Surgical Treatment of Lymphedema

Policy Number: SURGERY 123.2
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Instructions for Use

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Related Policy

- Pneumatic Compression Devices

Coverage Rationale

Surgical procedures for the treatment or prevention of Lymphedema are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy. These procedures include, but are not limited to:

- Liposuction/Lipectomy
- Microsurgical treatment
  - Lymphaticovenous Anastomosis
  - Lymphovenous bypass
- Vascularized Lymph Node Transfer

Definitions

Liposuction/Lipectomy: The surgical suctioning of fat deposits from specific parts of the body (MedicineNet)

Lymphaticovenular/Lymphaticovenous Anastomosis: A surgical procedure that connects small lymphatic vessels to adjacent venules to shunt excess lymphatic fluid (American Society of Plastic Surgeons)

Lymphedema: The build-up of fluid in soft body tissues when the lymph system is damaged or blocked (NCI)

Vascularized Lymph Node Transfer: A surgical procedure that transfers skin, fat, and lymph nodes for lymphatic reconstruction. (American Society of Plastic Surgeons)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
38999	Unlisted procedure, hemic or lymphatic system
49906	Free omental flap with microvascular anastomosis

Description of Services

Lymphedema is a chronic, progressive, incurable disease in which there is impaired drainage of interstitial fluid through the lymphatic system resulting in the accumulation of fluid and hypertrophic fat. There are two types of lymphedema. Primary lymphedema, in which there is abnormal development of the lymphatic system, and secondary lymphedema which is caused by damage to the lymphatic system from trauma, infections, and cancer surgeries and radiation. It is characterized by nonpitting swelling of an extremity (that typically excludes the fingers and toes) or trunk. It is associated with wound healing impairment, recurrent skin infections, and decreased quality of life.

The first line treatment of LE is conservative management with complete decongestive therapy (CDT) which is a combination of compressive garments, skin hygiene, limb compression, manual lymphatic drainage, and exercise. Intermittent external pneumatic compression may also provide additional improvement when used adjunctively. For patients whose LE is not controlled by CDT, surgical procedures such as Liposuction/Lipectomy, subcutaneous excision, and microsurgical procedures such as lymphovenous bypass (LVA) and Vascularized Lymph Node Transfer (VLNT) have been proposed. (Kareh 2020; NCI 2019)

Clinical Evidence

Liposuction/Lipectomy

Xin et al. (2022) conducted a retrospective observational study on the therapeutic outcomes of tumescent liposuction for cancer-related lower extremity LE. The study included 62 patients with unilateral cancer related lower extremity with Stage II or Stage III LE who had received liposuction only and wore compression stockings postoperatively and followed for more than 3 months. Half of the participants were in Stage III LE, and a third had a history of recurrent superficial skin infections. The results showed the appearance of the lymphedematous extremity significantly improved by 3 months postoperatively. The preoperative, postoperative, and 3-month follow-up percent volume reduction (PVDs) were 43.2 ±23.7%, 5.5 ±12.2%, and 11.6 ±18.4%, respectively. The PVD at the postoperative and 3-month follow-ups had significantly decreased compared with preoperative measurements, but it significantly increased at the 3-month follow-up compared with that immediately post

operatively. At 3 month follow up, patient reported outcomes of feelings of heaviness and fatigue of the affected limb was alleviated, however feelings of stiffness, tenderness, and tightness had worsened. There were no significant differences in pain, numbness and weakness reported. The authors concluded that liposuction has a positive effect on treating cancer related LE of the lower extremity. This study is limited by the retrospective design, and the short follow up period.

A 2020 Hayes health technology assessment, updated in 2022, reported on the use of liposuction plus compression therapy for the reductive surgical treatment of lymphedema of moderate-to-severe, nonpitting, primary or secondary lymphedema of the upper and lower extremities (UEL or LEL) in adult patients, as well as adult patients with head and neck cancer treatment–related lymphedema. The evidence included studies that reported on the following outcome measures: the efficacy of lymphatic function, limb size and volume reduction, changes in annual skin infections, changes in shoulder joint range of motion as well as patient reported changes. An overall low-quality body of evidence suggests that liposuction plus controlled congestive therapy (CCT) or complex decongestive therapy (CDT) is associated with greater limb size reduction, lower risk of infection, and improved patient-reported outcomes compared with CCT or CDT alone in patients with UEL or LEL that had not responded adequately to conservative therapies.

In 2019a, Forte et al. conducted a comprehensive systematic review of the results of 13 studies that reported on the outcomes of lipoaspiration followed by controlled compression therapy, as well as the differences in the outcomes in patients treated with compression therapy only, for the treatment of LE of the upper extremity. Ten studies reported outcomes of patients treated with lipoaspiration followed by compressive therapy, and three studies compared this procedure with patients that had only compressive therapy. The majority of patients were at Stage II or Stage III disease. The results showed that all studies showed a potential benefit in volume reduction in patients with chronic lymphedema up to 5 years post- operatively. Two studies showed a decrease in infections and cellulitis. In the 3 studies that compared liposuction with compression to compression alone, the results showed a statistically significant difference in volume reduction at 12 month follow up, with the postoperative reduction for patients with lipoaspiration and controlled compressive therapy 103%, 115%, and 113%, compared to the group treated with controlled compressive therapy alone, which was only were 50%, 54%, and 47%. No studies showed major surgical complications. The authors concluded that lipoaspiration is better suited in later stages of disease (Stage II and III) when controlled compression therapy alone was ineffective. This study is limited by the heterogeneity between studies regarding the measurement tool used, the follow-up of results, and the protocol established.

Forte et al. (2019b) conducted a systematic review of the results of eight studies (case series) that reported on the outcomes of liposuction for the treatment of LE of the lower extremities after compression therapy. A total of 191 patients with primary or secondary LE, most Stage II or III were included. The results showed that all studies reported volume reduction following lipoaspiration. One study reported a difference in volume reduction depending on the cause of LE and showed at 24 months follow up a reduction of 79% in patients with primary LE, and a volume reduction of 101% was found in patients with secondary LE. All studies reported improvement in function, quality of life and decreased infections. The authors concluded that lipoaspiration followed by controlled compression therapy has the potential to improve LE for patients in Stage II or Stage III disease when controlled compression therapy was ineffective . This study is limited by the heterogeneity between studies regarding the measurement tool used, the follow-up of results, and the protocol established.

Microsurgical Procedures

Lymphaticovenous Anastomosis (LVA)/Lymphovenous Bypass

LVA (also referred to as lymphovenous bypass or lymphaticovenular anastomosis) is a super microsurgical technique in which an anastomosis is created between the congested lymphatic vessel and a vein to improve lymphatic fluid transport.

Ciudad et al. (2022) conducted a systematic review and meta-analysis of the current evidence on the use of preventive lymphatic surgery (PLS) for reducing the risk of cancer related lymphedema (CRL). Twenty-four studies comprising 830 LVA procedures on 1547 patients fulfilled the inclusion criteria. Eighteen studies were observational studies, two were randomized control studies, one was a case series, and three were abstracts or conference presentations. 1247 patients (80.6%) underwent axillary lymph node dissection (ALND), three-hundred patients (19.4%) underwent ilioinguinal, para-aortic, inguinofemoral lymph node dissection, and/or wide tissue excision of the inguinal region (the type of cancer was highly heterogenous). The results showed in single cohort studies, the pooled cumulative rate of upper extremity lymphedema after ALND and PLS was 5.15% with no significant heterogeneity across studies. The pooled cumulative rate of lower extremity lymphedema after oncological surgical treatment and PLS was 6.66%. In double-arm studies for upper limb lymphedema, the pooled analysis showed that PLS reduced the rate of lymphedema after ALND by 18.7 per 100 patients' heterogeneity was substantial and had significant

clinical relevance. For lower limb lymphedema the pooled analysis showed that PLS reduced the rate of lymphedema after ilioinguinal lymph node dissection by 30.3 per 100 patients treated with no significant heterogeneity across the studies. The authors concluded that PLS is a promising treatment for the prevention of lymphedema following cancer related lump node dissection. This systematic review is limited by the highly heterogenous nature of the included studies. This includes different diagnostic methods, levels and regions of LND, type of LVA, different follow up periods, and patient characteristics such as past radiation therapy. High-quality studies are necessary to determine the outcomes and determine recommendations regarding the use of preventive lymphatic surgery.

Gupta et al. (2021) conducted a systematic review to analyze the outcomes of LVA for primary or secondary upper extremity (UE) lymphedema in various stages. Sixteen studies comprising 349 patients and 244 upper limbs were included. The authors reported on post operative limb circumference/volume reduction and differential, and patient reported improvements in quality of life and symptoms. Studies on filariasis-related lymphedema were excluded. The results showed, among 14 studies that reported on objective improvements, 11 stratified outcomes by UE, and improvements were seen in more than 90% of the patients. Seven studies reported on the results based on the Campisi stage of lymphedema, and 2 reported LVA resulted in better outcomes when done in the earlier stages. The authors concluded that LVA is a safe and effective emerging treatment for UE lymphedema refractory to decompressive treatment, and large controlled studies are required to validate these findings.

A 2020 Hayes health technology assessment, updated in 2021, regarding lymphovenous anastomosis for the treatment of primary and secondary lymphedema that has not responded adequately to conservative therapies, focused on the effectiveness on lymphatic function, limb size reduction and subjective changes such as decreased infections and changes in the use of compression garments. Based on a moderate sized body of low-quality evidence, it was concluded that LVA appears to be safe with a low risk of complications. There was an overall positive impact on baseline limb circumference, excess volume and patient reported outcomes such as the use of compression garments and infections. There is insufficient evidence to come to a conclusion regarding the efficacy compared to other surgical procedures or non-surgical procedures. This suggests the potential benefit of LVA, and prospective comparative or randomized controlled trials are warranted.

Vascularized Lymph Node Transfer (VLNT)

VLNT is the free transfer of lymph nodes from a donor site into a lymphedematous limb to reconstruct physiological lymphatic return. Donor sites are either from the peripheral regional lymph node basin, or from within the peritoneal cavity. While precise mechanisms are unknown, VLNT is thought to promote the formation of lymphatic vessels from pre-existing lymphatic vessels and wick lymphatic fluid for transport into proximal lymphatic channels, or act as pumps to push lymphatic fluid into the venous circulation.

Li et al. (2021) completed a systematic literature review and meta-analysis on intra-abdominal vascularized lymph node transfer for the treatment of LE. Primary outcomes were circumference/volume reduction, episodes of cellulitis reduction and lymph flow assessment. Secondary outcomes included donor and recipient site complications. Twenty-one studies (non-randomized controlled trial, 3 retrospective cohort studies, 5 prospective case series, and 12 retrospective case series) with omental/gastroepiploic, jejunal, ileocecal, and appendicular donor sites totaling 594 patients met the inclusion criteria. The results showed a mean reduction in circumference and volume rate ranged from 0.38% to 70.8%. Significant reduction in infectious episodes was reported in 10 studies. The pooled donor-site complication rate was 1.4%, and the pooled recipient-site complication rate was 3.2%. No donor site lymph disfunction was reported. The authors concluded that low quality evidence suggests there is improvement in lymphedema following intra-abdominal VLNT. However, they also note that these results were of low quality with great heterogeneity across almost all data. Further research with high quality randomized trials are needed to confirm these findings.

In a 2021 systematic review and meta-analysis, Ward et al. evaluated the effectiveness of VLNT in reducing UE and LE volume, and cellulitis episodes in patients with cancer treatment related lymphedema (CTRL). Thirty-one studies totaling 581 patients in which VLNT was the sole therapeutic procedure for CTRL, and reported limb volume, frequency of infection episodes and/or lymphedema specific quality-of-life data, were included. The results showed for the UE, after VLNT the pooled circumferential reduction rates (CRRs) were 42.7% above elbow, and 34.1% below elbow. For the LE, there was a CCR of 46.8% above knee and 54.6% below knee. In addition, patients experienced approximately 2 fewer cellulitis episodes per year, and had improved lymphoedema-Specific Quality of Life scores. The authors concluded that VLNT reduces limb volume and cellulitis and improves quality of life, however most studies analyzed were of low quality, and had limited to small numbers of participants and lacked long term follow up. Furthermore, there was an overall high degree of heterogeneity across all studies as it related to VLNT, and further methodologically rigorous RCTs that include standardization of reporting are required.

Preventive Microsurgical Procedures/Immediate Lymphatic Reconstruction/Lymphatic Microsurgical Preventive Healing Approach (LYMPHA)

LVA and VLNT have also been investigated for the prevention of lymphedema, and for that indication, they are done at the time of the index procedure. This is often called Lymphatic Microsurgical Healing Approach (LYMPHA).

In a 2022 single- arm meta-analysis, Chun et al. evaluated the effectiveness of immediate lymphatic reconstruction (ILR) to prevent secondary LE and provide suggestions for using the LYMPHA approach. This meta-analysis included 789 patients across 13 studies, and included upper and lower limb ILR, 10 studies address ILR for breast cancer axillary lymph node dissection (ALND) and 3 addressed malignant melanoma inguinal lymphadenectomy. The results showed for upper extremity LE, the pooled analysis indicated that 2.75% of patients developed LE after ALND with ILR. The average pooled follow up time was 11.6 months and that the incidence of LE started to increase immediately post operatively at 0.92%, 2.19% at 6 months and 2.50% at 12 months, and continued to increase beyond 12 months with the highest incident rate between one and two years. For lower extremity following lymphadenectomy, the results showed 3.6% of patients developed LE after inguinal lymphadenectomy with ILR for malignant melanoma treatment. The authors acknowledge there is a limitation to LYMPHA for lower extremity ILR due to the availability of recipient veins with appropriate size, arc of rotation, and venous valvular sufficiency. The authors concluded that ILR is a promising technique to mitigate LE. Future research should address standardization of techniques and focusing on specific patient populations and show the short-term efficacy and long-term outcomes.

In a 2022 systematic review and meta-analysis, Hill et al. analyzed the current evidence on the effects of immediate lymphatic reconstruction (ILR) on the incidence of breast cancer-related lymphedema (BCRL) following ALND. Eleven studies totaling 417 breast cancer patients met the inclusion criteria. These studies included one randomized control trial, seven prospective cohort studies, and three retrospective reviews. Four of the 11 studies with control groups could be included in a meta-analysis. The results showed 24 of 417 (5.7%) patients developed BCRL following ILR. Meta-analysis revealed that in the ILR group, 6 of 90 patients (6.7%) developed lymphedema, whereas in the control group, 17 of 50 patients (34%) developed lymphedema. Patients in the ILR group had a risk ratio of 0.22 (CI, 0.09 -0.52) of lymphedema with a number needed to treat (NNT) of four. The authors concluded that ILR can prevent BCRL. Randomized control trials are underway to validate these findings. ILR may prove to be a beneficial intervention for improving the quality of life of breast cancer survivors.

In a 2020 ECRI clinical evidence assessment regarding LYMPHA for Preventing Lymphedema, it was concluded that based on low-quality but consistent evidence from one systematic review (SR) with meta-analysis and one nonrandomized comparative study, LYMPHA procedures performed during axillary lymph node dissection (ALND) reduce lymphedema rates compared to ALND alone in patients with breast cancer, and larger, prospective controlled studies are needed to verify these findings and to determine whether it improves outcomes for patients with other cancer types who undergo lymph node dissection.

In a 2019 Cochrane systematic review of randomized controlled trials, Markkula et al. assessed and compared the efficacy of surgical interventions for the prevention of lymphedema in the arm after breast cancer treatment and to assess and compare to the treatment of existing lymphedema. Two studies involving 95 participants reported on the effectiveness of lymphaticovenular anastomosis for the prevention of breast cancer related lymphedema compared to non- surgical management and showed that LVA appears to result in a reduction in the incidence of lymphedema. Both studies had an unclear risk of bias and did not report secondary outcomes. The overall certainty of the evidence was low. One study involving 36 participants reported on the effectiveness of vascularized lymph node transfer for the treatment of existing lymphedema compared to no treatment, and showed that for participants with stage 2 lymphedema, there were reductions in limb volume, pain scores, heaviness sensation and overall function. Overall, the evidence was very low. The authors concluded that there is currently not enough high-quality evidence to support the widespread adoption of lymphaticovenular anastomosis or vascularized lymph node transfer techniques for the prevention or treatment of lymphedema. Well-designed randomized controlled trials that compare the effectiveness of surgical treatments to each other, and against the current gold standard non-surgical treatments are needed.

A 2019 Hayes health technology assessment, updated in 2021 regarding Microsurgery for Primary Prevention of Breast Cancer Related Lymphedema, evaluated the LYMPHA procedure for efficacy and safety. It was concluded that based on an overall low-quality body of evidence, the LYMPHA procedure appears to have a positive impact on the prevention of lymphedema resulting in a relatively low incidence of transient or persistent lymphedema. There is a reasonable degree of uncertainty with this finding, given the lack of comparative evidence and retrospective nature of many studies. Future research should focus on long-term safety and efficacy of LYMPHA, determination of which patients are most likely to benefit from this preventative microsurgical

approach, experimental study designs that support the earlier trial evidence, the impact of the procedure on additional conventional preventive therapies, patient quality of life, and related adverse events.

Head and Neck Cancer Treatment Related Lymphedema

A 2020 Hayes health technology assessment, updated in 2022, reported on the use of liposuction plus compression therapy for the reductive surgical treatment of lymphedema of moderate-to-severe, nonpitting, primary or secondary lymphedema of the upper and lower extremities (UEL or LEL) in adult patients, as well as adult patients with head and neck cancer treatment–related lymphedema. A very small body of low-quality evidence in patients with head and neck cancer–related lymphedema suggests that liposuction compared with no liposuction does have a positive impact on patient-reported subjective outcomes assessed 6 months after surgery.

Tyker et al. (2019) conducted a systematic review to evaluate all established treatment modalities for lymphedema resulting from head and neck cancer treatment. The authors concluded that the overall poor study quality limited the ability to draw conclusions regarding the benefit of these treatments. All studies had limitations of short follow-up times, lack of blinding and randomization of participants, heterogenous patient populations, and low numbers of participants, and there large multi-center RCTs which directly compare treatment modalities are required.

Clinical Practice Guidelines

American Venous Forum (AVF), American Vein and Lymphatic Society (AVLS) and the Society for Vascular Medicine (SVM)

In 2022, the AVF created a work group to develop a consensus statement regarding current practices on the diagnosis and treatment of lymphedema (Lurie et al.). The criteria for consensus panel participation included publications and presentations on lymphedema, participation with a specialty society, and significant representation of lymphedema patients in the expert's clinical practice. Participants included academic, private and hospital-based practice settings, as well as an international panel of experts. It was acknowledged that there is high variability in lymphedema care among experts in the field. Consensus was reached for the following treatments:

- The regular use of compression garments reduces progression of lymphedema
- Sequential pneumatic compression (SPC) should be recommended
- Manual lymphatic Drainage (MLD) should be a mandatory component of the management of patients with lymphedema

There was no consensus reached regarding surgical treatments.

International Society of Lymphology (ISL)

In a 2020 consensus document on the diagnosis and treatment of peripheral lymphedema, the ISL states the following:

- No treatment has undergone rigorous, randomized, stratified, long-term, controlled studies, and there remains some degree of uncertainty, ambiguity, and flexibility along with dissatisfaction with current lymphedema diagnosis and management.
- In carefully selected patients following full evaluation, microsurgical and supermicrosurgical procedures are an adjunct to CDT or when CDT has clearly been unsuccessful.
- Liposuction, lymphaticovenous anastomosis and lymph node transfer operations coupled with appropriate lymphedema therapy and compression are effective when used to treat properly selected lymphedema patients and performed by an experienced lymphedema surgeon.
- Debulking is mainly for the treatment of the most severe forms of fibrosclerotic lymphedema (elephantiasis) and in cases of advanced genital lymphedema.

National Cancer Institute (NCI)

The NCI Physician Data Query (PDQ) health professional version (2019) on lymphedema as a side effect of cancer treatment states that surgery is rarely performed on patients who have cancer-related lymphedema, and oncology patients are usually not a candidate for these procedures. 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. Furthermore, NCI states that many patients face complications such as skin necrosis, infection, and sensory abnormalities. Other surgical options include the following: Microsurgical lymphaticovenous anastomoses, liposuction, superficial lymphangiectomy, and fasciotomy.

National Lymphedema Network (NLN)

In a 2011 position statement, the NLN states that surgical treatment for lymphedema is associated with significant risks and may result in reduced swelling for an unknown time. CDT usually produces good management in compliant patients, and surgery is rarely a necessary consideration. When it is considered, it should always be done by a specialized surgeon with experience in lymphedema, and in conjunction with CDT. Surgical treatments do not eliminate the need for compression garments and Phase II maintenance.

The 2011 practice guideline states that all patients have pretreatment measurements of both arms. Post treatment measurements should be done on both arms at each visit with symptoms assessment for swelling, heaviness, and/or tightness in the affected arm/arms, and at-risk chest and truncal areas using consistent measurement methods. Circumferential tape measurements are acceptable when made with a flexible, non-elastic Gulick II (or similar) tape measure, and bioelectrical spectroscopy (BIS) or infrared perometry are suggested as alternative or adjunct methods.

National Institute for Health and Care Excellence (NICE)

In a 2022 interventional procedures guidance document, NICE states that the evidence regarding the safety and efficacy of liposuction for chronic lymphedema is adequate and should only be used for patients with lymphedema that has been non-responsive to conventional treatments. Patient selection must be done by a multidisciplinary team that specializes in managing lymphedema and should only be done in specialist centers with training and expertise in this procedure. The procedure is not curative, and effectiveness relies on lifelong wearing of compression garments.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved a number of devices for use for Liposuction. Refer to the following website for more information (use product codes MUU): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 4, 2022)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2022T0636A*]

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Policy History/Revision Information

Date	Summary of Changes
01/01/2023	Supporting Information • Removed *Prior Authorization Requirements* section • Archived previous policy version SURGERY 123.1 T2

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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