Lymphedema Pumps
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00081
Original Effective Date: 04/13/1994
Archived Date: 01/23/2008

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Lymphedema Pumps was selected for archive status based on the following guidelines:
- The need for policy has been resolved.

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Claims related to lymphedema pumps will be autoadjudicated to pay.

When Services May be Eligible for Coverage
Note: Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met

Based on review of available data, the Company may consider the use of a lymphedema pump to be eligible for coverage when patient selection criteria are met.

Patient Selection Criteria
Coverage eligibility will be considered for use of a lymphedema pump when all of the following criteria are met:
- Clinical records document the failure of response to conservative measures such as elevation of the limb and/or the use of elastic garments; and
- The pneumatic appliance is considered the most effective method of treatment for patients with intractable edema of the extremities (i.e., chronic lymphedema in the upper extremity following radical mastectomy with axillary dissection or chronic venous stasis of the lower extremity with ulceration or other significant complications); and
- The medical necessity for the appliance is supported in clinical documentation; and
- The physician can provide supporting documentation in the clinical or medical record to substantiate the indications for the appropriateness of the requested device.

When Services are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of a lymphedema pump when patient selection criteria are not met to be investigational.*
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Background/Overview
Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities due to obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels or congenital anomalies. Treatment includes mechanical measures (compression garments, bandaging, manual massage, pneumatic compression devices (i.e., lymphedema pumps), drugs, or rarely, surgery.

Many different lymphedema pumps are available, with varying materials, design and complexity. These devices can be classified into three types: 1) single compartment pumps; 2) multi-chamber devices with each chamber sequentially inflated but with fixed pressure in each; and 3) multi-chamber devices with sequential inflation and with manually calibrated pressure in each chamber. Lymphedema pumps may be used in lymphedema clinics, purchased or rented for home use. This policy addresses the home use of lymphedema pumps.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Several pneumatic compression pumps indicated for primary or adjunctive treatment of primary or secondary (e.g., postmastectomy) lymphedema have been cleared for marketing by the U.S FDA through the 510(k) process. Examples of devices with these indications that are intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (Medmark Technologies, LLC, Perkasie, PA); the Sequential Circulator (Bio Compression Systems, Inc., Moonarchie, NJ); and the Lymph-a-Press and Lymph-a-Press Optimal (Mego Afek, Israel), the Flexitouch™ system (Tactile Systems Technology, Inc.) and the PowerPress Unit Sequential Circulator (Hanuri Distribution, Inc, Chatsworth, CA).

Several pneumatic compression devices are cleared by the FDA for treatment of venous stasis ulcers. Examples include the Model GS-128, Lymph-a-Press, Flexitouch, and PowerPress Unit listed above as well as Nanotherm(TM) (ThermoTek, Inc.), CTU676(R) (Compression Technologies), and Recovery+(TM) (Pulsar Scientific)

Centers for Medicare and Medicaid Services (CMS)
A 2002 National Coverage Determination for Pneumatic Compression Devices (280.6) states the following:

A - Lymphedema
Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.
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B - Chronic Venous Insufficiency With Venous Stasis Ulcers

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers.

Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

Rationale/Source

Available data was inadequate to validate the superiority of one type of lymphedema pump over another. Only two trials including direct comparisons of pump types were identified.

Zanolla and colleagues compared a uni-chamber device and a multi-chamber device without gradient pressures and found no significant difference in efficacy. However, interpretation of this trial is limited by the small number of patients (n=60) and varying range of severity in lymphedema between the treatment groups.

In an unpublished trial, Bergan and colleagues used a multi-chamber device with gradient pressure programmed to simulate the other types of lymphedema pumps. A total of 32 patients were treated with the pump sequentially to simulate the different pump types. While the use of the multi-chamber device with gradient pressure was associated with a significant reduction in lymphedema compared to the other simulated pump types, interpretation of this study is limited by lack of appropriate statistical testing, including confidence intervals, and lack of data validating the degree to which the simulated pumps accurately reflect the performance of the true pumps.

Among additional uncontrolled studies, heterogeneity in the patient populations, etiology of lymphedema, location of lymphedema, and severity of illness also make it difficult to compare efficacy across the different trials. For example, efficacy of the pumps may differ in the lower extremities as compared to the upper extremities, or as a function of the etiology of lymphedema, particularly in primary versus secondary forms. Differences in severity of illness may be the most important of these factors affecting outcome. For patients with mild edema, the response to any form of therapy will likely be more favorable. Furthermore, the manner in which the response is calculated, i.e., percent reduction in edema, is a relative measure, and therefore dependent on the initial level of lymphedema. Therefore, when using this outcome measure to compare results, it is crucial that the underlying severity of illness is similar among groups being compared in order to draw meaningful conclusions.
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Despite these limitations, results across all of the studies were consistent in showing a substantial improvement in lymphedema following treatment with any of the pumps tested. It is possible to conclude, therefore, that pneumatic compression devices are efficacious to some degree. It is not possible to estimate precisely the magnitude of this effect.

References

Policy History
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<td>08/20/2001</td>
<td>Managed Care Advisory Council approval</td>
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<td>06/24/2002</td>
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Next Scheduled Review Date: Archived Medical Policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination We make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical
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**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.