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## Medical Policy



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**\*Current Policy Effective Date: 7/1/25**  
(See policy history boxes for previous effective dates)

### **Title: Ex Vivo Lung Perfusion (EVLN)**

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#### **Description/Background**

##### **LUNG TRANSPLANTATION**

Lung transplantation has become the mainstay of therapy for patients suffering from end-stage lung disease refractory to medical management. However, the number of patients listed for lung transplantation largely exceeds the donors available. Currently only 15 to 20% of the lungs that are offered from brain dead donors are used; while 80% of the remaining donor lungs are rejected by the transplant programs primarily due to "poor organ function". This low percentage of transplanted lung is likely due to the potential complications of the lung that might occur before and after donor brain death such as thoracic trauma, aspiration, ventilator associated barotrauma injury, ventilator associated pneumonia, and neurogenic pulmonary edema.<sup>1</sup>

Multiple ways are used to expand the donor pool as extended criteria donors, donation after cardiac death (DCD), and aggressive use of ECMO post-transplantation for marginal lungs, as well as lobar lung transplantations were used for patients with small thoracic volume as well.

Normothermic ex vivo lung perfusion (EVLN), assessment and evaluation of poorly functioning donor lungs may offer a more sensible utilization of potentially acceptable organs which are currently often discarded despite the relatively reversible nature of their imperfections. It appears one objective of the EVLN procedure is to expand the donor organ pool and thus reduce or possibly eliminate mortality and morbidity on the transplant waiting list.

##### **XVIVO PERFUSION SYSTEM (XPS™)**

The XVIVO Perfusion System (XPS™) with STEEN Solution™ Perfusate is indicated for the flushing and temporary continuous warm machine perfusion of initially unacceptable donor

lungs during which time the ex-vivo function of the lungs can be reassessed for transplantation. The STEEN Solution™ used in the XVIVO Perfusion System has been around for about 14 years and has been used in Europe and Canada. The XPS™ system has been used since 2011 and has just been approved under a Humanitarian Device Exemption (HDE) for use in the USA with STEEN Solution™. The system is used to pump STEEN Solution™ through the donated lungs from the time they have been removed from the cold preservation solution, connected to the device and re-warmed until they are cooled down again prior to being implanted. The perfusion solution (i.e., STEEN Solution™) is a combination of proteins, sugar, and soluble salts.

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## **Regulatory Status**

November 15, 2012 XVIVO Perfusion, Inc. received humanitarian device exemption (HDE) application approval from the Food and Drug Administration (FDA) for the XPS™ System with STEEN Solution™ Perfusate. This device is indicated for the flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex-vivo function of the lungs can be reassessed for transplantation. Continual approval of the HDE is contingent upon the submission of periodic reports at intervals of one year from the date of the original HDE approval.<sup>2</sup>

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## **Medical Policy Statement**

Ex vivo lung perfusion (EVLP) is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes.

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## **Inclusionary and Exclusionary Guidelines**

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

### **Established codes:**

N/A

### **Other codes (investigational, not medically necessary, etc.):**

0494T

0495T

0496T

*Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*

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## Rationale

Ex vivo lung perfusion (EVLP) is a novel approach for extended evaluation and/or reconditioning of donor lungs not meeting standard International Society for Heart and Lung Transplantation criteria for transplantation.

Zych et al (2012) retrospectively evaluated 13 consecutive EVLP runs. Lungs rejected for routine transplantation were implanted to the EVLP circuit and reperfused using acellular supplemented Steen Solution (Vitrolife, Göteborg, Sweden) up to a target flow rate of 40% of the donor's calculated flow at a cardiac index of 3.0 liters/min/m<sup>2</sup>; target left atrial pressure < 5 mm Hg; and pulmonary artery pressure <15 mm Hg. Mechanical ventilation was introduced after rewarming to 32°C: tidal volume, 6 to 8 ml/kg; respiratory rate, 7 to 8 breaths/min; duration of inspiration/expiration (I/E) ratio, 1:2; and positive end-expiratory pressure, 5 to 10 cm H<sub>2</sub>O. Hemodynamic and respiratory data monitoring with hourly clinical assessment were performed. Donor data, conversion rate to transplantation, and recipient outcome were analyzed. Donor data (n = 13) were: age, 44.23 ± 8.33 years; female/male, 8:5; cause of death: intracranial hemorrhage, 11 (85%), stroke, 1 (7.5%), hypoxic brain injury, 1 (7.5%); smoking history, 9 (69%), 17.44 ± 8.92 pack-years; mechanical ventilation, 102.6 ± 91.92 hours; chest x-ray imaging: abnormal, 12 (92.5%); normal, 1 (7.5%). EVLP: mean 141 ± 28.83 minutes. Arterial partial pressure of oxygen/fraction of inspired oxygen 100% before termination of the circuit vs. pre-retrieval value: 57.32 ± 9.1 vs. 42.36 ± 14.13 kPa (p <0.05). Six (46%) pairs of donor lungs were transplanted. Median follow-up was 297.5 days (range, 100-390 days), with 100% survival at 3 months. The authors concluded that EVLP may facilitate assessment and/or reconditioning of borderline lungs, with a conversion rate of 46% and good short-term survival.<sup>3</sup>

In an initial clinical experience with ex vivo lung perfusion, Wallinder et al (2012) reviewed early clinical outcomes in patients transplanted with reconditioned lungs. Six pairs of donor lungs deemed unsuitable for transplantation underwent EVLP with Steen solution mixed with red blood cells to a hematocrit of 10% to 15%. After reconditioning, lung function was evaluated, and acceptable lungs were transplanted. Technical experience with EVLP as well as clinical outcome for patients transplanted with EVLP-treated lungs were evaluated. Donor lungs initially rejected either as a result of an inferior partial pressure of arterial oxygen/ fraction of inspired oxygen (n = 5; mean, 20.5 kPa; range, 9.1-29.9 kPa) or infiltrate on chest radiograph (n = 1) improved their oxygenation capacity to a mean partial pressure of arterial oxygen/fraction of inspired oxygen of 57 ± 10 kPa during the EVLP (mean improvement, 33.6 kPa; range, 21-51 kPa; P < .01). During evaluation, hemodynamic (flow, vascular resistance, pressure) and respiratory (peak airway pressure, compliance) parameters were stable. Two single lungs were not used for lung transplantation because of subpleural hematoma or edema. Six recipients from the regular waiting list underwent single (n = 2) or double (n = 4) lung transplantation. One patient had primary graft dysfunction grade 2 at 72 hours. Median time to extubation was 7 hours. All patients survived 30 days and were discharged in good condition from the hospital. The authors concluded that the use of EVLP appears safe and may indicate that some lungs otherwise refused for lung transplantation can be recovered and transplanted with acceptable short-term results.<sup>4</sup>

Also in 2012, Valenza et al, obtained permission from the Ethics Committee to transplant lungs after EVLP reconditioning. ABO compatibility, size match, and donor arterial oxygen pressure ( $\text{PaO}_2$ )/fraction of inspired oxygen ( $\text{FiO}_2$ )  $\leq 300$  mm Hg were considered to be inclusion criteria, whereas the presence of chest trauma and lung contusion, evidence of gastric content aspiration, pneumonia, sepsis, or systemic disease were exclusion criteria. Subjects on an extra corporeal membrane oxygenation (ECMO) bridge to transplantation with rapid functional deterioration were considered as candidates. Using Steen solution with packed red blood cells oxygenated with 21%  $\text{O}_2$ , 5% to 7%  $\text{CO}_2$  was delivered, targeted with a blood flow of approximately 40% predicted cardiac output. Once normothermic, the lungs were ventilated with a tidal volume of 7 mL/kg a PEEP of 5 cm  $\text{H}_2\text{O}$  and a respiratory rate of 7 bpm. Lungs were considered to be suitable for transplantation if well oxygenated [ $\text{P}(\text{v-a}) \text{O}_2 > 350$  mm Hg on  $\text{FiO}_2$  100%], in the absence of deterioration of pulmonary vascular resistance and lung mechanics over the perfusion time. From March to September 2011, six lung transplantations were performed, including two with EVLP. The functional outcomes were similar between groups: at T72 post transplantation, the median  $\text{PaO}_2/\text{FiO}_2$  were 306 mm Hg (range, 282 to 331 mm Hg) and 323 mm Hg (range, 270 to 396 mm Hg) ( $P = 1$ , EVLP versus conventional). Intensive care unit ICU and hospital length of stay were similar ( $P = .533$  and  $P = .663$ , respectively) with no mortality at 60 days in both groups. EVLP donors were older ( $49 \pm 6$  y versus  $21 \pm 7$  y,  $P < .05$ ), less well oxygenated ( $184 \pm 6$  mm Hg versus  $570 \pm 30$ ,  $P < .05$ ), displaying higher Oto scores ( $9.5 \pm 0.7$  versus  $1.7 \pm 1.5$ ,  $P < .05$ ). The first 6 months of the EVLP program allowed for an increase in the number of organs available for transplantation with short-term outcomes comparable to conventional transplantations.<sup>5</sup>

Cypel et al (2012) studied 50 consecutive transplants after EVLP. A retrospective study using prospectively collected data was performed. High risk brain death donor lungs (defined as  $\text{PaO}_2/\text{FiO}_2 < 300$  mm Hg or lungs with radiographic or clinical findings of pulmonary edema) and lungs from cardiac death donors were subjected to 4 to 6 hours of ex vivo lung perfusion. Lungs that achieved stable airway and vascular pressures and  $\text{PaO}_2/\text{FiO}_2$  greater than 400 mm Hg during EVLP were transplanted. The primary end point was the incidence of primary graft dysfunction grade 3 at 72 hours after transplantation. End points were compared with lung transplants not treated with EVLP (controls). A total of 317 lung transplants were performed during the study period (39 months). Fifty-eight EVLP procedures were performed, resulting in 50 transplants (86% use). Of these, 22 were from cardiac death donors and 28 were from brain death donors. The mean donor  $\text{PaO}_2/\text{FiO}_2$  was 334 mm Hg in the ex vivo lung perfusion group and 452 mm Hg in the control group ( $P = .0001$ ). The incidence of primary graft dysfunction grade 3 at 72 hours was 2% in the EVLP group and 8.5% in the control group ( $P = .14$ ). One patient (2%) in the EVLP group and 7 patients (2.7%) in the control group required extracorporeal lung support for primary graft dysfunction ( $P = 1.00$ ). The median time to extubation, intensive care unit stay, and hospital length of stay were 2, 4, and 20 days, respectively, in the EVLP group and 2, 4, and 23 days, respectively, in the control group ( $P > .05$ ). Thirty-day mortality (4% in the EVLP group and 3.5% in the control group,  $P = 1.00$ ) and 1-year survival (87% in the EVLP group and 86% in the control group,  $P = 1.00$ ) were similar in both groups. The authors concluded that transplantation of high-risk donor lungs after 4 to 6 hours of EVLP may be safe, and outcomes are similar to those of conventional transplants.<sup>6</sup>

Beneficial effects of EVLP on physiologic function have been reported, but little is known about the effect of normothermic perfusion on the infectious burden of the donor lung. In 2014, Andreasson et al investigated the effect of EVLP on the microbial load of human donor lungs.<sup>7</sup> Lungs from 18 human donors considered unusable for transplantation underwent EVLP with a

perfusate containing high-dose, empirical, broad-spectrum anti-microbial agents. Quantitative cultures of bacteria and fungi were performed on bronchoalveolar lavage fluid from the donor lung before and after 3 to 6 hours of perfusion. The identification of any organisms and changes in number of colonies forming units before and after EVLP were assessed and anti-microbial susceptibilities identified. Thirteen out of 18 lungs had positive cultures, with bacterial loads significantly decreasing after EVLP. Yeast loads increased when no anti-fungal treatment was given but were reduced when prophylactic anti-fungal treatment was added to the circuit. Six lungs were ultimately transplanted into patients, all of whom survived to hospital discharge. There was 1 death at 11 months. This study shows that EVLP with high-dose, empirical anti-microbial agents in the perfusate may be associated with an effective reduction in the microbial burden of the donor lung, a benefit that has not previously been demonstrated.<sup>7</sup>

Sage et al (2014) reported on lung transplants (LTx) with initially rejected donors after ex vivo lung reconditioning (EVLRL).<sup>8</sup> From April 2011 to May 2013, EVLR was performed for 32 pairs of donor lungs deemed unsuitable for transplantation and rejected by the 11 French lung transplant teams. After EVLR, lungs with acceptable function were transplanted. During the same period, 81 double-lung transplantations (DLTx) were used as controls. During EVLR, 31 of 32 donor lungs recovered physiological function with a median  $Pao_2/Fio_2$  ratio increasing from 274 (range 162-404) mmHg to 511 (378-668) mmHg at the end of EVLR ( $P < 0.0001$ ). Thirty-one DLTx were performed. The incidence of primary graft dysfunction 72 h after LTx was 9.5% in the EVLR group and 8.5% in the control group ( $P = 1$ ). The median time of extubation, intensive care unit and hospital lengths of stay were 1, 9 and 37 days in the EVLR group and 1 ( $P = 0.17$ ), 6 ( $P = 0.06$ ) and 28 days ( $P = 0.09$ ) in the control group, respectively. Thirty-day mortality rates were 3.3% ( $n = 1$ ) in the EVLR group and 3.7% ( $n = 3$ ) in the control group ( $P = 0.69$ ). One-year survival rates were 93% in the EVLR group and 91% in the control group. The authors concluded that EVLR may be a reliable and repeatable technique that offers a significant increase of available donors. The results of LTx with EVLR lungs appear to be similar to those obtained with conventional donors.<sup>8</sup>

In 2014, Wallinder et al reviewed early clinical outcomes in patients transplanted with reconditioned lungs.<sup>9</sup> These clinical outcomes were reviewed and compared with those of contemporary non-EVLP controls. For 18 months starting January 2011, 11 pairs of donor lungs initially deemed unsuitable for transplantation underwent EVLP. Haemodynamic (pulmonary flow, vascular resistance and artery pressure) and respiratory (peak airway pressure and compliance) parameters were analyzed during evaluation. Lungs that improved ( $n = 11$ ) to meet International Society of Heart and Lung Transplantation criteria were transplanted and compared with patients transplanted with non-EVLP lungs ( $n = 47$ ) during the same time period. Donor lungs were initially rejected due to either inferior  $Pao_2/Fio_2$  ratio ( $n = 9$ ), bilateral infiltrate on chest X-ray ( $n = 1$ ) or ongoing extra corporeal membrane oxygenation ( $n = 1$ ). The donor lungs improved from a mean  $Pao_2/Fio_2$  ratio of 27.9 kPa in the donor to a mean of 59.6 kPa at the end of the EVLP (median improvement 28.4 kPa, range 21.0-50.7 kPa). Two single lungs were deemed unsuitable and not used for LTx. Eleven recipients from the regular waiting list underwent either single ( $n = 3$ ) LTx or double ( $n = 8$ ) LTx with EVLP-treated lungs. The median time to extubation (12 (range, 3-912) vs. 6 (range, 2-1296) h) and median intensive care unit (ICU) stay (152 (range, 40-625) vs. 48 (range, 22-1632) h) were longer in the EVLP group ( $P = 0.05$  and  $P = 0.01$ , respectively). There were no differences in length of hospital stay (median 28 (range 25-93) vs. 28 (18-209),  $P = 0.21$ ). Two patients in the EVLP group and 6 in the control group had primary graft dysfunction  $> Grade 1$  at 72 h

postoperatively. Three patients in the control group died before discharge. All recipients of EVLP lungs were discharged alive from hospital. The authors concluded that the use of EVLP seems safe and indicates that lungs otherwise refused for LTx can be recovered and subsequently used for transplantation, although time to extubation and ICU stay were longer for the EVLP group.<sup>9</sup>

Tikkanen et al (2015) conducted a retrospective single-center study included all lung transplants performed between September 2008 and December 2012.<sup>10</sup> The authors investigated whether survival or rate of chronic lung allograft dysfunction (CLAD) differed in recipients of EVLP-treated lungs compared with contemporaneous recipients of conventional donor lungs. They also studied functional (highest forced expiratory volume in 1 second predicted, change in 6-minute walk distance, number of acute rejection episodes) and quality of life outcomes. Of 403 lung transplants that were performed, 63 patients (15.6%) received EVLP-treated allografts. Allograft survival for EVLP and conventional donor lung recipients was 79% vs. 85%, 71% vs. 73%, and 58% vs. 57% at 1, 3, and 5 years after transplant, respectively (log-rank  $p$  = not significant). Freedom from CLAD was also similar (log-rank  $p$  = 0.53). There were no significant differences in functional outcomes such as highest forced expiratory volume in 1 second predicted ( $76.5\% \pm 23.8\%$  vs.  $75.8\% \pm 22.8\%$ ,  $p$  = 0.85), change in 6-minute walk distance ( $194 \pm 108$  meters vs.  $183 \pm 126$  meters,  $p$  = 0.57), or the number of acute rejection episodes ( $1.5 \pm 1.4$  vs.  $1.3 \pm 1.3$ ,  $p$  = 0.36). The EVLP and conventional donor groups both reported a significantly improved quality of life after transplantation, but there was no intergroup difference. Therefore, the authors conclude that EVLP may be a safe and effective method of assessing and using high-risk donor lungs before transplantation and leads to acceptable long-term survival, graft function, and improvements of quality of life that are comparable with conventionally selected donor lungs.<sup>10</sup>

Alboelnazar et al (2017) investigated whether a negative pressure ventilation (NPV) strategy would improve donor lung assessment during EVLP.<sup>11</sup> Thirty-two pig lungs were perfused ex vivo for 12 hours in a normothermic state, and were allocated equally to 4 groups according to the mode of ventilation (positive pressure ventilation [PPV] vs. NPV) and perfusate composition (acellular vs. RBC). The impact of ventilation strategy on the preservation of 6 unutilized human donor lungs was also evaluated. Physiologic parameters, cytokine profiles, lung injury, bullae and edema formation were compared between treatment groups. Perfused lungs demonstrated acceptable oxygenation (partial pressure of arterial oxygen/fraction of inspired oxygen ratio  $>350$  mm Hg) and physiologic parameters. However, there was less generation of pro-inflammatory cytokines (tumor necrosis factor- $\alpha$ , interleukin-6 and interleukin-8) in human and pig lungs perfused, irrespective of perfusate solution used, when comparing NPV with PPV ( $p < 0.05$ ), and a reduction in bullae formation with an NPV modality ( $p = 0.02$ ). Pig lungs developed less edema with NPV ( $p < 0.01$ ), and EVLP using an acellular perfusate solution had greater edema formation, irrespective of ventilation strategy ( $p = 0.01$ ). Interestingly, human lungs perfused with NPV developed negative edema, or "drying" ( $p < 0.01$ ), and lower composite acute lung injury ( $p < 0.01$ ). Utilization of an NPV strategy during extended EVLP is associated with significantly less inflammation, and lung injury, irrespective of perfusate solution composition.<sup>11</sup>

Luc et al (2017) reported on initial experience with the use of portable EVLP with the Organ Care System Lung device for evaluation of DCD lungs.<sup>12</sup> The authors performed a retrospective review of the DCD lung transplantation experience at a single institution through the use of a prospective database. From 2011 to 2015, 208 LTx were performed at the

University of Alberta, of which 11 were DCD LTx with 7 (64%) that underwent portable EVLP. DCD lungs preserved with portable EVLP had a significantly shorter cold ischemic time ( $161 \pm 44$  vs.  $234 \pm 60$  minutes,  $P = .045$ ), lower grade of primary graft dysfunction at 72 hours after LTx ( $0.4 \pm 0.5$  vs.  $2.1 \pm 0.7$ ,  $P = .003$ ), similar mechanical ventilation time ( $55 \pm 44$  vs.  $103 \pm 97$  hours,  $P = .281$ ), and hospital length of stay ( $29 \pm 11$  vs.  $33 \pm 10$  days,  $P = .610$ ). All patients were alive at 1-year follow-up after LTx with improved functional outcomes and acceptable quality of life compared with before LTx, although there were no intergroup differences. In this pilot cohort, portable EVLP appears to be a feasible modality to increase confidence in the use of DCD lungs with validated objective evidence of lung function during EVLP that translates to acceptable clinical outcomes and quality of life after LTx. Further studies are needed to validate these initial findings in a larger cohort.<sup>12</sup>

Luo et al (2019) comparatively analyzed the efficacy of EVLP and standard cold storage in lung transplantation.<sup>13</sup> The hazard ratio (HR), relative risk (RR), and weighted mean difference (WMD) were used as the effect size (ES) to evaluate the survival outcomes, categorical variables, and continuous variables respectively. A total of 20 published articles (including 2574 donors and 2567 recipients) were eligible. The chest x-ray manifestations and  $\text{PaO}_2/\text{FiO}_2$  100% were more deficient in the EVLP group than the standard group. EVLP improved the function of high-risk donor lungs with the conversion rate ranging from 34% to 100%. The EVLP group had a lower incidence of primary graft dysfunction 3, but longer intensive care unit stay. Other clinical outcomes between the 2 groups were similar. According to the authors, the pooled results indicated that EVLP could be used to assess and improve high-risk donor lungs and had non-inferior postoperative outcomes compared with the standard cold storage. EVLP not only increased the utilization of marginal donors but also could extend preservation time and reduce the total ischemia time of donors.

Lyengar et al (2022) questioned the safety strides in conclusively showing noninferiority of EVLP to cold storage in several trials. Recent advances have highlighted potential mechanisms by which EVLP in its current form may reduce the pathogenic origins of primary graft dysfunction.<sup>15</sup> Exciting work on organ reconditioning with EVLP via reduction in intermediaries of acute inflammation and oxidative stress have been performed in animal models. In addition, cross-circulation during EVLP has emerged as a method to achieve more prolonged ex situ storage. The impending translation of these to clinical use will markedly improve the overall value of EVLP. However, logistical hurdles have limited its widespread dissemination.

## **SUMMARY OF EVIDENCE**

The use of EVLP may result in an increase of lung transplants using grafts from marginal donor lung pool. Some studies have shown that the performance of these suboptimal lungs evaluated by EVLP may be similar to those lungs transplanted according to the standard criteria. However there continues to be gaps in knowledge that need to be addressed (e.g., optimal time needed to keep the lungs on EVLP, optimal time to start EVLP, what happens in double lung transplant, etc.). Although early results with EVLP have been encouraging and suggest a potential improvement to the quality of otherwise unacceptable donor lungs, there remains inconsistency with ex vivo lung protocols and the lung reconditioning process. The evidence is insufficient to determine the effects of this technology on health outcomes.

## **ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT05101460	An all-comers registry for normothermic Ex Vivo Lung Perfusion as assessment of donor lungs for transplant	315	Apr 2029
NCT05743751	Normothermic Machine Perfusion (NMP) Versus Hypothermic Machine Perfusion (HMP) in Human Kidney Transplantation	60	Sep 2025
NCT05175885	Ex Vivo Normothermic Perfusion in Kidney Transplantation. (KidneyARK)	100	Dec 2025
<b>Unpublished</b>			
NCT03053349	Ex vivo lung perfusion in Bergamo lung transplant program	10	Dec 2021 (unknown)
NCT01365429	Novel lung trial: normothermic EVLP as an assessment of extended / marginal donor lungs	252	Dec 2020 (unknown)
NCT03293043	The University of Alberta negative pressure ventilation EVLP trial (UA NPV-EVLP)	12	Dec 2020 (completed)
NCT03343535	Trial to evaluate the safety and effectiveness of the Portable Organ Care System (OCS™) lung system for recruiting, preserving and assessing non-ideal donor lungs for transplantation (OCS EXPAND II)	46	Dec 2022 (terminated)
NCT03641677	Increasing lung transplant availability using normothermic EVLP at a dedicated EVLP facility	186	Feb 2023
NCT02235610	Use of EVLP in reconditioning marginal donor lungs for transplantation (EVLP-CHUM)	50	Dec 2024
NCT04521569	Regadenoson infusion of marginalized donor lungs in an EVLP system	46	Aug 2023
NCT04744389	Comparison of Hypothermic Versus Normothermic Ex-vivo Preservation. (DCDNet)	60	Mar 2024
NCT04644744	Hypothermic Oxygenated (HOPE) Versus Normothermic Machine Perfusion (NMP) in Human Liver Transplantation (HOPE-NMP)	213	Dec 2024

NCT: national clinical trial; EVLP: ex vivo lung perfusion

## SUPPLEMENTAL INFORMATION

### PRACTICE GUIDELINES AND POSITION STATEMENTS

#### National Institute for Health and Care Excellence (NICE)

In 2006, NICE published guidelines for Living-donor Lung Transplantation for End-Stage Lung Disease. This guideline does not mention the use of EVLP.

In 2012, NICE had a guideline in development on Lung Transplantation with Ex-Vivo Perfusion. NICE was to monitor the procedure and further publication of literature on this procedure. In August 2016, this guideline was suspended without explanation.

#### The International Society for Heart and Lung Transplantation (ISHLT)

ISHLT does not have a guideline addressing EVLP.



## American Thoracic Society (ATS)

The ATS does not have a guideline addressing EVLP.

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## Government Regulations

### National:

There is no NCD addressing EVLP.

### Local:

LCD (L35490), Category III Codes, effective on or after 01/01/2025.

Codes 0494T-0496T **do not** appear on the list of Category III services determined by WPS GHA to be reasonable and medically necessary.<sup>14</sup>

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

Lung and Lobar Lung Transplantation

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## References

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2025, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/18	4/17/18	4/17/18	Joint policy established
7/1/19	4/16/19		Routine policy maintenance. No change in policy status.
7/1/20	4/14/20		Updated rationale section, added reference #13, routine policy maintenance. No change in policy status.
7/1/21	4/20/21		Routine policy maintenance, no change in policy status.
7/1/22	4/19/22		Routine policy maintenance, no change in policy status.
7/1/23	4/18/23		Updated rationale section, added reference 15, no change in policy status. Vendor managed: N/A. (ds)
7/1/24	4/16/24		Routine policy maintenance updated clinical trials table. No change in status. Vendor managed: N/A (ds)
7/1/25	4/15/25		Routine policy maintenance, no change in status. Vendor managed: N/A (ds)

Next Review Date: 2<sup>nd</sup> Qtr. 2026

### Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

**BLUE CARE NETWORK BENEFIT COVERAGE**  
**POLICY: EX VIVO LUNG PERFUSION**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered
<b>BCNA (Medicare Advantage)</b>	See government section
<b>BCN65 (Medicare Complementary)</b>	Not covered

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.