

Review of Evidence on Efficacy of Lymphedema Treatment Protocols

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Brief Author's Bio

My name is Robert Weiss. I am the spouse of an 18-year survivor of breast cancer who has lymphedema of the right arm as a sequela of her cancer treatment. I have been a lymphedema treatment advocate and activist for thirteen years, advocating for better access to quality treatment of lymphedema for my spouse, and for the 3 million other Americans with, or at risk for, lymphedema.

I am a retired aerospace engineer on fixed income, and derive no benefit from any of the manufacturers of lymphedema medical items, from any physician or therapist, from any charitable or for-profit organization or foundation for my work. The National Lymphedema Network encourages my efforts, and I am Co-Chair of their Insurance and Legislation Committee, for which I receive no remuneration.

I am a graduate of the National Breast Cancer Coalition Project LEAD and Quality Care LEAD, and of the National Lymphedema Network's Lymph Science Advocacy Program, and have amassed hundreds of hours of medical Continuing Education Units on the subject of lymphedema. I am the Chairman of the NLN Reimbursement and Legislation Committee and Co-Chair of the American Lymphedema Framework Project Public Policy Committee.

I assist a limited number of Medicare beneficiaries in using the Medicare appeal procedures to obtain reimbursement for the compression garments they use daily in the medical treatment of their lymphedema. I receive no payment whatsoever for my services. I am also working with the Centers for Medicare and Medicaid Services in developing and changing national and local coverage policy and interpretation of Medicare regulations relating to the narrow field of lymphedema treatment.

Key Points

- There is no standard measurement or definition of lymphedema
- Benefits have been demonstrated for treatment at any every stage, including *pre-clinical (pre-swelling) stage*
- Complex Decongestive Therapy (CDT), the current lymphedema treatment standard, is multimodal and multi-phasic
- Compression is a mandatory element of lymphedema treatment
- Medicare does not cover treatment *per current medical standard*
- Insurers and Providers cover *some or all CDT modalities*
- Reviews and systematic studies indicate efficacy of ALL modalities for SOME patient subset, albeit with little high-level evidence
- Randomized studies and cohort studies demonstrate efficacy of lymphedema protocols *singly or in combination*
- Preliminary studies indicate potential cost savings of lymphedema therapy
- Goal of Medicare should be to provide the *treating physician* and *lymphedema therapist* a choice of covered modalities which can be appropriately combined for the patient at any stage of treatment.

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Lymphedema Treatment Protocols Based on Expert Consensus and Clinical Experience

➤ Primary Treatment Modalities

- ❖ Manual Lymph Drainage
- ❖ Compression Bandaging
- ❖ Compression Garments
- ❖ Remedial Exercises
- ❖ Skin Care

Complex Decongestive
Therapy (CDT)
[Földi 1998]

➤ Adjunctive Modalities

- ❖ Sequential Pneumatic Compression
- ❖ Cold Laser
- ❖ Pharmaceuticals

➤ Surgical

- ❖ Debulking
- ❖ Liposuction
- ❖ Microsurgical

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1. International Society of Lymphology Executive Committee: **The diagnosis and treatment of peripheral lymphedema** *Lymphology* 2009;42:51-60.
2. American Cancer Society: **Workgroup III: Diagnosis and Management of Lymphedema** *Cancer*, Dec 15, 1998;83(12 Supplement):2882-5, American Cancer Society Workshop on Breast Cancer Treatment-Related Lymphedema, New York, NY, February 20-22, 1997.
3. Health Canada Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast cancer: **Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema** *CMAJ* Jan 23, 2001;164(2):191-9.
4. National Cancer Institute, U.S. National Institutes of Health: **Lymphedema (PDQ®), Health Professional Version** Version dated 06/30/2009
5. Italian College of Phlebology: **Guidelines for the diagnosis and therapy of the vein and lymphatic disorders- Evidence-based report by the Italian College of Phlebology, Revision 2004** *Internat Angiology*. Jun 2005;21(suppl.2 to issue 2)
6. National Lymphedema Network: **Position Paper on the Treatment of Lymphedema** October 2009 (Revision of original dated 08/10/2006).
7. Lymphedema Framework: **Best Practice for the Management of Lymphedema. International Consensus** London: MEP Ltd. 2006.
8. American Lymphedema Framework Project (in work)

Methods Used to Measure Lymphedema

Q1

- Circumferential (Limb only)
- Volumetric (Limb only)
 - ❖ Water Displacement [Brennan 1996]
 - ❖ Calculated circumferential measurements
 - ❖ Computed based on electro-optical inputs
- Tissue tonometry [Clodius 1976] Traditional
- Lymphoscintigraphy [Weissleder 1988, Szuba 2003]
- Bioelectrical impedance measurement [Mikes 1999, Cornish 2001]
- Dielectric skin fluid measurement [Lahtinen 2006]
- Ultrasonic skin thickness measurement [Shukla 1984, Warszawski 1998, Mellor 2004, Rönkä 2004]
- Magnetic resonance imaging of skin [Idy-Paretti 1998]
- Optical skin erythema measurement [Russell 1994]
- Skin visco-elasticity [Gorodetsky 1999, Marcenaro 2004]
- Dual-beam absorptiometry [Cluzan 1998]

Reviews

Mikes 1999
Gerber 1998
Casley-Smith 1994
Hoe 1992
Kissin 1986

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Clodius L, Deak L & Piller NB: “A new instrument for evaluation of tissue tonicity in lymphedema” *Lymphology* 1976;9:1-5.

Cluzan RV, Pecking A, Ruiz JC, Alliot F, Ghabboun S, Pascot M, Gachon-Lameyre V. Biphotonic absorbtometry of the secondary upper limb lymphedema. *Lymphology (Suppl)* 1998;31:296-8.

Cornish BH, Chapman M, Hirst C et. al.: “Early diagnosis of lymphedema using multiple frequency bioimpedance” *Lymphology* 2001;34:2-11.

Gorodetsky R, Lotan C, et. al.: “Late effects of dose fractionation on the mechanical properties of breast skin following post-mastectomy radiotherapy” *Int J Radiat Oncol Biol Phys.* 1999;45:893-900.

Idy-Paretti I, Bittoun J, Alliot FA et. al.: “Lymphedematous skin and subcutis: *In vivo* high resolution magnetic resonance imaging evaluation” *J Invest Dermatol.* 1998;110:782-7.

Lahtinen T, Nuutinen J & Mayrovitz HN: “A new water-specific technique for local measurement of edema and lymphedema induced by cancer therapy” *ESTRO Newsletter* Winter 2006;61:23-4.

Mellor RH, Bush NL, Stanton AWB, et. al.: “Dual-frequency ultrasound examination of skin and subcutis thickness in breast cancer-related lymphedema” *The Breast J.* Nov 2004;10(6):496.

Mikes DM, Cha BA, et.al.: “Bioelectrical impedance analysis revisited” *Lymphology* 1999;32:157-65.

Rönkä RH, Pamilo MS, von Smitten KAJ & Leidenius MHK: “Breast lymphedema after breast conserving treatment” *Acta Oncolog.* 2004;43(6):551-7.

Russell NS, Knoken H, et. al.: “Quantification of patient-to-patient variations of skin erythema developing as a response to radiotherapy” *Radiother Oncol.* 1994;30:213-21.

Shukla HS, Gravelle IH, et. al.: “Mammary skin oedema: a new prognostic indicator for breast cancer” *Br Med J (Clin Res Ed).* 1984;288(6427):1338-41.

Szuba A, Shin WS, Strauss HW & Rockson S: “The third circulation: Radionuclide lymphoscintigraphy in the evaluation of lymphedema” *J Nucl Med.* 2003;44(1):43-57.

Warszawski A, Rottinger EM, et. al.: “20-MHz ultrasonic imaging for quantitative assessment and documentation of early and late postradiation skin reactions in breast cancer patients” *Radiother Oncol.* 1998;47:241-7.

Weissleder H & Weissleder R.: “Lymphedema: evaluation of qualitative and quantitative lymphoscintigraphy in 238 patients” *Radiology,* 1988;167:729-35,

There is No Absolute Standard of Lymphedema Measurement but Relative Measurement is Essential to Treatment

Q1

Q8

- There is NO STANDARD measurement method or definition of lymphedema.
- Traditional methods of describing lymphedema of the limb are not applicable to describing or measuring lymphedema at other body sites (e.g. breast, upper torso, abdomen, genitalia) or of describing bi-lateral lymphedema.
- Traditional limb measuring methods are not adequate to detect pre-swelling changes in tissue that represent “pre-lymphedema” (so-called “stage-zero”) which may present attractive prevention targets.
- All of the previously listed methods have been or can be utilized to measure progression or regression of lymphedema for the purpose of determining the efficacy of the treatment modality, and enabling treatment changes.
- Some of the previously listed methods may be appropriate for measuring latent (stage-zero) lymphedema and some are able to measure lymphedema at any point on the body, not restricted to limbs. These methods require continuing development, validation and calibration.

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THERE IS NO “STANDARD” DEFINITION OR MEASURE

Any differential defines “swollen” [Lobb 1949]

“Significant” is $\Delta c > 0.5\text{cm}$ [Deland 1950]

Swelling is $\Delta c > 0.72\text{cm}$ [MacDonald 1955]

Lymphedema is $\Delta c \geq 2\text{cm}$ @ any of 3 points [Ozaslan 2004]

Presence of LE $\Delta c \geq 2\text{cm}$ [Armer 2004]

Lymph Edema “Present or Absent” [Schijven 2003]

Arm lymphedema present when $\Delta v \geq 200\text{mL}$ [Kwan 2002][Beaulac 2002], or when $\Delta v \geq 10\%$ [Kuehn 2000],[Tengrup 2000]

Sum of $\Delta c/c\%$ measured at 6 places $> 5\%$ defines lymphedema [Herd-Smith 2001]

LE present if $\Delta c > 2\text{cm}$ @ 2 points and if tissue consistency was typical of edema [Haid 2002]

Skin thickness $\Delta t > 2\text{mm}$ [Rönkä 2004]

Ratio of extracellular to intracellular fluid volumes [Cornish 2002]

Mechanisms & Effects of Compression Therapy in Lymphedema

Q5

Mechanism	Effect
∅ Increased interstitial pressure	1. Reduced capillary filtration ⁶⁻⁸ and production of lymph; limb volume decrease
∅ Shift of fluid into uncompressed areas	2. Proximal volume increase accommodated by normally working lymphatics in that region and assisted by manual lymphatic drainage ⁹
∅ Increased lymph reabsorption and stimulation of lymphatic contractions	3. Improvement of lymph kinetics as shown by lymphoscintigraphy ¹⁰ and intra lymphatic measurement of flow and pressure ^{11,12}
∅ Breakdown of fibrosclerotic tissue	4. Softening of tissue as shown by ultrasound ¹³ and durometer ¹⁴
∅ Improvement of venous pump in patients with venolymphatic dysfunction	5. Increased expelled blood volume; reduction of venous reflux and ambulatory venous hypertension ¹⁵

Reference: Table 1 of Partsch H & Jünger M: "Evidence for the use of compression Hosiery in lymphoedema" in **Lymphoedema Framework: Template for Practice: Compression Hosiery in Lymphoedema** London MEP Ltd. 2006

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6. Bates DO, Levick JR, Mortimer PS: "Subcutaneous interstitial fluid pressure and arm volume in lymphoedema" *Int J Microcirc Clin Exp* 1992; 11(4): 359-73.
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8. Levick JR: An Introduction to Cardiovascular Physiology. London: Arnold, 2003
9. Földi E, Földi M: "Die Anatomischen Grundlagen der Lymphodembehandlung" *Schweiz Runds Med Prax* 1983; 72(46): 1459-64.
10. Leduc O, Bourgeois P, Leduc A: "Manual lymphatic drainage: Scintigraphic demonstration of its efficacy on colloidal protein resorption" In: Partsch H (ed) Progress in Lymphology XI. Amsterdam: Excerpta Medica, 1988; 551-4.
11. Olszewski WL: "Lymph pressure and flow in limbs" In: Olszewski WL (Ed). Lymph Stasis: pathophysiology, diagnosis and treatment. Boca Raton, FL: CRC Press, 1991: 109-55.
12. Franzeck UK, Spiegel I, Fischer M, et al: "Combined physical therapy for lymphoedema evaluated by fluorescence microlymphography and lymph capillary pressure measurements" *J Vasc Res* 1997; 34(4): 306-11.
13. Gniadecka M: "Dermal oedema in lipodermatosclerosis: distribution, effects of posture and compressive therapy evaluated by high-frequency ultrasonography" *Acta Derm Venereol*. 1995; 75(2): 120-4.
14. Falanga V, Bucalo B: "Use of a durometer to assess skin hardness" *J Am Acad Dermatol*. 1993; 29(1): 47-51.
15. Partsch H: [Improving the venous pumping function in chronic venous insufficiency by compression as dependent on pressure and material] in German *Vasa* 1984; 13(1): 58-64.

Reviews and Systematic Studies of Lymphedema Treatment Protocols

Q5

There have been many reviews and systematic studies of the protocols of lymphedema treatment in the last decade.

Most have concluded that:

1. There is little high-level evidence;
2. The protocols of CDT (Manual Lymph Drainage, Compression with Non-Elastic Bandages and Garments and Exercise) and Intermittent Sequential Pumps have all been found to be effective in some combination;
3. Physician- and specialty trained Therapist-directed Complex Decongestive Therapy is the Clinical Standard of lymphedema treatment throughout the world.

- Földi 1989
- Brennan 1998
- *Megans 1998
- *Erickson 2001
- *Harris 2001
- Ciccone 2002
- *Badger 2004
- *Kligman 2004
- *CHBRP 2005
- *Moseley 2006
- Stubblefield 2006
- Elokda 2007
- United HC MTAC 2007
- *Hayes 2008

* Systematic studies

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• Reviews and Systematic Studies

- **Badger C**, Preston N, Seers K, Mortimer P. Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD003141. Included studies marked ◊ on RCT list next page.
- **Brennan MJ** & Miller LT: "Overview of Treatment Options and Review of the Current Role and Use of Compression Garments, Intermittent Pumps, and Exercise in the Management of Lymphedema" *Cancer*, Dec 15, 1998;83(12 Supplement):2821-7. American Cancer Society Workshop on Breast Cancer Treatment-Related Lymphedema, New York, NY, February 20-22, 1997.
- **CHBRP**: California Health Benefits Review Program: "Analysis of Assembly Bill 213 Health Care Coverage for Lymphedema" Report to California State Legislature, Oakland, CA: CHBRP 05-03 2005. www.chbrp.org/documents/ab_213final.pdf Included studies marked † on RCT list next page.
- **Elokda AS**. Lymphatic system disorders. In: Cameron MH, Monroe LG, editors. *Physical Rehabilitation: Evidence-Based Examination, Evaluation, and Intervention*. St Louis, MO: Saunders Elsevier; 2007:718-32.
- **Földi E**, Földi M & Clodius L: "The Lymphedema Chaos: A lancet" *Annals Plastic Surg*. June 1989;22(6):505-15.
- **Harris SR**, Hugi MR, Olivotto IA & Levine M: "Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema" *CMAJ* Jan 23, 2001;164(2):191-9. Included studies marked ¥ on RCT list next page.
- **Hayes SC**: "Review of research evidence on secondary lymphedema: Incidence, prevention, risk factors and treatment" National Breast and Ovarian Cancer Centre (Australia) Surry Hills, NSW March 2008
- **Kligman L**, Wong RK, Johnston M, Laetsch NS. The treatment of lymphedema related to breast cancer: a systematic review and evidence summary. *Supportive Care in Cancer* 2004;12(6):421-31. DOI: 10.1007/s00520-004-0627-0. Included studies marked f on RCT list next page
- **Megens A** & Harris SR: "Physical therapist management of lymphedema following treatment for breast cancer: a critical review of its effectiveness" *Phys Ther*. Dec 1998;78(12):1302-11.
- **Stubblefield MD**, Custodio CM, Franklin DJ. Cardiopulmonary rehabilitation and cancer rehabilitation. 3. Cancer rehabilitation. *Archives of Physical Medicine and Rehabilitation* 2006;87(3 Suppl 1):S65-71. DOI: 10.1016/j.apmr.2005.12.009.
- **United HC** Medical Technology Assessment Committee: Complex Decongestive Therapy for Lymphedema. Number 2007T0039E 11/1/2007

Randomized Studies Consider Different Combinations of CDT Modalities

Q5

	MLD	CB	CG	MLD+CB	Exercise	DCE	SLD	CDT	IPC
Ahmed 2006					0 NS				
Andersen 2000 †‡¶f	- NS		+ Sig	+ Sig					
Badger 2000 †‡		++Sig	+ Sig						
Bertelli 1991 ¶f			+ Sig						
Dini 1998 †¶f									+ Sig
Dubois 2004	√								√
Hornsby 1995 †‡f			√			√	√	+ Sig	
Johansson 1999 †¶		+ Sig		++Sig					
Johansson 1998 †¶f	+ Sig		+ Sig	+ Sig					+ Sig
McNeely 2004 †		+ Sig		++ Sig					
Mirola 1995									
Moseley 2007	+ Sig								
Sitzia 2002	+ Sig						+ Sig		
Szuba 2002 †				- NS					+ Sig
Wilburn 2006							- NS		- Sig
Williams 2002 †	+ Sig						+ NS		
Zanolla 1984	+ Sig								+ Sig

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Some RCTs on Efficacy of CDT Protocols

***Andersen** L, Højris I, Erlandsen M & Andersen J: "Treatment of breast-cancer-related lymphedema with or without manual lymphatic drainage. a randomized study". *Acta Oncol* 2000;39(3): 399-405.

Badger CMA, Peacock JL, Mortimer PS: "A Randomized, Controlled, Parallel-Group Clinical Trial Comparing Multilayer Bandaging Followed by Hosiery versus Hosiery Alone in the Treatment of Patients with Lymphedema of the Limb", *Cancer* Jun 15, 2000; 88(12): 2832-7.

Box RC, Reul-Hirche HM, Bullock-Saxton JE, & Furnival CM: "Physiotherapy after breast cancer Surgery: Results of a randomised controlled study to minimise lymphoedema." *Breast Cancer Res Treat* Sep 2002;75(1):51-64.

***Johansson** K, Lie E, Ekdahl C & Lindfeldt J: "A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema" *Lymphology* Jun 1998;31(2):56-64.

***Johansson** et. al. 1999: Johansson K, Albertsson M, Ingvar C & Ekdahl C: "Effects of Compression Bandaging With or Without Manual Lymph Drainage Treatment in Patients with Postoperative Arm Lymphedema" *Lymphology*, 1999;32(3):103-10. Erratum in *Lymphology* 1999;32(4):172. Comment in *Lymphology* Jun 2000;33(2):69-70. Also *NLN LymphLink*, Jan-Mar 2000;12(1):1-4, 18.

***McNeely** ML, Magee DJ, Lees AW, Bagnall KM, Haykowsky M, Hanson J: The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial. *Breast Cancer Research and Treatment* 2004;86(2):95-106.

Mondry TE, Riffenburgh RH, Johnstone PA: "Prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer therapy" *Cancer J*. 2004;10(1):42-8; discussion 17-9.

***Sitzia** J, Sobrido L & Harlow W: "Manual lymphatic drainage compared with simple lymphatic drainage in the treatment of post-mastectomy lymphedema" *Physiotherapy* 2002;88(2):99-107.

Wilburn O, Wilburn P & Rockson SG: "A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema" *BMC Cancer*. Mar 29 2006;6(1):84.

***Williams** AF, Vadgama A, Franks PJ & Mortimer PS: "A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema. *Eur J Cancer Care*. (Engl)Dec 2002;11(4):254-61.

Zanolla R, Monzeglio C, Balzarini A & Martino G: "Evaluation of the Results of Three Different Methods of Postmastectomy Lymphedema Treatment" *J Surg Oncol*. 1984;26:210-3.

Abstracted Results from Recent Systematic Studies

Q8

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	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).

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CAVEAT

“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]

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 [François 1989] 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, comorbidities and specific health status, to prescribe the combination of protocols most likely to have a positive outcome for the specific patient.

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 which 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..... (continued on next page notes)

Efficacy of Lymphedema Protocols Trials in Progress

Q8

National Cancer Institute/ NIH Grants

1. Home-based Compression Therapy for Arm and Truncal Lymphedema in Breast Cancer
2. Early Detection and Intervention for Mild and Moderate Lymphedema in Patients Treated for Breast Cancer
3. Phase I/II Study of a Lymphedema Symptom Checklist in Patients With Head and Neck Cancer, NCT00840814
4. Liposuction for Arm Lymphedema Following Breast Cancer Surgery
5. A Study of Vascular Endothelial Growth Factor (VEGF) Inhibition in Patients With Unilateral Upper Extremity Lymphedema Following Treatment for Cancer
6. A Pilot Study of VEGF Inhibition in Patients With Lymphedema Following Breast Cancer Treatment
7. Randomized Study of Education With or Without Exercise and Counseling in Preventing Lymphedema in Women With Stage I-III Breast Cancer Who Are Undergoing Axillary Lymph Node Dissection

8. Lymphedema Prophylaxis in Breast Cancer Survivors Who Show Early Evidence of High-risk Status
9. Prospective Measurement of Post-Treatment Lymphedema
10. Aquatic Exercise Study for Breast Cancer Patients With Lymphedema

American Cancer Society Grants

- A. Familial Susceptibility for Lymphedema Secondary to Breast Cancer Therapy RSG-06-212-01-LR
- B. Natural History and Cost Analysis of Lymphedema Secondary to Breast Cancer RSG-06-209-01-LR
- C. Effects of Expressive Writing in Breast Cancer Survivors with Lymphedema MRS-07-012-01-CPPB
- D. Burden of Breast Cancer Related Lymphedema on Working American Families RSGTL-05-093-01-CPHPS
- E. Pre-Clinical Model of Breast Cancer Treatment-Related Lymphedema RSGTL-05-090-01-CCE

NCT00376597

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NCT00498771

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CAVEAT CONTINUED

As another example of how differences in individual patient 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 François 1989 [François 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 François 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.

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.] 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”

*Vasc Surg.*1998(32):455-62.]

Cohort Studies Support Efficacy of CDT

“Case series collectively describing a mean 65% volume reduction in over
10,000 patients attest its efficacy” [Cheville 2003]

Q6

Study	No.	Measure	Mean Decrease	CDT Modalities
Boris 1997	119	Δ Volume	-63 to -69%	MLD, CB, Exer., CG
Bunce 1994	25	Δ Volume	-50%	MLD, CB, CG, Exer.
Casley-Smith 1992	200	Δ Volume	-60 to -103%	MLD, CB, CG, Exer.
Ferrandez 1992	102	Δ Circumference	-40 to -60%	MLD, CB, IPC
Földi 1989	399	Δ Volume	-54%	MLB, CB, CG, Exer.
Hamner 2007	135	Δ Volume	-13%	MLD, CG, Exer.
Hinrichs 2004	14	Δ Volume	-60%	MLD, CB, CG, Exer.
Karadibak 2008	62	Δ Volume	-26%	MLD, CG, Exer.
Ko 1998	299	Δ Volume	-59 to -68%	MLD, CB, CG, Exer.
Szuba 2000	54	Δ Volume	-38 to -41%	MLD, CB, CG, Exer.
Vignes 2006	537	Δ Volume	-30%	MLD, CB, CG, Exer.
Wozniewski 2001	208	Δ Volume	-19 to -43%	MLD, CG, Exer. (+IPC)
Yamamoto 2007	82	Δ Volume	-59 to -73%	2-Phase CDT

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Boris M, Weindorf S & Lasinski B: “Persistence of Lymphedema Reduction After Complex Lymphedema Therapy” *Oncology* (Huntingt) 1997;11(1):99-109, discussion 110, 113-4.

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Lymphedema \longleftrightarrow Cellulitis

Q4

- Lymphedema is a chronic medical condition known to increase the risk of infection [Brewer 2000, Cox 2006, Thiadens 1992, Kasseroller 1998, Swenson 2002, Moffatt 2003]
- There is evidence that there is suppression of immune competence in a lymphedematous limb [Mallon 1997]
- Infection is noted in 11-16% of breast cancer survivors at 1 year [Swenson 2002]
- The “vicious cycle” [Stoberl 1987, de Godoy 2000]
 - ❖ Lymphedema is a risk factor for cellulitis [Damstra 2008]
 - ❖ Cellulitis is a causative factor for lymphedema
 - ❖ Cycle leads to ever-worsening recurrent infections in untreated lymphedema patients
 - ❖ Cellulitis can recur even during prophylactic treatment [Vignes 2006]
- Increased cases of lymphedema of the breast are being noted, accompanied by “delayed breast cellulitis” [Hughes 1997, Mertz 1998]
- Treatment of lymphedema has been shown to decrease the frequency of infections [Földi 1996, Boris 1997, Ko 1998]
- The costs of treatment of lymphedema-related cellulitis are substantial and largely avoidable [Weiss 2006]

The chicken or the egg?

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Economic Impact of Lymphedema Treatment Q4

- Cost for healthcare of cancer survivor is additional burden [Shih 2009]
- Lymphedema is a chronic medical condition known to increase the risk of infection [Stoberl 1987, Brewer 2000, Cox 2006, Thiadens 1992, Kasseroller 1998, Swenson 2002, Moffatt 2003]
- Treatment of lymphedema involves initial and continuing costs
 - ❖ Initial decongestion: 2-4 weeks MLD, set of bandages, initial garment
 - ❖ Continuing self-treatment: bandages, daytime garments, nighttime devices
 - ❖ Average cost/year/contract of lymphedema treatment in VA is \$1.15-\$2.64
- Efficacy of treatment is a strong function of patient adherence [Casley-Smith 1998, Vignes 2006]
- Management of lymphedema reduces risk of lymphedema-related infection [Földi 1996, Boris 1997, Ko 1998]
- Pilot studies show that cost of treating lymphedema-related infections exceeds cost of treating lymphedema [Casley-Smith 1998, Shih 2009, Weiss 2009]

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Current Medicare Coverage of the Protocols of Complex Decongestive Therapy

Q7

Lymphedema Primary Protocol	Current Medicare Coverage
Manual Lymph Drainage	Statutory annual limit; No therapist training or competency requirement.
Compression Bandaging	Bandaging Systems denied. Therapist's bandaging services not covered.
Compression Garments	Day and night garments denied even though they meet CMS coverage policy requirements as prosthetic devices.
Exercise	Instruction is covered.

Adjunctive Protocol	Current Medicare Coverage
Sequential Pneumatic Compression	Covered. Coverage not coordinated with primary treatment modalities.

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Which Problems Can Be Addressed by CMS and Which by Congress?

A separate NCD or LCD for the Treatment of Lymphedema would be appropriate instead of the current use of uncoordinated Outpatient PT and OT LCD and the Lymphedema Pump NCD; Billing codes and guidelines for bandaging, measurement and fitting, patient education can be added to an appropriate LCD. Separate LMRPs have existed in the past (see next chart) and have been proposed by this author and by NLN ;

Lymphedema Sequential Pneumatic Pump NCD needs updating based on new lymphatic knowledge, new pump designs specifically developed for lymphedema and prevalence of combined lympho-venous swelling with and without ulcers;

Coverage of compression bandages, garments and devices can be done by CMS on the basis that these items meet the current definitions of "prosthetic devices" and are therefore covered by Medicare. New LCDs or NCD will be needed which will differentiate lymphedema treatment items from similarly appearing items which have other medical functions and fall into different benefit categories (e.g, surgical dressings, splints and braces, DME, burn care).

Current HCPCS Codes are inadequate for administration of lymphedema treatment materials. HCPCS Code Change Request #07-109 was a proposal to change the HCPCS codes to cover compression bandages, garments, devices and supplies used in the treatment of lymphedema. Insurance companies who cover lymphedema bandages and compression sleeves use non-covered HCPCS S-codes to administer these benefits.

Training and competency issues for PTs and OTs can be addressed by CMS, but issues regarding the provision of lymphedema therapy services by other medical personnel may require Congressional action (i.e. a change of C.F.R. 42 §484.4).

Deletion of annual therapy limits for rehabilitation will take Congressional action, and there are bills which have been introduced with this intent. But limits on the protocols of CDT should be governed by medical necessity, and not Congressional limits on rehabilitation.

Retired LMRPs “CDP for Lymphedema”

Q7

State	LMRP No.	Medicare Contractor	Year
AR, LA	(no number)	BCBS of Arkansas	1999,2000
CA-S	99-4.9	NHIC	2000
CO,NM, TX	Y-9A-R1	Trailblazer Health Enterprises	2002
DC,DE,MD	Y-9B	Trailblazer	2001
FL	97110	First Coast Service Options	2002
MT	00-05	BCBS of Montana	2000
TN	9906	CT General Life (CIGNA)	2002
AK,AS,AZ, HI,IA,ND, NV,OR,SD	99-6.1 99-06 99.13	Noridian Mutual Life Insurance Co.	2000,2002

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These Local Medical Review Policies usually covered the physical therapy and occupational therapy services of manual lymph drainage (CPT 97140), exercise (CPT 97110) and instructions for home use of pneumatic pumps CPT 97016). These services were usually broken out from the Outpatient Physical Therapy or Outpatient Occupational Therapy LMRPs and directed toward treatment of diagnosed lymphedema (ICD-9-CM 457.0, 457.1, or 757.0).

Left moot in all these policies was the billing for bandaging, garment measurement and fitting, patient education in self treatment in a home setting and any coverage criteria relating lymphedema pump coverage to the results of MLD and bandaging in the intensive phase of lymphedema treatment.

The bandages and garments themselves remained non-covered.

Insurance and Provider Medical Policies Cover Some or All CDT Modalities

Q7

Insurer/Provider	Primary Lymphedema Treatment Modalities				Adj.
	MLD	Bandages	Garments	Devices	Pumps
Aetna	0325	0069 ⁽¹⁾	0069 ⁽¹⁾	0069	0500
Anthem BCBS	REHAB-04,-05				DME-06
BBCS FL	09-E0000-31 ⁽²⁾	-31	-31	-31	-31
CareFirst VA	8.01.014 ⁽³⁾	8.01.014	8.01.014	8.01.014	8.01.014
CIGNA	0096 ⁽⁴⁾				0354
Excellus BCBS Univera HC	8.01.12		1.01.14	1.01.14	1.01.17
Kaiser Permanente	EoC ⁽⁵⁾	EoC	EoC	EoC	EoC
Milliman			ACG:A-0336		
United HealthCare	(6)	(6)	(6)	(6)	MMG

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NOTES

- (1) Unless contract excludes coverage of “supplies”. Garments for trunk and neck considered experimental because of lack of evidence. Policy # 0482 covers lower limb stockings for lymphedema.
- (2) Covers Diagnosis Codes 457.0, 457.1, 757.0 and 997.99. Utilizes HCPCS S-Code Group for bandages and sleeves, A-Code group for stockings and E-Code group for pumps.
- (3) No Medical Policy but coverage is determined by individual policy. Billing Guideline #027 covers lymphedema devices, intermittent pumps, sleeves, gloves, gauntlets and bandages (S-Codes for bandages and upper limb garments, L-code for lower limb).
- (4) Although CIGNA Policy #0096 covers Complex Lymphedema Therapy for treatment of lymphedema ICD-9-CM codes 457.0, 457.1 and 757.0, there is no billing information or details on coverage of garments, bandages and devices.
- (5) Kaiser Permanente (California) covers MLD, compression bandages and garments for home use, with replacements every 6 months for treatment of lymphedema. Their specific DME formulary is held to be “proprietary” even to patients whose coverage is bound by them. Like Medicare, there is no training requirement for physical therapists who provide lymphedema services, and there are very few therapists trained to national standards.
- (6) UnitedHealthcare/SecureHorizons retired their Complex Decongestive Physiotherapy for Lymphedema Medical Management Guideline effective 02/19/08. Their Medical Technology Assessment No. 2007T0039E dated 11/1/2007 concluded that “CDT is proven for treatment of lymphedema”, “CDT used following a lymphedema risk-inducing procedure is proven before symptoms become evident”, and “intermittent pneumatic compression is proven for the treatment of lymphedema.”

Provider Guidelines From NY to CA Recognize the Function of Compression Garments in Lymphedema Treatment

Q7

- New York State Medicare Contractor Policy on Surgical Stockings
 - ❖ Eligible for coverage as a **prosthetic/orthotic** for Lymphedema
- California Kaiser Permanente Health Plan
 - ❖ Covers compression burn garments and lymphedema wraps and garments as “**external prosthetics and orthotics**”.
- Widely-used Milliman insurance guidelines recognize compression garments as covered for the treatment of lymphedema, coded as **prosthetic services**.

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• According to the **New York State Medicare Contractor Policy on Surgical Stockings**, “**Surgical Stockings** or graduated compression stockings are custom-made or custom-fitted support for the lower extremities. Surgical stockings (e.g., Jobst, Sigvaris, and CircAid) are *eligible for coverage as a prosthetic/orthotic* for the following indications: Venous insufficiency; Varicose veins; Phlebitis/Thrombophlebitis; DVT prophylaxis during pregnancy and postpartum; Orthostatic hypotension; Ulceration due to chronic venous insufficiency; *Lymphedema*” [Excellus Blue Cross Blue Shield]

• Since July 1, 2000 Kaiser provides the following benefits “**for the treatment of lymphedema when prescribed by a Plan physician as part of a lymphedema treatment plan**: adjustable manual compression garments [e.g. Reid, CircAid, MedAssist, etc] , **elastic compression garments**, low-elastic extremity wraps, and pneumatic lymphedema pumps and appliances. Some coverage, like the pneumatic lymphedema pumps and appliances, is subject to the member having a Supplemental Durable Medical Equipment benefit in addition to their basic health care coverage. All members, however, are entitled to receive as a covered benefit the particular types of compression garments and extremity wraps that their clinical situation requires. Up to two of each required item will be initially provided. Replacement items will be issued when the existing items are no longer functional, and replacements will consist of up to two items of each type required. The need for replacements must be determined and documented by a Plan physician in order to be a covered benefit.” The bandages and sleeves are provided as “**Prosthetic and Orthotic Devices**” and are listed in the Evidence of Coverage under "external devices". Coverage is provided for "Compression burn garments and lymphedema wraps and garments.”

• **Insurance Guideline on Compression Stocking Coverage** Milliman Care Guideline ACG:A-0336 5/12/06: “**Compression stockings** are indicated for all patients with lymphedema after **axillary dissection** for tumor staging [C](11)”

“[C] Start early in treatment and replace compression stockings every 4 to 6 months or sooner if they become loose...”

“Codes – CPT® or HCPCS: L8100 through L8239 (graduated **compression stockings**) ICD-9 Diagnosis: 457.0, **457.1**, 757.0 (lymphedema all causes, **upper and lower limbs, congenital or secondary**)”

An Advocate's Proposal. Patient-Oriented Goals for Medicare Treatment of Lymphedema

Q7

- Provide coverage for every modality for which there is sufficient evidence of efficacy either separately or in combination with another modality for some lymphedema patient subset;
- Allow the treating physician and treating therapist to select from a “menu” of protocols to develop a plan of treatment for the patient reflecting the patient's instant medical needs;
- Monitor progress using physician/therapist-selected objective or subjective measure, and modify treatment plan when necessary to achieve target objectives.
- Assure that every therapist who provides lymphedema treatment services is “adequately trained and has demonstrated competence”.

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Final Comments

- It is within our power today to place in the hands of our medical practitioners the tools with which they can treat and manage lymphedema.
- Fifty years of clinical experience in Europe and Australia support the efficacy of the multi-modal, multi-phasic protocol comprising manual lymph drainage, compression bandaging, compression garments, exercise, skin care, and adjunctive sequential pneumatic compression.
- Consensus guidelines call out these protocols and Providers and Insurers already cover some or all of them. Three million Medicare Beneficiaries are entitled to them.
- The prompt diagnosis and treatment of lymphedema has been shown to reduce the rate of lymphedema-related cellulitis, and can potentially save Medicare hundreds of millions of dollars each year.

**Lymphedema Treatment is Good Business
As well as Good Medicine**

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Key Points

- There is no standard measurement or definition of lymphedema
- Benefits have been demonstrated for treatment at any every stage, including *pre-clinical (pre-swelling) stage*
- Complex Decongestive Therapy (CDT), the current lymphedema treatment standard, is multimodal and multi-phasic
- Compression is a mandatory element of lymphedema treatment
- Medicare does not cover treatment *per current medical standard*
- Insurers and Providers cover *some or all CDT modalities*
- Reviews and systematic studies indicate efficacy of ALL modalities for SOME patient subset, albeit with little high-level evidence
- Randomized studies and cohort studies demonstrate efficacy of lymphedema protocols *singly or in combination*
- Preliminary studies indicate potential cost savings of lymphedema therapy
- Goal of Medicare should be to provide the *treating physician* and *lymphedema therapist* a choice of covered modalities which can be appropriately combined for the patient at any stage of treatment.

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Lymphedema Treatment Protocols Based on Expert Consensus and Clinical Experience

➤ Primary Treatment Modalities

- ❖ Manual Lymph Drainage
- ❖ Compression Bandaging
- ❖ Compression Garments
- ❖ Remedial Exercises
- ❖ Skin Care

Complex Decongestive
Therapy (CDT)
[Földi 1998]

➤ Adjunctive Modalities

- ❖ Sequential Pneumatic Compression
- ❖ Cold Laser
- ❖ Pharmaceuticals

➤ Surgical

- ❖ Debulking
- ❖ Liposuction
- ❖ Microsurgical

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1. International Society of Lymphology Executive Committee: **The diagnosis and treatment of peripheral lymphedema** *Lymphology* 2009;42:51-60.
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3. Health Canada Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast cancer: **Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema** *CMAJ* Jan 23, 2001;164(2):191-9.
4. National Cancer Institute, U.S. National Institutes of Health: **Lymphedema (PDQ®), Health Professional Version** Version dated 06/30/2009
5. Italian College of Phlebology: **Guidelines for the diagnosis and therapy of the vein and lymphatic disorders- Evidence-based report by the Italian College of Phlebology, Revision 2004** *Internat Angiology*. Jun 2005;21(suppl.2 to issue 2)
6. National Lymphedema Network: **Position Paper on the Treatment of Lymphedema** October 2009 (Revision of original dated 08/10/2006).
7. Lymphedema Framework: **Best Practice for the Management of Lymphedema. International Consensus** London: MEP Ltd. 2006.
8. American Lymphedema Framework Project (in work)

Methods Used to Measure Lymphedema

Q1

- Circumferential (Limb only)
- Volumetric (Limb only)
 - ❖ Water Displacement [Brennan 1996]
 - ❖ Calculated circumferential measurements
 - ❖ Computed based on electro-optical inputs
- Tissue tonometry [Clodius 1976] ↑
Traditional
- Lymphoscintigraphy [Weissleder 1988, Szuba 2003]
- Bioelectrical impedance measurement [Mikes 1999, Cornish 2001]
- Dielectric skin fluid measurement [Lahtinen 2006]
- Ultrasonic skin thickness measurement [Shukla 1984, Warszawski 1998, Mellor 2004, Rönkä 2004]
- Magnetic resonance imaging of skin [Idy-Paretti 1998]
- Optical skin erythema measurement [Russell 1994]
- Skin visco-elasticity [Gorodetsky 1999, Marcenaro 2004]
- Dual-beam absorptiometry [Cluzan 1998]

Reviews

Mikes 1999
Gerber 1998
Casley-Smith 1994
Hoe 1992
Kissin 1986

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There is No Absolute Standard of Lymphedema Measurement but Relative Measurement is Essential to Treatment

Q1

Q8

- There is NO STANDARD measurement method or definition of lymphedema.
- Traditional methods of describing lymphedema of the limb are not applicable to describing or measuring lymphedema at other body sites (e.g. breast, upper torso, abdomen, genitalia) or of describing bi-lateral lymphedema.
- Traditional limb measuring methods are not adequate to detect pre-swelling changes in tissue that represent “pre-lymphedema” (so-called “stage-zero”) which may present attractive prevention targets.
- All of the previously listed methods have been or can be utilized to measure progression or regression of lymphedema for the purpose of determining the efficacy of the treatment modality, and enabling treatment changes.
- Some of the previously listed methods may be appropriate for measuring latent (stage-zero) lymphedema and some are able to measure lymphedema at any point on the body, not restricted to limbs. These methods require continuing development, validation and calibration.

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THERE IS NO “STANDARD” DEFINITION OR MEASURE

Any differential defines “swollen” [Lobb 1949]

“Significant” is $\Delta c > 0.5\text{cm}$ [Deland 1950]

Swelling is $\Delta c > 0.72\text{cm}$ [MacDonald 1955]

Lymphedema is $\Delta c \geq 2\text{cm}$ @ any of 3 points [Ozaslan 2004]

Presence of LE $\Delta c \geq 2\text{cm}$ [Armer 2004]

Lymph Edema “Present or Absent” [Schijven 2003]

Arm lymphedema present when $\Delta v \geq 200\text{mL}$ [Kwan 2002][Beaulac 2002], or when $\Delta v \geq 10\%$ [Kuehn 2000],[Tengrup 2000]

Sum of $\Delta c/c\%$ measured at 6 places $> 5\%$ defines lymphedema [Herd-Smith 2001]

LE present if $\Delta c > 2\text{cm}$ @ 2 points and if tissue consistency was typical of edema [Haid 2002]

Skin thickness $\Delta t > 2\text{mm}$ [Rönkä 2004]

Ratio of extracellular to intracellular fluid volumes [Cornish 2002]

Mechanisms & Effects of Compression Therapy in Lymphedema

Q5

Mechanism	Effect
∅ Increased interstitial pressure	1. Reduced capillary filtration ⁶⁻⁸ and production of lymph; limb volume decrease
∅ Shift of fluid into uncompressed areas	2. Proximal volume increase accommodated by normally working lymphatics in that region and assisted by manual lymphatic drainage ⁹
∅ Increased lymph reabsorption and stimulation of lymphatic contractions	3. Improvement of lymph kinetics as shown by lymphoscintigraphy ¹⁰ and intra lymphatic measurement of flow and pressure ^{11,12}
∅ Breakdown of fibrosclerotic tissue	4. Softening of tissue as shown by ultrasound ¹³ and durometer ¹⁴
∅ Improvement of venous pump in patients with venolymphatic dysfunction	5. Increased expelled blood volume; reduction of venous reflux and ambulatory venous hypertension ¹⁵

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Reviews and Systematic Studies of Lymphedema Treatment Protocols

Q5

There have been many reviews and systematic studies of the protocols of lymphedema treatment in the last decade.

Most have concluded that:

1. There is little high-level evidence;
2. The protocols of CDT (Manual Lymph Drainage, Compression with Non-Elastic Bandages and Garments and Exercise) and Intermittent Sequential Pumps have all been found to be effective in some combination;
3. Physician- and specially trained Therapist-directed Complex Decongestive Therapy is the Clinical Standard of lymphedema treatment throughout the world.

- Földi 1989
- Brennan 1998
- *Megans 1998
- *Erickson 2001
- *Harris 2001
- Ciccone 2002
- *Badger 2004
- *Kligman 2004
- *CHBRP 2005
- *Moseley 2006
- Stubblefield 2006
- Elokda 2007
- United HC MTAC 2007
- *Hayes 2008

* Systematic studies

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• Reviews and Systematic Studies

- **Badger C**, Preston N, Seers K, Mortimer P. Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD003141. Included studies marked ◊ on RCT list next page.
- **Brennan MJ** & Miller LT: "Overview of Treatment Options and Review of the Current Role and Use of Compression Garments, Intermittent Pumps, and Exercise in the Management of Lymphedema" *Cancer*, Dec 15, 1998;83(12 Supplement):2821-7. American Cancer Society Workshop on Breast Cancer Treatment-Related Lymphedema, New York, NY, February 20-22, 1997.
- **CHBRP**: California Health Benefits Review Program: "Analysis of Assembly Bill 213 Health Care Coverage for Lymphedema" Report to California State Legislature, Oakland, CA: CHBRP 05-03 2005. www.chbrp.org/documents/ab_213final.pdf Included studies marked † on RCT list next page.
- **Elokda AS**. Lymphatic system disorders. In: Cameron MH, Monroe LG, editors. *Physical Rehabilitation: Evidence-Based Examination, Evaluation, and Intervention*. St Louis, MO: Saunders Elsevier; 2007:718-32.
- **Földi E**, Földi M & Clodius L: "The Lymphedema Chaos: A lancet" *Annals Plastic Surg*. June 1989;22(6):505-15.
- **Harris SR**, Hugi MR, Olivotto IA & Levine M: "Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema" *CMAJ* Jan 23, 2001;164(2):191-9. Included studies marked ¥ on RCT list next page.
- **Hayes SC**: "Review of research evidence on secondary lymphedema: Incidence, prevention, risk factors and treatment" National Breast and Ovarian Cancer Centre (Australia) Surry Hills, NSW March 2008
- **Kligman L**, Wong RK, Johnston M, Laetsch NS. The treatment of lymphedema related to breast cancer: a systematic review and evidence summary. *Supportive Care in Cancer* 2004;12(6):421-31. DOI: 10.1007/s00520-004-0627-0. Included studies marked f on RCT list next page
- **Megens A** & Harris SR: "Physical therapist management of lymphedema following treatment for breast cancer: a critical review of its effectiveness" *Phys Ther*. Dec 1998;78(12):1302-11.
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- **United HC** Medical Technology Assessment Committee: Complex Decongestive Therapy for Lymphedema. Number 2007T0039E 11/1/2007

Randomized Studies Consider Different Combinations of CDT Modalities

Q5

	MLD	CB	CG	MLD+CB	Exercise	DCE	SLD	CDT	IPC
Ahmed 2006					0 NS				
Andersen 2000 †∅∫f	- NS		+ Sig	+ Sig					
Badger 2000 †∅		++Sig	+ Sig						
Bertelli 1991 √f			+ Sig						
Dini 1998 †∫f									+ Sig
Dubois 2004	√								√
Hornsby 1995 †∅f			√			√	√	+ Sig	
Johansson 1999 †∫		+ Sig		++Sig					
Johansson 1998 †∫f	+ Sig		+ Sig	+ Sig					+ Sig
McNeely 2004 †		+ Sig		++ Sig					
Mirolo 1995									
Moseley 2007	+ Sig								
Sitzia 2002	+ Sig						+ Sig		
Szuba 2002 †				- NS					+ Sig
Wilburn 2006							- NS		- Sig
Williams 2002 †	+ Sig						+ NS		
Zanolla 1984	+ Sig								+ Sig

“+” favorable, “-” not favorable, “Sig” statistically significant, “NS” not statistically significant, “√” considered

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Some RCTs on Efficacy of CDT Protocols

***Andersen** L, Højris I, Erlandsen M & Andersen J: “Treatment of breast-cancer-related lymphedema with or without manual lymphatic drainage. a randomized study”. *Acta Oncol* 2000;39(3): 399-405.

Badger CMA, Peacock JL, Mortimer PS: "A Randomized, Controlled, Parallel-Group Clinical Trial Comparing Multilayer Bandaging Followed by Hosiery versus Hosiery Alone in the Treatment of Patients with Lymphedema of the Limb", *Cancer* Jun 15, 2000; 88(12): 2832-7.

Box RC, Reul-Hirche HM, Bullock-Saxton JE, & Furnival CM: "Physiotherapy after breast cancer Surgery: Results of a randomised controlled study to minimise lymphoedema." *Breast Cancer Res Treat* Sep 2002;75(1):51-64.

***Johansson** K, Lie E, Ekdahl C & Lindfeldt J: “A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema” *Lymphology* Jun 1998;31(2):56-64.

***Johansson** et. al. 1999: Johansson K, Albertsson M, Ingvar C & Ekdahl C: "Effects of Compression Bandaging With or Without Manual Lymph Drainage Treatment in Patients with Postoperative Arm Lymphedema" *Lymphology*, 1999;32(3):103-10. Erratum in *Lymphology* 1999;32(4):172. Comment in *Lymphology* Jun 2000;33(2):69-70. Also NLN *LymphLink*, Jan-Mar 2000;12(1):1-4, 18.

***McNeely** ML, Magee DJ, Lees AW, Bagnall KM, Haykowsky M, Hanson J: The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial. *Breast Cancer Research and Treatment* 2004;86(2):95-106.

Mondry TE, Riffenburgh RH, Johnstone PA: “Prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer therapy” *Cancer J.* 2004;10(1):42-8; discussion 17-9.

***Sitzia** J, Sobrido L & Harlow W: “Manual lymphatic drainage compared with simple lymphatic drainage in the treatment of post-mastectomy lymphedema” *Physiotherapy* 2002;88(2):99-107.

Wilburn O, Wilburn P & Rockson SG: “A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema” *BMC Cancer.* Mar 29 2006;6(1):84.

***Williams** AF, Vadgama A, Franks PJ & Mortimer PS: "A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema. *Eur J Cancer Care.* (Engl)Dec 2002;11(4):254-61.

Zanolla R, Monzeglio C, Balzarini A & Martino G: “Evaluation of the Results of Three Different Methods of Postmastectomy Lymphedema Treatment” *J Surg Oncol.* 1984;26:210-3.

Abstracted Results from Recent Systematic Studies

Q8

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	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).

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CAVEAT

“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*]

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 [François 1989] 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.

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 which 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..... (continued on next page notes)

Efficacy of Lymphedema Protocols Trials in Progress

Q8

National Cancer Institute/ NIH Grants

1. Home-based Compression Therapy for Arm and Truncal Lymphedema in Breast Cancer
2. Early Detection and Intervention for Mild and Moderate Lymphedema in Patients Treated for Breast Cancer
3. Phase I/II Study of a Lymphedema Symptom Checklist in Patients With Head and Neck Cancer, NCT00840814
4. Liposuction for Arm Lymphedema Following Breast Cancer Surgery
5. A Study of Vascular Endothelial Growth Factor (VEGF) Inhibition in Patients With Unilateral Upper Extremity Lymphedema Following Treatment for Cancer
6. A Pilot Study of VEGF Inhibition in Patients With Lymphedema Following Breast Cancer Treatment
7. Randomized Study of Education With or Without Exercise and Counseling in Preventing Lymphedema in Women With Stage I-III Breast Cancer Who Are Undergoing Axillary Lymph Node Dissection

8. Lymphedema Prophylaxis in Breast Cancer Survivors Who Show Early Evidence of High-risk Status
9. Prospective Measurement of Post-Treatment Lymphedema
10. Aquatic Exercise Study for Breast Cancer Patients With Lymphedema

American Cancer Society Grants

- A. Familial Susceptibility for Lymphedema Secondary to Breast Cancer Therapy RSG-06-212-01-LR
- B. Natural History and Cost Analysis of Lymphedema Secondary to Breast Cancer RSG-06-209-01-LR
- C. Effects of Expressive Writing in Breast Cancer Survivors with Lymphedema MRS-07-012-01-CPPB
- D. Burden of Breast Cancer Related Lymphedema on Working American Families RSGTL-05-093-01-CPHPS
- E. Pre-Clinical Model of Breast Cancer Treatment-Related Lymphedema RSGTL-05-090-01-CCE

NCT00376597

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NCT00498771

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CAVEAT CONTINUED

As another example of how differences in individual patient 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 François 1989 [François 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 François 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.

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.] 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”

*Vasc Surg.*1998(32):455-62.]

Cohort Studies Support Efficacy of CDT

“Case series collectively describing a mean 65% volume reduction in over
10,000 patients attest its efficacy” [Cheville 2003]

Q6

Study	No.	Measure	Mean Decrease	CDT Modalities
Boris 1997	119	Δ Volume	-63 to -69%	MLD, CB, Exer., CG
Bunce 1994	25	Δ Volume	-50%	MLD, CB, CG, Exer.
Casley-Smith 1992	200	Δ Volume	-60 to -103%	MLD, CB, CG, Exer.
Ferrandez 1992	102	Δ Circumference	-40 to -60%	MLD, CB, IPC
Földi 1989	399	Δ Volume	-54%	MLB, CB, CG, Exer.
Hamner 2007	135	Δ Volume	-13%	MLD, CG, Exer.
Hinrichs 2004	14	Δ Volume	-60%	MLD, CB, CG, Exer.
Karadibak 2008	62	Δ Volume	-26%	MLD, CG, Exer.
Ko 1998	299	Δ Volume	-59 to -68%	MLD, CB, CG, Exer.
Szuba 2000	54	Δ Volume	-38 to -41%	MLD, CB, CG, Exer.
Vignes 2006	537	Δ Volume	-30%	MLD, CB, CG, Exer.
Wozniewski 2001	208	Δ Volume	-19 to -43%	MLD, CG, Exer. (+IPC)
Yamamoto 2007	82	Δ Volume	-59 to -73%	2-Phase CDT

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Boris M, Weindorf S & Lasinski B: “Persistence of Lymphedema Reduction After Complex Lymphedema Therapy” *Oncology* (Huntingt) 1997;11(1):99-109, discussion 110, 113-4.

Casley-Smith JR, Casley-Smith JR.: "Modern Treatment of Lymphoedema, I: Complex Physical Therapy—The First 200 Australian Limbs", *Australasian J Dermatol*, 1992;33(2):61-8.

Ferrandez JC & Serin D: “Post-therapeutic upper limb lymphedemas: Analysis of the results of the physical treatment according to the clinical characteristics” *Eur J Lymphol Related Prob* 1992;3(11):79-84.

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Hamner JB & Fleming MD: “Lymphedema therapy reduces the volume of edema and pain in patients with breast cancer” *Annals of Surgical Oncol*, 2007;14(6):1904-8.

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Szuba A, Cooke JP, Yousuf S & Rockson SG: "Decongestive lymphatic therapy for patients with cancer-related or primary lymphedema” *Am J Med*. Sep 2000;109(4):296-300.

Thomas RC, Hawkins K, Kirkpatrick SH, Mondry TE, Gebram-Mendola S & Johnstone PA: “Reduction of lymphedema using complete decongestive therapy: roles of prior radiation therapy and extent of axillary dissection” *J Soc Integr Oncol*. Summer 2007;5(3):87-91.

Vignes S, Porcher R, Arrault M & Dupuy A: “Long-Term Management of Breast Cancer-Related Lymphedema after Intensive Decongestive Physiotherapy” *Breast Cancer Res Treat*. 2007;101(3):285-90.

Wozniewski M, Jasinski R, Pilch U & Dabrowska G: “Complex physical therapy for lymphoedema of the limbs” *Physiotherapy* 2001;87(5):252-6.

Yamamoto R & Yamamoto T: “Effectiveness of the treatment phase of two-phase complex decongestive physiotherapy for the treatment of extremity lymphedema” *Inter J Clin Oncol*. Dec 2007;12(6):463-8.

Lymphedema \longleftrightarrow Cellulitis

Q4

- Lymphedema is a chronic medical condition known to increase the risk of infection [Brewer 2000, Cox 2006, Thiadens 1992, Kasseroller 1998, Swenson 2002, Moffatt 2003]
- There is evidence that there is suppression of immune competence in a lymphedematous limb [Mallon 1997]
- Infection is noted in 11-16% of breast cancer survivors at 1 year [Swenson 2002]
- The “vicious cycle” [Stoberl 1987, de Godoy 2000]
 - ❖ Lymphedema is a risk factor for cellulitis [Damstra 2008]
 - ❖ Cellulitis is a causative factor for lymphedema
 - ❖ Cycle leads to ever-worsening recurrent infections in untreated lymphedema patients
 - ❖ Cellulitis can recur even during prophylactic treatment [Vignes 2006]
- Increased cases of lymphedema of the breast are being noted, accompanied by “delayed breast cellulitis” [Hughes 1997, Mertz 1998]
- Treatment of lymphedema has been shown to decrease the frequency of infections [Földi 1996, Boris 1997, Ko 1998]
- The costs of treatment of lymphedema-related cellulitis are substantial and largely avoidable [Weiss 2006]

The chicken or the egg?

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Brewer VH, Rohrbach BW & Baddour LM: “Risk factor analysis for breast cellulitis complicating breast conservation therapy” *Clin Infect Dis*. 2000;31:654-9.

Cox NH: “Oedema as a risk factor for multiple episodes of cellulitis/erysipelas of the lower leg: a series with community follow-up” *Brit J Derm*. 2006;155:947-50.

Damstra RJ, van Steensel MA, Boomsma JH, Nelemans P, Veraart JC: “Erysipelas as a sign of subclinical primary lymphoedema: a prospective quantitative scintigraphic study of 40 patients with unilateral erysipelas of the leg” *Br J Dermatol*. 2008;158(6):1210–5.

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Földi MD, E.: "Prevention of Dermatolymphangioadenitis by Combined Physiotherapy of the Swollen Arm after Treatment of Breast Cancer", *Lymphology*, 1996;29:91-94.

Hughes LL, TM Styblo and WW Thoms, "Cellulitis of the breast as a complication of breast conserving surgery and irradiation" *Am J Clin Oncol*. 1997;20(4):338–41.

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Stoberl C & Partsch H: “Erysipel und Lymphodem: Ei oder henne?” [Erysipelas and lymphedema: egg or chicken?] in German *Z Hautkr*. 1987;62:56–62.

Swenson KK, Nissen MJ, Ceronsky C, Swenson L, Lee MW & Tuttle TM: "Comparison of side effects between sentinel lymph node and axillary lymph node dissection for breast cancer" *Ann Surg Oncol*. 2002;9(8):745-53.

Vignes S & Dupuy A: “Recurrence of lymphoedema-associated cellulitis (erysipelas) under prophylactic antibiotherapy: a retrospective cohort study” *J Eur Acad Dermatol Venereol*. 2006 Aug;20(7):818-22.

Weiss R. “Development of an estimate of the potential healthcare savings through proper treatment of lymphedema” 2006 unpublished

Economic Impact of Lymphedema Treatment Q4

- Cost for healthcare of cancer survivor is additional burden [Shih 2009]
- Lymphedema is a chronic medical condition known to increase the risk of infection [Stoberl 1987, Brewer 2000, Cox 2006, Thiadens 1992, Kasseroller 1998, Swenson 2002, Moffatt 2003]
- Treatment of lymphedema involves initial and continuing costs
 - ❖ Initial decongestion: 2-4 weeks MLD, set of bandages, initial garment
 - ❖ Continuing self-treatment: bandages, daytime garments, nighttime devices
 - ❖ Average cost/year/contract of lymphedema treatment in VA is \$1.15-\$2.64
- Efficacy of treatment is a strong function of patient adherence [Casley-Smith 1998, Vignes 2006]
- Management of lymphedema reduces risk of lymphedema-related infection [Földi 1996, Boris 1997, Ko 1998]
- Pilot studies show that cost of treating lymphedema-related infections exceeds cost of treating lymphedema [Casley-Smith 1998, Shih 2009, Weiss 2009]

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Boris, MD, M., Weindorf, MD, S., Lasinski, M.A., P.T., B.: “Persistence of Lymphedema Reduction After Complex Lymphedema Therapy” *Oncology*, 1997;11(1):99-109, discussion pp. 110, 113-114.

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Weiss R. “Development of an estimate of the potential healthcare savings through proper treatment of lymphedema” 2006 unpublished

Current Medicare Coverage of the Protocols of Complex Decongestive Therapy

Q7

Lymphedema Primary Protocol	Current Medicare Coverage
Manual Lymph Drainage	Statutory annual limit; No therapist training or competency requirement.
Compression Bandaging	Bandaging Systems denied. Therapist's bandaging services not covered.
Compression Garments	Day and night garments denied even though they meet CMS coverage policy requirements as prosthetic devices.
Exercise	Instruction is covered.

Adjunctive Protocol	Current Medicare Coverage
Sequential Pneumatic Compression	Covered. Coverage not coordinated with primary treatment modalities.

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Which Problems Can Be Addressed by CMS and Which by Congress?

A separate NCD or LCD for the Treatment of Lymphedema would be appropriate instead of the current use of uncoordinated Outpatient PT and OT LCD and the Lymphedema Pump NCD; Billing codes and guidelines for bandaging, measurement and fitting, patient education can be added to an appropriate LCD. Separate LMRPs have existed in the past (see next chart) and have been proposed by this author and by NLN ;

Lymphedema Sequential Pneumatic Pump NCD needs updating based on new lymphatic knowledge, new pump designs specifically developed for lymphedema and prevalence of combined lympho-venous swelling with and without ulcers;

Coverage of compression bandages, garments and devices can be done by CMS on the basis that these items meet the current definitions of "prosthetic devices" and are therefore covered by Medicare. New LCDs or NCD will be needed which will differentiate lymphedema treatment items from similarly appearing items which have other medical functions and fall into different benefit categories (e.g, surgical dressings, splints and braces, DME, burn care).

Current HCPCS Codes are inadequate for administration of lymphedema treatment materials. HCPCS Code Change Request #07-109 was a proposal to change the HCPCS codes to cover compression bandages, garments, devices and supplies used in the treatment of lymphedema. Insurance companies who cover lymphedema bandages and compression sleeves use non-covered HCPCS S-codes to administer these benefits.

Training and competency issues for PTs and OTs can be addressed by CMS, but issues regarding the provision of lymphedema therapy services by other medical personnel may require Congressional action (i.e. a change of C.F.R. 42 §484.4).

Deletion of annual therapy limits for rehabilitation will take Congressional action, and there are bills which have been introduced with this intent. But limits on the protocols of CDT should be governed by medical necessity, and not Congressional limits on rehabilitation.

Retired LMRPs “CDP for Lymphedema”

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State	LMRP No.	Medicare Contractor	Year
AR, LA	(no number)	BCBS of Arkansas	1999,2000
CA-S	99-4.9	NHIC	2000
CO,NM, TX	Y-9A-R1	Trailblazer Health Enterprises	2002
DC,DE,MD	Y-9B	Trailblazer	2001
FL	97110	First Coast Service Options	2002
MT	00-05	BCBS of Montana	2000
TN	9906	CT General Life (CIGNA)	2002
AK,AS,AZ, HI,IA,ND, NV,OR,SD	99-6.1 99-06 99.13	Noridian Mutual Life Insurance Co.	2000,2002

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These Local Medical Review Policies usually covered the physical therapy and occupational therapy services of manual lymph drainage (CPT 97140), exercise (CPT 97110) and instructions for home use of pneumatic pumps CPT 97016). These services were usually broken out from the Outpatient Physical Therapy or Outpatient Occupational Therapy LMRPs and directed toward treatment of diagnosed lymphedema (ICD-9-CM 457.0, 457.1, or 757.0).

Left moot in all these policies was the billing for bandaging, garment measurement and fitting, patient education in self treatment in a home setting and any coverage criteria relating lymphedema pump coverage to the results of MLD and bandaging in the intensive phase of lymphedema treatment.

The bandages and garments themselves remained non-covered.

Insurance and Provider Medical Policies Cover Some or All CDT Modalities

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Insurer/Provider	Primary Lymphedema Treatment Modalities				Adj.
	MLD	Bandages	Garments	Devices	Pumps
Aetna	0325	0069 ⁽¹⁾	0069 ⁽¹⁾	0069	0500
Anthem BCBS	REHAB-04,-05				DME-06
BBCS FL	09-E0000-31 ⁽²⁾	-31	-31	-31	-31
CareFirst VA	8.01.014 ⁽³⁾	8.01.014	8.01.014	8.01.014	8.01.014
CIGNA	0096 ⁽⁴⁾				0354
Excellus BCBS Univera HC	8.01.12		1.01.14	1.01.14	1.01.17
Kaiser Permanente	EoC ⁽⁵⁾	EoC	EoC	EoC	EoC
Milliman			ACG:A-0336		
United HealthCare	(6)	(6)	(6)	(6)	MMG

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NOTES

- (1) Unless contract excludes coverage of “supplies”. Garments for trunk and neck considered experimental because of lack of evidence. Policy # 0482 covers lower limb stockings for lymphedema.
- (2) Covers Diagnosis Codes 457.0, 457.1, 757.0 and 997.99. Utilizes HCPCS S-Code Group for bandages and sleeves, A-Code group for stockings and E-Code group for pumps.
- (3) No Medical Policy but coverage is determined by individual policy. Billing Guideline #027 covers lymphedema devices, intermittent pumps, sleeves, gloves, gauntlets and bandages (S-Codes for bandages and upper limb garments, L-code for lower limb).
- (4) Although CIGNA Policy #0096 covers Complex Lymphedema Therapy for treatment of lymphedema ICD-9-CM codes 457.0, 457.1 and 757.0, there is no billing information or details on coverage of garments, bandages and devices.
- (5) Kaiser Permanente (California) covers MLD, compression bandages and garments for home use, with replacements every 6 months for treatment of lymphedema. Their specific DME formulary is held to be “proprietary” even to patients whose coverage is bound by them. Like Medicare, there is no training requirement for physical therapists who provide lymphedema services, and there are very few therapists trained to national standards.
- (6) UnitedHealthcare/SecureHorizons retired their Complex Decongestive Physiotherapy for Lymphedema Medical Management Guideline effective 02/19/08. Their Medical Technology Assessment No. 2007T0039E dated 11/1/2007 concluded that “CDT is proven for treatment of lymphedema”, “CDT used following a lymphedema risk-inducing procedure is proven before symptoms become evident”, and “intermittent pneumatic compression is proven for the treatment of lymphedema.”

Provider Guidelines From NY to CA Recognize the Function of Compression Garments in Lymphedema Treatment

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- New York State Medicare Contractor Policy on Surgical Stockings
 - ❖ Eligible for coverage as a **prosthetic/orthotic** for Lymphedema
- California Kaiser Permanente Health Plan
 - ❖ Covers compression burn garments and lymphedema wraps and garments as “**external prosthetics and orthotics**”.
- Widely-used Milliman insurance guidelines recognize compression garments as covered for the treatment of lymphedema, coded as **prosthetic services**.

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• According to the **New York State Medicare Contractor Policy on Surgical Stockings**, “**Surgical Stockings** or graduated compression stockings are custom-made or custom-fitted support for the lower extremities. Surgical stockings (e.g., Jobst, Sigvaris, and CircAid) are *eligible for coverage as a prosthetic/orthotic* for the following indications: Venous insufficiency; Varicose veins; Phlebitis/Thrombophlebitis; DVT prophylaxis during pregnancy and postpartum; Orthostatic hypotension; Ulceration due to chronic venous insufficiency; *Lymphedema*” [Excellus Blue Cross Blue Shield]

• Since July 1, 2000 Kaiser provides the following benefits “**for the treatment of lymphedema when prescribed by a Plan physician as part of a lymphedema treatment plan**: adjustable manual compression garments [e.g. Reid, CircAid, MedAssist, etc] , **elastic compression garments**, low-elastic extremity wraps, and pneumatic lymphedema pumps and appliances. Some coverage, like the pneumatic lymphedema pumps and appliances, is subject to the member having a Supplemental Durable Medical Equipment benefit in addition to their basic health care coverage. All members, however, are entitled to receive as a covered benefit the particular types of compression garments and extremity wraps that their clinical situation requires. Up to two of each required item will be initially provided. Replacement items will be issued when the existing items are no longer functional, and replacements will consist of up to two items of each type required. The need for replacements must be determined and documented by a Plan physician in order to be a covered benefit.” The bandages and sleeves are provided as “**Prosthetic and Orthotic Devices**” and are listed in the Evidence of Coverage under "external devices". Coverage is provided for "Compression burn garments and lymphedema wraps and garments.”

• **Insurance Guideline on Compression Stocking Coverage** Milliman Care Guideline ACG:A-0336 5/12/06: “**Compression stockings** are indicated for all patients with lymphedema after **axillary dissection** for tumor staging [C](11)”

“[C] Start early in treatment and replace compression stockings every 4 to 6 months or sooner if they become loose...”

“Codes – CPT® or HCPCS: L8100 through L8239 (graduated **compression stockings**) ICD-9 Diagnosis: 457.0, **457.1**, 757.0 (lymphedema all causes, **upper and lower limbs, congenital or secondary**)”

An Advocate's Proposal. Patient-Oriented Goals for Medicare Treatment of Lymphedema

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- Provide coverage for every modality for which there is sufficient evidence of efficacy either separately or in combination with another modality for some lymphedema patient subset;
- Allow the treating physician and treating therapist to select from a “menu” of protocols to develop a plan of treatment for the patient reflecting the patient's instant medical needs;
- Monitor progress using physician/therapist-selected objective or subjective measure, and modify treatment plan when necessary to achieve target objectives.
- Assure that every therapist who provides lymphedema treatment services is “adequately trained and has demonstrated competence”.

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Final Comments

- It is within our power today to place in the hands of our medical practitioners the tools with which they can treat and manage lymphedema.
- Fifty years of clinical experience in Europe and Australia support the efficacy of the multi-modal, multi-phasic protocol comprising manual lymph drainage, compression bandaging, compression garments, exercise, skin care, and adjunctive sequential pneumatic compression.
- Consensus guidelines call out these protocols and Providers and Insurers already cover some or all of them. Three million Medicare Beneficiaries are entitled to them.
- The prompt diagnosis and treatment of lymphedema has been shown to reduce the rate of lymphedema-related cellulitis, and can potentially save Medicare hundreds of millions of dollars each year.

**Lymphedema Treatment is Good Business
As well as Good Medicine**

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