

Lymphedema – Diagnosis and Treatment



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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NCD	Pneumatic Compression Devices	280.6		
LCA	Lymphedema Decongestive Treatment	A55710	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Pneumatic Compression Devices	L33829 A52488	DME A - Noridian Healthcare Solutions, LLC (DME MAC) DME B - CGS Administrators, LLC (DME MAC) DME C - CGS Administrators, LLC (DME MAC) DME D - Noridian Healthcare Solutions, LLC (DME MAC)	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT IL, IN, KY, MI, MN, OH, WI AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands

Description

Lymphedema is swelling caused by an abnormal collection of fluid beneath the skin resulting from lymph vessel impairment or lymph node removal. It is generally categorized as primary or secondary; primary is caused by problems with the development of lymph vessels, while secondary is related to something that has damaged the lymph nodes or vessels (eg, surgery, radiation, cancer, infection). Lymphedema differs from edema which is swelling caused by excess fluid that becomes trapped in the body’s tissues as a result of medication, pregnancy or underlying disease (eg, heart failure, venous insufficiency, kidney disease, cirrhosis of the liver).

Diagnosis

Assessment and monitoring of lymphedema can be accomplished by a number of methods. One of the most common is circumferential measurement of limb volume. The volume is calculated with measurements obtained with a tape measure at various locations on the limb; it may be compared to

measurements of the opposite limb. Another method is the water displacement measurement. The limb is submerged into a container of water and the amount that is displaced is measured.

Bioimpedance spectroscopy (BIS), also referred to as bioelectrical impedance analysis, has been proposed as an alternative method to diagnose/monitor lymphedema. This device measures the impedance (resistance) of electrical current through extracellular fluid via electrodes that have been attached to the wrist when testing the arm or the ankle when testing the leg. A mild electrical current is passed through the electrode and a measurement of the resistance of the current flow through the fluid is obtained. An example of this device is the **L-Dex**.

Treatment

Treatment of lymphedema may be undertaken by a number of methods, either alone or in combination, including, but not limited to, the use of lymphedema garments, manual lymph drainage massage, lymphedema pumps and/or surgery.

Lymphedema garments (also referred to as compression garments), which include sleeves, gloves and stockings, are special bandages that can be worn on the arms, legs, hands or feet to help reduce swelling that is caused by the removal or injury of nearby lymphatic vessels or nodes. The garments provide specific amounts of pressure to keep the fluid from accumulating in the limb.

Manual lymph drainage massage (also known as **complex decongestive physiotherapy** or **complete decongestive physiotherapy**) may be performed by a physical therapist or occupational therapist certified in manual lymph drainage. This technique combines massage, bandaging, exercise and skin care in an attempt to reduce the accumulation of fluid.

Lymphedema pumps (pneumatic compression pumps) are devices that use compressed air to apply pressure to a limb in order to move excess lymph fluid into the rest of the body. A unicompartamental (nonsegmented) device consists of a rubberized sleeve or boot (the sleeve or boot may also be referred to as an appliance) with a single inflatable chamber that exerts uniform pressure along the affected limb. A multicompartamental (segmented) device has multiple chambers in the rubberized sleeve or boot that inflate and deflate in a sequential fashion. These devices may be controlled either with or without manual control of the amount of pressure used in the compartments (manual control is also known as gradient pressure).

An advanced **multicompartamental programmable pneumatic compression device** (formerly referred to as a two-stage multichamber programmable pneumatic compression device) operates similar to the principles of manual lymph drainage (treat the proximal areas first, which is theorized to prepare the distal areas for drainage). Examples of this type of pump include, but may not be limited to, the **AIROS 6**, **AIROS 8**, **Flexitouch (Flexitouch Plus)** or **Lympha Press Optimal (Lympha Press Optimal Plus)**.

A variation of the multicompartamental pneumatic compression pump is the **CircuFlow 5200 Sequential Compression Device**, which combines intermittent pneumatic compression with a sustained gradient pressure.

A new device has been proposed as an alternative treatment for lymphedema, the **Dayspring Limb Compression System**, which unlike pneumatic compression pumps, does not use air to produce the

compression, but rather uses a nickel-titanium shape-memory alloy to apply sequential gradient compression. The device is wearable (portable), programmable and battery powered, consisting of the controller and a garment (limb sleeve). It may also be referred to as a nonpneumatic compression controller.

Surgery, though not curative and rarely performed, has been suggested as a treatment for those with refractory lymphedema who have not improved with conservative management. Lymphedema surgery may be classified as reconstructive or excisional. Excisional surgical procedures for lymphedema include, but may not be limited to, debulking and liposuction. Reconstructive surgical procedures include, but may not be limited to, microsurgical treatment (eg, microsurgical lymphatico-venous anastomosis, lymphatic-capsular-venous anastomosis, lymphovenous bypass), lymph node transfer (also known as vascularized lymph node transfer) and tissue transfers (eg, omental flap).

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Compression (Lymphedema) Garments

Custom-made compression (lymphedema) garments for the extremities (eg, **gloves, sleeves or stockings**) will be considered medically reasonable and necessary for the treatment of primary or secondary lymphedema. These compression garments must be of medical grade, providing adequate graduated compression starting with a minimum of 30mm Hg distally.⁸

Two sets of lymphedema garments per affected extremity are allowed initially; 1 set per affected extremity may be covered thereafter in a [rolling 12 month period](#).^{*} (Sleeves and gloves are separate items; as such, if both should be required for treatment, 2 gloves and 2 sleeves would be allowed initially, with 1 additional of each in subsequent years, if needed.)

^{*}A rolling 12 month period is 12 months after an event, regardless of what month the initial event took place; eg, the initial sets of garments are provided on May 1, 2023, the rolling 12 month period would end on April 30, 2024; in this example, no additional garments would be authorized until May 1, 2024.

Lymphedema Pumps (Pneumatic Compression Pumps)

Please refer to the above CMS guidance for information regarding **pneumatic compression pumps**.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically

necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following **treatments/devices** will **not** be considered medically reasonable and necessary for diagnosis or treatment of lymphedema:

- Bioimpedance spectroscopy including, but not limited to, the L-Dex for diagnosing, monitoring or pre- or postoperative assessment of lymphedema; **OR**
- Compression garments for the chest, head, neck or trunk; **OR**
- Dayspring nonpneumatic compression system controller (with or without sequential calibrated gradient pressure) or garments for any indication; **OR**
- Immediate lymphatic reconstruction surgery for prevention of breast cancer-related lymphedema; **OR**
- Lymphedema pumps (E0650, E0651, E0652) (and the associated appliance) for treatment of lymphedema to the head or neck; **OR**
- Pumps/devices with a sustained gradient pressure while also delivering a higher intermittent pneumatic compression including, but not limited to, the CircuFlow 5200 Sequential Compression Device for any indication. These are considered not medically necessary; **OR**
- Ready-made (prefabricated) compression garments/stockings for any indication. Although they may be prescribed by a health care practitioner, ready-made compression garments/stockings are also available without a prescription and may be obtained over-the-counter (OTC) and are therefore generally considered not covered under Medicare. (Please check the Member Evidence of Coverage (EOC) for any additional coverage.); **OR**
- Surgical treatment of lymphedema including, but may not be limited to:
 - Excisional procedures (eg, debulking, liposuction); **OR**
 - Lymph node transfer (also known as vascularized lymph node transfer); **OR**
 - Microsurgical treatment (eg, lymphatico-venous anastomosis, lymphatic-capsular-venous anastomosis, lymphovenous bypass); **OR**
 - Tissue transfer (eg, omental flap)

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

Bioimpedance Spectroscopy (BIS)

Bundred, et al reported on a prospective multicenter study of 612 women who had undergone axillary node clearance for breast cancer and concluded that the modest correlation between multifrequency bioimpedance electrical analysis and arm measurement for the early detection of lymphedema at 6 months indicated that arm volume measurements remains the gold standard; however, longer-term data are needed.³²

ECRI¹¹ concluded that the evidence was inconclusive, due to too few data, noting that the available study provided only concordance data with the predicate device and no data on important clinical outcomes of interest (lymphedema diagnosis and evaluation using clinical criteria, follow-up), no studies provided data on the diagnostic accuracy with respect to clinical lymphedema assessment, and no studies reported on clinical outcomes of lymphedema treatment guided by BIS with the SOZO (L-Dex) device.

Hayes¹⁹ noted that the body of evidence concerning BIS for diagnosing, predicting development, and monitoring of lymphedema was large in size and low in quality. The overall low-quality rating for the body of evidence reflected individual study limitations and lack of comparison of BIS with all relevant technologies. They went on to note that the best available studies of BIS found that the clinical performance and accuracy of BIS was similar to, or somewhat lower than, the accuracy of other techniques for lymphedema diagnosis, prediction of lymphedema development, and guidance of lymphedema treatment. With regard to clinical utility, although 7 of the reviewed studies investigated the capacity of BIS to guide management of patients at risk for lymphedema, those studies did not provide conclusive evidence of clinical utility. Additional studies are needed to determine the clinical role of BIS relative to established techniques such as manual circumferential measurement, automated perometry, self-monitoring, and water displacement volumetry for lymphedema diagnosis, prediction of lymphedema development, and guidance of lymphedema therapy.

UpToDate, in their report Clinical Features and Diagnosis of Peripheral Lymphedema, does not include BIS in their discussion for identifying lymphedema, only referencing extremity measurements/limb circumference, limb volume (water displacement, optoelectronic volumetry, limb volume calculation) or imaging.³⁹

Dayspring Nonpneumatic Compression System Controller

ECRI's⁸ conclusion for this device was that the evidence was inconclusive, due to too few data on outcomes of interest (how effective the Dayspring is for treating lymphedema and how it compares with other treatments). Their identified evidence gaps included the need for large, multicenter, randomized controlled trials, looking at the Dayspring versus other pneumatic compression pumps and other lymphedema treatments, as well as the need for studies with long-term patient-oriented outcomes.

Hayes¹⁶ reported identifying only one randomized controlled trial comparing the Dayspring to an advanced pneumatic compression pump, which was of relatively small sample size (50 women with unilateral breast cancer-related lymphedema), and rather short term (28 days of use). The study found that the Dayspring device was an effective maintenance treatment for reducing the limb volume in these patients, and did have greater adherence compared with the advanced pneumatic compression pumps. They did go on to note, though that future studies are needed to examine the effects of early intervention which would aid in determining long-term adherence to the use of the device to prevent the progression of lymphedema.

Lymphedema Pumps for Treatment of Head or Neck Lymphedema

Currently the Flexitouch System is the only pneumatic compression device with Food & Drug Administration (FDA) approval to treat head and neck lymphedema. Hayes,¹⁸ in their report, found that evidence from 1 poor-quality randomized controlled trial (RCT) and 3 very-poor-quality pretest/posttest studies suggested that the Flexitouch Plus System reduced symptoms of head and neck lymphedema, with no reported severe device-related adverse events. The RCT also indicated improved pain control and patient-reported soft tissue symptoms over self-management and reported no benefit in function, quality of life, or objectively measured swelling. Whether the Flexitouch Plus System provides sustained benefits or advantages compared with alternative treatments was unclear due to limited comparative clinical evidence. They concluded that there is minimal support in their review of full-text clinical studies for use of the Flexitouch system for treating lymphedema of the head and neck.

Surgical Treatment of Lymphedema

Excisional procedures (eg, debulking, liposuction)

These procedures are designed to reduce bulk due to lymphedema; they are not generally considered curative for individuals with secondary lymphedema, but rather considered palliative.

Hayes²⁰ concluded in their report a finding of a moderate-size body of low-quality evidence supporting the use of liposuction plus compression therapy in patients with upper or lower extremity lymphedema, noting that it appears to be safe and with low risk of complications who have not responded to standard care.

They went on to note that despite the weakness of the evidence base, it may be the only treatment option for patients with advanced, late-stage lymphedema that is causing severe disability or other complications such as repeated infections. Potential benefits should be weighed against risks when treatment options are considered. The absence of well-designed clinical studies may require treatment decisions to be made on the basis of lower-quality data.

Immediate Lymphatic Reconstruction (LYMPHA procedure)

Lymphovenous bypass (referred to as lymphatic microsurgical preventing healing approach [LYMPHA] or immediate lymphatic reconstruction [ILR]) may be performed at the time of lymph node dissection to help prevent lymphedema. According to UpToDate,³⁸ in the largest series of 74 patients with an average follow-up of four years, only 4 percent of patients treated with LYMPHA developed lymphedema compared with historical rates of 15 to 65 percent. Several centers have ongoing studies attempting to confirm the validity of these findings. ECRI¹⁰ notes that the evidence is somewhat favorable, noting that they did not identify any randomized controlled trials; studies that were included in the systematic reviews were case series, and in their opinion were all at high risk of bias. Their reason for the determination of the risk for bias included three or more of the following: single-center focus, retrospective design, small size, and lack of randomization, blinding, and parallel controls.

Lymph Node Transfer (also known as vascularized lymph node transfer); Tissue Transfer (eg, omental flap)

Hayes²¹ reports an overall low-quality of evidence that suggests lymph node transfer is associated with greater limb size reduction when compared with other treatment modalities for individuals with upper or lower extremity lymphedema. They go on to note that despite the lack of well-designed controlled trials and the weaknesses in the design of the available studies, the current evidence suggests a benefit of LNT in selected patients with lymphedema who have not responded adequately to standard nonsurgical therapies. However, the lack of consensus on assessment and staging of lymphedema, they noted, made it difficult to compare the results of studies, and the scarcity of well-designed clinical studies in this patient population may require treatment decisions to be made on the basis of lower-quality data.

Microsurgical Treatment (eg, lymphatico-venous anastomosis, lymphatic-capsular-venous anastomosis, lymphovenous bypass)

A review of the current medical literature indicates that the existing published studies are of poor or very poor quality due to a high risk of bias. Reasons for bias include three or more of the following: single-center focus, retrospective design, small size, and lack of randomization, blinding, and parallel controls. The only available randomized-controlled trial was performed outside of the US using data from a single center. Comparisons across studies is challenging, given the variation in how lymphedema was defined, measured and graded.

The findings from an overall low-quality body of evidence suggest that lymphatic microvascular surgery for individuals with breast cancer who require lymph node dissection, may have a positive impact on the prevention of lymphedema resulting in a relatively low incidence of transient or persistent lymphedema. Data from two recent meta-analyses also support this conclusion with a reasonable degree of uncertainty given the lack of comparative evidence and retrospective nature of many study designs. Additional experimental studies, large multicenter retrospective studies, and studies having follow-up to 5 or more years would help ascertain which patients would benefit most and establish long term safety and efficacy.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
38308	Lymphangiomyotomy or other operations on lymphatic channels	
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)	
97016	Application of a modality to 1 or more areas; vasopneumatic devices	

97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes	
CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
A6549	Gradient compression stocking/sleeve, not otherwise specified	Not Covered
E0650	Pneumatic compressor, nonsegmental home model	
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure	
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure	
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm	
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk	
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest	
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg	
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm	
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg	
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg	
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm	
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg	
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk	
E0671	Segmental gradient pressure pneumatic appliance, full leg	
E0672	Segmental gradient pressure pneumatic appliance, full arm	
E0673	Segmental gradient pressure pneumatic appliance, half leg	
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)	

E0676	Intermittent limb compression device (includes all accessories), not otherwise specified	
E0677	Non-pneumatic sequential compression garment, trunk	
E1399	Durable medical equipment, miscellaneous	
K1024	Nonpneumatic compression controller with sequential calibrated gradient pressure	
K1025	Nonpneumatic sequential compression garment, full arm	
K1031	Non-pneumatic compression controller without calibrated gradient pressure	
K1032	Non-pneumatic sequential compression garment, full leg	
K1033	Non-pneumatic sequential compression garment, half leg	
L8010	Breast prosthesis, mastectomy sleeve	

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Change Summary

- 01/01/2024 New Policy.

