U.S. MEDICAL COMPRESSION CONSENSUS DOCUMENT

I. INTRODUCTION: The following document is the result of a collaborative effort undertaken in 2018 by lymphedema advocates, industry members, patients, lymphedema therapists, oncology specialists and other health care providers. Its purpose is to serve as an overview for lymphedema standard-of-care treatment in the United States, as well as summarize industry specifications for medically prescribed compression garments and supplies.

II. ABOUT LYMPHEDEMA: Lymphedema is a chronic and progressive condition caused by regional or systemic failure of the Lymphatic System. It manifests as swelling of the affected body part. As the disease progresses, affected areas may develop hardening (fibrosis), fatty tissue deposition, massive enlargement, warty growths, and frequent cellulitis[1].

III. TYPES OF LYMPHEDEMA: Lymphedema can affect any part of the body. Most commonly it affects one or more limbs but may also affect other areas such as the head, neck, trunk, or genitalia. Lymphedema can be classified as either primary or secondary depending on the etiology. Primary lymphedema results from congenital malformations of the lymphatic system. Secondary is due to damage to the lymphatic vessels and/or nodes. In patients with chronic lymphedema, significant amounts of subcutaneous adipose tissue may be deposited in the affected body segment leading to hardening and heaviness as well as edema[2].

IV. EFFECTS OF LYMPHEDEMA: Lymphedema can result in significant physical, social, fiscal, and psychological morbidity. Pain is common as is a predisposition to acute cellulitis which may give rise to frequent hospitalizations. Disability, isolation, and depression can result. Lymphedema is chronic and not currently curable; however, its symptoms and progression may be mitigated by appropriate management. If poorly treated or not treated, it can become more severe and difficult to manage.[3-8] Proper treatment has been shown to reduce the incidence of hospitalization for complications, as well as reduce the number of physician and therapy visits[9-10].

V. RISK FACTORS FOR LYMPHEDEMA: Risk factors for lymphedema include but are not limited to: lymphatic vessel and lymph node excision, radiotherapy, burns, large wounds, metastasis, chronic venous insufficiency, post-thrombotic syndrome, cellulitis, lymphadenitis, lymphatic overload, genetic predisposition, obesity, orthopedic surgery, phlebitis, advanced cancer, recurrent soft tissue infections, and chemotherapy[1].

VI. EPIDEMIOLOGY OF LYMPHEDEMA: It is estimated that one in 6,000 individuals will develop primary lymphedema [11-12]. In developed countries, the most common cause of lymphedema is secondary and resultant from cancer treatment. The overall cancer-related lymphedema incidence rate is 15.5% [13], with breast cancer-related lymphedema having the highest rate of occurrence at 42% [14]. Other causes of lymphedema include but are not limited to: trauma, poor venous function, obesity, cardiac disease, or filariasis[12,15].

VII. STAGING OF LYMPHEDEMA: The staging of lymphedema according to the International Society of Lymphology (ISL) is as follows.[1]

Stage 0: is a subclinical or latent condition where swelling is not evident despite impaired lymphatic transport. Most patients are asymptomatic, but some report a feeling of heaviness in the limb. Stage 0 may exist for months or years before the onset of overt lymphedema occurs (i.e., Stage I, II, or III below).

Stage I: is characterized by the accumulation of fluid relatively high in protein content that subsides with limb elevation, usually within 24 hours. The appearance is that of soft edema that may pit, with no evidence of dermal fibrosis. Stage I corresponds to a mild grade of lymphedema.

Stage II: does not resolve with limb elevation alone. This reflects the evolution of dermal fibrosis. As the fibrosis progresses, the limb may no longer pit upon examination. This is sometimes called spontaneously irreversible lymphedema. Stage II corresponds roughly to a moderate grade of lymphedema.

Stage III: is characterized by lymphostatic elephantiasis. On exam, pitting can be absent, and there will be trophic skin changes such as fat deposits, acanthosis, and warty overgrowths. Stage III corresponds to a severe grade of lymphedema.

VIII. SEVERITY OF LYMPHEDEMA: Apart from staging, the severity of lymphedema can be clinically assessed as mild, moderate or severe when considering the following set of characteristics.[1]

- measurement of excess limb volume (in unilateral lymphedema)
- tissue swelling (mild, moderate, severe, pitting/non-pitting etc.)
- skin condition (thickened, warty, bumpy, ulcerated)
- psychosocial morbidity
- impairment of limb function
- limb shape change/disfigurement
- subcutaneous tissue changes (fatty/rubbery, hardening)
- frequency of cellulitis/erysipelas
- internal organ complications (chylous ascites, pleural fluid)

IX. BEST PRACTICE FOR THE MANAGEMENT OF LYMPHEDEMA: The best practice for the management of lymphedema is a multidisciplinary approach known as Complete Decongestive Therapy (CDT)[1]. CDT includes:

1) manual lymphatic drainage (MLD)
2) skin care to optimize skin health and reduce infection risk
3) the use of compression bandages, garments, and supplies

4) exercises that enhance lymphatic flow
5) education regarding risk reduction practices

Typically, patients undergo an intensive phase of initial decongestion followed by a life-long maintenance phase. In both phases, all elements of CDT are utilized, though the frequency, intensity, and/or materials used will vary.

X. COMPRESSION BANDAGES AND GARMENTS FOR LYMPHEDEMA: Medical compression bandages and garments are a critical element in the treatment of patients with lymphedema and may be used from the point of diagnosis through life-long self-care. These bandages and garments must be prescribed and should be fitted by appropriately-trained professionals. Compression garments may be used for at-risk patients who do not appear to have visible signs of lymphedema (Stage 0) but are imperative for patients with more advanced lymphedema (Stages 1-3). Each patient's clinical presentation is unique so that therapists and providers must tailor decisions on the types of material utilized (short-stretch, circular knit, flat knit or inelastic/low elastic material). Compression bandages and garments are categorized according to the method of manufacture.[16]

The exact management program will depend on the site, stage, severity and complexity of lymphedema, the existence of any contraindications to components of therapy, the extent of access to treatment supplies and specialized care, as well as the patient's psychosocial circumstances[17]. There are two categories of compression that are outlined in subsections A and B to follow.

A. Elastic Compression:

Circular knit – the material is continuously knitted on a cylinder with a fixed number of needles, has graduated compression, and has no seam. Commonly, circular knit garments are ready to wear. These garments have a high 'resting pressure' (pressure when inactive) so are designed for use when the patient is active, typically during the daytime, and are not recommended for use while sleeping. Circular knit garments are the most elastic of the forms of compression, and, when a proper fit is possible, can be used to treat early stage lymphedema.

Flat knit – The material is more firm and dense than circular knit and is generally considered more containing. The garments are not knitted on a cylinder but knitted as a flat piece that adds needles as the garments get larger. This provides a more homogenous, higher stiffness in the knit and the piece is then folded over and joined by a seam. This process allows for custom shapes and sizes and will not cause a tourniquet effect in individuals with irregularly shaped limbs or folds. It also allows for foam padding to be added to inside pockets for a more targeted pressure. The final product contains edema better than circular knit garments. Flat knit garments are semi-elastic and offer a preferable 'working pressure' (with activity) rather than high pressure at rest.

B. Inelastic / Low-Elastic Compression:

Multi-layer Bandaging Systems: Bandage systems consist of a combination of specialized "short-stretch" low-elastic bandages, liners and foam padding, as well as foam inserts and medical tape. Bandaging is used in the initial intensive decongestive phase of CDT. Short-stretch bandages have a low resting pressure which prevents a tourniquet effect. A set of bandages can

last three to six months and can be washed. Typically, patients are advised to have two sets of bandages for each affected body part so one set can be worn while the other is washed. When initiating bandaging, therapists will first bandage patients in the office/clinic. Later, if possible, patients are taught to self-bandage. During initial phase of reduction of the swollen area, patients may wear the bandages 23 hours a day and remove them only to bathe.[17] During the self-management phase, patients may bandage at night (while wearing a garment in the day).

Compression wraps: Compression wraps are a short-stretch laminate material cut and sewn to fit different shapes that produce high compression while walking and low resting pressure when not active. They wrap around the limb and are closed with a "hook & loop" system that allows the patient to adjust them throughout the day. Patients who have difficulty in donning a traditional compression garment may find the hook & loop system easier to manipulate. There are also wraps available that can substitute for bandaging in the initial decongestive phase and are appropriate for some patients who are unable to self-bandage. Inelastic / low-elastic products are ideal for difficult to fit shapes and sizes as well as maximum containment requirements.

Padded / Foam Garments: Inelastic material used in non-elastic and low-elastic compression garments produces a low resting pressure and a high working pressure (pressure with movement). These garments provide resistance to peak pressures generated in the tissues during muscle contractions. These are denser fabric products and can thus contain more severe lymphedema while providing comfortable support. They allow for bridging of compression across skin folds and can adapt to challenging limb contours. In some cases, these garments can be worn overnight.[16]

Class of Gradient Compression Garments: Compression pressure is measured in millimeters of mercury (mmHg). There are specific ranges of compression pressure. The listed compression ranges below are the ranges used in the United States and are measured at the ankle (leg garments) or wrist (arm garments). All products sold in the US should list the compression ranges in mmHg.[16]

Circular knit:

- 20-30 mmHg, low medical compression
- 30-40 mmHg, medium medical compression
- 40-50 mmHg, high medical compression

Flat knit:

- 15-21 mmHg - low medical compression (upper extremity)
- 18-21 mmHg – low medical compression (lower extremity)
- 23-32 mmHg – medium medical compression
- 34-46 mmHg – high medical compression
- 49+ mmHg – very high medical compression

Wraps and Padded products:

- 20-50 mmHg – variable compression due to patient adjustment

XI. FITTING OF MEDICAL COMPRESSION GARMENTS: Compression garments should be fitted by a trained medical professional [17]. Garment manufacturers offer certification courses for fitters and trained medical professional to educate them on relevant patient conditions, proper measuring for garments, selection of materials, and style for the indication, as well as proper ordering procedures.

Once decongestion has been achieved and the affected limb has reached a stable reduction and consistent size, patients are then measured for a compression garment based on circumferential and longitudinal findings, and it is determined whether a standard fit or custom fit garment is necessary. Many factors are taken into consideration when prescribing a compression garment. This is a highly specialized process requiring up to 50 individual measurements to ensure the garment fits with precision, subjecting the patient to a lengthy fitting session in order to achieve a proper fit. In all cases, the garments are clinically designed to help support the decongestion of fluid during active and resting periods.[17]

XII. ASSESSMENT OF FIT: A trained practitioner should check that a newly prescribed garment is as ordered, fits properly, and fully covers the area requiring treatment. Initial fitting should include a demonstration of how to put on and remove the garment, and observation of the patient's application and removal technique. Clear verbal and written instructions should be given, including how to care for the garment.[17]

XIII. REPLACEMENT: The typical lifespan of compression bandages, garments, and supplies is six months, but some patients may require more frequent replacement due to a change in size or condition.[17] Patients must have two compression garments for each affected body part at all times, so that one is being worn while the other is being laundered. Some Inelastic/Low Elastic products may have a longer lifespan and offer a one-year warranty due to product composition and expected patient usage time.

XIV. SUMMARY: Lymphedema is a chronic and progressive swelling disorder, which has a significant impact on the physical, social, financial, emotional and well-being of affected patients. The effective use of compression is one of the cornerstones of Complete Decongestive Therapy and is integral to the successful treatment and management of lymphedema. Compression is used both for the initial phase of limb decongestion, as well as for maintenance of the affected body part in its reduced state. It is the component of therapy that has the greatest impact on minimizing hospitalization, reducing exposure to other medical complications, and maintaining active daily living skills.[1]

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1. International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology. Lymphology 2016, 49(4): 170-84.

2. Browse N, Burnand K, Mortimer P. Diseases of the Lymphatics, London: Arnold, 2003.

3. Tobin MB, Lacey HJ, Meyer L, Mortimer PS. The psychological morbidity of breast cancer-related arm swelling. Cancer 1993; 72(11): 3248-52.

4. De Godoy JMP, Braile DM, de Fatima Godoy M, Longo O Jr. Quality of life and peripheral lymphedema. Lymphology 2002; 35(2): 44- 50.

5. Williams AF, Moffatt CJ, Franks PJ. A phenomenological study of the lived experiences of people with lymphoedema. Int J Palliat Nurs 2004; 10(6): 279-86.

6. McWayne J, Heiney SP. Psychologic and social sequelae of secondary lymphedema: a review. Cancer 2005; 104(3): 457-66.

7. Carroll D, Rose K. Treatment leads to significant improvement. Effect of conservative treatment on pain in lymphoedema. Prof Nurse 1992; 8(1): 32-36.

8. Mortimer PS. Managing lymphedema. Clin Exp Dermatol 1995; 20(2): 98-106.

9. Arsenault, K PT, MHS, CLT-LANA;1; Rielly, L PT, PhD; Wise, H PhD. Effects of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema Rehabilitation Oncology: 2011 - Volume 29 - Issue 3 - p 14–20

10. Weiss, R. Cost of a lymphedema treatment mandate-10 years of experience in the Commonwealth of Virginia. Health Econ Rev (2016) 6: 42.

11. Dale RF. The inheritance of primary lymphoedema. J Med Genet 1985; 22(4): 274-78.

12. Moffatt CJ, Franks PJ, Doherty D, et al. Lymphoedema: an underestimated health problem. QJM 2003; 96: 731-38.

13. Cormier JN(1), Askew RL, Mungovan KS, Xing Y, Ross MI, Armer JM. Lymphedema beyond breast cancer: a systematic review and meta-analysis of cancer-related secondary lymphedema. Cancer. 2010 Nov 15;116(22):5138-49. doi: 10.1002/cncr.25458.

14. Norman SA1, Localio AR, Potashnik SL, Simoes Torpey HA, Kallan MJ, Weber AL, Miller LT, Demichele A, Solin LJ. Lymphedema in breast cancer survivors: incidence, degree, time course, treatment, and symptoms. J Clin Oncol. 2009 Jan 20;27(3):390-7. doi: 10.1200/JCO.2008.17.9291. Epub 2008 Dec 8.

15. Hardy D, Taylor J. An audit of non-cancer-related lymphoedema in a hospice setting. Int J Palliat Nurs1999; 5: 18, 20-27

16. Clark, M, Krimmel G. Lymphoedema and the construction and classification of compression hosiery. In: Lymphoedema Framework. Template for Practice compression hosiery in lymphoedema. London: MEP LTD, 2006: 2-4.

17. Doherty, DC, Morgan, PA, Moffatt, CJ, Role of hosiery in lower limb lymphedema in: Lymphoedema Framework. Template for Practice compression hosiery in lymphoedema. London: MEP LTD, 2006: 10-21.