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## Medical Policy

### Extracorporeal Membrane Oxygenation

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#### Related Policies

Inhaled Nitric Oxide as a Treatment of Hypoxic Respiratory Failure in Neonates, #[100](#)

#### Policy

##### **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

ECMO for newborn and children up to 18 years of age may be [MEDICALLY NECESSARY](#).

The use of extracorporeal membrane oxygenation (ECMO) in adults may be considered [MEDICALLY NECESSARY](#) for the management of adults with acute respiratory failure when all of the following criteria are met:

- Respiratory failure is due to a potentially reversible etiology AND
- Respiratory failure is severe, as determined by one of the following:
  - A standardized severity instrument such as the Murray score\*;
  - OR
  - One of the criteria for respiratory failure severity\*\*AND
- None of the following contraindications are present:
  - High ventilator pressure (peak inspiratory pressure >30 cm H<sub>2</sub>O) or high FIO<sub>2</sub> (>80%) ventilation for more than 168 hours;
  - Signs of intracranial bleeding;
  - Multisystem organ failure;
  - Prior (ie, before onset of need for ECMO) diagnosis of a terminal condition with expected survival <6 months;
  - A do-not-resuscitate (DNR) directive;
  - Cardiac decompensation in a patient already declined for ventricular assist device (VAD) or transplant;
  - KNOWN neurologic devastation without potential to recover meaningful function;
  - Determination of care futility\*\*\*.

**\*Murray Score**

One commonly used system for classifying the severity of respiratory failure is the Murray scoring system, which was developed for use in ARDS but has been applied to other indications. This score includes 4 subscales, each of which is scored from 0 to 4. The final score is obtained by dividing the collective score by the number of subscales used. A score of 0 indicates no lung injury; a score of 1 to 2.5 indicates mild or moderate lung injury; and a score of 2.5 indicates severe lung injury, eg, ARDS. Table 2 shows the components of the Murray scoring system.

**Table 2: Murray Lung Injury Score**

Subscale	Criteria	Score
Chest x-ray score	No alveolar consolidation	0
	Alveolar consolidation confined to 1 quadrant	1
	Alveolar consolidation confined to 2 quadrants	2
	Alveolar consolidation confined to 3 quadrants	3
	Alveolar consolidation in all 4 quadrants	4
Hypoxemia score	PaO <sub>2</sub> /FIO <sub>2</sub> >300	0
	PaO <sub>2</sub> /FIO <sub>2</sub> 225-299	1
	PaO <sub>2</sub> /FIO <sub>2</sub> 175-224	2
	PaO <sub>2</sub> /FIO <sub>2</sub> 100-174	3
	PaO <sub>2</sub> /FIO <sub>2</sub> ≤100	4
PEEP score (when ventilated)	PEEP ≤ 5 cm H <sub>2</sub> O	0
	PEEP 6-8 cm H <sub>2</sub> O	1
	PEEP 9-11 cm H <sub>2</sub> O	2
	PEEP 12-14 cm H <sub>2</sub> O	3
	PEEP ≥15 cm H <sub>2</sub> O	4
Respiratory system compliance score (when available)	Compliance >80 mL/cm H <sub>2</sub> O	0
	Compliance 60-79 mL/cm H <sub>2</sub> O	1
	Compliance 40-59 mL/cm H <sub>2</sub> O	2
	Compliance 20-39 mL/cm H <sub>2</sub> O	3
	Compliance ≤19 mL/cm H <sub>2</sub> O	4

CPAP: continuous positive airway pressure; FIO<sub>2</sub>: fraction of inspired oxygen; PaO<sub>2</sub>: partial pressure of oxygen in arterial blood; PEEP: peak end expiratory pressure.

**\*\* Alternative Respiratory Failure Severity Criteria**

Respiratory failure is considered severe if the patient meets one or more of the following criteria:

- Uncompensated hypercapnia with a pH less than 7.2; **or**
- PaO<sub>2</sub>/FIO<sub>2</sub> of <100 mm Hg on fraction of inspired oxygen (FIO<sub>2</sub>) >90%; **or**
- Inability to maintain airway plateau pressure (Pplat) <30 cm H<sub>2</sub>O despite a tidal volume of 4 to 6 mL/kg ideal body weight (IBW); **or**
- Oxygenation Index >30: Oxygenation Index = FIO<sub>2</sub> × 100 × MAP/PaO<sub>2</sub> mm Hg. [FIO<sub>2</sub> x 100 = FIO<sub>2</sub> as percentage; MAP = mean airway pressure in cm H<sub>2</sub>O; PaO<sub>2</sub>=partial pressure of oxygen in arterial blood]; **or**
- CO<sub>2</sub> retention despite high Pplat (>30 cm H<sub>2</sub>O).

**\*\*\* Assessment of ECMO Futility**

Patients undergoing ECMO treatment should be periodically reassessed for clinical improvement. ECMO should not be continued indefinitely if the following criteria are met:

- Neurologic devastation as defined by the following:
  - Consensus from 2 attending physicians that there is no likelihood of an outcome better than “persistent vegetative state” at 6 month, **AND**
  - At least one of the attending physicians is an expert in neurologic disease and/or intensive care medicine, **AND**
  - Determination made following studies including CT, EEG and exam.

**OR**

- Inability to provide aerobic metabolism, defined by the following:
  - Refractory hypotension and/or hypoxemia, **OR**
  - Evidence of profound tissue ischemia based on creatine phosphokinase (CPK) or lactate levels, lactate-to-pyruvate ratio, or near-infrared spectroscopy (NIRS)
- OR**
- Presumed end-stage cardiac or lung failure without “exit” plan (ie, declined for assist device and/or transplantation).

The use of ECMO in adults may be considered **MEDICALLY NECESSARY** as a bridge to heart, lung, or combined heart-lung transplantation for the management of adults with respiratory, cardiac, or combined cardiorespiratory failure refractory to optimal conventional therapy.

The use of ECMO in adult patients is considered **INVESTIGATIONAL** when the above criteria are not met, including but not limited to acute and refractory cardiogenic shock and as an adjunct to cardiopulmonary resuscitation.

NOTE: Extracorporeal membrane oxygenation (ECMO) is considered investigational for most cases of cardiogenic shock. However, in individual clinical situations, ECMO may be considered beneficial/lifesaving for relatively short-term support (ie, days) for cardiogenic shock refractory to standard therapy in specific situations when shock is thought to be due to a potentially reversible condition, such as ST elevation acute myocardial infarction, acute myocarditis, peripartum cardiomyopathy, or acute rejection in a heart transplant, AND when there is reasonable expectation for recovery.

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

## CPT Codes

CPT codes:	Code Description
33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous
33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial
33948	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-venous
33949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial
33951	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)
33952	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)
33953	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age
33954	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older
33955	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age
33956	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older
33957	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)
33958	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)
33959	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age (includes fluoroscopic guidance, when performed)
33962	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)
33963	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age (includes fluoroscopic guidance, when performed)
33964	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed)
33965	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age
33966	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older

33969	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age
33984	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older
33985	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age
33986	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older
33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS

## ICD-10 Procedure Codes

ICD-10-PCS-procedure codes:	Code Description
5A1522F	Extracorporeal Oxygenation, Membrane, Central
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous

## Description

### Extracorporeal Membrane Oxygenation

Extracorporeal membrane oxygenation (ECMO) provides extracorporeal circulation and physiologic gas exchange for temporary cardiorespiratory support in cases of severe respiratory and cardiorespiratory failure. ECMO devices use an extracorporeal circuit, combining a pump and a membrane oxygenator, to undertake oxygenation of and removal of carbon dioxide from the blood.

Developed in the 1970s and widely used, ECMO has proven effective in pediatric patients, particularly neonates suffering with respiratory and cardiopulmonary failure.<sup>1</sup> In adult populations, ECMO had little to no clinical value as an intervention for cardiorespiratory conditions such as severe acute respiratory distress syndrome (ARDS). Early trials correlated its use with higher complication rates due to the anticoagulation required for the ECMO circuit.<sup>2</sup> In addition, Zapol et al (1979), published a randomized controlled trial of ECMO in adults; the results indicate that both the intervention and control group had a 90% mortality rate, representing a 0% survival benefit for patients treated with ECMO.<sup>3</sup>

With improvements in ECMO circuit technology and methods of supportive care, interest in the use of ECMO in adults has renewed. For example, during the 2009-2010 H1N1 influenza pandemic, the occurrence of influenza-related ARDS in relatively young healthy people prompted an interest of ECMO for adults.

ECMO has generally been used in clinical situations of respiratory or cardiac failure, or both. In these situations, death is imminent unless medical interventions immediately reverse the underlying disease process, physiologic functions can be supported until normal reparative processes, treatment can occur (eg, resolution of ARDS, treatment of infection), or other life-saving interventions can be delivered (eg, provision of a lung transplant).

### **Disease-Specific Indications for Extracorporeal Membrane Oxygenation**

Venoarterial (VA) and venovenous (VV) ECMO have been investigated for a wide range of adult conditions that can lead to respiratory or cardiorespiratory failure, some of which overlap clinical categories (eg, H1N1 influenza infection leading to ARDS *and* cardiovascular collapse), which makes categorization difficult. However, in general, indications for ECMO can be categorized as follows: (1) acute respiratory failure due to potentially reversible causes; (2) bridge to lung transplant; (3) acute-onset cardiogenic or obstructive shock; and (4) ECMO-assisted cardiopulmonary resuscitation.

Acute respiratory failure refers to the failure of either oxygenation, removal of carbon dioxide, or both, and may be due to a wide range of causes. ARDS has been defined by consensus in the Berlin definition, which includes criteria for the timing of symptoms, imaging findings, exclusion of other causes, and degree of oxygenation.<sup>2</sup> In ARDS cases, ECMO is most often used as a bridge to recovery. Specific potentially reversible or treatable indications for ECMO may include ARDS, acute pneumonia, and various pulmonary disorders.

Lung transplant is used to manage chronic respiratory failure, most frequently in the setting of advanced chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, emphysema due to  $\alpha_1$ -antitrypsin deficiency, and idiopathic pulmonary arterial hypertension. In the end stages of these diseases, patients may require additional respiratory support while awaiting an appropriate donor. Also, patients who have had a transplant may require retransplantation due to graft dysfunction of the primary transplant.

Acute-onset cardiogenic or obstructive shock is due to cardiac pump failure or vascular obstruction refractory to inotropes and/or other mechanical circulatory support. Examples include postcardiotomy syndrome (ie, failure to wean from bypass), acute coronary syndrome, myocarditis, cardiomyopathy, massive pulmonary embolism, and prolonged arrhythmias.

ECMO-assisted cardiopulmonary resuscitation can be used as an adjunct to cardiopulmonary resuscitation in patients who do not respond to initial resuscitation measures.

### **Technology Description**

The basic components of ECMO include a pump, an oxygenator, sometimes referred to as a "membrane lung," and some form of vascular access. Based on the vascular access type, ECMO can be described as VV or VA. VA ECMO has the potential to provide cardiac and ventilatory support.

### **Venovenous Extracorporeal Membrane Oxygenation**

#### **Technique**

In VV ECMO, the ECMO oxygenator is in series with the native lungs, and the ECMO circuit provides respiratory support. Venous blood is withdrawn through a large-bore intravenous line, oxygen is added, and CO<sub>2</sub> removed, and oxygenated blood is returned to the venous circulation near the right atrium. Venous access for VV ECMO can be configured through two single lumen catheters (typically in the right internal jugular and femoral veins), or through one dual-lumen catheter in the right internal jugular vein. In the femorojugular approach, a single large multiperforated drainage cannula is inserted in the femoral vein and advanced to the cavo-atrial junction, and the return cannula is inserted into the superior vena cava via the right internal jugular vein. Alternatively, in the bi-femoral-jugular approach, drainage cannulae are placed in the superior vena cava and the inferior vena cava via the jugular and femoral veins, and a femoral return cannula is advanced to the right atrium. In the dual-lumen catheter approach, a single bicaval cannula is inserted via the right jugular vein and positioned to allow drainage from the inferior vena cava and superior vena cava and return via the right atrium.

#### **Indications**

VV ECMO provides only respiratory support and therefore is used for conditions in which there is a progressive loss in the ability to provide adequate gas exchange due to abnormalities in the lung parenchyma, airways, or chest wall. Right ventricular dysfunction due to pulmonary hypertension secondary to parenchymal lung disease can sometimes be effectively treated by VV ECMO. However,

acute or chronic obstruction of the pulmonary vasculature (eg, saddle pulmonary embolism) might require VA ECMO as might cases in which right ventricular dysfunction due to pulmonary hypertension caused by severe parenchymal lung disease is severe enough. In adults, VV ECMO is generally used when all other reasonable avenues of respiratory support have been exhausted, including mechanical ventilation with lung protective strategies, pharmacologic therapy, and prone positioning.

## **Venoarterial Extracorporeal Membrane Oxygenation**

### **Technique**

In VA ECMO, the ECMO oxygenator operates in parallel with the native lungs, and the ECMO circuit provides both cardiac and respiratory support. In VA ECMO, venous blood is withdrawn, oxygen is added, and CO<sub>2</sub> removed similar to VV ECMO, but blood is returned to the arterial circulation. Cannulation for VA ECMO can be done peripherally, with the withdrawal of blood from a cannula in the femoral or internal jugular vein and the return of blood through a cannula in the femoral or subclavian artery. Alternatively, it can be done centrally, with the withdrawal of blood directly from a cannula in the right atrium and return of blood through a cannula in the aorta. VA ECMO typically requires a high blood flow extracorporeal circuit.

### **Indications**

VA ECMO provides both cardiac and respiratory support. Thus, it is used in situations of significant cardiac dysfunction refractory to other therapies, when significant respiratory involvement is suspected or demonstrated, such as treatment-resistant cardiogenic shock, pulmonary embolism, or primary parenchymal lung disease severe enough to compromise right heart function. Echocardiography should be used before ECMO is considered or started to identify severe left ventricular dysfunction that might necessitate the use of VA ECMO. The use of peripheral VA ECMO in the presence of adequate cardiac function may cause severe hypoxia in the upper part of the body (brain and heart) in the setting of a severe pulmonary shunt.<sup>4</sup>

### **Extracorporeal Carbon Dioxide Removal**

Also, to complete ECMO systems, there are ventilation support devices that provide oxygenation and remove CO<sub>2</sub> without the use of a pump system or interventional lung assist devices (eg, iLA® Membrane Ventilator; Novalung GmbH). At present, none of these systems has U.S. Food and Drug Administration (FDA) approval for use in the U. S. These technologies are not the focus of this evidence review but are briefly described because there is overlap in patient populations treated with extracorporeal carbon dioxide removal and those treated with ECMO, and some studies have reported on both technologies.

Unlike VA and VV ECMO, which use large-bore catheters and generally high-flow through the ECMO circuits, other systems use pumpless systems to remove CO<sub>2</sub>. These pumpless devices achieve extracorporeal carbon dioxide removal via a thin double-lumen central venous catheter and relatively low extracorporeal blood flow. They have been investigated as a means to allow low tidal volume ventilator strategies, which may have benefit in ARDS and other conditions where lung compliance is affected. Although ECMO systems can affect CO<sub>2</sub> removal, dedicated extracorporeal carbon dioxide systems are differentiated by simpler mechanics and by no need for dedicated staff.<sup>5</sup>

### **Medical Management During Extracorporeal Membrane Oxygenation**

During ECMO, patients require supportive care and treatment for their underlying medical condition, including ventilator management, fluid management, and systemic anticoagulation to prevent circuit clotting, nutritional management, and appropriate antimicrobials. Maintenance of the ECMO circuit requires frequent monitoring by medical and nursing staff and evaluation at least once per 24 hours by a perfusion expert.

ECMO may be associated with significant complications, which can be related to the vascular access needed for systemic anticoagulation, including hemorrhage, limb ischemia, compartment syndrome, cannula thrombosis, and limb amputation. Patients are also at risk of progression of their underlying disease.

## Summary

Extracorporeal membrane oxygenation (ECMO) provides extracorporeal circulation and physiologic gas exchange for temporary cardiorespiratory support in cases of severe respiratory and cardiorespiratory failure. ECMO has generally been used in clinical situations in which there is respiratory or cardiac failure, or both, in which death would be imminent unless medical interventions can immediately reverse the underlying disease process, or physiologic functions can be supported long enough that normal reparative processes or treatment can occur (eg, resolution of acute respiratory distress syndrome, treatment of infection) or other life-saving intervention can be delivered (eg, provision of a lung transplant). Potential indications for ECMO in the adults include acute, potentially reversible respiratory failure due to a variety of causes; as a bridge to lung transplant; in potentially reversible cardiogenic shock; and as an adjunct to cardiopulmonary resuscitation (ECMO-assisted cardiopulmonary resuscitation [ECPR]).

For individuals who are adults with acute respiratory failure who receive ECMO, the evidence includes RCTs, systematic reviews, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival (OS), change in disease status, morbid events, and treatment-related mortality and morbidity. The most direct evidence on the efficacy of ECMO in adult respiratory failure comes from the CESAR trial. Although this trial had limitations, including nonstandardized management of the control group and unequal intensity of treatment between treatment and control groups, for the trial's primary outcome (disability-free survival at 6 months), there was a large effect size, with an absolute risk reduction in mortality of 16.25%. Recent nonrandomized comparative studies have generally reported improvements in outcomes with ECMO. The available evidence supports the conclusion that outcomes are improved for adults with acute respiratory failure, particularly those who meet the patient selection criteria outlined in the CESAR trial. However, questions remain about the generalizability of findings to other patient populations, and additional clinical trials in more specific patient populations are needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adult lung transplant candidates who receive ECMO as a bridge to lung transplantation, the evidence includes two large nonrandomized comparator studies and small case series. Relevant outcomes are OS, change in disease status, morbid events, and treatment-related mortality and morbidity. One of the large comparator studies found that patients receiving ECMO had three-year survival rates similar to patients receiving no support and significantly better survival rates than patients receiving invasive mechanical support. Single-arm series have reported rates of the successful bridge to transplant on the order of 70% to 80%. Given the lack of other treatment options for this population and the suggestive clinical evidence ECMO may be an appropriate therapy for this patient population. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with acute cardiac failure who receive ECMO, the evidence includes meta-analyses, observational studies, case series, and case reports. Relevant outcomes are OS, change in disease status, morbid events, and treatment-related mortality and morbidity. Case series in patients with postcardiotomy failure to wean off bypass have reported rates of successful decannulation from ECMO on the order of 60%. Case series in populations affected by other causes of acute cardiac failure have reported rates of survival to discharge of 40% to 60%. Complication rates are high. Evidence comparing ECMO with other medical therapy options is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults in cardiac arrest who receive ECMO with cardiopulmonary resuscitation (ECPR), the evidence includes meta-analyses of nonrandomized comparative studies and case series. Relevant outcomes are OS, change in disease status, morbid events, and treatment-related mortality and morbidity. A meta-analysis of non-randomized comparative studies found an increased odd of survival and odds of remaining neurologically intact with ECPR. However, the benefit associated with using ECPR is uncertain given the potential for bias in nonrandomized studies. Additionally, factors related to the implementation of ECPR procedures in practice need better delineation. Multiple unanswered questions remain about the role of ECPR in refractory cardiac arrest, including appropriate patient populations,



duration of conventional CPR, and assessment of futility. Studies have begun to address these questions, with results indicating that patients with an initial shockable cardiac rhythm, shorter low-flow duration, higher arterial pH, and lower serum lactate concentrations on hospital admission experienced favorable outcomes. Further study is needed to evaluate efficacy and define the population that may benefit from this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2015 supported the use of ECMO in adult lung transplant candidates as a bridge to pulmonary transplant. Given the lack of other treatment options for this population, the suggestive clinical evidence, and the support from clinical input, ECMO may be considered medically necessary for this patient population.

## Policy History

Date	Action
7/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	Clarified coding information.
6/2018	New references added from BCBSA National medical policy. Background and summary clarified.
6/2017	New references added from BCBSA National medical policy.
7/2016	New references added from BCBSA National medical policy.
6/2015	New medical policy describing medically necessary and investigational indications. Effective 6/1/2015.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Maslach-Hubbard A, Bratton SL. Extracorporeal membrane oxygenation for pediatric respiratory failure: History, development and current status. *World J Crit Care Med.* Nov 04 2013; 2(4): 29-39. PMID 24701414
2. Morris AH, Wallace CJ, Menlove RL, et al. Randomized clinical trial of pressure-controlled inverse ratio ventilation and extracorporeal CO<sub>2</sub> removal for adult respiratory distress syndrome. *Am J Respir Crit Care Med.* Feb 1994; 149(2 Pt 1): 295-305. PMID 8306022
3. Zapol WM, Snider MT, Hill JD, et al. Extracorporeal membrane oxygenation in severe acute respiratory failure. A randomized prospective study. *JAMA.* Nov 16 1979; 242(20): 2193-6. PMID 490805
4. Combes A, Bacchetta M, Brodie D, et al. Extracorporeal membrane oxygenation for respiratory failure in adults. *Curr Opin Crit Care.* Feb 2012; 18(1): 99-104. PMID 22186218
5. Morimont P, Batchinsky A, Lambermont B. Update on the role of extracorporeal CO removal as an adjunct to mechanical ventilation in ARDS. *Crit Care.* Mar 16 2015; 19: 117. PMID 25888428
6. U.S. Food and Drug Administration. Enforcement policy for extracorporeal membrane oxygenation and cardiopulmonary bypass devices during the coronavirus disease 2019 (COVID-19) public health emergency. Guidance for industry and Food and Drug Administration Staff. April 2020. <https://www.fda.gov/media/136734/download>. Accessed April 27, 2020.
7. U.S. Food and Drug Administration. Anesthesiology Devices; Reclassification of Membrane Lung for Long-Term Pulmonary Support; Redesignation as Extracorporeal Circuit and Accessories for Long-Term Respiratory/Cardiopulmonary Failure. 2016;

<https://www.federalregister.gov/documents/2016/02/12/2016-02876/anesthesiology-devices-reclassification-of-membrane-lung-for-long-term-pulmonary-support>. Accessed April 27, 2020.

8. Tramm R, Ilic D, Davies AR, et al. Extracorporeal membrane oxygenation for critically ill adults. *Cochrane Database Syst Rev*. Jan 22 2015; 1: CD010381. PMID 25608845
9. Peek GJ, Mugford M, Tiruvoipati R, et al. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial. *Lancet*. Oct 17 2009; 374(9698): 1351-63. PMID 19762075
10. Bein T, Weber-Carstens S, Goldmann A, et al. Lower tidal volume strategy (3 ml/kg) combined with extracorporeal CO<sub>2</sub> removal versus 'conventional' protective ventilation (6 ml/kg) in severe ARDS: the prospective randomized Xtravent-study. *Intensive Care Med*. May 2013; 39(5): 847-56. PMID 23306584
11. Vaquer S, de Haro C, Peruga P, et al. Systematic review and meta-analysis of complications and mortality of veno-venous extracorporeal membrane oxygenation for refractory acute respiratory distress syndrome. *Ann Intensive Care*. Dec 2017; 7(1): 51. PMID 28500585
12. Zampieri FG, Mendes PV, Ranzani OT, et al. Extracorporeal membrane oxygenation for severe respiratory failure in adult patients: a systematic review and meta-analysis of current evidence. *J Crit Care*. Dec 2013; 28(6): 998-1005. PMID 23954453
13. Noah MA, Peek GJ, Finney SJ, et al. Referral to an extracorporeal membrane oxygenation center and mortality among patients with severe 2009 influenza A(H1N1). *JAMA*. Oct 19 2011; 306(15): 1659-68. PMID 21976615
14. Pham T, Combes A, Roze H, et al. Extracorporeal membrane oxygenation for pandemic influenza A(H1N1)-induced acute respiratory distress syndrome: a cohort study and propensity-matched analysis. *Am J Respir Crit Care Med*. Feb 01 2013; 187(3): 276-85. PMID 23155145
15. Zangrillo A, Biondi-Zoccai G, Landoni G, et al. Extracorporeal membrane oxygenation (ECMO) in patients with H1N1 influenza infection: a systematic review and meta-analysis including 8 studies and 266 patients receiving ECMO. *Crit Care*. Feb 13 2013; 17(1): R30. PMID 23406535
16. Combes A, Hajage D, Capellier G, et al. Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Distress Syndrome. *N Engl J Med*. May 24 2018; 378(21): 1965-1975. PMID 29791822
17. Roch A, Lepaul-Ercole R, Grisoli D, et al. Extracorporeal membrane oxygenation for severe influenza A (H1N1) acute respiratory distress syndrome: a prospective observational comparative study. *Intensive Care Med*. Nov 2010; 36(11): 1899-905. PMID 20721530
18. Davies A, Jones D, Bailey M, et al. Extracorporeal Membrane Oxygenation for 2009 Influenza A(H1N1) Acute Respiratory Distress Syndrome. *JAMA*. Nov 04 2009; 302(17): 1888-95. PMID 19822628
19. Guirand DM, Okoye OT, Schmidt BS, et al. Venovenous extracorporeal life support improves survival in adult trauma patients with acute hypoxemic respiratory failure: a multicenter retrospective cohort study. *J Trauma Acute Care Surg*. May 2014; 76(5): 1275-81. PMID 24747460
20. Schechter MA, Ganapathi AM, Englum BR, et al. Spontaneously Breathing Extracorporeal Membrane Oxygenation Support Provides the Optimal Bridge to Lung Transplantation. *Transplantation*. Dec 2016; 100(12): 2699-2704. PMID 26910331
21. Hayes D, Higgins RS, Kilic A, et al. Extracorporeal membrane oxygenation and retransplantation in lung transplantation: an analysis of the UNOS registry. *Lung*. Aug 2014; 192(4): 571-6. PMID 24816903
22. Nosotti M, Rosso L, Tosi D, et al. Extracorporeal membrane oxygenation with spontaneous breathing as a bridge to lung transplantation. *Interact Cardiovasc Thorac Surg*. Jan 2013; 16(1): 55-9. PMID 23097371
23. Rehder KJ, Turner DA, Hartwig MG, et al. Active rehabilitation during extracorporeal membrane oxygenation as a bridge to lung transplantation. *Respir Care*. Aug 2013; 58(8): 1291-8. PMID 23232742
24. Inci I, Klinzing S, Schneider D, et al. Outcome of Extracorporeal Membrane Oxygenation as a Bridge To Lung Transplantation: An Institutional Experience and Literature Review. *Transplantation*. Aug 2015; 99(8): 1667-71. PMID 26308302
25. Hoopes CW, Kukreja J, Golden J, et al. Extracorporeal membrane oxygenation as a bridge to pulmonary transplantation. *J Thorac Cardiovasc Surg*. Mar 2013; 145(3): 862-7; discussion 867-8. PMID 23312979

26. Lafarge M, Mordant P, Thabut G, et al. Experience of extracorporeal membrane oxygenation as a bridge to lung transplantation in France. *J Heart Lung Transplant*. Sep 2013; 32(9): 905-13. PMID 23953818
27. Wang L, Wang H, Hou X. Clinical Outcomes of Adult Patients Who Receive Extracorporeal Membrane Oxygenation for Postcardiotomy Cardiogenic Shock: A Systematic Review and Meta-Analysis. *J Cardiothorac Vasc Anesth*. Oct 2018; 32(5): 2087-2093. PMID 29678433
28. Rastan AJ, Dege A, Mohr M, et al. Early and late outcomes of 517 consecutive adult patients treated with extracorporeal membrane oxygenation for refractory postcardiotomy cardiogenic shock. *J Thorac Cardiovasc Surg*. Feb 2010; 139(2): 302-11, 311.e1. PMID 20106393
29. Slottosch I, Liakopoulos O, Kuhn E, et al. Outcomes after peripheral extracorporeal membrane oxygenation therapy for postcardiotomy cardiogenic shock: a single-center experience. *J Surg Res*. May 2013; 181(2): e47-55. PMID 22878151
30. Bakhtiary F, Keller H, Dogan S, et al. Venoarterial extracorporeal membrane oxygenation for treatment of cardiogenic shock: clinical experiences in 45 adult patients. *J Thorac Cardiovasc Surg*. Feb 2008; 135(2): 382-8. PMID 18242273
31. Xie A, Phan K, Tsai YC, et al. Venoarterial extracorporeal membrane oxygenation for cardiogenic shock and cardiac arrest: a meta-analysis. *J Cardiothorac Vasc Anesth*. 2015; 29(3): 637-45. PMID 25543217
32. Dobrilovic N, Lateef O, Michalak L, et al. Extracorporeal Membrane Oxygenation Bridges Inoperable Patients to Definitive Cardiac Operation. *ASAIO J*. Jan 2019; 65(1): 43-48. PMID 29240627
33. Aso S, Matsui H, Fushimi K, et al. In-hospital mortality and successful weaning from venoarterial extracorporeal membrane oxygenation: analysis of 5,263 patients using a national inpatient database in Japan. *Crit Care*. Apr 05 2016; 20: 80. PMID 27044572
34. Diddle JW, Almodovar MC, Rajagopal SK, et al. Extracorporeal membrane oxygenation for the support of adults with acute myocarditis. *Crit Care Med*. May 2015; 43(5): 1016-25. PMID 25738858
35. Lorusso R, Centofanti P, Gelsomino S, et al. Venoarterial Extracorporeal Membrane Oxygenation for Acute Fulminant Myocarditis in Adult Patients: A 5-Year Multi-Institutional Experience. *Ann Thorac Surg*. Mar 2016; 101(3): 919-26. PMID 26518372
36. Debaty G, Babaz V, Durand M, et al. Prognostic factors for extracorporeal cardiopulmonary resuscitation recipients following out-of-hospital refractory cardiac arrest. A systematic review and meta-analysis. *Resuscitation*. Mar 2017; 112: 1-10. PMID 28007504
37. Twhig CJ, Singer B, Grier G, et al. A systematic literature review and meta-analysis of the effectiveness of extracorporeal-CPR versus conventional-CPR for adult patients in cardiac arrest. *J Intensive Care Soc*. Nov 2019; 20(4): 347-357. PMID 31695740
38. Link MS, Berkow LC, Kudenchuk PJ, et al. Part 7: Adult Advanced Cardiovascular Life Support: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. Nov 03 2015; 132(18 Suppl 2): S444-64. PMID 26472995
39. Shin TG, Choi JH, Jo IJ, et al. Extracorporeal cardiopulmonary resuscitation in patients with inhospital cardiac arrest: A comparison with conventional cardiopulmonary resuscitation. *Crit Care Med*. Jan 2011; 39(1): 1-7. PMID 21057309
40. Chen YS, Lin JW, Yu HY, et al. Cardiopulmonary resuscitation with assisted extracorporeal life-support versus conventional cardiopulmonary resuscitation in adults with in-hospital cardiac arrest: an observational study and propensity analysis. *Lancet*. Aug 16 2008; 372(9638): 554-61. PMID 18603291
41. Gray BW, Haft JW, Hirsch JC, et al. Extracorporeal life support: experience with 2,000 patients. *ASAIO J*. Jan-Feb 2015; 61(1): 2-7. PMID 25251585
42. Guttendorf J, Boujoukos AJ, Ren D, et al. Discharge outcome in adults treated with extracorporeal membrane oxygenation. *Am J Crit Care*. Sep 2014; 23(5): 365-77. PMID 25179031
43. Omar HR, Mirsaeidi M, Shumac J, et al. Incidence and predictors of ischemic cerebrovascular stroke among patients on extracorporeal membrane oxygenation support. *J Crit Care*. Apr 2016; 32: 48-51. PMID 26705764
44. Aubron C, Cheng AC, Pilcher D, et al. Factors associated with outcomes of patients on extracorporeal membrane oxygenation support: a 5-year cohort study. *Crit Care*. Apr 18 2013; 17(2): R73. PMID 23594433

45. Combes A, Brodie D, Bartlett R, et al. Position paper for the organization of extracorporeal membrane oxygenation programs for acute respiratory failure in adult patients. *Am J Respir Crit Care Med*. Sep 01 2014; 190(5): 488-96. PMID 25062496
46. National Institute for Health and Care Excellence (NICE). Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults [IPG482]. 2014; <https://www.nice.org.uk/Guidance/ipg482>. Accessed April 28, 2020.
47. National Institute for Health and Care Excellence (NICE). Extracorporeal membrane oxygenation for severe acute respiratory failure in adults [IPG391]. 2011; <https://www.nice.org.uk/guidance/IPG391/chapter/1-guidance>. Accessed April 28, 2020.