secondary lymphedema (including lymphedema secondary to breast cancer, melanoma, and other etiologies) - Patients are randomized into one of the following five treatment groups: o 'conservative' care: elevation, exercise and a gradient compression sleeve o use of the Huntleigh Flowtron Hydroven' 3, an E0650 PCD with a non-sequential pneumatic waveform o use of the Lymphapress Petite Basic System (Model 701A), an E0651 PCD with a sequential, non-gradient pneumatic waveform o use of the Bio Compression Sequential Circulator 3008, an E0652 PCD with a sequential, gradient pneumatic waveform o use of the NormaTec PCD, an E0652 PCD with peristaltic pulse pneumatic waveform - All treatment is done at home, the devices are used 2 hours a day, and the length of treatment is 6 months - Additionally, the project includes a cross-over design: all patients will then be treated with the NormaTec PCD during month 7 - Primary outcome measurement is change in limb volume as measured by water displacement - Other outcome measurements include circumferential limb measurements and quality of life questionnaires - The project is being sponsored by the Lymphedema clinic at Boston Children's Hospital (Department of Plastic Surgery), and the Principal Investigator is Arin Greene, MD, of the Department of Plastic Surgery. It is hoped that this RCT project will yield the clinical data that will provide clinicians, patients, and health insurers the information they need to make the critical decisions regarding medically necessary healthcare.	
Lasinski, Bonnie B. MA, PT, CI, CLT-LANA	Lymphedema Therapy, Woodbury, New York	NA	It is frustrating that the articles listed at the end of this statement were not considered for this review. These articles show that following a course of Complete Decongestive Therapy (CDT), patients can maintain their edema reductions by adherence to wearing compression garments and performing self Manual Lymph Drainage and a patient specific lymphatic exercise program. In	These articles do not contain comparison groups and, as such, were excluded from the TA. Articles without comparison groups cannot be used to ascertain the efficacy of treatment. These articles merely suggest hypotheses for further testing in comparative studies.

			these studies, good adherence to the self-care program led to positive outcomes for patients with breast cancer related lymphedema as well as lymphedema secondary to gynecological/oncologic surgeries/radiation, and lymphedema secondary to chronic venous insufficiency. Although these were retrospective studies, they nevertheless are important and are some of the few with long-term follow-up from 36-60 months post treatment of lymphedema with CDT. Please consider reviewing these studies which address the long-term maintenance of reduction of lymphedema after a single course of CDT with only adherence to wearing compression garments and performing self MLD and exercises daily. No additional courses of treatment were given to these patients. Patient education in self-care is an essential part of Complete Decongestive Therapy and is likely the reason for the good outcomes in these studies. Therapists need sufficient time to not only provide physical treatment but to teach their patients how to help themselves manage this chronic condition. Thank you for your consideration. Sincerely, Bonnie B. Lasinski, MA, PT, CI, CLT-LANA Clinical Director Lymphedema Therapy Woodbury, New York 516-364-2200 Boris M, Weindorf S, Lasinski, B: Lymphedema reduction by noninvasive complex lymphedema therapy, Oncology 8(9):95-106, 1994. Boris M, Weindorf S, Lasinski, B: Persistence of lymphedema reduction after noninvasive complex lymphedema therapy, Oncology 11(1): 99-109, 1997. Lasinski B, Boris M. Comprehensive Lymphedema Management; Results of a 5-Year Follow-Up. Lymphology 35 (Suppl):301-304, 2002.	
Leiserowitz, Andréa MPT, CLT	Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center	NA	I have specialized in oncology rehabilitation as a physical therapist for 13 years, working at NIH, MD Anderson Cancer Center, University of Washington Medical Center and currently the Seattle Cancer Care Alliance/Fred Hutchinson Cancer Center with pediatric and adult patients and teaching oncology rehabilitation locally and nationally.	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA

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			Any patient post lymph node dissection and/or radiation is at risk for secondary lymphehdema. This is not simply a breast cancer issue but an issue for a large percentage of oncology patients: melanoma, lymphoma, sarcoma, prostate, head/neck, GYN cancers, etc. Most of these patients have no knowledge of lymphedema, it's risks, how to reduce their risk of cellulitis, how to reduce the risk of lymphedmea, etc. Because of the focus mostly on breast cancer, the rest of these patients tend to have symptoms of lymphedema for months or years often with concurrent wounds before being referred to a physical therapist. Lymphedema is a lifelong condition and it occurs even with sentinel node biopsy alone. Lack of medical coverage is devastating to these men, women and children who due to improper management, have chronic flares over his/her lifetime necessitating immediate and appropriate care. Our health care costs rise substantially when patients lack knowledge for risk reduction, immediate care for new lymphedema or new flares, or are referred in the later stages when they require exponentially more appointments and targeted therapy. Please consider the millions of past, current and future patients who are at risk of or have/will develop secondary lympehdema. It costs our nation much more when we do not provide adequate medical coverage initially.	
Litterini, Amy PT, DPT	Center for Cancer Care at Exeter Hospital..	NA	Lymphedema management is a critical component of comprehensive oncology rehabilitation for cancer survivors and others who suffer from secondary lymphedema. Without it, patients are forced to suffer with a reminder of their cancer history that can be disfiguring, increase their risk for infection, cause disability from functional limitations and cause pain from increased weight of lymphatic fluid. I have been fortunate enough to see the benefits of lymphedema management first hand since 1996 when I began successfully treating patients with manual lymphatic drainage massage, compression techniques and exercise. Without this valuable service, many patients will suffer needlessly. In addition, untreated or undertreated lymphedema also increases	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA.

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			healthcare costs due to often recurrent infections that can result in hospitalization. I urge you to allow for this important care to be provided to our patients.	
Lovejoy-Evans, Loraine MPT, DPT	Physical Therapist	NA	My name is Loraine Lovejoy-Evans, MPT, DPT, I was trained in two weekend courses on treating lymphedema and had fabulous success with the treatment protocols for the lymphatic system treatment. Then I was lucky enough to spend 4 weeks in Hinterzarten, Germany where I studied with Michael and Ethel F'ldi, M.D. at their clinic that specializes in only treating swelling pathologies. At that time I also became certified in treating lymphedema. Since returning to the US from this training in 1999 I have specialized in treating swelling pathologies. I think it is a mistake for us to focus on a diagnosis and have always felt this way. I teach continuing education courses across the country to beginning through advanced physical therapists on using lymphatic system treatments to address edemas from all diagnoses. I also teach as an adjunct faculty at the University of Puget Sound in Tacoma, WA to the doctoral physical therapy students. In that program we primarily focus on using lymphatic system treatments to improve the outcome in orthopedic patients. I have routinely seen dramatic reduction in pain and improvements in AROM with these treatments in the orthopedic arena. Therefore I do not think of myself as treating lymphedema only but rather as a swelling disorder specialist. The other main approach I believe is having a very large impact is to recognize that all cancer patients and all surgical patients are at risk for developing lymphedema and I try to catch patients on the left side of the curve to run a preventative protocol. In the past year we have seen breast cancer patients in our region the first week of radiation-we have seen many more patients this past year compared with the previous 7 years since opening my private practice. However, I am very pleased to say that we have not had to put one new breast cancer patient in a compression sleeve for full-blown lymphedema since we have started this more aggressive preventative protocol. So I believe that the more we can advocate for early education and prevention the less care patients will need in the long run.	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA

			However, until that day patients have lymphedema from several etiologies and will need care. The patients seen in the clinic are on a spectrum. Some come early with barely perceptible lymphedema but others have gross severe swelling and severe fibrosis from inadequate recognition of this problem or lack of knowledge from primary care providers that treatment is now available for these conditions. With appropriate treatment using Complete Lymphedema Therapy (CLT) which is also know with several different names-I learned it 12 years ago as Complex Decongestive Physiotherapy (CDP) protocol-patients can have remarkable improvements in functional mobility and quality of life. Insurance has a huge cost savings in reduction of medical office visits with their primary care provider or specialist; reduction in infections and medications and hospitalization that can be required; and even reduction in need for caregivers and medical equipment to improve locomotion for several patients. CLT treatment consists of four main components with Manual Lymphatic Drainage (MLD) highly specialized soft tissue mobilization techniques to redirect stagnating protein-enriched fluid to healthy functioning lymphatic quadrants and the regional lymph node groups to proximally pull the fluid centrally; compression with short-stretch compression bandages and specialized foams to break down congestion and promote reabsorption of fluid and especially protein molecules; patient education in skin care and prevention of dry skin and skin breakdown; and exercises of all natures including stretching, lymphatic stimulating, progressive resistive strength training, and cardiovascular at the current functional capacity of each patient. Bandaging must be reapplied on a frequent enough basis to capture the education and continue to progress the reduction rather than allowing the bandages to be so loose they fill back up again. Typically this can be done TIW, but initially if it is done daily this is even more effective. Compression bandaging continues until the fibrosis softens and the girth reduces adequately so the skin mobility is within normal limits or bone is palpated such as at the anterior tibia or malleoli for the lower extremities. Once adequate reduction has occurred the patient is then fit with appropriate	

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			compression to maintain this reduction of girth and improvement in skin mobility for the remainder of their life. This is where the art of medicine comes in to play. Each patient is different and it takes a physical therapist to assess their ability to don socks with appropriate hip mobility, lumbar spine mobility, arm strength etc. Many times patients cannot tolerate appropriate compression garments so other options have to be sought out to work. Often times patients do not have the cognition or the ability to don compression so a caregiver is needed. The greater the swelling present, the more fibrosis present, the longer the care will be needed in compression bandaging to achieve the appropriate outcomes. The earlier in the swelling spectrum we can have the patients in the clinic the less care will be needed. For my doctoral study that we are currently writing up, for example, we saw knee pain reducing from 8/10 to 2/10 with 2 weeks of a home program using these treatment protocols. However, since primary care providers are sending patients once they have reached the right side of the spectrum these patients require more care. Patients with severe lymphedema and severe fibrosis and those with wounds will require 3-5 times a week for 4-12 weeks per limb with 60 to 120 minutes of care each visit. Those with moderate edema and mild to moderate fibrosis may only require TIW for 3-4 weeks and those with mild edema and little to no fibrosis may only require TIW for 2 weeks. Those with edema that does not appear to be a problem to the medical field or the patient may only require 3-4 visits to instruct them on their etiology of pathology and a home program. I am so excited personally to see such a reduction in need for more aggressive care by focusing on the prevention protocols and catching people on the left side of the swelling spectrum. The Oncology Section of the American Physical Therapy Association has laid out a very nice strategic plan to help improve the education level of all PTs coming out of academic facilities. Then the focus will be to work on educating the primary care providers and specialists that this care is available. Then we will help to educate the patients that this care is available. There is definitely a ground swell of physical therapists who are taking continuing education	

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			and there are several universities promoting this education so we are well on our way. Many of the PTs across the country have gone on for more intensive training and received certifications such as myself from a variety of groups. I want to make sure to help you understand that my training at the weekend courses I started with provided me with adequate information to practice this care and in fact I was seeing remarkable outcomes applying these treatment approaches even before I went to Germany to study. So I am not of the belief that one has to be "certified" to treat patients with lymphedema. As with other complex cases, if a therapist does not have the skill to appropriately provide care for a patient they will send them on to someone with more training or experience. However, I do not believe reimbursement should be limited to those with certification. All educational programs and all learners are not alike. I have seen remarkable outcomes from my students who took my 2-day advanced course on a weekend. As an educator I took out the extensive practice under my eyes. I made sure each student had the ability to appropriately understand the anatomy and physiology and especially the pathophysiology and etiological understanding of the problem. Then they also received a strong understanding of clinical contraindications against treatment. Focusing on understanding the pathophysiology and the physiological properties of the treatment components to promote normal facilitation of the lymphatic system helps make each student a knowlegible clinician with good judgement and ability to provide this care. Each student must be able to demonstrate ability to perform all of the components of treatment and then they go back to their clinics to practice what they have learned in these courses. The photos and stories of success I hear back are truly inspiring. I hope this outline will help to promote a better understanding of the treatment approaches for lymphedema in the clinic. My personal hope is that CMS will open a dialogue to help promote prevention protocols which will show a dramatic reduction in costs overall and need for services for those more lymphedematous limbs. I am a wound care specialist as well and have used these treatment approaches to heal wounds in 1/4 the time it typically	

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			takes with venous stasis ulcerations. I believe strongly that we can prevent all venous stasis ulcerations (and the cost associated which was 7 Billion annually last time I looked) by having CMS cover the cost of appropriate compression garments before the wound ever develops. I have been working on this contacting Medicare without success for over 10 years. I believe that the TECH Assessment has pointed out what we have been working on over the past several years which is improved research. As a clinician I have primarily been focused on seeing 9-10 hours of patients per day. If I have funding I can do research and hope to be able to partner up with a group to be able to further study the work I am doing to get it published. I would love to be on a task force or a committee to help promote a preventative protocol to educate health care providers and Medicare in a cost-savings program for all. It is my ardent wish to never have to wrap another arm or leg of a patient living with lymphedema. Prevention is so much kinder for all. I have worked for years in contacting Medicare and other insurance companies to help them understand these treatment protocols and to improve reimbursement for patients. I serve on the reimbursement committee for the State of Washington Chapter and the Oncology Section of the American Physical Therapy Association. I also contacted Medicare and was told that decisions for coverage were made from the Provider Outreach and Education Advisory Group and am a member of that group. However, it has become obvious that this is not the best place to help make these treatments more understood to improve reimbursement. I would like to help with this if given the chance. Thank you for your willingness to consider this information.	
Lovelace-Chandler, Venita PT, PhD, PCS	APTA member and survivor	NA	I am a physical therapist who has had cancer 3 times. I had initial breast cancer in 1996, local recurrence in 2000, and level 3 lymph node involvement in 2005. I did not get any lymphedema with the first cancer even after agressive treatment (chemotherapy). However, after the second treatment for cancer (chemo and radiation), I got some lymphedema. My husband, a PT, could help me that time, but after the third time and agressive chemotherapy,	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA.

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			he and I just couldn't do it alone. We are pediatric physical therapists. I have had to work to prevent lymphedema in my arms and trunk. I am a PhD professor of physical therapy, but I could not manage this care without help from a physical therapist with expertise in that area. I have to be very careful about my arms and trunk, and I am certain I will need more therapy if I am able to continue to survive. If I have another recurrence and have to face even more chemo, then I will need a significant amount of help to manage the lymphedema. If I become terminal, I will want to stay functional as long as possible for my children, husband, and 5 grandchildren. I am fortunate to know how to seek care, but other women need to have these services available to them. Please help us.	
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of support: The length and detail of this report (125 pages) attests to the extensive amount of time and effort afforded its investigation, analysis and summary of conclusions. The purpose statement and salient questions were clearly defined for the technology assessment of diagnosis and treatment secondary lymphedema. Additionally, the questions as posed by AHRQ to contractor appeared timely and appropriate to advance the understanding, rationale and effectiveness supported by current evidence in the literature.	Thank You
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of concern: While it understood that AHRQ has established affiliation with a number of evidence based practice centers, the rationale or process for choice of selection of McMaster University Evidence Based Practice Center (MU-EPC) over other sites identified below was not identified or described. Additionally, it appears that certain sites designated by the superscript of ‘(as seen below), are institutions that specifically focus on technology assessments for CMS, the intended recipient of this report. The center chosen for this report, McMaster University Evidence Based Practice Center, does not have such designation, but obviously selected for based on other criteria. Lastly, a reader, (especially an American citizen/ taxpayer), of this report may be justified in questioning why a non-United States based academic site was contracted to conduct a technology	AHRQ assigned the TA to McMaster University EPC. We did not compete for the TA. The TA was an unbiased examination of the published, scientific evidence for diagnostic tests and treatments for secondary lymphedema. The scientific process used to conduct this assessment does not differ depending on institution, region, or country. It appears that only 4 of the CMS locations have been identified on the EPC website. McMaster is the 5th. We will notify AHRQ that the oversight should be corrected. McMaster University has been part of the AHRQ EPC program since its inception in 1997.

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			assessment of a health care issue which could have significant ramifications for health care policy, coding or reimbursement involving patients, providers and third party payers in the United States. Further, while it has been clearly established that the report 'does not represent and should not be construed to represent an AHRQ determination or policy,' the dissemination of this report to the US health care systems and general public through the media has the potential to impact the attitude, credibility and confidence associated with existing science and clinical practice in diagnosis and management of secondary lymphedema. • Blue Cross and Blue Shield Association, Technology Evaluation Center. • Duke University. (1) • ECRI Institute. (1) • Johns Hopkins University. • McMaster University. • Minnesota Evidence-based Practice Center. • Oregon Evidence-based Practice Center. (2) • RTI International - University of North Carolina. • Southern California. • Tufts-New England Medical Center. (1) • University of Alberta. (1) • University of Connecticut. • University of Ottawa. • Vanderbilt University. 1. EPCs that focus on technology assessments for CMS. 2. EPC that focuses on evidence reports for the USPSTF. The credentials of the authors for the report are not listed, adding an additional question of the qualifications of the writers, but especially the "team of trained raters" (not identified) that applied the inclusion and exclusion criteria to the three levels of evidence screening. Source: http://www.ahrq.gov/clinic/epc/	
McGarvey, Charles	CLM Consulting	NA	Statement of support: Differentiation between primary and secondary lymphedema was	Thank you

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	Services LLC		well described and consistent with current clinical understanding of the pathophysiology and epidemiology of the impairment. Current clinical methods employed in the assessment and diagnosis of lymphedema were also well summarized. The additional identification of which methods and devices were cleared by the Food and Drug Administration (FDA) were extremely helpful in qualifying which of the devices have been evaluated, at what level and for what intended purpose.	
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of concern: The description of the staging of lymphedema as proposed and published by the International Society of Lymphology (ISL) is acknowledged as one, but not necessarily the only, staging or classification schema used by researchers or clinicians. This staging method relies on a qualitative or descriptive method to operationally define various levels of severity versus other methods that employ a more quantifiable measure of anthropometric change. Traditional units of measure used to identify various levels of severity or grade include centimeters (cm), millimeters (mm), inches (in.) percentage (%) etc and have been described by a number of past authors. The following chart represents a summary of the methods employed by various researchers and clinicians: Descriptive: Stage I Reversible Stage III Spontaneously Irreversible Stage III Lymphostatic Elephantiasis (Vodder) Circumferential girth: Difference of 1.5-3 cm is Mild (Markowski 1981) Difference > than 2.0 cm at any 4 points considered mild lymphedema and warrants treatment (Harris 2001) 2-4 cm difference (LENT/SOMA 1995) < 3 cm (mild) 3-5 cm (moderate) (APTA 2001) Difference of 2.5 cm (Box 2002, Johansson, 2002 and Armer 2005) Percentage 15-22% difference is classified mild (Healey, 1971) Volume: 0-150 ml difference is classified Insignificant 150-400 ml difference is classified Slight (Tracy, 1961)	Since we were charged with reviewing the evidence for the diagnosis and treatment of secondary lymphedema, the issue of staging is rather tangential to the TA itself. We agree with the reviewer that multiple staging systems have been proposed, and many of these have been systems of convenience used by study authors, but they have not been widely adopted by other researchers or in practice. Since ISL staging was borne out of a consensus statement from many internationally respected lymphedema researchers, it has been adopted as a commonly accepted system. Certainly this could change if another system was developed that demonstrates better clinical utility (e.g., such as providing prognostic information). We are pleased to see that several classification systems have been proposed for secondary lymphedema. However, a review of these systems was beyond the scope of the TA. Researchers conducting studies in the future may wish to reference these systems as a yardstick for designing their studies.

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			5-10 % (CTCAE 3.0 NCI 2003) 200 ml (Armer 2005) > 3% volume change (Stout et al: 2008) Bioimpedance (Ohms, Intracellular/Extracellular Ratios (ICR/ECR) and Delta change of 10 of L-Dex units) Cornish, Ward, Hayes, Kilbreath and Ridner (2001-2008) While the description of these various methods and metrics to identify and classify lymphedema support the point that there is currently no 'gold standard' it does illustrate a long history of clinical inquiry and contributions toward advancing the science and attempts toward establishing a single standardized method of diagnosis. There have also been previous attempts to establish professional and organizational consensus and guidelines by various entities. Below are selected quotations and citations for those sources: International Society of Lymphology (ISL): The International Society of Lymphology published a Consensus document in 2003 which included the following statement: 'In each patient undergoing therapy, an assessment of limb volume should be made before, during and after treatment. Tissue alterations and fluid changes may also be examined by tonometry and bio-electrical impedance.' (p.90) Source: The Diagnosis and Treatment of Peripheral Lymphedema: Consensus Document of the International Society of Lymphology. Lymphology 36 (2003) pp 84-91 Canada: Canada published a series of clinical practice guidelines in 2001 in which they recommended pre and postoperative measurements of both arms. Abstract Objective: To provide information and recommendations for	

			women and their physicians when making decisions about the management of lymphedema related to breast cancer. Method of Evidence: Systematic review of English-language literature retrieved primarily from MEDLINE (1966 to April 2000) and CANCERLIT (1985 to April 2000). Nonsystematic review of breast cancer literature published to October 2000. Recommendations: ‘‘ Pre- and postoperative measurements of both arms are useful in the assessment and diagnosis of lymphedema.’ Source: Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema Susan R. Harris, Maria R. Hugi, Ivo A. Olivotto, Mark Levine, for the Steering Committee for Clinical Practice Guidelines for the Care and Treatment of Breast Cancer CMAJ JAN. 23, 2001; 164 (2) 191 Northern Ireland CREST Guidelines in Northern Ireland: - Limb volume measurements should be made as a baseline prior to treatment (e.g. surgery or radiotherapy), which is likely to cause lymphoedema. - Multiple frequency bioimpedance measurement has advantages over measurement of limb circumference in that it is applicable to bilateral limb lymphoedema (as the limb can be used as its own control). Source: Guidelines for the Diagnosis, Assessment and Management of Lymphoedma Feb. 2008 ISBN: 978-1-903982-32-7 http://www.crestni.org.uk/crest_guidelines_on_the_diagnosis__assessment_and_management_of_lymphoedema.pdf Germany 2007 Lymphedema in Patients with Breast Cancer A Consensus	

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			Regarding Diagnostics and Therapy in Patients with Postoperative Lymphedema after Primary Breast Cancer The need for improving oncological management for early diagnosis and referral for effective treatment of lymphedema is a major goal of breast cancer heath care while survival improves. Source: Seifart U et al. Lymph dem bei Mammakarzinom Konsensus Rehabilitation 2007; 46: 340-348 DOI 10.1055/s-2007-985170 Rehabilitation 2007; 46: 340-348 Georg Thieme Verlag KG Stuttgart New York ISSN 0034-3536 Also, there are four relatively recent, and seminal reference sources that have been supported directly, or in part, by the US Federal Government which were apparently omitted, or not included, in the final draft of the report which describe recommendations for grading, classification, timing of treatment and r intervention based on diagnostic criteria and follow-up care. First Source: The CTCAE 3.0 Adverse events classification system supported by the National Cancer Institute, National Institutes of Health provides a grading classification system specific to lymphedema. This grading system has been mandated for use by those investigators that have been provided federal funding for clinical research trials in the United States. Source: http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf Pp.39 and 40 Second Source: A comprehensive article describing the various grading of lymphedema in Oncology Clinical trials not referenced in the TAR: This review article summarizes established clinically based rating scales and quantitative instruments. The review conducted by the authors of this article served at the basis for the development and publication of the CTC v 3.0 quantitative techniques for the assessment of lymphedema.	

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			Source: Cheville AL, McGarvey CL, Petrek JA, Russo SA, Thiadens SR, Taylor ME. The Grading of Lymphedema in Oncology Clinical Trials? Semin Radiat Oncol. 2003 Jul; 13(3): pp: 214-25. Third Source: Published findings of a recent intramural five year clinical trial conducted and supported by the National Institutes of Health: In the study, the authors: demonstrated the effectiveness of a surveillance program that included preoperative limb volume measurement and interval postoperative follow-up to detect and treat subclinical LE. The article also contained a proposed a new classification system based on study findings and an extrapolation of data. Source: 1. Preoperative assessment enables the early diagnosis and successful treatment of lymphedema: Stout N, Pfalzer L, McGarvey C, Springer B,. Gerber L, Soballe P.Cancer Volume 112, Issue 12, Pages 2809-2819, 15 June 2008 Fourth Source: A series of charts and algorithms related to the Rehabilitation Treatment Recommended for Breast Cancer Patients (related to lymphedema) published in a highly recognized and prestigious medical textbook in 2004. The charts and algorithms specific to lymphedema are as follow: Table 89.2 Scheme for Rehabilitation Intervention (identifying initial intervention and follow-up visits) p.1407 Table 89.8 Summary Recommendation for Rehabilitation Treatments (Preoperative and Postoperative Evaluation and Intervention) p1412 Table 89.10 National Institutes of Health Clinical Classification for Secondary Lymphedema p.1413 Source: Gerber LH, Augustine E, McGarvey C and Pflazer L. Preserving and Restoring Function in Breast Cancer Survivors. In Harris J,	

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			Lippman M, Morrow M and Osborne C (Eds) Diseases of the Breast 3rd Ed. Lippincott Williams and Wilkins. Philadelphia 2004. pp. 1405-1417.	
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of support The description of the method to conduct the literature search appeared clear, typical and appropriate for the subject matter being investigated. Further description of inclusion and exclusion criteria was also clearly stated, specifically, the exclusion of surgery and drug therapy. The description of instruments used: QUADAS scale to assess the quality of the diagnosis literature And For assessment of the quality of treatment studies, the Jadad scale for RCTs and the Newcastle-Ottawa Scale (NOS) for cohort and case control studies. Personal note: Not being an epidemiologist by training, I assumed these instruments to be appropriate and accurate tools for such analysis. Further, I assumed the instruments were previously considered by AHRQ as valid and reliable instruments for such analysis. The figure on p.25 illustrated the process of screening the articles. Subsequent figures on pp. 26-28 illustrated the quality rankings for diagnostic and treatment studies in a clear and readable format.	Thank you
McGarvey, Charles	CLM Consulting Services LLC	NA	Instrumentation (QUADAS, Jadad and NOS) Again, not being an epidemiologist by training, it is assumed that these instruments to be appropriate and accurate devices and considered by AHRQ as valid and reliable instruments for such analysis. Never-the-less, following a cursory investigation to confirm psychometric properties applications, limitations and/or weaknesses of these instruments, comments and statements were discovered which may, or may not, have had an impact of the credibility or integrity of this report. The following represent selected quotes from literature and are provided below for further review and consideration: QUADAS: (From the original developers and authors of tool)	QUADAS or Jadad were not used to exclude studies. All studies that met our inclusion criteria were included in the TA, regardless of quality. We recognize the limitations of any quality assessment instrument. We leave it up to the reader to determine the value of the quality rating obtained via QUADAS or Jadad.

			There are a number of limitations to this project, and the QUADAS tool. The main problem relates to the development of a single tool which can be applied to all diagnostic accuracy studies. The objective of this project was not to produce a tool to cover everything, but to produce a quality assessment tool that can be used to assess the quality of primary studies included in systematic reviews.' Source: Whiting P, Rutjes AW Reitsma et al: The development of the QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. BMC Med Res Methodol 2003;3(25). QUADAS: Another direct quote from the original authors of the QUADAS in a subsequent evaluation of the QUADAS identified a potential problem in establishing the construct validity of the tool was published in 2006: Ideally, we would have liked to assess the 'construct validity' of the tool- 'the degree to which a test measures what it claims, or purports, to measure'. Source: Whiting P, Westwood M Rutjes A et al: Evaluation of QUADAS, a tool for the quality of diagnostic accuracy studies. BMC Medical Research Methodology, 2006 6:9 Another application of the QUADAS by investigators investigating accuracy of tools used for low back pain concluded the following: CONCLUSION: Five clinical features were identified that can be used to screen for vertebral fracture. The psychometric properties of the QUADAS scale raise concerns about its use to rate the quality of low back pain diagnosis studies.? Source: Henschke N Maher CG and Refshauge KM: A systematic review identifies five "red flags" to screen for vertebral fracture in patients with low back pain. J Clin Epidemiology 2008 Feb ;61(2) pp110-118	

			In another study conducted the validity and reliability of the QUADAS was questioned based on statistical analysis of individual QUADAS questions: RESULTS: Most studies in our review were judged to have used an accurate reference standard. Conversely, the MRS literature frequently failed to specify the length of time between index and reference tests or that the clinicians were unaware of the index test findings when reporting the reference standard. There was good correlation (rho = 0.78) between reviewers in assessment of the overall number of quality criteria met. However, mean agreement for individual QUADAS questions was only fair (kappa = 0.22) and ranged from no agreement beyond chance (kappa < 0) to moderate agreement (kappa = 0.58). CONCLUSION: Inter-rater reliability in our study was relatively low. Nevertheless, we believe that QUADAS potentially is a useful tool for highlighting the strengths and weaknesses of existing diagnostic accuracy studies. Low reliability suggests that different reviewers will reach different conclusions if QUADAS is used to exclude "low-quality" articles from meta-analyses. We discuss methods for improving the validity and reliability of QUADAS.' Source: Hollingworth W, Medina LS, Lenkinski RE et al: Interrater reliability in assessing quality of diagnositic accuracy studies using the QUADAS tool. A preliminary Assessment. Acad Radiol 2006 Jul;13 (7):803-10 In another study assessing the psychometric properties of the Jadad, the validity for it use in physical therapy trials was apparently not supported in their analysis. RESULTS: One hundred five relevant studies were identified. They accounted for 21 scales and their modifications. The majority of scales had not been rigorously developed or tested for validity and reliability. The Jadad Scale presented the best validity and reliability evidence; however, its validity for physical therapy trials has not been supported. DISCUSSION AND CONCLUSION: Many scales are used to evaluate the methodological quality of RCTs, but most of these scales have not been adequately developed and have not been adequately tested for validity and reliability. A valid and reliable scale for the assessment of the methodological	

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			quality of physical therapy trials needs to be developed. Source: Olivo SA, Macedo LG, Gadotti IC et al: Scales to assess the quality of randomized controlled trials: a systemic review.Phys Ther. 2008 Feb;88(2) 156-75.	
McGarvey, Charles	CLM Consulting Services LLC	NA	Additional Statement of concern: Section: Selection of reviewed studies (diagnostic and treatment) p.25 The figure on p. 25 illustrates that of the total number of articles screened (3186), 31, or 0.97%, of the diagnosis articles were considered for final analysis and scoring. Additionally 28 articles, or 0.87%, of the treatment articles were considered for final analysis and scoring. Combined, the total number of articles for both diagnosis and treatment equaled 59, or just less than 1.8% of all studies identified by the literature search. As such it would appear that 98.2% of all studies identified were either eliminated, or were unable to be located through the screening process and analysis using either QUADAS, Jadad or NOS instruments. Subsequent basis for the findings, analysis and conclusions contained in the body of this technical report appear to be based on a sum total of 1.8 % of the articles identified by the authors.	The elimination of such a large percentage of citations is common in most systematic reviews because the initial search criteria are intentionally set to be broad enough to capture all relevant articles. This broadness comes at a cost, namely the initial capture of a large percentage of irrelevant articles that often have little or no direct relevance to the topic of the review. These articles (the 'noise') represent the largest proportion of excluded articles.
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of support: The authors provide the lengthily and comprehensive summary of their findings tailored to answer each of the previous questions established by the original purpose of this technology assessment contract. In essence, the authors were tasked in the original objective statement with ?examining the performance of diagnostic tests for preclinical or clinically significant secondary lymphedema, as well as to assess conservative, non-pharmacological and non-surgical treatments for secondary lymphedema.? The actual series of questions answered by the investigators involved one main question and 11 sub-questions for diagnostics, and one main question and 23 sub-questions for treatment. Essentially, the technical assessment contained a total of 36 questions to be answered by the review, scoring and analysis of 59 articles.	Thank you
McGarvey, Charles	CLM Consulting	NA	Statement of concern: In my opinion, the credibility of the findings listed on pp.29-45 for	The raters were experienced raters with university degrees or student raters, all of whom were trained to

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	Services LLC		each of the questions as listed in this report, is at best, suspect, especially when one considers the following: The literature review, study selection and abstraction may not have been conducted in an accurate and standardized manner. While the process has been described, the details related to the credentials or experience of the raters was not established, nor was the inter-rater or intra-rater reliability of the process identified or described. Additionally, the elimination, or lack there of, of over 98% of all articles identified by the search raised a major sampling or the possible bias of inclusion/exclusion criteria used. Ultimately, the selection of so few articles draws into question a concern for the basis of the generalizations and conclusions provided by the authors. The instrumentation used in this project may, or may not, have been the most appropriate quality assessment tools for the systematic review of either diagnostic or treatments related to secondary lymphedema. There appears to be evidence in the literature questioning the psychometrics of the instruments and their applicability in certain areas of medicine, specifically physical therapy. Since a major portion of past studies are considered within the professional domains of rehabilitation medicine and physical therapy, utilization of tools such as the Jadad may be suspect and therefore the credibility of findings unsupported.	rate using standardized forms. Conflicts were resolved by authors who had previous experience in doing TAs for AHRQ/CMS) The elimination of such a large percentage of citations retrieved in the literature search is not necessarily indicative of a bias due to inclusion/exclusion criteria. In fact, such a high elimination percentage is common in most systematic reviews because the initial search criteria are intentionally set to be broad enough to capture all relevant articles. This broadness comes at a cost, namely the initial capture of a large percentage of irrelevant articles that often have little or no direct relevance to the topic of the review. These articles (the 'noise') represent the largest proportion of excluded articles.
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of support The authors synthesized the findings for each of the questions in a succinct and easy to read manner. Summary statements reflected overall findings in such a way as to provide answers to the questions originally posed in the objectives and purpose of the project. Many of the findings identified confounding variables including: heterogeneity of study populations, poor standardization of measurement, lack of appropriate follow-up, poor description of psychometric properties of instruments, lack of appropriate number of subjects to power studies, lack of RCT's necessary to establish a "gold standard" of detection or "best" method of treatment. These findings are consistent with the current scientific and clinical perceptions of many professionals in the field.	Thank you

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			The field of research related to lymphedema appears "immature", and, as has been identified by this report, fraught with operational and methodological problems as are well documented in similar areas of medical research. The authors should be commended on their work and effort in conducting this analysis as it assists in defining areas of weakness in the available literature and certain other areas in need of significant improvement.	
McGarvey, Charles	CLM Consulting Services LLC	NA	Statement of concern: As a professional clinician, researcher and educator in the field of oncology rehabilitation, I have actively participated in the development of clinical theory, research, and practice related to the assessment and treatment of lymphedema in patients with breast and other cancers. Based on that knowledge and experience, it is true that there is limited evidence of efficacy in the literature, however, there is none-the-less a body of evidence in the fair to good range that supports newer diagnostic methods. Examples include the use of opto-electronic volumetry and bioimpedance spectroscopy to identify early tissue changes enabling clinicians to diagnose patients with sub-clinical, latent or stage 0 lymphedema. Further, there is additional and compelling evidence that a prospective or surveillance method of screening patients at high risk of lymphedema is among the most promising areas of recent research. Both of these developments as reflected in the literature, in the opinion of this reviewer, have not been adequately or fairly addressed by this review.	We included articles without regard to specific tests or treatment used. If an article was excluded, then it was because it did not meet the inclusion criteria. Furthermore, we were not tasked with examining screening or surveillance methods.
McGarvey, Charles	CLM Consulting Services LLC	NA	Additionally, the term 'gold standard' is not typically used, or recommended, in establishing a diagnostic benchmark in medicine. Instead, the phrase criterion standard is the preferred term advocated by the American Medical Association (AMA) Style Guide and apparently mandated by the Archives of Physical Medicine and Rehabilitation. (http://en.wikipedia.org/wiki/Gold_standard_(test) As such, the suggestion by the authors of a 'de facto gold standard' endorsing circumference (using a cloth tape measure) or limb volume (calculated by disk or truncated cone formula), based on these methods being most identified in the literature, rather than sensitivity and specificity, appears rather inappropriate. Use of a cloth tape measure to obtain circumferential girth and/or	'Gold standard' is a commonly used term, notwithstanding the specific style guides of certain medical journals. We noted that the lymphedema literature does not refer to a clear gold standard diagnostic test. However, volume and circumference are used in most of the published literature, so they have achieved the status as a sort of de facto gold standard. We do not comment on the wisdom underlying the reliance on volume or circumference, rather we simply report on a clearly observable trend in the literature. We did find the psychometric properties of volume and circumference to be generally good, although we did point out the

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			volume represents an indirect form of volume or lymphedema measurement. These techniques include measures of muscle, bone and other tissues which can result in confounding factors in the assessment of lymphedema. Circumferential girth using a tape measure, has often been cited in the literature due in most part to "methods of convenience", rather than use of newer technologies with better validity and reliability properties. Further, use of a tape measure is time consuming and fraught with potential inter, intra-rater measurement error. Measurement of extracelluar fluid, the primary mechanism involved in the formation of secondary lymphedema, appears to be the most appropriate direct measurement of secondary lymphedema. The authors of this report do not appear to place appropriate "weight" on the psychometric properties of newer technologies, specifically opto-electronic volumetry or bioimpedance in demonstrating the ability to identify lymphedema at early stages of formation. Such discrimination does not advance the provider, patient or general public understanding of current medical science, or relative importance of earlier identification and treatment of lymphedema. Additionally, objectives as cited in this the report do not appear to specify investigation of factors related to ease of use, or cost of diagnostic or treatment procedures as a measure of performance. Summary statements by the authors attesting to the simplicity, usability and expense of existing methods appear unsupported. Curiously, little emphasis or consideration is placed on diagnostic methods cleared by the Food and Drug Administration (FDA) for assessment of lymphedema in the report. According to the report, bioimpedance appears to be the only FDA cleared clinical device to assess lymphedema.	lack of standardization of methods for measuring volume or circumference.
McGarvey, Charles	CLM Consulting Services LLC	NA	Secondary lymphedema is neither an abstract medical condition, nor concept, it represents a common, chronic and poorly understood impairment whose severity could be reduced and managed more effectively with proper identification and timely intervention. With an estimated 11 million cancer survivors in the United States today, and incidence rates of lymphedema ranging between 10-30% following primary medical treatment, the projected number of 2-3 million Americans with lymphedema	The TA was designed to assess the available, published evidence for diagnostic tests and treatments in secondary lymphedema. If the published evidence fails to reflect current practice, then clearly a research gap exists and the lymphedema community is free to fill this gap with high-quality research. This is especially so if the lymphedema community wishes to obtain coverage for treatments.

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			appears significant. Functional limitations, cosmetic impact and cost of managing this chronic and debilitating impairment appears also remarkable and worthy of attention. Secondary lymphedema associated with primary cancer treatment is currently diagnosed by various methods, and managed effectively with different modalities. It is clear to most clinicians, that certain diagnostic methods appear more accurate than others, and certain treatment methods more efficacious than others. This has been the basis for while academic and professional curriculums have included additional coursework emphasizing these diagnostic and treatment techniques. However, based on the findings of this report the current literature does not appear to support technological advances made in the last 20 years in diagnosis or treatment of this impairment. While the level of empirical evidence is admittedly lacking to establish the same level of consistency or credibility reserved for large scale clinical trials evaluating surgical or pharmaceutical interventions necessary to establish risk and benefit, lymphedema represents an issue of morbidity (adverse effect)" and not mortality. As a scientist and clinician, I would argue that this area of rehabilitation medicine should not be subjected to the same rigors of scrutiny required to decide issues related to mortality or significant morbidity. If, however, one evaluates the evidence anecdotal, empirical, qualitative and quantitative using a balanced process of RCTs AND best evidence synthesis, the report might reflect a more accurate and realistic account of the progress made in the field of lymphedema diagnosis and management. The apparent objective of this technology assessment project was to provide an analysis of the available evidence to assess efficacy of performance in diagnosis and treatment of secondary lymphedema. The conclusions and summary statements contained in this report appear to emphasize a lack of confirmatory science and or therapeutic benefit by exercising a process of omission, elimination and possible selection bias in the analysis.	
McGarvey, Charles	CLM Consulting Services LLC	NA	Depending on one's perspective, or objective, one could utilize the findings and conclusions in this report to provide the basis, or lack of basis, for determination of coverage for diagnostic and/or treatment approaches. Establishment of high levels of comparative	The AHRQ's EPC Program is designed to provide an objective scientific inquiry into a specific research area. As stated in the report, the findings and conclusions in a technology assessment are those of the

			effectiveness (CE) could result in higher coverage and higher health care costs for the Federal Government and third party payers. Conversely, establishment of lower levels of comparative effectiveness (CE) could result in lower determinations of coverage and lower health care costs for the same groups except patients and consumers of such services. As such, one could appreciate the potential for an apparent or real conflict of interest, as a possible outcome of the findings and conclusions stated in this report? dependent on the source and purpose of the requesting/contracting entity. Of particular note, and example, are recent media reports of controversial findings associated with the recommendations from a US Preventive Service Task Force, an element of AHRQ, which produced recommendations based on the apparent efficacy of mammograms for breast cancer screening at various ages. Among the points raised were issues related to whether such reports/recommendations were designed to confirm the lack of evidence based literature to support coverage, thereby potentially reducing the overall cost of such screening. Similar media reports on screening for pelvic cancer including cervical and prostate cancer have generated the same questions and strong public and professional response. While the media reports have resulted in an increased awareness of the issues, the current political and economic climate around health care issues has apparently become less about evidence, and more about cost, and entitlement and personal convictions about appropriate health care screening. Of special note, the Director, Center for Outcomes and Evidence, AHRQ, recently provided a presentation entitled, 'Comparative Effectiveness: A View from AHRQ' at a Managed Care Forum in Las Vegas NV on November 12, 2009 in which she summarized the major focus, priorities and challenges in the AHRQ Effective Health Care Program. The Director provided a definition for what is meant by the term, Evidence Based Medicine (EBM) and quoted Sackett et al; 2001 in suggesting that; "Evidence-based medicine is the integration of the best research	authors, who are responsible for its contents. CMS had no influence on the authors in reaching their conclusions.

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			evidence with clinical expertise and patient values." Further she differentiated what Comparative Effectiveness (CE) was, and was not: "Comparative Effectiveness (CE) is Focused on real-world circumstance and decisions Intended to help make decisions more consistent, transparent and rationale Useful in identifying gaps and uncertainties" "Comparative Effectiveness (CE) is not Solely about effectiveness Cost-effectiveness Intended as regulatory or directive Restricted to Randomized Controlled Trials Exclusionary of clinical judgment or the Circumstances of the individual patient Aimed at limiting or restricting health services" Lastly she described the AHRQ Effective Health Care Program as an effort to: - improve the quality, effectiveness, and efficiency of health care delivered through Medicare, Medicaid, and S-Chip by focusing on: What is known now What research gaps are critical to fill? Clinical Effectiveness? Assuming all of this to be an accurate reflection of the mission, goals, objectives and priorities of the AHRQ, this particular technical report appears limited in its application, accuracy and potential use in support or achieving those goals.	
McGarvey, Charles	CLM Consulting Services LLC	NA	In summary, while the Federal government (AHRQ and CMS) has attempted to proceed in an appropriate and diligent manner, to answer important questions related to the diagnosis and treatment of secondary lymphedema. The review contains a series of statements of support and concern, together with sources and citations to reference those statements. In my opinion, the current draft of the TAR may be faulty based on the following:	We have already responded to the issue regarding elimination of 98% of the initial citations. The discussion of the lymphedema classification system in Chapter 1 was provided for background purposes only and did not drive our inclusion/exclusion criteria. Our screening criteria captured all relevant articles related to diagnosis or treatment provided that the

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			Elimination of over 98% of existing articles for review and analysis; Apparent omission of certain articles; Apparent omission of previously published classification, guidelines consensus and recommendations; and Use of questionable screening and instrumentation procedures or tools. Further these factors may have contributed to a potential bias in the final analysis, findings and conclusions contained in this report. Lastly, the TAR does not appear to be representative of the current science and practice of diagnosis or treatment of secondary lymphedema. Recently published review articles by Rockson (2007), Warren (2007) and Lawenda (2009) contain more accurate descriptions of the current science, technology and treatment of lymphedema than those consistently referenced by the authors to the medical textbook: Lymphedma: Diagnosis and Treatment (2008).	authors had a comparison group. We have already addressed the use of the QUADAS and Jadad scales to rate article quality. Though recently published reviews by Rockson 2007, Warren 2007 and Lawenda 2009 provide useful information about the current science, technology and treatment of lymphedema, the authors feel that the references cited in Chapter 1 of the TA offered accurate information about lymphedema.
McGarvey, Charles	CLM Consulting Services LLC	NA	Again, as stated earlier in this review, while it is understood that this draft report "does not represent and should not be construed to represent an AHRQ determination or policy," it should be noted that the dissemination of this report to US health care providers professional organizations, advocacy groups and general public through the media has the potential to impact attitude, credibility and confidence associated with the existing science and clinical practice of diagnosis and management of secondary lymphedema.	Thank you for concern
McGarvey, Charles	CLM Consulting Services LLC	NA	Of additional concern is that this technical report was posted on the CMS website on November 2, 2009, http://www.cms.hhs.gov/mcd/viewmcac.asp?from2=viewmcac.asp&where=index&mid=51& 16 days in advance of a CMS MEDCAC public hearing held November 18, 2009. Apparently, the purpose of public hearing conducted by CMS was to discuss, and obtain an expert panel member vote on a number of recommendations related to the diagnosis and management of secondary lymphedema based in part on this report. Footnoted on that downloadable document obtained from the CMS website was the comment: Draft report: not for citation or dissemination. As such the request for an expert review by AHRQ of apparently	CMS posts the report on the CMS website for public information prior to the MedCAC meeting. AHRQ posts the report on the AHRQ website as part of the peer and public review process. The report is revised after comments are considered and the final document is submitted to CMS for their consideration. AHRQ received your comment for consideration.

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			the same draft document on November 6th, 2009, 4 days after public dissemination via the CMS website, appears to pose some confusion of the original intent of reviewing the document for accuracy prior to use of the document, by CMS and/or dissemination to the public by the Federal government.	
Mercogliano, Melissa PT, DPT, OCS	NA	NA	Thank you to the committee for its review of the literature regarding diagnosis and treatment of secondary lymphedema. I believe that further research in this field is indicated to delineate which treatment interventions or combinations of treatment are most effective in treating this populations of patients; however, I would strongly recommend that ample time be given to allow the research be done thoroughly. In the meantime, these patients are being helped daily with current interventions and that should not be stopped. Funding for this research is needed and the American Physical Therapy Association is working hard to get the studies done. I would also like to suggest that studies that included primary lymphedema patients be considered in the literature review since the treatment and diagnosis for this form of lymphedema is the same as secondary although the mechanism for its onset is different. Please also consider reviewing articles that target patients with chronic venous insufficiencies since there in the long term due develop lymphedema as the venous and secondarily the lymphatic systems fail. It would also be helpful to look at the prevention aspect of secondary lymphedema as a part of the overall treatment intervention. Several very good RCT have been completed that demonstrate early intervention prior to the onset of symptoms reduces the incidence and severity of lymphedema.(BOX et al, Stout Gergich et al)	The pathophysiology of primary and secondary lymphedema is different and thus we cannot assume equal treatment benefits between the two groups. Since the scope of the TA was secondary lymphedema, we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup). The assigned scope of the review did not include prevention questions. The question of prevention is an excellent topic for future research.
Nichols Sharp, Sarah (multiple documents-see Zip) ALSO APTA	APTA	NA	On behalf of the American Physical Therapy Association, I would like to thank the Agency for Health Care Research and Quality (AHRQ) for the opportunity to comment on the draft report entitled "Diagnosis and Treatment of Secondary Lymphedema." APTA is a professional association representing over 72,000 physical therapists, physical therapist assistants, and students of physical	Thank you for your concern. The issues that you raise are important, but they are beyond the scope of the TA. The issue of where prevention stops and early detection/treatment begins is insufficiently defined in the literature. Thus, we took a conservative approach

document			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. As a result, APTA would like to ensure that a technology assessment of the available literature regarding lymphedema diagnosis and treatment is comprehensive and accurately reflects the evidence. Therefore, we strongly encourage AHRQ to revise its current research criteria to ensure that any technology assessment of lymphedema reflects best practices and is in the best interest of patients. 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 healthcare providers, manage the condition to prevent disabling side effects and potentially lethal complications. 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 prevent 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 can provide interventions 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	and classified studies as ‘prevention’ if the study authors described their research as ‘prevention’ or reported features of a prevention study in their methods, e.g., treatment for lymphedema was initiated on all study participants regardless of symptomatology or diagnosis. We did not exclude studies based on the timing of diagnosis or treatment, provided study participants were described as having secondary lymphedema. Therefore, comparative studies undertaken to evaluate diagnostic tests or treatments for early stage secondary lymphedema were within the scope of the technology assessment.

			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 individuals who are at high risk for developing lymphedema and for individuals with lymphedema to assure disease management. Patients who develop lymphedema and the providers, such as physical therapists, who care for them, face many obstacles relative to the current structure for reimbursement. Coverage for services related to the treatment of lymphedema is limited, preventing timely or appropriate care and 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.	
Nichols Sharp, Sarah	APTA	NA	Recommendations for the Draft Technology Assessment APTA has identified several areas of concern related to the design of this technology assessment. Limitations of the Literature Review:	In our update, we have expanded some of the search terms (see Appendix A for search strategy) and found that the original results of the TA were not changed. We were not asked to include lymphedema as an outcome (adverse effect) for cancer or surgery. We

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			Problem: The McMaster University Evidence-based Practice Center only searched the term lymphedema or lymphoedema. This limited the number of articles, studies, and other literature for McMaster to review. Recommended remedy: A search of the cancer or surgical literature that identifies lymphedema as a variable to study outcomes could help AHRQ develop a more accurate picture regarding the incidence of lymphedema.	were asked to examine the evidence for the diagnosis or treatment of secondary lymphedema; our search strategy would have found these articles.
Nichols Sharp, Sarah	APTA	NA	Problem: McMaster limited its results to literature published in English. This limitation was imposed on both the diagnostic and treatment literature. Recommended remedy: This limitation may prove to have excluded relevant literature and we ask AHRQ to consider including articles in other languages to help better assess the state of research regarding the effective diagnosis and treatment of lymphedema.	A foreign language search was completed and the results did not change the original conclusions of the TA
Nichols Sharp, Sarah	APTA	NA	Other Relevant Forms of Evidence not Included: Problem: In its analysis of the literature related to the treatment of lymphedema, McMaster limited its review to randomized controlled studies (RCTs) and observational studies with comparison groups such as cohort or case control studies. Recommended remedy: While RCTs and observational studies are important forms of evidence, other forms, such as clinical consensus are recognized as pillars of evidence based medicine and should be included. Specific documents include: The International Lymphedema Society consensus document in 2009 which demonstrated agreement along clinicians who diagnose and treat lymphedema. (Lymphology 2009) The Oncology Section of the American Physical Therapy Association has also produced a consensus document regarding lymphedema that should be considered as part of this technology	Clinical consensus documents are considered level 5 evidence, which is a level of evidence that is far below the type of evidence included in most systematic reviews. The optimal means of evaluating treatment efficacy is via a head-to-head comparison, preferably in an RCT. Therefore, we intentionally included only RCTs or observational studies with comparison groups. Studies referenced in clinical consensus documents would have been included in the TA if they met our inclusion criteria. Boris 1994 and Boris 1997 did not have control groups and thus these articles did not satisfy the inclusion criteria for the TA.

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			assessment. In work conducted by Foldi and Foldi, their clinical experiences with lymphedema treatment has helped to lay the groundwork for evidence-based medicine. We recommend that AHRQ consider the importance and validity of clinical consensus and experience as a level of evidence. Retrospective reviews also provide important and relevant information specific references include: Boris M, Weindorf S, Lasinski B, et al: Lymphedema reduction by noninvasive complex lymphedema therapy. Oncology (Huntingt) 8:95-106, 1994 Boris M, Weindorf S, Lasinski G: Persistence of lymphedema reduction after non-invasive complex lymphedema therapy. Oncology 11 (1997) 99-10	
Nichols Sharp, Sarah	APTA	NA	Errant Classification of Primary Lymphedema in Studies Clearly Investigating Secondary Lymphedema: Problem: Stratification of primary and secondary lymphedema was faulty in the report of excluded studies (Appendix C) and calls into question the entire validity of the technology assessment. A notable flaw in the review of research reports must be remedied. The reviewers excluded several studies which they classified as "primary lymphedema" but were clearly secondary lymphedema studies as noted in their titles or abstracts. The authors of these excluded studies expressly defined their study population as "breast cancer patients," "patients after mastectomy," or "cancer patients," however; since they did not use the specific words "secondary lymphedema" they were incorrectly excluded. The definition of secondary lymphedema is that which results from cancer treatment (among other inciting factors), therefore a study including only patients with lymphedema who have had cancer treatment is inherently a study of secondary lymphedema. This significant flaw is noted in the following studies that were noted as excluded in Appendix C; Bertalli et al, Brorson et al (Plas Reconstr Surg 1998 & Lymphology 1998) Frischenschlager et al, Gothard et al, Gozza et al, Lette et al, Sander et al and Venturini et al.	A review of the excluded studies list was conducted and only Frischenschlager et al was incorrectly excluded and thus added to the TA. All other articles mentioned did not meet inclusion criteria for the TA

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			Recommended remedy: This oversight must be remedied to validate the technology assessment.	
Nichols Sharp, Sarah	APTA	NA	Excluded Studies that were Conducted on Patient Cohorts that Included both Primary and Secondary Lymphedema: Problem: Many well-designed studies, focused on the efficacy of treatment modalities, were excluded because they included both primary and secondary lymphedema patients. Scientific rigor in randomized controlled trials dictates that if study results are to be extrapolable to the greater population, then like representation of the population should be exhibited in the study design. Excellent studies such as Badger et al, Bergan et al, Damstra et al, Matthews et al, Mayrovitz et al (Lymphology 2005) Mayrovitz et al (Lymphology 2006) and Monnin-Delhom et al, that demonstrate sound efficacy of a treatment modality for lymphedema were excluded from consideration because of the integration of primary lymphedema patients into the study. It is unreasonable to believe that these studies would be scientifically valid if they did not explore application in both primary and secondary lymphedema. It is also unreasonable that their results should not be considered extrapolable to secondary lymphedema. A significant limitation exists in constraining the technology assessment to explore only studies that offered treatment for secondary lymphedema. Regardless of the pathogenesis of the condition (primary vs. secondary) the treatment interventions are the same and the modalities used in intervention are likewise the same. It is unreasonable to believe that a modality which demonstrates successful efficacy in a population cannot be extrapolated to the other. The modality impacts the mechanism of fluid exchange and resorption. In both primary and secondary lymphedema conditions, this mechanism is faulty. Although the pathogenesis of the conditions differs, the mechanism of fluid congestion is the same and therefore the treatment of congestion is the same. Recommended Remedy: These articles should be re-considered for	The pathophysiology of primary and secondary lymphedema is different and one cannot therefore automatically assume equal treatment benefits between groups. Since the scope of the TA was secondary lymphedema, we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup).

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			inclusion to the technology assessment.	
Nichols Sharp, Sarah	APTA	NA	We also encourage AHRQ to consider literature related to lymphedema in both the upper and lower extremities. Secondary lymphedema as a result of cancer can occur in both the upper and lower extremities. The following studies provide examples of a studies that were not included in the review yet demonstrate treatment efficacy in lower extremity lymphedema: Hinrichs CS, Gibbs JF, Driscoll D, et al. The effectiveness of complete decongestivephysiotherapy for the treatment of lymphedema following groin dissection for melanoma. J Surg Oncol. 2004;85:187-192	The Hinrichs 2004 study does not have a control group and thus it did not meet inclusion criteria for the TA.
Nichols Sharp, Sarah	APTA	NA	Prevention Studies Errantly Classified: Problem: Studies investigating risk reduction interventions were considered as prevention studies and excluded from the report. These studies highlight vital information for the clinical interventions necessary to identify lymphedema at the earliest onset and to treat lymphedema at an early stage. Well designed prospective cohort studies illustrating clinical paradigms for prospective surveillance include patient education interventions, exercise interventions, models for measurement, and clinical follow up that are standardized and controlled in the context of these trials (Box et al, and Cornish et al 2000). The implementation of these models enables the early detection and treatment of lymphedema with minimal cost and intensity of intervention. The purpose in each of these studies is not presented as a prevention trial. In fact, each highlights that early detection and management of early stage lymphedema is the goal. This challenges us to look beyond the current construct of "treating an existing impairment" and encourages us to consider a new paradigm of care that focuses on "early identification and treatment of an impairment." These methods of intervention are vastly different as the latter takes on a preventive approach in identifying impairments that will present and managing them at an early stage. This is considered a "Secondary Prevention" approach and is	The assigned scope of the review did not include prevention questions. The question of prevention is an excellent topic for future research. The issue of where prevention stops and early detection/treatment begins is insufficiently defined in the literature. Thus, we took a conservative approach and classified studies as 'prevention' if the study authors described their research as 'prevention' or reported features of a prevention study in their methods, e.g., treatment for lymphedema was initiated on all study participants regardless of symptomatology or diagnosis. We did not exclude studies based on the timing of diagnosis or treatment, provided study participants were described as having secondary lymphedema. Therefore, comparative studies undertaken to evaluate diagnostic tests or treatments for early stage secondary lymphedema were within the scope of the technology assessment.

			espoused in the realm of public health as an optimal construct for disease morbidity intervention and ultimate cost savings. This construct should be embraced as we investigate the secondary lymphedema literature. Secondary lymphedema is a morbidity directly related to primary cancer disease treatment and secondary prevention approaches such as those espoused in these excluded research studies should be considered by the technical report.	
Nichols Sharp, Sarah	APTA	NA	Definition of Diagnostic Exploratory Studies: It is unclear why 'Diagnostic Exploratory Studies' were excluded when a specific charge for the review was to identify studies that offered sufficient evidence of 'Quantitative techniques to determine limb volume/skin elasticity' and 'Patient reported symptomatology' (MedCAC Question 1, Part b and c). Quantitative techniques were explored in adequately powered and controlled studies by: Balzarini et al, Berard et al, Mayrovitz et al (Lymphology 2007 and Physicol Funct Imaging 2009), and Ward et al. These studies should be reconsidered.	The name 'diagnostic exploratory studies' is misleading. We will remove the name to provide more clarity. The studies excluded under the term 'diagnostic exploratory studies' were not actually applying methods to diagnose lymphedema (they may have been discussing the theoretical rational for a test or measuring volume or circumference on healthy subjects or inert objects).
Nichols Sharp, Sarah	APTA	NA	Finally, while we acknowledge the time constraints associated with the development of a technology assessment in response to a request by the Centers for Medicare and Medicaid Services (CMS), articles published after March 2009 were not included. In that time, literature has been published and should be considered as part of a comprehensive technology assessment for the diagnosis and treatment of secondary lymphedema. Please refer to our bibliography below which includes literature excluded due to time constraints. Bibliography: We note that several studies that should have been included in this technology assessment were not. As a result, we would like to provide this bibliography for consideration. This is a representative, not exhaustive, list. 1. Foldi M, Foldi E, Kubik S. Textbook of Lymphology for	We have performed an updated search to the end of 2009. 1. Foldi M 2003 is a textbook and thus does not meet

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			Physicians and Lymphedema Therapists. Munich: Urban & Fischer; 2003	the inclusion criteria of the systematic review.
			2. Foldi E. The treatment of lymphedema. Cancer. 1998;83:2833-2834.	2. Foldi E 1998 is a review article and thus does not meet the inclusion criteria for the TA.
			3. F?ldi, E, F?ldi M, Clodius L: The lymphedema chaos: A Lancet. Annals of Plastic Surgery 22 (1989) 505-515.	3. Foldi E 1989 is a review article and does not meet the TA inclusion criteria.
			4. Boris M, Weindorf S, Lasinski G: Lymphedema reduction by non-invasive complex lymphedema therapy. Oncology 8 (1994) 95-106.	4. Boris 1994 had no control group and thus does not meet inclusion criteria of TA
			5. Boris M, Weindorf S, Lasinski G: Persistence of lymphedema reduction after non-invasive complex lymphedema therapy. Oncology 11 (1997) 99-109	5. Boris 1997 had no control group and thus does not meet inclusion criteria of TA
			6. Hinrichs CS, Gibbs JF, Driscoll D, et al. The effectiveness of complete decongestive physiotherapy for the treatment of lymphedema following groin dissection for melanoma. J Surg Oncol. 2004;85:187-192	6. Hinrichs 2004 does not have a control group and thus does not meet inclusion criteria of the TA
			7. Stout, Gergich, et al. , Pfalzer LA, McGarvey C, Springer B, Gerber LH, Soballe P. Preoperative assessment enables the early diagnosis and successful treatment of lymphedema. Cancer 2008;112:2809?19.	7. Stout-Gergich 2008 did not have a control group and thus did not meet inclusion criteria for the TA
			8. Badger C, Preston N, Seers K, Mortimer P. Physical therapies for reducing and controlling lymphoedema of the limbs. Cochrane Database Syst Rev. 2004;(4):	8. Badger 2004 is a systematic review. We had previously looked at the reference list of this review to ensure that we had not missed any articles for our TA. The Badger review, like our TA concluded that more randomized control trials are needed so that the best approach for managing lymphedema can be determined.
			9. Cooke, JP, Rooke TW: Lymphedema. Vascular Medicin, 1st Edition, Chapter 40. Loscalzo, J, MA Creager, VJ Dzau (Eds), Little, Brown and Co pp. 1099-1113, 1992.	9. Cooke 1992 is a textbook and does not meet the inclusion criteria for the TA.

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			10. Dicken S, Ko C, Lerner R, Klose G, Cosimi AB. Effective Treat of Lymphedema of the Extremities. Archives of Surgery April 1998, Vol 133. 52-58.	10. Dicken 1998 had no control group and thus did not meet inclusion criteria for TA.
			11. Oncology Section of the American Physical Therapy Association. Position Statement-Physical Therapy: Management of lymphedema in patients with a history of cancer. Rehab Oncology 18 (2000) 9-12.	11. APTA position statement 2000 is not a controlled study and thus did not meet the inclusion criteria for the TA
			12. Yamamoto R, Yamamoto T. Effectiveness of the treatment-phase of 2-phase complex decongestive physiotherapy for the treatment of extremity lymphedema. Int J Clin Oncol. 2007;12:463-468	12. Yamamoto 2007 does not have a control group and thus did not meet the inclusion criteria for the TA
			13. Carlson J, Kauderer J, Walker J, Gold M, O?Malley D, et al. Phase III trial of Tisseel to reduce lymphedema after inguinal lymph node dissection: a gynecologic oncology study group. Proceedings of the 38th annual meeting on women?s cancer (abstract 228). San Diego, CA; 2007.	13. Carlson 2007 looks at the efficacy of a surgical technique for LE reduction and is also a conference proceeding and thus does not meet the TA inclusion criteria on two accounts.
			14. Werngren-Elgstrom, M Lidman, D. Lymphedema of the lower extremities after surgery and radiotherapy for c,cancer of the cervix. Scandinavian J Plast Reconstruction Surg and Hand Surg. 1994; 28: 289-293.	14. Werngren-Elgstrom 1994 examines the incidence of lower extremity lymphedema it does not look at the effectivness of a treatment for lymphedema and thus was excluded from the TA.
			15. Mondry TE. Riffenburgh RH, Johnstone PA. Prospective trial of complete decongestive therapy and manual lymphatic drainage on treatment-related lymphedema in breast cancer therapy. Cancer J. 2004; 10 (1): 42-48.	15. Mondry 2004 does not have a control group and thus did not meet the inclusion criteria for the TA
			16. Koul R, Dufan T, Russell C, Guenther W, Nugent Z, Sun X, et al. Efficacy of complete decongestive therapy and manual lymphatic drainage on treatment-related lymphedema in breast cancer. Int J Radiat Oncol Bio Phys. 2007; 67 (3): 841-46.	16. Koul 2007 does not have a control group and thus did not meet the inclusion criteria for the TA
			17. Ko DS, Lerner R, Klose G, Cosimi AB. Effective treatment of lymphedema of the extremities. Arch Surg. 1998; 133	17. Ko 1998 does not have a control group and thus did not meet the inclusion criteria for the TA

			(4): 452-58.	
			18. Hinrichs CS, Gibbs, JF, Driscoll D, Kepner JL, Wilinson NW, Edge SB. Et al. The effectiveness of complete decongestive therapies for the treatment of lymphedema following groin dissection for melanoma. J. Surg. Oncol. 2004; 85 (4): 187-92.	18. Hinrichs 2004-same citation as #6 above-excluded because no control group.
			19. Todd J, Scally A, Dodwell D, Horgan, K, Topping A. A randomized controlled trial of two programs of shoulder exercise following axillary node dissection for invasive breast cancer. Physiotherapy December 2008 (Vol. 94, Issue 4, Pages 265-273)	19. Todd 2008 compares two programs of shoulder mobilization and tracks the incidence of lymphedema. As this study does not examine the efficacy of lymphedema treatment it does not meet inclusion criteria for the TA.
			20. Lawenda B, Mondry T, Johnstone P. Lypmhedema: A primer on the identification and management of a chronic condition in oncologic treatment. A Cancer Journal for Clinicians. 2009; 59; 8-24.	20. Lawenda B 2009 is a review article and thus does not meet inclusion criteria for the TA.
			21. Box RC, Reul-Hirche HM, Bullock-Saxton JE, Furnival CM. Shoulder movement after breast cancer surgery: results of a randomised controlled study of postoperative physiotherapy Breast Cancer Res Treat. 2002 Sep;75(1):35-50.	21. Box RC 2002 was examining shoulder ROM not efficacy of LE treatment and thus did not meet inclusion criteria for TA
			22. Shih YC, Xu Y, Cormier JN, Giordano S, Ridner SH, Buchholz TA, Perkins GH, Elting LS Incidence, treatment costs, and complications of lymphedema after breast cancer among women of working age: a 2- year follow-up study. J Clin Oncol. 2009 Apr 20;27(12):2007-14.	22. Shih 2009 does not look at diagnosis or treatment for lymphedema and thus did not meet inclusion criteria for TA.
			23. Gordon K, Mortimer P. A Guide to Lymphedema. Expert Review of Dermatology. 2007; 2 (6).	23. Gordon 2007 is a review article and does not meet the inclusion criteria for the TA
			24. The Diagnosis and Treatment of Peripheral Lymphedema: 2009 Consensus Document of the International Society of Lymphedema. 2009; 42.	24. ISL 2009 consensus statement is cited in the background section of the TA (Ch.1).
			25. Mergens A, Harris S. Physical Therapist Management of Lymphedema Following Treatment for Breast Cancer: A Critical	25. Mergens 1998 is a review and does not meet the inclusion criteria for the TA

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			Review of Its Effectiveness. Physical Therapy. 1998; 78 (12). Conclusion In conclusion, APTA would like to thank AHRQ for the opportunity to comment on this technology assessment. We look forward to working with AHRQ in the future to ensure that this technology assessment is comprehensive and reflects best practices.	
Nudelman, Judith MD	Brown University	NA	I believe the ideal treatment team for secondary lymphedema should include: 1) a well trained and informed physician (almost non-existent) , 2) a well trained PT/OT, 3)a well trained LMT and possible 4) an RN can substitute for the PT/OT if adequately trained. The current reimbursement does not allow LMT's or RN's to receive payment for lymphedema therapy, yet allowing reimbursement, especially for LMT's would significantly lower health care costs, improve access to care and allow patients to receive the chronic treatment they require. Allowing RN's to receive reimbursement would also improve patient care and access. I currently see a LANA certified, Klose and Vodder trained LMT: I have to pay her out of pocket. Yet her care is essential in treating and maintaining my lymphedema and allowing me to remain in clinical practice. Her cost is a fraction of the price of seeing a physical therapist. And her care is complementary with the expertise of PT's, and most do not have extensive experience in lymphatic drainage massage. I believe the current reimbursement structure is impairing care for patients with lymphedema and should allow reimbursement to LMT"s and RN's who meet the NLN guidelines for sufficient training in lymphedema care.	Thank you for your comments. We are an evidence based practice center and have no influence on funding decisions
Nudelman, Judith MD	Brown University	NA	I am a family physician, a clinical assistant professor who teaches and does clinical work in a radiation oncology setting. I am also a woman with secondary lymphedema after breast cancer treatment.	We examined the published evidence for diagnosis and treatment of secondary lymphedema. The 'over-representation' of certain items in the TA was a function of the published literature. What may drive the literature is an issue that is beyond the scope of the

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			My experience is that although lymphedema does not meet criteria for an orphan disease, it is a disease of abandonment. As you noted, treatment is preformed by PT's (and OT's--and not by RN's and LMT's due to lack of reimbursement) but MD involvement is minimal to none. Lymphedema is not taught in either medical schools or residencies. None of my treating physicians know how to treat lymphedema--and as you noted in your draft, there is no standardized training for lymphedema therapists, so the patient, with a chronic, incurable disease, must navigate the treatment essentially alone. Physical therapy is not considered a treatment for chronic disease, so most PT's are more comfortable with the model of limited treatment. Yet lymphedema is chronic. The costs of lymphedema are huge: lost wages, treatment costs, psychosocial issues and the cost of the garments, bandages or other necessary items. You discarded many studies: most research in this country is driven by pharmaceutical companies (and there are no medications for lymphedema), marketing of medical devices (that may be why the devices, such as laser, pumps and bioimpedance were over-represented in your studies.) Third party reimbursement is key to access to treatment: you noted in your draft that the accepted--by insurance--gold standard of a 2 cm arm circumference difference--as clinically relevant was created by two PT's in one study, with no scientific data. Articles by AW Stanton would argue that subtle changes in limb contour are important and sensitive indicators of lymphedema, the survey created by Mei Fu PhD argues a change of the diagnostic paradigm to one of symptoms--with greater sensitivity. You did not conclude that complete decongestive therapy was the superior treatment, and I find that concerning.	TA. Our conclusions regarding CDT were based on the published medical evidence. Since we conducted a review of the literature, it is natural that the TA would report on modalities that have appeared in the literature. We were tasked with examining published evidence for treating secondary lymphedema. The question of whether current treatment is 'flawed' was beyond the scope of our TA. We mentioned training schools that appeared in the literature that we reviewed for the TA. Position papers are not considered 'evidence' for inclusion in systematic reviews.

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			I felt your conclusions were biased toward pumps, the low level laser and other modalities that would have more studies in the literature, as there is potential profit in marketing these devices. Every day in my practice I see patients with lymphedema: after breast cancer, prostate cancer, endometrial cancer, multiple myeloma and melanoma, and almost universally I am the only treating physician on their treatment team who assesses for lymphedema and can discuss therapy with them. I have evaluated the lymphedema clinics in the surrounding area, checked the training of the therapists and keep in close contact with them. I was abandoned to manage my disease alone, but my patients will not be. Yet, every day I see patients who do not have the emotional or financial resources to get lymphedema treatment--they may be on medicare, or have a limited PT and DME benefit, or can't miss time out of work. Or they've had an initial course of treatment and were dismissed, and are under the impression that nothing more can be done for them. I'm concerned that your study--while comprehensive and desperately needed, does not address the flawed method of treatment of lymphedema in our health care system. Ideally I'd like to see lymphedema included in medical education, and breast surgeons and oncologists should have extensive knowledge of lymphedema--and assess for it and partner with patients in its treatment. Lymphedema should be considered a quality measure. Patients should be routinely educated in lymphedema risk reduction--most are not, currently. Third party payors should reimburse well trained LMT's and RN's for lymphedema therapy. A national standard for lymphedema training should be set, maintained and monitored. Studies show that PT's receive almost	

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			no training in lymphedema during their regular education. And far too many take weekend courses and start to treat patients without supervision. You did not mention the other training schools-such as Klose, that offer extended training. I was in my third decade of clinical practice when I developed lymphedema, and I had never attended a lecture about it, had a question about it on my boards, had it included in the syllabus of the physical exam course that I teach: I knew nothing about it. And neither did my surgeon, oncologist or primary care physician. My radiation oncologist told me that radiation was not a risk factor for lymphedema (incorrect.) Everything I learned about how to manage my lymphedema was taught to me by patient advocates. Women who have the condition and are committed to helping others. This chronic, incurable disfiguring disease goes unrecognized and untreated. My oncology text says the most common approach to lymphedema is therapeutic nihilism. Your systematic review is a start, but please recognize that the quality of the evidence is relatively poor and scant, and the conclusions will therefore be limited if only the published evidence is used as a criteria for clinical decisions. About a decade ago, I published a brief article in American Family Physician, "Cochrane for Clinicians: the use of antibiotics for sinustis." At that point, the inclusion criteria for studies was that they had sinus aspirations or plain radiographs, so out of about 3000 possible studies, only a handful were used. No conclusion could be drawn. Evidence based medicine is not without flaws. If the studies are scant, of poor quality and/or the inclusion criteria are incorrect, the conclusions drawn will be of limited value. There is no mention of the National Lymphedema Network and their position papers, which state "NOTE: Given that there is little evidence-based literature regarding many of these practices, the	

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			majority of the recommendations must at this time be based on the knowledge of pathophysiology and decades of clinical experience by experts in the field. " Please recognize the limits of objective evidence when a disease is little studied, and please realize the vast ignorance about lymphedema in the medical field, and attempt to remediate this. Patients with lymphedema tend to feel marginalized and abandoned, with good reason. I hope your draft will be a step toward remediating that situation, and not used to create more barriers to early diagnosis and proper--lifelong care of secondary lymphedema.	
Podolsky, Tracey MPT, CLT-LANA	NA	NA	I strongly support our interventions in lymphedema. Complete Decongestive Therapy (CDT)is our specialty at our facility and we have 3 Certified Lymphedema Therapists that are changing people's lives every day. We need more research to support our interventions! Patient's who suffer with primary or secondary lymphedema benefit GREATLY from CDT. I have so much confidence in it that my patients are highly compliant with their self care and therefore much more successful in managing this lifelong condition. Please acknowledge this condition and support improved reimbursement not only for the intensive treatment component but for the self care component as well which includes follow ups and coverage for compression garments and supplies. My whole career changed after treating my first lymphedema patient who suffered from lymphedema for 56 years. When I saw that fibrosis can soften even after 56 years of accumulating, I was so inspired to help those patients who suffer with this severity of lymphedema and to also prevent any other patients from progressing to this stage. Without proper support, research, and insurance coverage, these patients are at risk for progression of lymphedema which can only lead to joint immobility, depression, recurrent cellulitis, and poor quality of life. I strongly urge everyone to take a stand for these patients because they are so commonly left in the dark without any resources.	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA
Ratliff,	University of	NA	Very thorough. It is a shame that there is not more published on	Thank you for your comment. We also noted in our

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Catherine, M.D.	Virginia		lower limb lymphedema. I did not see anywhere that skin care or Kinesio taping was addressed. However,there may not be published studies on these topics.	review that there is a lack of literature on lower limb lymphedema.
Roberge, Nancy J.	American Physical Therapy Association, Oncology Section, Legislative Committee Chair	NA	I am a seasoned (35 years) Physical Therapist who specializes in the patient with breast cancer. I have seen their struggles over the past 17 years of specializing in breast cancer. One of the most dreaded fears of these women is lymphedema. I believe in trying to help them lower their risk of lymphedema through education (to risky behaviors for their limb at risk and proper care of their limb at risk), manual physical therapy (to minimize scar tissue from surgery and fibrosis from radiation or mediate the after-effects of these interventions) and therapeutic exercise to improve the muscle-pump action which improves lymphatic transport capacity. Together, these interventions may reduce the incidence of lymphedema or delay it for these women improving their quality of life. It is critical to have trained professionals educating and treating these women to these risk-reduction strategies which ultimately saves healthcare dollars and much human suffering. If women do get lymphedema, early intervention is critical to the control of the swelling and possibly the amount of swelling. This then impacts the quality of life of this woman, her family and the need for additional interventions. Early intervention, in almost all medical conditions, helps save healthcare dollars. I acknowledge that we need more research on the topic of lymphedema. Our American Physical Therapy Association Oncology Section is very aware of this and is actively working to be involved in more research to support treatment of lymphedema. We know that active treatment works and we know we need to validate our interventions through research. Please do not penalize those with lymphedema, who require Physical Therapy intervention, just because we have been slow to do the research. Cellulitis from lymphedema is an emergent and possibly life-	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA.

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			threatening situation. That is what we prevent when we treat these patients. If lymphedema goes un-treated, un-managed, these women risk repeated hospitalizations due to cellulitis infections costing our healthcare system more. Please realize that these women need compression bandages, compression garments and Physical Therapy to treat their lymphedema. Please support these individuals who have already marched to hell and back with their cancer diagnosis. Lymphedema also affects others with other cancer diagnoses. It can affect the legs, the trunk, the head or neck region. It is not a "pretty" consequence of a cancer diagnosis. PLEASE help people to realize a higher quality of life after cancer diagnosis and treatment by supporting the professionals and by reimbursing for the supplies that these individuals need to have some quality of life. Thank you for your due consideration. It is a most difficult diagnosis to receive, and then lymphedema is the feared life-time after effect.	
Smith, Linda	patient	NA	I am a lymphedema patient, and have been for 9 years. I have mine under control, with the help of my physical therapist, and compression garments. It is my belief that medicare should pay not only for treatment of this possibly debilitating disease, but should at least help to pay for the garments. The cost of custom fit compression garments is prohibitive at best, and without medical coverage, many patients do without. This creates the catch-22 of continuing treatment that sometimes is controlled by compression garments and a home program. Without this treatment and garments, these patients are more prone to infections and serious illness due to their compromised lymphatic system. Please consider coverage for this disease, as treatment and compression can save money and lives.	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA
Smoot, Betty PT, DPTSc	University of California San Francisco	NA	**Comment 1:** Thank you for the Tech Draft Report on Diagnosis and Treatment of Secondary Lymphedema. This is a much needed review and highlights the need for continued research in this field. **Comment 2**: I would like to point out that since publication of this draft more studies have been published on diagnosis and	Comment 1: Thank you. Comment 2: An update has been completed to ensure that any eligible articles published up to December

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			management, and research continues. I have been involved in breast cancer related lymphedema (BCRL) research for the past 3 years. We have one paper on functional consequences of BCRL currently under review. Our findings support those of others, detailing the greater limitations in shoulder motion and function in women with lymphedema following treatment for breast cancer. Our current paper (completion date extimated at 1-15-09)compares diagnostic/assessment methods used for BRCL, using ROC and AUC statistical analysis. **Comment 3:** I strongly support continued research in this area. Lymphedema can be disabling and progressive. With the numbers of women with or at risk for lymphedema it is imperative that we continue to perform quality research, and provide appropriate care.	2009 are included. Comment 3: We agree.
Weiss, Robert	National Lymphedema Network	NA	The treatment of lymphedema is a multimodal, multi-phase therapy which comprises manual lymph drainage to reduce swelling by stimulating the lymphatics, compression to prevent re-swelling, exercise with compression to facilitate decongestion and skin care to maintain skin integrity. Any attempt to select one modality to the exclusion of the others will result in a partial and ineffective treatment for this chronic, ever changing, and progressive medical condition.	Most of the studies included in the TA used multi-modal therapies.
Weiss, Robert	National Lymphedema Network	NA	Current Medicare coverage fails the lymphedema patient because it does not cover compression therapy, places fixed limits on the intensive phase treatment and has no requirements on the competency of the therapists providing therapy services. Many of the necessary treatment elements are not addressed or billable, such as measurement, compression bandaging, patient instruction, garment measurement and fitting. Pumps are covered for treatment of lymphedema but criteria for coverage are not coordinated with the primary lymphedema treatment services and results. The generalized criteria for selection of lymphedema pumps often downgrade the pumps to provide a medically incorrect type of pump.	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA
Weiss, Robert	National Lymphedema Network	NA	Any assessment of the efficacy of the protocols for lymphedema treatment must consider the natural history of the lymphedema and the required combination of protocols for any given patient at given	Thank you for your observation.

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			time. Assessment of published clinical trials must take into account the characteristics of the trial cohort and the stage, extent and nature of their lymphedema before any conclusions can be made as to the efficacy of any treatment protocol, and the measured efficacy cannot be extended to other populations or disease stages.	
Weiss, Robert	National Lymphedema Network	NA	Selection of the proper combination of treatment protocols for the treatment of an individual patient is the responsibility of the treating physician and trained therapist on the basis of the patient's medical needs at the moment. Medicare must provide a selection of covered protocols shown to be effective in treating some subset of lymphedema stages, types, body sites, etiology, duration, co-conditions, etc.	Thank you for your observation.
Weiss, Robert	National Lymphedema Network	NA	? There is no evidence that treatment protocols for primary and secondary lymphedema are different, and so excluding trials that may have contained mixed cohorts may not be appropriate, and may result in discarding valuable evidence of the efficacy of treating any lymphedema. On the contrary, recent research seems to be leading to the idea that genetic differences determine the inherent susceptibility to lymphedema, and some ?secondary? cases may actually be ?primary? (genetically susceptible because of a marginally functional lymphatic system) with a precipitating trauma or event causing it to be classified as ?secondary? [Rockson 2008, Stanton 2009]. Clinical studies on diagnosed breast cancer patients purport to be able to determine, prior to breast surgery and radiation, which patient will develop lymphedema [Campisi 2002] based on pre-surgical lymphatic transport measurements.	While protocols may be similar, it doesn't mean that the benefits are similar. While some patients may have differing baseline risks for lymphedema based on genetics, it doesn't make sense to call it "primary" once a patient has undergone breast cancer treatment – that would clearly be the precipitating factor. Also, even if that was the case, primary lymphedema is quite a rare condition, so even if a few breast cancer patients do develop lymphedema from a primary cause, independent of their surgery and radiation, they must be very rare patients indeed. Since the scope of the TA was secondary lymphedema, we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup).
Weiss, Robert	National Lymphedema Network	NA	Early detection of lymphatic changes and early intervention is being shown to prevent fibro-sclerotic tissue changes and infections that are responsible for the progression of lymphedema. There is no current Medicare coverage for the early detection of pre-clinical	Thank you for your observation. The question of prevention is an excellent topic for future research. The issue of where prevention stops and early

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			lymphedema or for its preventive treatment, in spite of the preventive potential.	detection/treatment begins is insufficiently defined in the literature. Thus, we took a conservative approach and classified studies as 'prevention' if the study authors described their research as 'prevention' or reported features of a prevention study in their methods, e.g., treatment for lymphedema was initiated on all study participants regardless of symptomatology or diagnosis. We did not exclude studies based on the timing of diagnosis or treatment, provided study participants were described as having secondary lymphedema. Therefore, comparative studies undertaken to evaluate diagnostic tests or treatments for early stage secondary lymphedema were within the scope of the technology assessment.
Weiss, Robert	National Lymphedema Network	NA	The Many Faces of Lymphedema There is no best treatment modality because of the variety of lymphatic presentations, affected sites and the temporal evolution of the condition. What is 'best' today for a given patient may not be 'best' as the condition either worsens or improves. Nor is a single selected modality or treatment appropriate for the heterogeneous population of lymphedema patients.	Statement only, no response required
Weiss, Robert	National Lymphedema Network	NA	The question arises, has Evidence Based Medicine (EBM) got a role to play in lymphoedema treatment? It probably has but with the acknowledgement that EBM generally deals with group response and then generally with the quantitative aspects of it. 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? [Manual Lymphatic Drainage -- an effective treatment for lymphoedemas By Neil B Piller and Jan Douglass, ca. 2003]	The respondent raises an interesting question about the role of EBM in the assessment and treatment of lymphedema. While this is an interesting issue to consider, it is beyond the specific scope of this TA. EBM came about as a result of the gulf between what can be done optimally and what is done in reality. EBM is designed to understand this gap. Other fields of medicine deal with patients who present with a unique situation and respond to treatment differently, yet they are held to the higher standard of EBM by either governments, third party providers or

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			There is an infinite variety of lymphedema manifestations as functions of: Affected body site(s) Amount of swelling Patency of lymphatic network Tissue fibrosis Lymphangion autonomous functionality Skin integrity Skin elasticity Patency and functionality of venous system Co-morbidities	their own professional bodies. Lymphedema researchers should not be exempt from this standard. The Canadian Guidelines published in 2001 (Harris, CMAJ) clearly stated the need for high level evidence: Accurate assessment requires agreement on a standardized and reliable system of measurement. Randomized controlled trials to answer these questions should be encouraged and funded whenever possible.
Weiss, Robert	National Lymphedema Network	NA	Lymphedema patient individuality forces the treating physician to perform a differential diagnosis before determining treatment modalities. It also requires the evidence analyst to be careful to determine whether there is patient bias in a given study, whether the intervention is being applied to the correct lymphedema patient subset and whether the conclusions are extrapolatable to a general population. Given this variability between patients, it may be prudent for the analyst to highlight the characteristics of the trial cohort for which favorable results accrued and allow the physician and lymphedema therapist, familiar with the patient's lymphedema etiology, co-morbidities and specific health status, to prescribe the combination of protocols most likely to have a positive outcome for the specific patient.	We agree with this comment. However, as we discussed in the TA, the dearth of studies in secondary lymphedema prevented us from drawing conclusions about appropriate treatment options for specific cohorts of patients.
Weiss, Robert	National Lymphedema Network	NA	For example, in a recent study by Olszewski, the patient population comprised Stage 3 lower limb lymphedema patients with "obliterated lymphatics". Fluid flow in this case is not through a patent network of lymphangions and nodes, but through the affected limb tissue space. The study concluded that MLD was ineffective, and that a sequential pump was designed to emulate MLD in stimulating lymphangion contractions was ineffective. These results are hardly applicable to the lymphedema of a recent breast cancer survivor. Reviewers must be very careful that the patient population involves lymphedema, and not venous insufficiency, lipedema, myxedema, or other causes of swollen limbs.	We ensured that the patient populations in the included studies had lymphedema.
Weiss, Robert	National	NA	As another example of how differences in individual patient	Yes we agree that heterogenous patient populations

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	Lymphedema Network		conditions have a great effect on the effectiveness of a given modality arises in the randomized study of the effectiveness of MLD when added to compression bandaging [McNeely 2004]. A sub-analysis of the trial data showed that the MLD was effective in patients with early stage lymphedema whereas it was not effective in longer-standing cases. The author postulated that in the 'early' lymphedema the lymphangions were still functional and were stimulated by MLD to increase lymphatic flow and establish collateral flow, whereas in the late chronic or severe cases the lymphatic system was more compromised and compression was the dominant mode of tissue fluid drainage. In these older chronic lymphedema cases the compression bandaging effects dominated in both arms of the trial, and the addition of MLD was not productive. This result is substantiated in Johansson 1999 in a cohort of recent breast cancer survivors. How differences in the nature of the lymphedema can affect the efficacy of a treatment modality can be found in Francois 1989 [Francois A, Richaud C, Bouchet JY, Franco A & Comet M: "Does medical treatment of lymphedema act by increasing lymph flow?" Vasa 1989;18(4):281-6]. In this paper Francois observes two MLD response groups among his lower limb cohort undergoing an 8-day trial of MLD, leg elevation and exercises while under double compression bandaging--those whose lymph flow responds immediately to MLD (n=16) and those whose lymph flow did not increase (n=9) in spite of a decrease in their leg edema. The author postulates that there must be another mechanism other than increased lymph flow, such as an increase in fluid resorption in the venous capillaries. There is no evidence that treatment protocols for primary and secondary lymphedema are different, and so excluding trials that may have contained mixed cohorts may not be appropriate, and may result in discarding valuable evidence of the efficacy of treating any lymphedema. Szuba 2000 concluded in his Decongestive Lymphatic Therapy for Patients with Cancer-related or Primary Lymphedema: The results of this investigation suggest that manual lymphatic	may lead to invalid conclusions. Szuba 2000 examines the effect of treatment on upper and lower extremity lymphedema but does not stratify results by primary and secondary lymphedema. Without stratification of results, it is not possible to make comparisons or draw conclusions about the effect of treatment related to primary versus secondary lymphedema. Since the scope of the TA was secondary lymphedema, we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup).

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			therapy provides measurable therapeutic benefits in all subgroups of our lymphedema patients. Decongestive lymphatic therapy was effective both in the acute, intensive phase of limb volume reduction, when performed by trained therapists in the institutional setting, as well as in the maintenance phase, where it helped to promote effective self-management of edema.? The cohort for this trial included patients with lymphedema after breast cancer (43), pelvic cancer (12), infection (2), injury (1), metastatic cancer (4) and primary lymphedema (16).	
Weiss, Robert	National Lymphedema Network	NA	Technology Assessments and Systematic Reviews Technology assessments designed to determine whether one treatment modality is 'better' than another may be significantly distorting the issue of whether Combined Decongestive Therapy (CDT) is effective in the treatment of lymphedema. CDT is a multimodal therapy recognized as the standard of lymphedema care. It makes no more sense asking the question is MLD better than exercise than to ask in the treatment of breast cancer ? Is radiotherapy better than chemotherapy? The selection of the modalities to treat lymphedema or breast cancer is the responsibility of the treating physician based on the individual patient?s medical needs. It is not a decision to be made by Medicare. It could be that the conclusions of lack of effectiveness of MLD in some studies [Andersen 2000 and McNeely 2004] are only artifacts of the analytic goals or the questions asked. In an attempt to reduce the oedema developing after mastectomy in 39 breast cancer patients, a number of physiotherapy techniques were applied in various combinations over 6 months. The techniques included massage, isometric exercises and an elastic sleeve. In the first week of the daily treatment a decrease of 11-13% in the volume of oedema was recorded, but in the next 3 weeks the benefit achieved declined sharply. To maintain the reduction in volume of the swollen arm, an elastic sleeve was applied. During the 4 weeks that the sleeve was worn there was no significant increase in volume. There was a correlation between an objective reduction in the volume of the arm and the patient's rating of the improvement.? [Swedborg I: Effectiveness of combined	Through EBM, we can assess if CDT should be the standard of lymphedema care. Based on our review of literature, we failed to find any evidence to suggest that CDT should be the standard of care. Future studies, specifically designed to address this issue, could be a future course of research. Swedborg 1980 does not meet inclusion criteria for the TA because it was published before 1990. Zanolla 1984 does not meet inclusion criteria for the TA as the year of publication is prior to 1990 which was the cutoff for the TA. Sitzia 2002, Williams 2002, Anderson 2000, Bertelli 1991, Johansson 1998 and McNeely 2004 were all included in the TA. Badger 2000 was excluded because of mixed population (not stratified).

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			methods of physiotherapy for post-mastectomy lymphoedema? Scand J Rehabil Med. 1980;12(2):77-85.] There are many studies that have shown the effectiveness of MLD in reducing swelling [e.g. Moseley 2007, Sitzia 2002, Williams 2002, Zanolla 1984]. There are many studies that demonstrate the efficacy of compression garments [e.g. Andersen 2000, Badger 2000, Bertelli 1991, Johansson 1998]. And some studies show that the combination of these modalities may be better than each used singly [e.g. Johansson 1999, McNeely 2004]. Each therapeutic modality has a unique physiological action on the lymphedematous site, and their effects have different temporal effectiveness. For full and lasting treatment of lymphedema for a given patient, a combination of modalities is appropriate.	
Weiss, Robert	National Lymphedema Network	NA	A number of systematic reviews of lymphedema treatment protocols have been performed over the last decade. In essence, the conclusions of these systematic studies was that, although there is a paucity of high-level evidence, ALL of the considered physical therapy interventions (MLD, SLD, compression bandages, compression garments, decompression exercise) were effective in the treatment of lymphedema on some subset of the tested population. Brennan 1996: Acquired lymphedema is a relatively frequent complication of axillary node dissection. Patients afflicted with this condition are prone to physical and psychological consequences, including pain, lost function, and depression. There is no cure for acquired lymphedema, but treatment options are available. Unfortunately, the evidence supporting many of these forms of treatment is less than optimal. Claims and counterclaims from biased practitioners have served to further muddy the waters, leaving many clinicians confused about the best options for their patients. A combination of garments, massage, and the appropriate use of sequential pumps at a sufficient pressure should form the core program for most patients with lymphedema. Though data supporting complex decongestive therapy is primarily anecdotal, it may be an option for some patients. However, its limited availability and significant cost preclude many patients from	The reference lists of recent systematic reviews were checked prior to publication of draft TA (see Chapter 3 of TA)

			receiving it. Megans & Harris 1998: Despite the relatively limited scientific evidence in support of physical therapy interventions for the management of lymphedema following breast cancer treatment, the following clinical recommendations are suggested: Physical therapists should encourage consistent and long-term use of compression garments in patients with lymphedema. Whether these garments need to be custom-fitted sleeves or standard-sized sleeves is not clear from the studies reviewed, nor is there consistency among the studies in the suggested amount of compression provided. Combined techniques, involving massage, sequential pneumatic compression, compression garments or compression bandaging, and exercise, may also be effective. It is not clear, however, whether such a combined program is actually more effective than a program involving pneumatic compression only followed by compression garments. Based on one study, modified CPT may be just as effective as standard CPT, and it is far less labor intensive and therefore less costly. Erickson 2001: Non-pharmacologic treatments, such as massage and exercise, have been shown to be effective therapies for lymphedema. Complex physical therapy (also known as complex decongestive therapy, complex lymphedema therapy, multimodal physical therapy, complex decongestive physiotherapy, and complete decongestive physiotherapy), which consists of skin care, manual lymphedema treatment, exercises, and compression wrapping, followed by a maintenance program and psychosocial rehabilitation, has been recommended as a primary treatment by consensus panels and is an effective therapy for lymphedema unresponsive to standard elastic compression therapy. Complex physical therapy resulted in some volume reduction of the affected extremity in 95% of 399 patients (>50% reduction in 56% of patients, 25%?49% reduction in 31%, and 1%?24% reduction in 8%), 54% of whom maintained the therapeutic result at 3 years. Karki 2001: In physical therapy various methods are used after a breast cancer operation. This systematic review aims to evaluate	

			the effects of lymphedema therapy methods, postoperative shoulder exercise, exercise therapy, and aerobic exercise. The evolving data and calculations regarding the effect size support the delayed onset of postoperative shoulder exercise. Numerous studies concerning lymphedema therapy suffered methodological deficits. Elastic sleeve therapy is the only method shown to be effective when used alone. Treatment combinations were examined in many studies and treatment bias therefore restricted conclusions regarding the effectiveness of one method alone. Studies concerning exercise therapy and exercise were few and only two were true-experimental clinical trials. Three studies of exercise therapy showed in some measured variables that the experimental group had better results when following the effects of an exercise program for 1?3 months, although further conclusions were prevented because of the treatment bias. Kligman 2004: Among the RCTs evaluating physical therapies, the only positive finding was an incremental benefit when an elastic sleeve was added to self-massage therapy. Pneumatic compression, compared with no intervention, was not associated with a significant improvement. However, the direction of the observed response rates and changes in arm volume favored pneumatic compression. Compression garments must be worn on a daily basis. Badger 2004: One crossover study of manual lymph drainage (MLD) followed by self-administered massage versus no treatment, concluded that improvements seen in both groups were attributable to the use of compression sleeves and that MLD provided no extra benefit at any point during the trial. Another trial looked at hosiery versus no treatment. The authors concluded that wearing a compression sleeve is beneficial. The bandage plus hosiery versus hosiery alone trial concluded that in this mixed group of participants bandage plus hosiery resulted in a greater reduction in excess limb volume than hosiery alone and this difference in reduction was maintained long-term. CHBRP 2005: Physical therapy interventions (outcome reduction in volume of edema) favorable for most interventions: Multi-layer	

			bandaging favorable; Compression bandaging favorable; MLD ambiguous, mixed evidence, favorable for patients with mild lymphedema; Simple lymphatic drainage pattern toward favorable; Exercise pattern toward no effect, weak evidence; MLD+compression bandaging pattern toward favorable. Moseley 2006: This systematic review undertook a broad investigation of commonly instigated conservative therapies for secondary arm lymphoedema including; complex physical therapy, manual lymphatic drainage, pneumatic pumps, oral pharmaceuticals, low level laser therapy, compression bandaging and garments, limb exercises and limb elevation. It was found that the more intensive and health professional based therapies, such as complex physical therapy, manual lymphatic drainage, pneumatic pump and laser therapy generally yielded the greater volume reductions, whilst self instigated therapies such as compression garment wear, exercises and limb elevation yielded smaller reductions. All conservative therapies produced improvements in subjective arm symptoms and quality of life issues, where these were measured. Evaluated by average volume change, all manual therapeutic protocols were beneficial (MLD + compression, CPT, MLD, IPC, compression, exercise and elevation--in order of efficacy). Level of Evidence was low (III-2 and III-3). Florez-Garcia 2007: We reviewed the following databases: Medline, Physiotherapy Evidence Database and the Cochrane Library up to May 2006. We also made a used a complete web in Google. Articles selection. We found 15 randomized clinical trials, 4 systematic reviews, 3 clinical guidelines, 3 technological evaluations reports and 3 Cochrane Collaboration documents (1 review and 2 protocols). We did not find any high quality scientific evidence. The most reliable information available is based on randomized clinical trials with small samples. Follow- up was long term in only a few studies (equal or higher to one year). None of the studies used the blinded method, and only a few clinical trials used a "patients lost to follow-up" analysis. Physical therapy had a moderate effect on edema reduction. Compression garments are probably the main treatment. Using those garments we could	

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			expect stabilization and usually modest recovery. There is a weak and contradictory evidence of the short-term utility of manual lymph drainage and external pneumatic compression. Complete decongestive therapy has shown no special utility versus the simpler alternatives. Arm elevation and exercises may produce a small improvement in combination with other techniques. The positive results observed with laser therapy are still very preliminary. Hayes 2008: In summary, research on the effects of complex physical therapy, manual lymph drainage, compression and massage as options for the management of secondary lymphoedema has produced consistent results, with volume reductions demonstrated. However, the low level evidence (Level III-1 or lower studies) and the focus on only breast cancer patients, limits the generalizability of these findings. There is also the potential for over-reporting of positive treatment effects given that the characteristics of those lost to follow-up were not presented.	
Weiss, Robert	National Lymphedema Network	NA	Randomized Clinical Trials Document Efficacy of Treatment Protocols The following randomized clinical trials RCTs have been accepted for review by one or another of the systematic reviews listed above. There is credible evidence to show that every manual modality can benefit some population subset. Shown on the following table are the lead author and date of the RCT, the systematic review which used the RCT, characteristics of the trial cohort, modalities employed, summary results in terms of edema reduction and comments on the length of the trial or follow-up. Reference Study* Population** Modalities*** Reduction? Comments Andersen 2000 TBCKF 42-38 BCRL CGE/CGE+MLD 60%/48% NS 3 Mos. Badger 2000 BCF 83 Upper & Lower CB+CG/CG 31%/16% 24 Wks. Barclay 2006 F BCRL Aromatherapy None Bertelli 1991 TEKMF 60 BCRL ?c?10cm CG/	Anderson 2000 included in TA Badger 2000 was excluded because of mixed population. Barclay 2006 was excluded because primary and secondary LE were not stratified and did not meet the inclusion criteria of the TA

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			CG+ESLD 17-21/16-17% 2-6 Mo. Bertelli 1992 EM 120 BCRL?c?10cm CG, IPC, ESLD 15/13% 2/6 Mo. Boris 1998 C 128 LLLE IPC/No IPC 43%/3% GLE Genital LE Carati 2003 TF 64 BCRL LLLT/Placebo -90/+32 mL 3 Mo. Didem 2005 THF 53 BCRL for 3 Yr. CDT+HT 56% Short Term Dini 1998 TCEHKF 80 BCRL < 1 Yr. IPC 11% Short Term F?ldi 1996 C 150 BCRL+RC CDT Reduced DLA 2 Yr. Hamner 2007 H 135 BCRL CDT 42% Short Term Hayes 2008 T 32 BCRL E <1% 3 Mo. Hornsby 1995 BCK 25 SLD, E/+ CG 36%, 86% 16 Wk. Jahr 2008 T 21 BCRL MLD+DO/MLD -16/+13mL Breast LE Jeffs 2006 H 74 BCRL CDT 5 to18% 1 Yr. Johansson 1998 TCKF 28+12/12 BCRL CG+SPC/MLD 7%+ 7%/15% 2.5 Yr. Johansson 1999 C 38 BCRL CB\CB+MLD/CB 26%\11/4% Short Term Kaviani 2006 TF 8 BCRL LLLT/Sham Favors LLLT 22 Wk. Kessler 2003 T 21 Hindfoot Surgery E+MLD/E 6%/0% Koul 2007 H 138 BCRL CDT, MLD, HT -56, 41, 24% 1 Yr. Kozanoglu 2009 T 47 BCRL IPC+E/LLLT+E LLLT fav. LT 12 Mo. Maiya 2008 T 20 BCRL LLLT+E/CG+E 10 Days McKenzie 2003 TCF 14 BCRL E Nil 2	Bertelli 1991 included in TA Bertelli 1992 was excluded because it did not have a control group Boris 1998 was excluded because it did not have a control group Carati 2003 was included in the TA Didem 2005 was included in the TA Dini 1998 was included in the TA We attempted to retrieve the 'Foldi 1996' article using several avenues (inter-library loan, contacting journal and author), but were unable to retrieve a copy. We seriously doubt this omission casts doubt on the TA. Any article of great importance to the field of lymphedema would likely be published in a medium where retrieval is not a challenge. Hammer 2007 was excluded because it did not have a control group We could not find an article for 'Hayes 2008' with n=32. Our comments regarding Foldi above apply to this article as well. Hornsby 1995 was excluded because it was an overview Jahr 2008 was included in the TA Jeffs 2006 audit of patients did not meet TA inclusion criteria. Johansson 1998 was included in the TA Johansson 1999 was included in the TA Kaviani 2006 was included in the TA Kessler 2003 was included in the TA Koul 2007 did not have a control group and thus did not meet inclusion criteria for the TA Kozanoglu 2009 was included in the TA Maiya 2008 was included in the TA McKenzie 2003 was included in the TA McNeely 2004 was included in the TA Radakovic 1998 was included in the TA Shaw 2007 x2 were both included in the TA Sitzia 2002 was included in the TA

			Mo. McNeely 2004 TCF 50 BCRL MLD+CB/CB 46%/16% 1 Mo. Radakovic 1998 T 36 BCRL MLD/IPC 0.9/2.24cm Short Term Shaw 2007 T 21 BCRL WR/CG 7% 12 Wk. Shaw 2007 T 51 BCRL Obese WR+CB+CG/CG WL?>Red 24 Wk. Sitzia 2002 TF 28 BCRL CB\MLD/SLD 34/22% 2 WK. Szuba 2002-1 TCF 23 BCRL 12 Yrs. CDT+IPC/CDT 30%/27% 40 Days. Szuba 2002-2 TCF 25 BCRL 9.5 Yrs. CDT+IPC/CDT 90/33mL 6 Mo. Vignes 2006 H 357 BCRL CDT 404 mL Short Term Vignes 2007 H 356 BCRL CDT 67% 1 Yr. Wilburn 2006 TH 10 BCRL 3-24 Yrs. SM/IPC +52/-208 mL 42 Days Williams 2002 TCF 29 BCRL MLD+SLD 71/30 mL 12 Wk. * The review or systematic study which identified the RCT: C=CHBRP 2005; Erickson 2001; H=Hayes 2008; K=Kligman 2003; M= Megens 1998; T=Technology Assessment-McMasters; ** BCRL=breast cancer-related lymphedema; LLLE=lower-limb lymphedema; RC=recurrent cellulitis *** CB=compression bandaging; CDT=complex decongestive therapy; CG=compression garment; CGE=compression garment plus exercise; DO=Deep Oscillation; E=exercise; ESLD=electrically-stimulated lymph drainage; HT=home therapy; IPC=intermittent pneumatic compression; MLD=manual lymph drainage; SM=simple massage; SP=standard physiotherapy; WR=weight reduction ? DLA=Dermatolymphangioadenitis; GLE=genital lymphedema; NS=not significant	Szuba 2002 x2 both included in TA Vignes 2006 had no control group and thus did not meet inclusion criteria for TA Vignes 2007 was excluded because it did not have a control group Wilburn 2006 was included in the TA Williams 2002 was included in the TA
Weiss, Robert	National	NA	Cohort Studies Show Efficacy of Combined Decongestive Therapy	Boris 1997 did not have a control group and was

	Lymphedema Network		In view of the paucity of high-level evidence, we must rely on the vast number of cohort studies which demonstrate the efficacy of the multimodal protocol of CDT in the treatment of lymphedema [Boris 1997, Bunce 1994, Casley-Smith 1992, Ferrandez 1992, F?ldi 1989, Hamner 2007, Hinrichs 2004, Karadibak 2008, Ko 1998, Szuba 2000, Vignes 2006, Wozniewski 2001, Yamamoto 2007] Together these references document an almost 50% reduction of the volumes of the lymphedematous limbs of over 2,200 patients. In 1995 E. F?ldi commented in an editorial in Lymphology ?Combined physiotherapy which we employ in the treatment of lymphedema is a tetrad phenomenon consisting of skin care, manual lymphedema treatment (MLT), remedial exercises and compression therapy. Compression is applied as long as edema prevails by circumferential wrapping or ?bandaging? and, after the evacuation of edema fluid, by elastic stockings and sleeves. It is not my aim to comment on combined physiotherapy further. I wish only to stress that MLT performed as an isolated therapeutic application has little or no beneficial effect in the treatment of peripheral lymphedema.? ? Bertelli comments [Bertelli 1991] on single modality treatments for lymphedema ?Clearly, neither ESD nor the elastic sleeve are the definitive answer to the problem of post-mastectomy lymphedema: on the basis of this study and on our previous experience with ESD as single therapy, they can both be considered as moderately effective treatments which will benefit a given subset of patients. In the present study the combination of the two did not result in an increase of effectiveness. Wearing an elastic sleeve is a simple and economical treatment of post-mastectomy lymphedema: however, not all patients will be able or willing to use it with the same regularity as the women enrolled in this study. Such patients could benefit from ambulatory sessions of ESD or other treatments.? Study No. Measure Mean Decrease CDT Modalities Boris 1997 119 ? Volume -63 to -69% MLD, CB, Exer., CG	excluded from the TA Bunce 1994 did not have a control group and was excluded from the TA Casley-Smith 1992 did not have a control group and was excluded from the TA Ferrandez 1992 did not have a control group and did not meet inclusion criteria for TA Foldi 1989 does not meet inclusion criteria for the TA as it was published prior to 1990 Hammer 2007 was excluded because it does not have a control group Hinrichs 2004 had no control group and did not meet inclusion criteria for TA Karadibak 2008 had no control group and did not meet inclusion criteria for TA Ko 1998 had no control group and did not meet inclusion criteria for TA Szuba 2000 primary and secondary lymphedema not stratified and thus study did not meet inclusion criteria for TA Vignes 2006 had no control group and thus did not meet inclusion criteria for TA Wozniewski 2001 had no control group and thus did not meet inclusion criteria for TA Yamamoto 2007 had no control group and thus did not

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			Bunce 1994 25 ? Volume -50% MLD, CB, CG, Exer. Casley-Smith 1992 200 ? Volume -60 to -103% MLD, CB, CG, Exer. Ferrandez 1992 102 ?Circumference -40 to -60% MLD, CB, IPC F?ldi 1989 399 ? Volume -54% MLB, CB, CG, Exer. Hamner 2007 135 ? Volume -13% MLD, CG, Exer. Hinrichs 2004 14 ? Volume LL -60% MLD, CB, CG, Exer. Karadibak 2008 62 ? Volume -26% MLD, CG, Exer. Ko 1998 299 ? Volume -59 to -68% MLD, CB, CG, Exer. Szuba 2000 40 ? Volume -38 to -44% MLD, CB, CG, Exer. Vignes 2006 537 ? Volume -30% MLD. CB, CG, Exer. Wozniewski 2001 208 ? Volume -19 to -43% MLD, CG, Exer. (+IPC) Yamamoto 2007 82 ? Volume -59 to -73% 2-Phase CDT	meet inclusion criteria for TA
Weiss, Robert	National Lymphedema Network	NA	Value of Repeated Intensive Course of Treatment There are indications in some references of the additional value of a repeated intensive course of lymphedema after an initial course and many months of home maintenance treatment [Casley-Smith 1992]. Lifetime limitations of treatment of this chronic medical condition are not medically sound. Prevention of Lymphedema A few randomized controlled trials addressed the question of whether early intervention can prevent or delay the development of lymphedema [Box 2002, Stout 2008]. Coupled with patient education in detecting early signs of lymphedema and arm volume measurement, these preliminary trials confirm that lymphedema	The assigned scope of the review did not include prevention questions. The question of prevention is an excellent topic to be addressed in the future.

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			can be prevented by early intervention with exercises or simple wearing of compression garments. The use of pre-operative and post-operative lymphoscintigraphy to detect lymphatic system deficiencies before appearance of swelling allowed the early intervention with CDT to prevent the appearance of clinical lymphedema [Campisi 2002].	
Weiss, Robert	National Lymphedema Network	NA	Initiation and Termination of Lymphedema Treatment ? In view of the early indications that prevention of or retarding progression of lymphedema may be a highly beneficial medical strategy, the question of initiation and termination of treatment of this chronic and progressive medical condition may have lost its meaning. Lymphedema brings with it a heightened risk of infection, which in turn has been determined to worsen the lymphedema and make it more difficult to treat. The answer is to detect lymphedema in its pre-clinical stage in the at-risk patient population, and apply conservative preventive measures to prevent progression. This places the stress on developing more sensitive methods of detection than the ?gold standard? of volumetry to enable earlier pre-clinical detection and early intervention. Termination of treatment is an interesting question when applied to a chronic disease. When do we terminate treatment of diabetes, or asthma, or congestive heart failure? The stated aim of lymphedema intense phase treatment is to reduce swelling to a plateau that can be maintained by the patient through home self-treatment. Part of the intense training phase is patient education on self bandaging, wearing and care of compression garments and devices, self-MLD or simple decongestion, use of an ancillary pneumatic sequential pump, skin care and awareness of infection. The required intense phase treatment plan, developed by the patient?s therapist and treating physician, defines the treatment goals and the criteria for determining termination point. This is partly a function of when the patient is ready to assume self-treatment. Periodic evaluations and perhaps additional intense courses of treatment may be expected for refitting new garments, modifying treatment goals or protocols, and integration of home treatment with co-morbidities.	We agree that length of treatment/termination of treatment is an important issue to consider when evaluating the efficacy of therapy. We examined this issue and found that the published literature was ambiguous on this point.
Weiss, Robert	National	NA	Lymphedema of the Head and Neck and Trunk	Thank you for your concern. We have no influence on

	Lymphedema Network		? Few randomized studies have been performed on the measurement or treatment of lymphedema of the breast, back, trunk and genitalia. Commonly used methods of lymphedema measurement for the limbs by measuring or calculating limb volume or limb circumference are not appropriate for measurement of lymphedema of the trunk, head, neck and genitalia. Other properties of the skin such as skin thickness or skin fluid content have been employed in a research setting, such as ultrasonic detection of skin thickness, MRI measurement of skin thickness and sub-facial structure, inference of fluid content from skin bioelectric impedance [Ward 2009] or tissue dielectric constant [Mayrovitz 2007]. It is unfortunate that in the studies of efficacy of treatment of lymphedema of the limbs, researchers seldom account for the displacement of lymphatic fluid from the limb to the adjacent body quadrant, where lymphedema may be created in areas it didn't exist before, and we have no way of measurement. This issue is addressed in Williams 2002. Intermittent Sequential Pneumatic Pumps ? The efficacy of an intermittent pneumatic compression pump will be a strong function of not only the individual patient and lymphedema etiology, but on the construction and operational details of the device. [Mayrovitz HN: ?Interface pressures produced by two different types of lymphedema therapy devices? Phys Ther. 2007;87:1379-88.] In view of the diversity of lymphedema etiology and presentation, and the diversity of pump configurations and operational principles, future studies of the efficacy of intermittent sequential pneumatic pumps must better select and describe the trial cohort and the pump details before conclusions can be made about the use and efficacy of pumps. Medicare coverage policy currently requires trial and failure of a simple pump before an appropriate segmental gradient pump will be covered in spite of ample evidence that the simple pumps are not effective for early stage lymphedema. [Bergan JJ, Sparks S, Angle N: ?A comparison of compression pumps in the treatment of lymphedema?	funding decisions, which are beyond the scope of the TA

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			Vasc Surg.1998(32):455-62.] The generalized Medicare criteria for selection of lymphedema pumps often downgrade the pumps to provide a medically incorrect type of pump. It is important that the type of pump appropriate to treat a particular patient be determined by the prescribing physician and not determined by a non-medical Medicare Contractor clerk on the basis of an interpretation of a policy.	
Weiss, Robert	National Lymphedema Network	NA	Lymphedema Treatment Provider Qualifications The provider of CDT lymphedema treatment must have training and experience in the specialized techniques of manual lymph drainage, compression bandaging, garment fitting and decongestive exercises. These are not generally a part of the curriculum for a Physical Therapist (PT) or an Occupational Therapist (OT) degree, nor is it a part of the testing for a license in these fields even though lymphedema treatment is within the scope of license of a licensed PT or OT. The Technology Assessment wisely notes the training of the physiotherapist in MLD for each RCT, for this is an important factor in evaluating the trial results. Medicare policies have no requirement on the provider of MLD and CDT except that they be licensed PTs or OTs. A training and competency requirement on therapists providing CDT might improve the efficacy of Medicare lymphedema treatment.	Thank you for your comment.
Weiss, Robert	National Lymphedema Network	NA	Summation The conclusions of the Technology Assessment are in essential agreement with the others performed over the last decade. Although there is a lack of high-level evidence in support of the de facto lymphedema treatment protocol of complex decongestive therapy, this multi-modal multi-phasic treatment has been found to be effective in treating tens of thousands of patients in the U.S., Europe and Australia over the last 50 years. It is important for Medicare to cover a variety of measurement and treatment modalities and 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.	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA.

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Wong, Julie, PT, CLT	Julie Wong's Proactive Clinic		Lymphedema care needs to be addressed because when a person has lymphedema from breast cancer surgery, it will decrease a person's quality care. I can attest to it because as a physical therapist and abreast cancer survivor, I had 2 inches of swelling in both arms that limited my ability to work with my patients. It took me over a year before I was able to get the proper care to resolve the swelling. It was VERY difficult to treat the patients because of total upper arm nerve compression with every reaching movement. Not only did it limit me in movement, without proper care, I was at risk for cellucitis which is more debilitating and costly to the health care system! We need legislators who understands that lymphedema treatment and the cost of the supplies must be included in a patient's care!	Thank you for your concern. We have no influence on funding decisions, which are beyond the scope of the TA
Zucker, Jeannette DPT, CLT-LANA, CSCS, WCC	Memorial Sloan-Kettering Cancer Center	NA	Thank you for what appears to be a comprehensive review of the literature currently available regarding lymphedema and its various treatments. However, the duration of time permitted for peer and public review is not commeasured to the time spent on the creation of this document. If the response from the healthcare professionals who have devoted their careers to lymphedema is underwhelming it would be incorrect to assume that there is a lack of interest or that the conclusions made in this report are accurate by default. For example on page 20 where it lists the schools that offer certification: The Norton School of Lymphatic Therapy, Klose Training and Consulting, and the Academy of Lymphatic Studies were not included. It is possible that when reviewing the available studies, an exhaustive research was not completed. Furthermore, the inclusion criteria consisted of studies available only in English. There is a plethora of studies available in other languages and it is the opinion of the therapist that those not be overlooked for the sake of convenience. Additional time is necessary to review the validity and accuracy of this document.	We have made a change in the text so that examples of U.S training schools are mentioned instead of foreign schools. We have done a foreign language search and the results did not change the original conclusions of the TA

[1] Names are alphabetized by last name. Those who did not disclose name are labeled "Anonymous Reviewer 1," "Anonymous Reviewer 2," etc.

[2] Affiliation is labeled "NA" for those who did not disclose affiliation.

[3] If listed, page number, line number, or section refers to the draft report.

[4] If listed, page number, line number, or section refers to the final report.