Surgical Treatments for Lymphedema and Lipedema

Table of Contents

Coverage Policy .................................................. 1
Overview .............................................................. 1
General Background ........................................... 1
Coding/Billing Information ................................. 14
References ........................................................ 14

Related Coverage Resources

- Pneumatic Compression Devices and Compression Garments
- Complex Lymphedema Therapy (Complete Decongestive Therapy)
- Cryounits/Cooling Devices
- Physical Therapy

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Coverage Policy

The following surgical treatments for lymphedema are considered experimental, investigational or unproven:

- excisional procedures (e.g., debulking and liposuction)
- microsurgical treatment (e.g., microsurgical lymphatico-venous anastomosis, lymphatic- capsular-venous anastomosis, lymphovenous bypass)
- vascularized lymph node transfer
- tissue transfer (e.g., omental or mesenteric flap)

Liposuction for the treatment of lipedema is considered experimental, investigational or unproven.

Overview

This Coverage Policy addresses surgical treatments for lymphedema and lipedema.

General Background
Lymphedema is a chronic condition that develops over months to years of an increasing lymphatic load that exceeds the lymphatic system’s transport capacity. Impairment of lymphatic transport leads to interstitial accumulation of a protein-rich fluid that are normally transported by the lymphatic system from the interstitium into the circulation. Lymphedema can affect any body part including trunk, limbs, head/neck, and genitals. Lymphedema is classified into primary and secondary forms. Primary lymphedema occurs when the lymphatic system does not mature properly during fetal development. It can be familial, genetic, or hereditary. Secondary lymphedema occurs secondary to a disruption or obstruction of the lymphatic system caused by: filariasis (primary cause worldwide), lymph node surgery/radiation due to cancer (primary cause in the United States) or by another cause such as chronic venous insufficiency (CVI), deep vein thrombosis (DVT), infection, surgery/trauma, lipedema, and obesity (Ferri, 2018; Bello, et al., 2017).

Lymphedema may be clinically apparent but imaging is required for confirmation and to rule out other conditions that may confound the clinical presentation. Imaging technologies to confirm lymphedema or plan surgery include lymphoscintigraphy, or indocyanine green lymphangiography, possibly complemented by magnetic resonance imaging (Hayes, 2017; International Society of Lymphology [ISL], 2013).

Once diagnosed, lymphedema may be staged by severity. There are 2 main staging methods—the International Society of Lymphology (ISL) scale and the Campisi scale. The International Society of Lymphology (ISL) staging guidelines for lymphedema states (Mehrara, 2018; Bello, et al., 2017; Hayes, 2017; ISL, 2013):

- **Stage 0: Latent or Subclinical**
  - impaired lymphatic transport
  - no evident edema, subtle changes in tissue fluid/composition
  - changes in subjective symptoms
  - may last months or years before progression

- **Stage I: Spontaneously Reversible**
  - early accumulation of protein-rich fluid
  - pitting edema
  - subsides with elevation

- **Stage II: Spontaneously Irreversible**
  - accumulation of protein-rich fluid
  - pitting edema may progress to nonpitting as excess fat and fibrosis develop
  - does not resolve with elevation alone

- **Stage III: Lymphostatic Elephantiasis**
  - nonpitting
  - significant fibrosis
  - trophic skin changes

The Campisi staging system for lymphedema:

- **Stage I**: *Latent* lymphedema without clinical evidence of edema, but with impaired lymph transport capacity (provable by lymphoscintigraphy) and with initial immune-histochemical alterations of lymph nodes, lymph vessels, and extracellular matrix.
- **Stage II**: *Initial* lymphedema, totally or partially decreasing by rest and draining position, with worsening impairment of lymph transport capacity and of immune-histochemical alterations of lymph collectors, nodes, and extracellular matrix.
- **Stage III**: *Increasing* lymphedema, with vanishing lymph transport capacity, relapsing lymphangitic attacks, fibroinudervative skin changes, and developing disability.
- **Stage IV**: *Column shaped* limb fibrolymphedema, with lymphostatic skin changes, suppressed lymph transport capacity, and worsening disability.
- **Stage V**: Properly called *elephantitis*, with scleroindurative pachydermatitis, papillomatous lymphostatic verrucosis, no lymph transport capacity, and life-threatening disability.
Nonsurgical or conservative treatment options for lymphedema are primarily physical and include elevation, exercise, skin care (to prevent drying, cracking, and infection), limb elevation, elastic stockings or other pressure garments or bandages, physical therapy, manual lymph drainage, massage therapy, and pneumatic compression devices; these are often used in combination such as with complex decongestive therapy (CDT) or intermittent pneumatic compression therapy. CDT, also known as complex lymphedema therapy (CLT) or complete decongestive physiotherapy (CDP) is a noninvasive treatment that is considered a standard of care for lymphedema. The main goal of treatment of lymphedema is volume reduction of the affected limb, improvement in patient symptoms as well as a reduction of or elimination of any recurrent infections (Garza, et al., 2017; Hayes, 2017; Lasinski and Boris, 2002; MacDonald, et al., 2003).

Nonsurgical treatments can be intensive and may require extensive, and time-consuming, ongoing intervention. For some individuals the nonsurgical treatments yield inadequate lymphedema control. Lymphedema surgery has been proposed to reduce limb size and improve quality of life (QOL) and function when conservative nonsurgical management yields inadequate results. The goals of surgical management of lymphedema are to retain or restore function, alleviate pain and discomfort, reduce the risk of infection, prevent disease progression, improve cosmesis, and limit deformity. There is no consensus regarding the role of surgery, the optimal surgical approach, or the timing of an operative procedure for extremity lymphedema. Conservative or nonsurgical treatment options are often resumed after surgery to maintain surgical benefits (Mehrara, 2018, Bello, et al., 2017; Garza, et al., 2017; Hayes, 2017).

Operations for lymphedema are classified in two main categories: excisional operations and lymphatic reconstruction. Surgical management of lymphedema is categorized into two general approaches: physiologic techniques and reductive/ablative techniques. Physiologic procedures are proposed for individuals with early stage lymphedema prior to deposition of excess fat and extensive tissue fibrosis. Reductive/ablative techniques are proposed for individuals who present with more advanced lymphedema after fat deposition and tissue fibrosis has occurred. Individuals with more advanced lymphedema have been treated with physiologic techniques, however, the results are variable, and only limited numbers of patients have been analyzed (Mehrara, 2018).

The issue in monitoring success of surgical interventions is that there is no set standard for measuring degree of lymphedema and no standardized conservative treatment protocol before or after surgery. Additionally, presently there is no uniformity in the literature with regards to a protocol for diagnosing and monitoring lymphedema. Providers who follow these patients have reported objective and subjective improvements in the majority of lymphedema patients who have undergone surgical intervention. Most studies that report on the surgical management of lymphedema monitor limb circumference, volume reduction, and incidence of cellulitis as their endpoints. Recently, patient self-reported quality of life outcome tools specific for lymphedema have been included as an additional end point. The most commonly performed surgical procedures for lymphedema are lymphaticovenular anastomosis and vascularized lymph node transfer (Garz, et al., 2017).

A textbook review of the surgical treatment of lymphedema concluded that lymphatic microsurgery continues to be promising but it requires extensive microsurgical training. Long-term patency rates associated with documented clinical and functional improvement must be reproduced in a larger numbers of patients and several medical centers before this operation can be recommended for routine treatment or as an alternative to conservative measures (Trinidad-Hernandez and Gloviczki, 2013).

Multiple ongoing clinical trials for the surgical treatment of lymphedema can be found on the ClinicalTrials.gov database.

**Physiologic Techniques**

The surgical approaches include lymphatic bypass procedures, flap transposition procedures, and vascularized lymph node transfers. The lymphatic bypass procedures are the most commonly used of the physiological techniques. These procedures require a high level of technical skill, and it is recommended that performance of these procedures be reserved for those surgeons who have expertise in microvascular surgery (Mehrara, 2018).
Lymphatic bypass procedures: The lymphatic bypass procedures are categorized as lymphatic-lymphatic bypass and lymphovenous bypass procedures. Lymphaticovenular bypass procedures are a variation of the lymphovenous approach. There are several methods used to perform a bypass procedure. There is no consensus for the specific type of lymphatic bypass procedure to be performed; these decisions are made based on surgeon preference and experience. To help identify the lymphatic vessels, prior to making an incision, isosulfan blue dye is injected into the subcutaneous tissue distal to the operative site. The most common approaches are described as follows (Mehrara, 2018; Garza, et al., 2017):

- **Lymphatic-lymphatic bypass:** Lympholymphatic bypass transfers soft tissue resected from an unaffected site to a site that is proximal to that affected by lymphedema and followed by a direct anastomosis of the lymphatic vessels.
- **Lymphovenous bypass:** Lymphovenous bypass is an alternative to the lymphatic-lymphatic technique. A vein interposition graft is used to connect the distal lymphatic vessels with vessels proximal to the obstruction. Proximal vessels used in this technique include lymphatic vessels, adjacent veins, or deeper and larger veins. Multiple lymphatic vessels can be anastomosed to the vein graft.
- **Lymphaticovenular anastomosis (LVA):** This is a super microsurgical technique used to anastomose distal subdermal lymphatic vessels and adjacent venules less than 0.8 mm in diameter. Distal subdermal lymphatics are less affected by lymphedema and are more readily available for a bypass procedure than deeper lymphatic channels.
- **Vascularized lymph node transfer (VLNT):** This approach utilizes microsurgical techniques to transfer lymph nodes from an unaffected site to the affected limb with the intent of restoring lymphatic function and promoting lymph drainage. A limiting factor of this approach is that lymphedema can develop in the donor extremity.
- **Flap/tissue transfer:** Due to the risk of donor site lymphedema, clinicians have sought out other sources of vascularized lymphatic tissue. The omentum’s function as lymphatic organ and mesenteric lymph nodes have both been explored for possible applications in lymphedema management. Results from these approaches have yet to be fully validated.

Reducive/Ablative Techniques

Reducive techniques, also called ablative techniques, remove fibrofatty tissue that has formed from sustained lymphatic fluid stasis. Reductive techniques include direct excision and liposuction (Mehrara, 2018; Hayes, 2017; Trinidad-Hernandez and Gloviczki, 2013):

- **Direct excision:** A variety of direct excision procedures have been described for the treatment of extremity and genital lymphedema. Excisional operations remove excess subcutaneous tissue to decrease the volume of the extremity. Lymphedematous tissues are excised together, including the skin and soft tissues. The resulting defects are covered either with tissue flaps (e.g., Sistrunk, Homans, Thompson procedures) or with skin grafts (e.g., Charles procedure). Prolonged hospitalization, poor wound healing, large surgical scars, sensory nerve damage, and residual edema of the foot and ankle are reported problems. These common complications limit such procedures to individuals with disabling, advanced or end-stage lymphedema that is not responding to maximal medical therapy.
- **Liposuction:** This ablative surgery removes fatty and fibrotic depositions through multiple small incisions of the affected limb in patients with more advanced lymphedema. It is sometimes called suction-assisted lipectomy. It is proposed for patients with stage II or III lymphedema. Postoperative placement of compression garments prevents swelling recurrence, must be refitted regularly, and may be required for life to maintain surgical benefits.

**U.S. Food and Drug Administration (FDA)**

The FDA does not regulate surgical procedures. Any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

**Literature Review**

**Lymphatic bypass procedures:** In a prospective cohort study, Poumellec et al. (2017) analyzed the results of lymphaticovenous anastomoses (LVA) on 31 patients and reviewed the existing literature. This study comprised 31 female patients presenting lymphedema of the upper limb following treatment for breast cancer for which
surgical treatment was given by microsurgery consisting of three stepped LVA performed in an outpatient setting. The post-LVA arm circumference was measured at three levels (wrist, forearm, and arm) in 31 female patients. Mean follow-up time was 12.8 months. Reduction in the circumference was 22.5, 21.32, and 30.2%, respectively, in the wrist, forearm, and arm. Functional improvement was observed in the majority (84%) of patients ranging from moderate to substantial. Only two patients had no result. The only patients to experience recurrence were those with a high level of lymphedema. The review of the current literature and the present study revealed modest results in terms of decreased excess volume, although a major improvement in function points to LVA as a useful technique in this indication. Progress in imaging techniques has enhanced the results achieved with this procedure, although further studies on recurrence rates are needed with a follow-up greater than one year.

In a prospective study, Cornelissen et al. (2017) analyzed the effect of lymphaticovenous anastomosis (LVA) on quality of life (n=20). Inclusion criteria consisted of an evidenced upper limb lymphedema secondary to breast cancer in stage 1 or 2A according to the International Society of Lymphology (ISL) classification, patent lymphatic ducts seen by indocyanine green (ICG) lymphangiography and an absence of skin infections and complex decongestive therapy for at least three months. Quality of life was considered as the primary outcome, measured by the Lymphedema international classification of functioning (Lymph-ICF) questionnaire. Secondary outcomes were the use of compressive stockings and arm volume changes according to the Upper Extremity Lymphedema index (UEL-index). Measurements were obtained preoperatively and at one, three, six and 12 months postoperatively. The mean follow-up was 7.8 ± 1.5 months. Statistically significant improvement in quality of life was achieved in the total score and for all the quality of life domains after one year of follow-up (p<0.05). The discontinuation rate in compressive stockings use was 85%. The mean relative volume difference in UEL between a healthy and lymphoedematous arm preoperatively was 14.92 ± 8.01 and postoperatively (p<0.05). The staging system of lymphedema was inconsistent across studies. Lymphovenous shunt procedures were performed in 22 studies and lymph node transplantation was performed in five studies. Excess circumference was reduced by 48.8 ± 6.0%, and absolute circumference was reduced by 3.31 ± 0.73 cm. Studies reporting change in volume demonstrated reduction in excess volume by 56.6 ± 9.1%, and absolute volume was reduced by 23.6 ± 2.1%. The incidence of no improvement in lymphedema postoperatively was 11.8% and 91.2% of patients reported subjective improvement. Approximately 64.8% of patients discontinued compression garments at follow-up. Complications included operative-site infection (4.7%), lymphorrhea (7.7%), reexploration for flap congestion (2.7%), and additional procedures (22.6%). Limitations of this study are: heterogeneity of the patient population; assessment modalities; and inconsistent reporting of complications. The authors concluded that lymph node transplantation may provide better outcomes compared with lymphovenous shunt, but well-designed head-to-head comparisons are needed to evaluate this further.

Basta et al (2014) conducted a systematic review and meta-analysis to quantify the efficacy and safety of microsurgery for lymphedema. Studies meeting criteria for inclusion were rated on methodologic quality based on the American Society of Plastic Surgeons levels of evidence. Demographic information, cause of lymphedema, and surgical technique were recorded. Quantitative change in lymphedema and perioperative complications were noted. A total of 27 studies were included, with 24 level IV evidence and three level III evidence. Overall, the study population consisted of 1619 patients, with a female-to-male ratio of approximately 3:2. The vast majority of patients suffered from postsurgical lymphedema associated with oncologic conditions, including breast cancer and various gynecologic cancers. The staging system of lymphedema was inconsistent across studies. Lymphovenous shunt procedures were performed in 22 studies and lymph node transplantation was performed in five studies. Excess circumference was reduced by 48.8 ± 6.0%, and absolute circumference was reduced by 3.31 ± 0.73 cm. Studies reporting change in volume demonstrated reduction in excess volume by 56.6 ± 9.1%, and absolute volume was reduced by 23.6 ± 2.1%. The incidence of no improvement in lymphedema postoperatively was 11.8% and 91.2% of patients reported subjective improvement. Approximately 64.8% of patients discontinued compression garments at follow-up. Complications included operative-site infection (4.7%), lymphorrhea (7.7%), reexploration for flap congestion (2.7%), and additional procedures (22.6%). Limitations of this study are: heterogeneity of the patient population; assessment modalities; and inconsistent reporting of complications. The authors concluded that lymph node transplantation may provide better outcomes compared with lymphovenous shunt, but well-designed head-to-head comparisons are needed to evaluate this further.
the included studies was too short to make a reliable statement about sustained benefits of LVA surgery. Additionally, the deficiency of comparative designed studies and uniform outcome measurements continues to prevents drawing evidence based conclusions.

In a 2018 UptoDate topic on surgical treatment of primary and secondary lymphedema the author states that “outcome data for physiologic techniques are from retrospective reviews of mostly lymphatic bypass procedures. Lymphatic bypass procedures result in highly variable responses, ranging from a complete response to none. The variability of results among the different studies is likely due to a number of factors including differences in assessing volume or circumference, length of follow-up, variable use of postoperative compression garments and/or physical therapy, and the use of non-standardized or non-validated questionnaires for subjective analysis. There has been no standardization of assessing volume of lymphedematous limb, and numerous techniques are reported to approximate volume changes following an operative procedure. Few studies report the use of complimentary techniques (e.g., volume measurements and bioimpedance or lymphoscintigraphy) to corroborate measurements. Other caveats include mixed series of patients, either based upon etiology (e.g., primary congenital conditions, or secondary lymphedema following nodal resections, trauma, or filariasis); location of lymphedema (e.g., upper or lower extremity); and/or variable criteria for patient selection, selection of procedures, timing of intervention, and identification of suitable lymphatic vessels for bypass surgery” (Mehrara, 2018).

In a Hayes Medical Technology Directory Report on Surgical Treatment of Lymphedema: A Review of Reviews, the authors summarized the overall quality of the evidence for LVA was low-quality. Among 12 studies reviewed, 3074 patients were treated with LVA for upper extremity lymphedema (n=310), lower extremity lymphedema (n=164), or a mix that could not be differentiated (n=2600). No studies directly comparing LVA with nonsurgical treatment for lymphedema were identified. Of the nine studies noting lymphedema staging schemes, both the International Society of Lymphology (ISL) scheme and the Campisi lymphedema staging scheme were used. The duration of follow-up ranged from 3-120 months, but most studies reported 12-32 months of follow-up. In the studies reviewed, information on the performance of LVA itself was limited. Most studies were characterized as using LVA, but one study also implemented lymphaticovenous implantation, and one used lymph vessel transplantation. An average absolute circumference reduction of 5.8% (95% CI, 0.07-11.5%) in three studies with 33 patients, an average excess circumference reduction of 16.1% (95% CI, 2.6-29.6%) in four studies with 69 patients, and an average excess volume reduction of 33.1% (95% CI, 14.4-51.9%) in four studies involving 172 patients. The studies reviewed did not report QOL using standard instruments; five studies reported related outcomes. A majority of patients responded positively in terms of QOL. One study reported 91.7% symptom improvement and two other studies reported mean satisfaction of 94.5%. Two other studies reported 50% patients with subjective improvement. Two studies reported an overall complication rate of 5.9%, consisting of partial skin ulceration in one patient and wound dehiscence in one patient. After surgery, in 10 of 11 studies that reported additional interventions, the patients used compression garments. Of those, three reported additional interventions such as physical therapy or manual drainage. One study used physical therapy alone for postoperative care. The authors reported that although the meta-analyses of various limb-reduction measures were statistically significant when studies were combined, the average reductions in limb circumference were modest, particularly when the lower CI is considered. Not all studies reported statistically significant limb size reduction, although power may have been an issue. QOL was generally not assessed using a standard instrument, which decreases the overall quality of this outcome; however, available results suggest most patients had satisfactory improvement (Hayes 2018, 2017).

Vascularized Lymph Node Transfer (VLNT): In a prospective study, Maranado et al. (2017) evaluated the flap and the donor site morbidity of the supraclavicular (SC) VLNT. A review of a prospective database was performed for patients who had undergone SC VLNT to treat upper or lower extremity lymphedema. Flap and donor site complications were registered for each patient. One hundred consecutive patients with lower or upper extremity lymphedema underwent SC VLNT (84% from the right side) with a mean of 11-months follow-up (range 3-19 months). There were no flap loss but three flaps (3%) required re-exploration due to venous congestion of the skin paddle. Two patients had local infection and three patients developed chyle leak (3%) at the donor site but resolved spontaneously. No donor site secondary lymphedema was noted. This study focused on donor site. No limb size reduction outcomes were reported.
In a prospective study, Gratzon et al. (2017) evaluated the clinical, psychosocial, and functional outcomes of patients who underwent VLNT to the axilla for the treatment of upper extremity lymphedema after breast cancer therapy (n=50). Patients were evaluated preoperatively and postoperatively at one-, three-, six-, nine-, and 12-month intervals by circumferential measurements, pain/heaviness scales, and lymphedema quality of life (LYMQOL) questionnaires. Preliminary results showed a decrease in arm volumes by 34.57 % at one month, 52.03 % at three months, 42.34 % at six months, 65.23 % at nine months, and 58.68 % at 12 months. Pain and heaviness consistently decreased over time at 12 months. Overall quality of life scores steadily improved at 12 months. There was a significant decrease in the number of infections of the affected arm postoperatively and a decreased need for physiotherapy. Complications occurred in 17 patients and consisted mainly of minor wound complications. The authors reported that a consensus of surgical and postoperative protocols for VLNT is needed among studies to assess adequately its utility in the treatment of lymphedema. Although preliminary results are promising, larger studies with longer follow-up are needed to evaluate the efficacy and safety of this procedure.

In a randomized prospective control study, Dionyssiou et al. (2016) evaluated the effectiveness of free vascularized lymph node transfer (LNT) in stage II breast cancer-related lymphedema patients in comparison with non-surgical management. A total of 36 cases were included in this study and randomly divided in two groups: group A patients (n=18) underwent microsurgical LNT; followed by six months of physiotherapy and compression, while group B patients (n=18) were managed by physiotherapy and compression alone for six months. Patients of both groups removed their elastic garments after six months and were re-examined one year later. Limb volume reduction was observed in both groups; mean reduction was greater in group A (57%) than in group B (18%). Infection episodes in group A were significantly reduced compared to those in group B patients. All group A patients reported painless and feeling of heaviness-free extremities with overall functional improvement, while the corresponding changes in group B patients were no more than marginal. This study is limited by small sample size and short-term follow-up.

In a case series study, Saaristo et al. (2012) describe a modified breast reconstruction flap containing lymph nodes from the groin area to reconstruct both the missing breast and the lymphatic network anatomy in the operated axilla. Breast reconstruction was completed in 87 patients. For all patients with lymphedema symptoms (n=9), a modified lower abdominal reconstruction flap containing lymph nodes and lymphatic vessels surrounding the superficial circumflex vessel pedicle was performed. Operation time, donor site morbidity, and postoperative recovery between the two groups (lymphedema breast reconstruction and breast reconstruction) were compared. The effect on the postoperative lymphatic vessel function was examined. The average operation time was 426 minutes in the lymphedema breast reconstruction group and 391 minutes in the breast reconstruction group. The postoperative abdominal seroma formation was increased in patients with lymphedema. Postoperative lymphoscintigraphy demonstrated at least some improvement in lymphatic vessel function in five of six patients with lymphedema. The upper limb perimeter decreased in seven of nine patients. Physiotherapy and compression was no longer needed in three of nine patients. No edema problems were detected in the lymph node donor area. None of the operated patients with lymphedema reported pain, hernias, or edema symptoms in the donor area (low abdominal wall or lower limb). A total of three of nine patients with lymphedema have discontinued the use of compression and physiotherapy eight months to two years after the breast reconstruction and lymph node transfer. The authors reported that the lymph node transfer is still considered an experimental surgery and this study is the third report on the efficacy of the lymph node transfer in the treatment of lymphedema.

In a case series study, Gharb et al. (2011) reported the outcome of vascularized lymph node transfer with hilar perforators compared with the conventional technique. A total of 21 patients affected by early stage II upper limb lymphedema were included in the study. A total of 11 patients received a free groin flap containing lymph nodes, and 10 patients received vascularized inguinal lymph nodes with hilar perforators. Mean follow-up was 46 and 40 months, respectively. Complications, secondary procedures, circumference of the limb, and subjective symptomatology were registered. There was no statistical difference in the limb circumference measurements between the two groups preoperatively. Differences between preoperative and postoperative measurements were statistically significant only in the perforator-based group at the levels below elbow, wrist, and midpalm (p=0.004, 0.002, 0.007, respectively). All the other differences were not statistically significant. The number of secondary procedures was significantly higher in the standard group (p=0.03). There were two cases of partial
flap loss and donor site lymphorrhea in the standard group. In both the groups, visual analog scale scores improved after the operation.

In a case series study, Lin et al. (2009) evaluated the outcome of vascularized groin lymph node transfer using the wrist as a recipient site in patients with post-mastectomy upper extremity lymphedema. A total of 13 consecutive patients underwent vascularized groin lymph node transfer for post-mastectomy upper extremity lymphedema. A vascularized groin lymph node nourished by the superficial circumflex iliac vessels was harvested and transferred to the dorsal wrist of the lymphedematous limb. The superficial radial artery and the cephalic vein were used as the recipient vessels. Outcome was assessed by upper limb girth, incidence of cellulitis, and lymphoscintigraphy. All flaps survived, and one flap required re-exploration, with successful salvage. No donor-site morbidity was encountered. At a mean follow-up of 56.31 ± 27.12 months, the mean reduction rate (50.55±19.26%) of the lymphedematous limb was statistically significant between the preoperative and postoperative groups (p<0.01). The incidence of cellulitis was decreased in 11 patients. Postoperative lymphoscintigraphy indicated improved lymph drainage of the affected arm, revealing decreased lymph stasis and rapid lymphatic clearance.

In an initial report of this surgery which was performed in France, Becker et al. (2006) reported on retrospective data collected on 24 patients treated with inguinal lymph node transfers to the axillary region. Patients with lymphedema for more than five years underwent lymph node transplantation. In this case series, upper limb perimeter returned to normal in 10 cases, decreased in 12 cases, and remained unchanged in two cases. The 10 cases in which upper limb perimeter returned to normal were described as being "cured." The authors reported that “no current gold standard for evaluation of lymphedema exists; hence, evaluating results of treatments remains difficult and appears controversial”. Long-term results were evaluated according to skin elasticity and existence of infectious disease, decrease or disappearance of the lymphedema assessed by measurements, effects observed on isotopic lymphangiography, and ability to stop or to discontinue physiotherapy after six months. Long-term results were also evaluated according to the duration of the lymphedema before surgery and occurrence of downstaging after surgery. Physiotherapy was discontinued after six months in 14 patients and after 12 months in one patient. In the nine other patients, physiotherapy remained necessary and was performed once weekly in seven patients. Physiotherapy was thus discontinued in 15 patients (62.5%). No results were reported after 12 months.

In a review of the literature, Scaglioni et al. (2018) evaluated outcomes and complications of vascularized lymph node transfer (VLNT) for the treatment of lymphedema. A total 24 studies encompassing 271 vascularized lymph node transfers were included. There were 260 free vascularized lymph node transfers performed, and 11 pedicle lymph node flaps. Measurements reported were heterogeneous. The follow-up time ranged from 1 to 96 months. The inguinal nodes were the most commonly used donor site followed by the lateral thoracic lymph nodes. The lateral thoracic lymph nodes were the least effective and had the highest complication rates (27.5%) compared to other lymph node donor sites (inguinal: 10.3% and supraclavicular: 5.6%). Upper extremity lymphedema responded better compared to lower extremity (74.2 vs. 53.2%), but there was no difference in placing the lymph nodes more proximally versus distally on the extremity (proximal: 76.9% vs. distal: 80.4%). The number and degree of improvement following VNLT was not thoroughly or consistently documented in the majority of studies. Twenty-five patients underwent additional adjuvant debulking procedures secondary to the lymph node transfers. The authors reported that more structured, prospective research to document outcomes in a more objective fashion is needed to know which donor and recipient site is best. Many of the studies included in the current analysis did not specify these details. Standardization in the parameters used to measure lymphedema following surgical intervention is needed.

In a Hayes Medical Technology Directory Report on Surgical Treatment of Lymphedema: A Review of Reviews, the authors summarized the overall quality of the evidence for vascularized lymph node transfer (VLNT) was low-quality. Among 10 studies enrolling 111 patients with upper limb lymphedema and 74 with lower limb lymphedema of stage IIa to III reported average absolute circumference limb reduction at follow-up of 39.5% (95% CI, 36.0-43.0%) in four studies with 69 patients, an average absolute volume reduction of –4.04% (95% CI, −23.6–15.5%) in two studies with 32 patients, and an average excess volume reduction of 26.4% (95% CI, −7.98–60.8%) in four studies with 77 patients. Although the average circumference reduction was statistically significant, the average absolute and excess volume reductions were not. Quality of life (QOL) measured on standard instruments was not reported, but patients in four studies reported improved function, appearance, and
mood, as well as decreased pain. Seven studies reported an overall rate of complications of 30%, including cellulitis, wound infection, lymphocele, donor site pain, seroma, and lymphedema. The authors reported that “Some uncertainties about the safety and efficacy of VLNT remain. Outcomes did not consistently indicate that VLNT was successful for the treatment of lymphedema; however, some evidence suggests that many patients were satisfied with their surgery. Benefits over conservative care are suggested by the results of a single randomized controlled trial (RCT) of patients who had been treated for breast cancer. More complications were reported for VLNT than for other surgeries” (Hayes, 2017; 2018).

Raju et al. (2014) completed a review of the literature for VLNT with updates and comparisons on current application, techniques, results, studies and possible future implications. The authors concluded that “Although the results with the use of VLNT for treatment of lymphedema have been largely positive, further exploration into standardized protocols for diagnosis, treatment optimization, and patient outcomes assessment is needed”.

**Flap/Tissue Transfer:** In a prospective study, Nguyen et al. (2017) report the long-term outcomes of the minimally invasive free vascularized omental lymphatic flap for the treatment of lymphedema. All consecutive patients with advanced lymphedema undergoing minimally invasive free vascularized omental lymphatic flap transfer were included (n=42). Perioperative evaluation included qualitative assessments, lymphoscintigraphy, and volumetric measurements with a mean follow-up of 14 (3–32) months. Subjective improvements were noted in 83% of patients. Mean volumetric improvement was 22%. Complications occurred in 16% (n=7) of patients. There was one episode of pancreatitis and one flap loss. Postoperative imaging revealed viable lymphatic transfers. Cellulitis history was present in 74% (n=31) patients with post-operative cellulitis occurring in 5% (n=2) patients. The collection of quality of life outcomes measures was incomplete.

**Reductive/Ablative Techniques:** In a cohort study, Lamprou et al. (2017) reported the long-term results of circumferential suction-assisted lipectomy (CSAL) in end-stage primary and secondary lymphedema of the leg. Patients were treated with CSAL for unilateral chronic irreversible lymphedema of the leg (n=88). Compression therapy was resumed after surgery. Leg volumes were measured before surgery, and at one, six, 12 and 24 months after the procedure. A total of 47 patients with primary lymphedema had a median preoperative volume difference between affected and unaffected legs of 3686 (interquartile range [IQR]), 2851 to 5121) ml. Two years after surgery, this volume difference was reduced to 761 ml, a 79% reduction. In the 41 patients treated for secondary lymphedema, the median preoperative volume difference was 3320 (IQR 2533-4783) ml, decreasing after two years to -38 ml indicating a 100% reduction in excess volume on average. The preoperative volume difference and the sex of the patient significantly influenced the final outcome after two years. The outcome was not related to body mass index (BMI) or other patient characteristics. Subsequent continuous compression, weight control, physical exercise, and lifestyle alterations are still needed to achieve the maximum effect.

In a cohort study, Hoffner et al. (2017) assessed liposuction plus controlled compression therapy in patients with lymphedema of an arm secondary to breast cancer treatment. The aim of the study is to test the hypothesis that liposuction improves health-related quality of life (HRQoL). Sixty female patients with arm lymphedema were followed for a one-year period after surgery. The 36-item short-form health survey (SF-36) was used to assess HRQoL. Patients completed the SF-36 questionnaire before liposuction, and after one, three, six, and 12 months. They reported a mean difference between affected and unaffected limbs of 1365 mL (standard error of the mean [SEM] 73) at baseline, which declined to 75 mL (SEM 35) at one month, –26 mL (SEM 40) at three months, –133 mL (SEM 40) at six months, and –213 mL (SEM 35) at one year, indicating > 100% reduction in excess volume on average. They reported that 82% (49 of 60) patients had complete resolution of their lymphedema. The adipose tissue volume removed at surgery was 1373 – 56mL. One month after liposuction, better scores were found in mental health. After three months, an increase in physical functioning, bodily pain, and vitality was detected. After one year, an increase was also seen for social functioning. The physical component score was higher at three months and thereafter, while the mental component score was improved at three and 12 months. Limitation of this study include: a lack of control or comparator group; observational study; insufficient length of follow-up to determine long-term outcomes.

In a 2018 UptoDate topic on surgical treatment of primary and secondary lymphedema the author states that most of the outcome data for reductive/ablative techniques for the treatment of lymphedema are from retrospective reviews, small case series and case reports. At this time there are no randomized trials to determine the optimal reductive procedure to treat lymphedema (Mehrara, 2018).
In a Hayes Medical Technology Directory Report on Surgical Treatment of Lymphedema: A Review of Reviews, the authors summarized the evidence for excision to treat late-stage lymphedema of the extremities. There is limited, low-quality evidence from five cohort studies. A total of 65 patients with lower extremity lymphedema and 11 with upper extremity lymphedema that was stage IIb or higher in each study found consistent improvements, including reductions in absolute circumference ranging from 12-16%, and a 52% reduction in excess circumference. Duration of follow-up ranged from 13-48 months. Two out of five studies reported quality of life results stating improvements in well-being and function. There was a moderate incidence of complications. Four of the five studies reported on complications and those experienced by 2-4 patients in total included prolonged numbness, cellulitis, wound breakdown, and need for additional grafting. Other complications experienced by one patient each included infection, seroma, hematoma, and hyperesthesia. In all studies reviewed, patients were encouraged to wear compression garments to maintain surgical benefits (Hayes, 2017; 2018).

The Hayes Medical Technology Directory Report on Surgical Treatment of Lymphedema: A Review of Reviews, summarized the evidence for liposuction. There is low-quality evidence from four studies enrolling 111 patients with upper extremity lymphedema and 74 with lower extremity lymphedema. Of the two studies that reported on stage, one reported ISL stage II-III and the other reported stage II. Three studies reported follow-up of 12 months and the fourth reported a mean follow-up of 38.4 months. Details of the liposuction or suction assisted lipectomy procedures was not reported in the studies. Reported weighted mean excess volume reduction (compared with the contralateral side) of 96.6% (95% CI, 86.2% to 107%) for a meta-analysis of three studies with 70 patients. Three studies followed patients for 12 months and the fourth for a mean of 38.4 months. All three studies reporting quality of life (QOL) found improved well-being and decreased depression and anxiety. It is unclear whether standard instruments were used to assess QOL. No perioperative complications were reported. In all studies, patients were encouraged to wear compression garments to maintain surgical benefits.

Systematic Reviews: In a systematic review (SR), Carl et al. (2017) reviewed the literature to develop a treatment algorithm based on highest-quality lymphedema research. The SR addressed lymphovenous anastomosis (LVAs), vascularized lymph node transfer (VLNT), liposuction, excision, and multiple/comboination surgical approaches for the treatment of lymphedema. The inclusion criteria was surgical therapy of extremity lymphedema studies with ≥ eight patients. A total of 69 articles met inclusion criteria and were assigned Methodological Index for Nonrandomized Studies (MINORS) scores with a maximum score of 16 or 24 for noncomparative or comparative studies, respectively. The average MINORS scores using noncomparative criteria were 12.1 for excision, 13.2 for liposuction, 12.6 for LVA, 13.1 for VLNT, and 13.5 for combined/multiple approaches. Loss to follow-up was the most common cause of low scores. A total of 39/69 cohort studies rated as high quality by MINORS instrument were included in the review: LVA (12), VLNT (10), excision (5), liposuction (4), combined/multiple approaches (8). The sample size was 8-2600. Follow-up 6-120 months. In studies measuring excess volume reduction, the mean reduction was 96.6% for liposuction, 33.1% for LVA, and 26.4% for VLNT. Included excision articles did not report excess volume reduction. The authors stated that further studies with a particular focus on patient follow-up will improve the validity of lymphedema surgery research. The authors also noted that the biggest drawback of this study was the heterogeneity of the included studies in terms of lymphedema stage and etiology, method of assessing surgical outcomes, and inconsistent reporting of complications and quality of life outcomes. Additionally, to better delineate indications for LVA versus VLNT and validate their proposed algorithm, more head-to-head comparative studies that adopt an accepted staging system, such as the ISL system, are needed. Randomized controlled trials with homogeneous patient populations in term of etiology and stage that compare surgical treatments to conservative therapies would help further define the most appropriate interventions for patients according to their clinical stage.

In a systematic review, Cormier et al. (2012) evaluated the surgical treatment of lymphedema. A total of 20 retrospective and prospective studies met inclusion criteria; procedures were categorized as excisional procedures (e.g., debulking, amputation, and liposuction) (n=8), lymphatic reconstruction (n=8), and tissue transfer (e.g., lymph node transplantation, pedicled omentum, bone marrow stromal cell transplantation). (n=4). The reported incidence of volume reduction of lymphedema in these studies varied from 118% reduction to a 13% increase over the follow-up intervals ranging from six months to 15 years. The largest reported reductions were noted after excisional procedures (91.1%), lymphatic reconstruction (54.9%), and tissue transfer procedures (47.6%). Procedure complications were rarely reported. The authors concluded that most of these reports are based on small numbers of patients, use non-standardized or inconsistent measurement techniques,
and lack long-term follow-up. In addition, although these surgical techniques have shown promising results, nearly all note that the procedures do not obviate the need for continued use of conventional therapies, including compression, for long-term maintenance.

In a Hayes Medical Technology Directory Report on Surgical Treatment of Lymphedema: A Review of Reviews, the authors summarized the evidence for lymphedema surgery stating that “Lymphedema surgery is relatively safe and may be efficacious for many patients, although not all findings were consistent across the studies of the various surgeries. The results of lymphedema surgery are related to the selection of the appropriate therapy according to lymphedema severity. Finally, for some surgeries, limitations of the body of evidence preclude the drawing of firm conclusions. The literature should be monitored for additional evidence on a greater total number of patients, safety and long-term outcomes, and data on quality of life (QOL) and function measured by validated instruments, which may increase the strength of the evidence” (Hayes 2017, 2018).

Professional Societies/Organizations
National Cancer Institute (NCI): The 2018 NCI Health Professional Version [Physician Data Query (PDQ®)] on lymphedema states that “Surgery is rarely performed on patients who have cancer-related lymphedema. The primary surgical method for treating lymphedema consists of removing the subcutaneous fat and fibrous tissue with or without creation of a dermal flap within the muscle to encourage superficial-to-deep lymphatic anastomoses. These methods have not been evaluated in prospective trials, with adequate results for only 30% of patients in one retrospective review. In addition, many patients face complications such as skin necrosis, infection, and sensory abnormalities. The oncology patient is usually not a candidate for these procedures. Other surgical options include the following: Microsurgical lymphaticovenous anastomoses in which the lymph is drained into the venous circulation or the lymphatic collectors above the area of lymphatic obstruction; liposuction; superficial lymphangiectomy; fasciotomy”.


Use Outside of the US
National Institute for Health and Care Excellence (NICE): NICE issued clinical guidance addressing the use of liposuction for chronic lymphedema in 2017 (NICE, 2017). The guidance reviewed the evidence and concluded that current evidence on the safety and efficacy of liposuction for chronic lymphedema is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Patient selection should only be done by a multidisciplinary team as part of a lymphedema service.

International Society of Lymphology (ISL): In 2013 the ISL published an updated consensus document regarding the diagnosis and treatment of peripheral lymphedema (ISL, 2013). The document makes the following comments regarding operative treatment of lymphedema:

- Treatment of peripheral lymphedema is divided into conservative (i.e., nonoperative methods) and operative methods. Both methods include an understanding that meticulous skin hygiene and care is of extreme importance to the success of all treatment approaches.
- Operations designed to alleviate peripheral lymphedema by enhancing lymph return have gained increased acceptance worldwide, but usually require combined physiotherapy or other compression after the procedure to maintain edema reduction and ensure vascular/shunt patency.

Lipedema
Lipedema is a rare disorder of adipose tissue that primarily affects females and is often misdiagnosed as obesity or lymphedema. There are numerous synonyms to refer to this condition (e.g. adipositas dolorosa, lipomatosis dolorosa, painful lipohypertrophy). In the majority of the cases, lipedema is located in lower limbs with the feet unaffected. There is usually minimal pitting edema. The pathogenesis is unknown and no curative treatment is available. Patients may complain of tenderness and pain and sustain easy bruising. Elevating the limbs has no effect on the involved limbs. When lipedema remains untreated, increased lymphatic load continually exceeds lymphatic transport capacity resulting the decompensation of lymphatic system therefore uni-, or much more
typically, bilateral lymphedema can develop. The combination of lymphatic insufficiency and lipedema is called lipolymphedema or lympho-lipedema depending on the terminology. Concomitant severe venous insufficiency is rare; however, varicosity is often seen among lipedematous patients. Diagnosis of lipedema is generally made on the basis of clinical features. Usually, the medical history and clinical examination are enough to suspect the diagnosis (Mehrara, 2018; Forner-Cordero, et al., 2012).

Based on inspection and palpation, lipedema can be classified in three clinical stages according to severity (Forner-Cordero, et al., 2012):

- **Stage I**: the skin surface is normal and the subcutaneous fatty tissue has a soft consistency but multiple small nodules can be palpated.
- **Stage II**: the skin surface becomes uneven and harder due to the increasing nodular structure (big nodules) of the subcutaneous fatty tissue (liposclerosis).
- **Stage III**: is characterized by lobular deformation of the skin surface due to increased adipose tissue.

The standard conservative therapy for lipedema significantly differs from that of lymphedema. Management of lipedema is complex and distinct from lymphedema. Complete decongestive therapy is the standard of care in most countries. However, even with strict diet and exercise regimens, the disease may progress and further treatment may be necessary. Surgical options of liposuction and excisional lipectomy are proposed in patients who are resistant to conservative treatment. Techniques employed for lipectomy of lipedema fat are different from the techniques used for cosmetic liposuction. The techniques employed for lipedema liposuction utilize devices that remove fat in a gentler manner, such as water-assisted liposuction or vibrating cannula associated with power-assisted liposuction. Often, multiple sessions are necessary to adequately treat the extremities circumferentially and along their entire length. Liposuction can only reduce the amount of fatty tissue, but not completely remove it. Many patients often require ongoing conservative treatment postoperatively to maintain results. Additionally, the avoidance of postoperative weight gain is essential in order to maintain the results of surgery (Dadras, et al., 2017; Warren and Kappos, 2016; Buck and Herbst, 2016).

**Literature Review**

In a case series study, Dadras et al. (2017) reported the outcome of liposuction used as treatment for lipedema. Twenty-five patients who received 72 liposuction procedures for the treatment of lipedema completed a standardized questionnaire. All patients had lipedema of the lower limb. Additional upper limb involvement was present in nine patients. One patient had stage I lipedema, 11 patients had stage II lipedema, and 13 patients had stage III lipedema. Lipedema-associated complaints and the need for combined decongestive therapy (CDT) were assessed for the preoperative period and during two separate postoperative follow-ups using a visual analog scale and a composite CDT score. The mean follow-up times for the first postoperative follow-up and the second postoperative follow-up were 16 months and 37 months, respectively. In 41 liposuctions, a vibration-assisted device was used, and in 31 liposuctions, a water jet-assisted device was used. Patients showed significant reductions in spontaneous pain, sensitivity to pressure, bruising, feeling of tension, cosmetic impairment, and general impairment to quality of life from the preoperative period to the first postoperative follow-up, and these results remained consistent until the second postoperative follow-up. The complication rate was 1.39%. An analysis of the different stages of the disease suggest that more sustainable results could be achieved if patients were treated in earlier stages.

In a case series study, Schmeller et al. (2012) reported the efficacy of liposuction concerning appearance (body shape) and associated complaints after a long-term period in patients with lipedema. A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anesthesia with vibrating microcannulas. A total of 112 could be re-evaluated with a standardized questionnaire after a mean of three years and eight months (range one year and one month to seven years and four months) following the initial surgery and a mean of two years and 11 months (eight months to six years and 10 months) following the last surgery. All patients showed reduction of subcutaneous fatty tissue (average 9846 mL per person) with improvement of shape and normalization of body proportions. They reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, edema, bruising, restriction of movement and cosmetic impairment, resulting in a tremendous increase in quality of life; all these complaints were reduced significantly (p<0.001). Patients with lipoedema stage II and III showed better improvement compared with patients with stage I. Physical decongestive therapy could be either omitted (22.4%
of cases) or continued to a much lower degree. No serious complications (wound infection rate 1.4%, bleeding rate 0.3%) were observed following surgery.

After an average of eight years, using the same questionnaire, Baumgartner et al. (2016) studied the continued long-lasting treatment success of the patient group from the above study by Schmeller et al. (2012). Twenty-seven of these patients could no longer be reached or did not respond. The remaining patients returned questionnaires that could be evaluated, which corresponds to a return rate of 76%. In some of the cases, the patients were also examined or submitted photos that were evaluated. Compared with the results after an average of four years, the improvement in spontaneous pain, sensitivity to pressure, edema, bruising and restriction of movement persisted. The same held true for patient self-assessment of cosmetic appearance, quality of life and overall impairment. No clinically relevant worsening of complaints occurred. Eight years after surgery, the reduction in the amount of conservative treatment (combined decongestive therapy, compression garments) was similar to that observed four years earlier. Only one-third of the patients were completely free of symptoms. This study did not re-examine the changes in morphology.

In a single center case series study, Rapprich et al. (2011) examined 25 patients using various measurement parameters to assess the status of lipedema before liposuction and six months after to evaluate its effectiveness in lipedema. The diagnosis of lipedema was confirmed in all patients included in the study on the basis of guideline criteria. Twenty patients had lipedema affecting the whole leg, three had lipedema of the thigh, and two had lower leg involvement only. Clinical examination included height, weight, waist circumference, leg volume measurement using 3D imaging, and a self-assessment of symptoms. The survey included the measurement of the volume of the legs and several parameters of typical pain and discomfort. The parameters were measured using visual analogue scales (VAS, scale 0–10). The survey was completed prior to beginning therapy and again at six months after the final liposuction treatment. Liposuction was performed under tumescent local anesthesia with vibrating cannulae. Three sessions at four week intervals were generally needed. For larger-volume thighs, four sessions (three patients) or five sessions (one patient) were required. Two patients received inpatient treatment, and 23 patients were treated on an outpatient basis. The volume of the leg was reduced by 6.9%. Pain, as the predominant symptom in lipedema, was significantly reduced from 7.2 to 2.1 (p<0.001). Quality of life as a measure of the psychological strain caused by lipedema improved from 8.7 to 3.6 (p < 0.001). Other parameters also showed a significant improvement and the over-all severity score improved in all patients. There was no new incidence of lymphedema. Fifteen out of 25 patients (reported regular use of compression therapy prior to liposuction therapy (76%). Six months after the final liposuction session, four (16%) patients reported continuing compression therapy. The follow-up period of six months in this study is too short to assess long-term recurrence of lipedema.

In a case series study, Schmeller et al. (2006) reported the efficacy and safety of surgery (liposuction) concerning appearance and associated complaints. Twenty-eight patients, who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anesthesia with vibrating microcannulas. Twenty-one could be reevaluated after an average of 12.2 (1–26) months. From 28 patients, 15 were operated on once, eight twice, two three times, and three four times. The average amount of fat removed per session was 3017 mL, with a range of 1060 to 5500 mL depending on the size and number of operated areas. The authors reported that all patients showed improvement, with normalization of body proportions. Spontaneous pain, sensitivity to pressure, and bruising either disappeared completely or improved. Other than minor swelling for a few days, no complications could be observed following surgery. All patients reported an increase in their quality of life. Physical therapy had to be continued to a much lower degree.

Forner-Cordero 2012 reported in a systematic review that there is a lack of knowledge and little evidence about lipedema, especially among obesity experts. Treatment protocols are stated to be comprised of conservative (decongestive lymphatic therapy) and surgical (liposuction) approaches. Authors concluded current knowledge about lipedema as a hidden epidemic is scarce, but the scientific interest is increasing. More studies are required to know the real prevalence and to reach an earlier diagnosis of this disorder. Diagnosis and treatment should be made as early as possible to prevent complications associated with increased functional and cosmetic morbidity.

A 2017 Hayes Search and Summary on liposuction for the treatment of lipedema states there is insufficient published evidence to assess the safety and health outcomes of liposuction for treatment of lipedema. The body
of evidence is small and consists of one case series, one survey, two systematic reviews, and four review articles.

**Professional Societies/Organizations**

No evidence-based clinical practice guidelines were located for lipedema.

**Use Outside of the US**

Halk and Damastra (2017), in a systematic review of the literature to June 2013, reported on Dutch guidelines for lipedema. The authors state there is little consistent information about the diagnosis or therapy of lipedema in the literature and indicate lipedema is frequently misdiagnosed. Surgery was noted to be the only available technique to correct the abnormal adipose tissue and tumescent liposuction was referenced as the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures.

**Coding/Billing Information**

**Note:**
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Experimental/Investigational/Unproven:**

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Considered Experimental/Investigational/Unproven when used to report any surgical treatment indicated in this coverage policy as experimental, investigational or unproven:

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**References**


