Medical Policy
Extracorporeal Membrane Oxygenation

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Information Pertaining to All Policies
- Policy History
- References

Policy Number: 726
BCBSA Reference Number: 8.01.60
NCD/LCD: N/A

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 BlueSM and Medicare PPO BlueSM 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 H2O) or high FIO2 (>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

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest x-ray score</td>
<td>No alveolar consolidation</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Alveolar consolidation confined to 1 quadrant</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Alveolar consolidation confined to 2 quadrants</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Alveolar consolidation confined to 3 quadrants</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Alveolar consolidation in all 4 quadrants</td>
<td>4</td>
</tr>
<tr>
<td>Hypoxemia score</td>
<td>PaO2/FIO2 &gt;300</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PaO2/FIO2 225-299</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PaO2/FIO2 175-224</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>PaO2/FIO2 100-174</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>PaO2/FIO2 ≤100</td>
<td>4</td>
</tr>
<tr>
<td>PEEP score (when ventilated)</td>
<td>PEEP ≤ 5 cm H2O</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>PEEP 6-8 cm H2O</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>PEEP 9-11 cm H2O</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>PEEP 12-14 cm H2O</td>
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</tr>
<tr>
<td></td>
<td>PEEP ≥15 cm H2O</td>
<td>4</td>
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<tr>
<td>Respiratory system compliance</td>
<td>Compliance &gt;80 mL/cm H2O</td>
<td>0</td>
</tr>
<tr>
<td>score</td>
<td>Compliance 60-79 mL/cm H2O</td>
<td>1</td>
</tr>
<tr>
<td>(when available)</td>
<td>Compliance 40-59 mL/cm H2O</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Compliance 20-39 mL/cm H2O</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Compliance ≤19 mL/cm H2O</td>
<td>4</td>
</tr>
</tbody>
</table>

CPAP: continuous positive airway pressure; FIO2: fraction of inspired oxygen; PaO2: 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
- PaO2/FIO2 of <100 mm Hg on fraction of inspired oxygen (FIO2) >90%; or
- Inability to maintain airway plateau pressure (Pplat) <30 cm H2O despite a tidal volume of 4 to 6 mL/kg ideal body weight (IBW); or
- Oxygenation Index >30: Oxygenation Index = FIO2 x 100 MAP/PaO2 mm Hg. [FIO2 x 100 = FIO2 as percentage; MAP = mean airway pressure in cm H2O; PaO2=partial pressure of oxygen in arterial blood]; or
- CO2 retention despite high Pplat (>30 cm H2O).

***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:
  o Refractory hypotension and/or hypoxemia, OR
  o 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.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>Prior authorization is required.</td>
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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:
<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33946</td>
<td>Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous</td>
</tr>
<tr>
<td>33947</td>
<td>Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial</td>
</tr>
<tr>
<td>33948</td>
<td>Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-venous</td>
</tr>
<tr>
<td>33949</td>
<td>Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial</td>
</tr>
<tr>
<td>33951</td>
<td>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)</td>
</tr>
<tr>
<td>33952</td>
<td>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)</td>
</tr>
<tr>
<td>33953</td>
<td>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</td>
</tr>
<tr>
<td>33954</td>
<td>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</td>
</tr>
<tr>
<td>33955</td>
<td>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</td>
</tr>
<tr>
<td>33956</td>
<td>Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older</td>
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<td>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)</td>
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<tr>
<td>33958</td>
<td>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)</td>
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<tr>
<td>33959</td>
<td>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)</td>
</tr>
<tr>
<td>33962</td>
<td>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)</td>
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<td>33963</td>
<td>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)</td>
</tr>
<tr>
<td>33964</td>
<td>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)</td>
</tr>
<tr>
<td>33965</td>
<td>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</td>
</tr>
<tr>
<td>33966</td>
<td>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</td>
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</tbody>
</table>
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

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

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

Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older

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)

Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS

Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS

ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS-procedure codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5A1522F</td>
<td>Extracorporeal Oxygenation, Membrane, Central</td>
</tr>
<tr>
<td>5A1522G</td>
<td>Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial</td>
</tr>
<tr>
<td>5A1522H</td>
<td>Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous</td>
</tr>
</tbody>
</table>

Description

Extracorporeal Membrane Oxygenation

ECMO provides extracorporeal circulation and physiologic gas exchange for temporary cardiopulmonary 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. In adult populations, ECMO had little to no clinical value as an intervention for cardiopulmonary 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. 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.

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 ECMO
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. 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 ECMO

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 \( \text{CO}_2 \) is 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 femor jugular 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 femor jugular 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 ECMO**

**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 CO₂ 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. ⁴

**Extracorporeal Carbon Dioxide Removal**
Also, to complete ECMO systems, there are ventilation support devices that provide oxygenation and remove CO₂ 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 CO₂. 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 CO₂ removal, dedicated extracorporeal carbon dioxide systems are differentiated by simpler mechanics and by no need for dedicated staff. ⁵

**Medical Management During ECMO**
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.

**Outcome Measures**
Outcomes should include short- and long-term mortality, along with measures of significant morbidity (eg, intracranial hemorrhage, thrombosis, vascular access site hemorrhage, limb ischemia) and short- and long-term disability and quality-of-life measures.

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 randomized controlled trials, systematic reviews, nonrandomized comparative studies, and case series. The 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 conventional ventilatory support vs extracorporeal membrane oxygenation for severe adult respiratory failure 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 conventional ventilatory support vs extracorporeal membrane oxygenation for severe adult respiratory failure 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. The 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.

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.

For individuals who are adults with acute cardiac failure who receive ECMO, the evidence includes meta-analyses, observational studies, case series, and case reports. The relevant outcomes are OS, change in disease status, morbid events, and treatment-related mortality and morbidity. Case series in patients with postcardiomyotomy 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 ECPR, the evidence includes systematic reviews, nonrandomized comparative studies, and case series. The relevant outcomes are OS, change in disease status, morbid events, and treatment-related mortality and morbidity. The meta-analysis addressed which patients would benefit most from ECPR and reported that patients who had initial shockable cardiac rhythms, shorter low-flow duration, higher arterial pH, and lower serum lactate concentrations experienced more favorable outcomes. The most direct evidence comes from an observational study comparing ECPR with standard cardiopulmonary resuscitation, using propensity score matching. It reported higher rates of survival to discharge, with minimal neurologic impairment with ECPR. Other nonrandomized studies have reported better survival in ECPR groups. 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>10/2018</td>
<td>Clarified coding information.</td>
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<tr>
<td>6/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>7/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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</table>

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

6. 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;


