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Subject: Extracorporeal Membrane Oxygenation (ECMO) for Adult Conditions

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DESCRIPTION:

Extracorporeal membrane oxygenation (ECMO) has proven effective and is considered a standard of care in pediatrics, particularly neonates suffering with respiratory and cardiopulmonary failure.

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.

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).

Summary and Analysis of Evidence: Shrestha et al (2022) performed a systematic review and meta-analysis of trials conducted after 2000 comparing ECMO with standard mechanical ventilation. A total of 11 trials (2 RCTs) were included in the meta-analysis. ECMO did not significantly improve in-hospital mortality or hospital length of stay; however, 30-day and 90-day mortality were improved in patients treated with ECMO compared with these managed with standard mechanical ventilation.

Combes et al (2020) performed an individual patient data meta-analysis of the 2 most recent RCTs that compared VV ECMO to standard mechanical ventilation in severe acute respiratory distress syndrome (ARDS). The 2 RCTs included a total of 429 patients. The primary outcome of the meta-analysis was 90-day mortality. Mortality rates at 90 days were 36% in the ECMO group and 48% in the standard mechanical ventilation group (relative risk [RR], 0.75; 95% confidence interval [CI], 0.6 to 0.94; p=.013;

I2=0%). The risk of 90-day treatment failure, defined as death for the ECMO group and death or crossover to ECMO for the mechanical ventilation group, was also lower in the ECMO group.

Vaquer et al (2017) performed a systematic review and meta-analysis analyzing complications and hospital mortality in ARDS patients who underwent VV ECMO. Twelve studies were included that comprised 1042 patients with refractory ARDS. The pooled mortality at hospital discharge was 37.7% (z = -3.73; 95% CI, 31.8% to 44.1%; I2=74.2%; p<.001). This review included some H1N1 influenza A populations. H1N1 influenza A as the underlying cause of ARDS was determined to be an independent moderator of mortality.

Combes et al (2018) reported the findings of a French-sponsored RCT that aimed to assess the efficacy of ECMO in patients with "very severe ARDS," defined by the authors through disease severity criteria outlined in their Supplementary Materials. Efficacy was measured by comparing the 60-day mortality rates of patients randomized to the ECMO treatment group with those of patients randomized to the control group (conventional mechanical ventilation). After the assessment of 1015 patients, 728 were excluded and 38 were not randomized. The 249 patients randomized were distributed into the ECMO group (n=124) and the control group (n=125). At 60 days, 44 patients (35%) in the ECMO group and 57 (46%) in the control group had died. Adverse events included death as a result of surgical intervention (2 patients, 1 per group). Patients in the ECMO group had significantly higher rates of severe thrombocytopenia (27%) versus patients in the control group. While the number randomized at the onset of the study is unchanged for each group during analysis, only 121 of the 124 patients in the ECMO group received the treatment. Furthermore, of the 125 patients randomized to the control group, 35 (28%) required rescue ECMO for refractory hypoxemia, crossing from the control to the ECMO group, at a mean of 6.5±9.7 days post-randomization. One limitation of this study involves the risk of bias due to crossover, such as carryover, period effects, and missing data. Another limitation of this study was the possible confounding factors associated with non-standardized treatment protocols between the 2 groups. The ECMO group underwent percutaneous VV cannulation and received heparin in varying doses to achieve a targeted activated partial thromboplastin time; the control group was not exposed to these variables. In contrast, the control group was exposed to ventilatory treatment, neuromuscular blocking agents, and prone positioning that differed from the comparative group, limiting the generalizability of any findings.

Shaefi et al (2021) published a multicenter retrospective cohort study examining ECMO receipt versus no ECMO receipt within 7 days of ICU admission in mechanically-ventilated patients with severe respiratory failure due to coronavirus disease 2019 (COVID-19). The study used data from the Study of the Treatment and Outcomes in Critically Ill Patients with COVID-19 (STOP-COVID) and performed a target trial emulation that included 130 ECMO-treated patients and 1167 patients who did not receive ECMO. During a median follow-up of 38 days, 45 (34.6%) patients who received ECMO and 553 (47.4%) patients who did not died.

Schechter et al (2016) published a survival analysis comparing types of preoperative support prior to lung transplantation, using data from the United Network for Organ Sharing. Included in the analysis were 12,403 adult lung transplantations from 2005 through 2013: 11,607 (94.6%) did not receive invasive support prior to transplantation, 612 (4.9%) received invasive mechanical ventilation only, 119 (1%) received invasive mechanical ventilation plus ECMO, and 65 (0.5%) received ECMO only. Compared with patients with no invasive support, patients receiving invasive mechanical ventilation with or without ECMO had an increased mortality risk. Patients receiving ECMO alone had mortality rates

comparable to patients receiving no support at 3 years. A limitation of the study relates to its use of registry data, in that complications due to the bridge strategy and certain details (eg, equipment, the technique of ECMO) were not available.

Utilizing a systematic review and meta-analysis of 20 observational studies, Wang et al (2018) investigated the clinical outcomes for adults with postcardiotomy cardiogenic shock (PCCS) who received ECMO. The primary outcome of interest was the rate of survival to hospital discharge for PCCS patients who received ECMO. Secondary outcomes included 1-year and mid-term survival rates (defined as 3 to 5 years), several comorbidities, and select adverse effects, as well as PCCS-related and ECMO-related survival rates. Studies included in the meta-analysis were published from 1996 to 2017 and included a total pooled population of 2877 participants. Regarding the primary outcome (survival rate to discharge), of the total population in all studies (N=2877), 964 (32.85%) patients survived to discharge. The pooled rate of survival to discharge was 34.0% in PCCS patients that underwent ECMO. One limitation of this study is due to the retrospective nature of the analysis, the quality of most of the studies was low.

Xie et al (2015) conducted a meta-analysis evaluating VA ECMO for cardiogenic shock and cardiac arrest that included observational studies and clinical trials with at least 10 adults. Twenty-two studies, all observational, with a total of 1199 patients (12 studies [n=659 patients] with cardiogenic shock; 5 studies [n=277 patients] with cardiac arrest; 5 studies [n=263 patients] with both patient types) met inclusion criteria. Across the 16 studies (n=841 patients) that reported survival to discharge, the weighted average survival was 40.2%. Across the 14 studies that reported 30-day survival, the weighted average survival was 52.8% (95% CI, 43.9% to 61.6%), with similar survival rates at 3, 6, and 12 months across studies that reported those outcomes. Across studies that reported on cardiogenic shock only, the weighted average survival rate to discharge was 42.1%. Across all studies, complications were common, most frequently acute kidney injury, followed by renal dialysis and reoperation for bleeding. However, reviewers expressed uncertainty that the complications were entirely due to ECMO, given the underlying illness in patients who receive ECMO.

Lemor et al (2020) reported a retrospective comparison between ECMO and Impella placement in 6290 patients with cardiogenic shock secondary to acute myocardial infarction. Study data were derived from the National Inpatient Sample, a publicly available database of all-payer hospital inpatient stays developed by the Agency for Healthcare Research and Quality. After propensity score matching (n=450 propensity score-matched patients per treatment), in-hospital mortality was higher among patients who received ECMO. Before propensity score matching, the incidence of acute ischemic stroke was greater in the ECMO group, but this difference was not significant after propensity score matching. Vascular complications were greater in ECMO-treated patients (propensity score-matched cohort.

Yannopoulos et al (2020) reported the results of the Advanced REperfusion STrategies for Refractory Cardiac Arrest (ARREST) trial, a small (N=30) phase 2 adaptive RCT comparing early ECPR to standard ED-based advanced cardiac life support (ACLS) for out-of-hospital cardiac arrest. Patients were randomized to treatment groups upon arrival to the hospital. Patients without pulses who were assigned to standard ACLS were treated for at least 15 minutes after ED arrival or for at least 60 minutes after the 911 call; after that, declaration of death or continuation of CPR was at the discretion of the treating emergency physician. Only 2 patients in the standard ACLS group achieved return of spontaneous circulation in the ED and were admitted to the hospital. In the early ECPR group, 2 patients were declared dead prior to starting ECMO due to severe metabolic derangement and hypoxemia on presentation. The trial was

terminated early after a planned interim analysis showed that the posterior probability of ECMO superiority exceeded the prespecified monitoring boundary. Members of the data safety and monitoring board indicated given that the primary endpoint was survival to hospital discharge, that there were ethical concerns with continuing the trial in the presence of strong evidence for efficacy. Cumulative survival over 6 months was also significantly better with early ECPR than with standard ACLS treatment. No unanticipated serious adverse events occurred during the trial.

Belohlavek et al (2022) conducted an RCT at a single-center in the Czech Republic (the Prague OHCA [out-of-hospital cardiac arrest] study) comparing an early invasive approach including ECPR to a standard ACLS approach in adults experiencing refractory out-of-hospital cardiac arrest (N=264). The trial was terminated early at the recommendations of the data safety and monitoring board because the standardized test statistics for results of the primary end point (survival with minimal or no neurologic impairment at 180 days) intersected a prespecified stopping rule for futility. The authors concluded that an invasive strategy of intra-arrest transport, ECPR, and invasive assessment and treatment did not significantly improve survival with neurologically favorable outcomes at 180 days as compared to standard resuscitation. The authors reanalyzed the data of the Prague OHCA trial dividing all participants into 3 cohorts: those who achieved prehospital spontaneous circulation (n=83), those who did not achieve prehospital spontaneous circulation and received conventional CPR (n=81), and those who did not achieve prehospital spontaneous circulation and received ECPR (n=92). The overall 180-day survival was longest in patients who achieved spontaneous circulation (61.5%) and lower in those who did not achieve spontaneous circulation (1.2% in patients with CPR and 23.9% in patients with ECPR). ECPR was associated with a lower risk of 180-day death.

A 2021 Extracorporeal Life Support Organization (ELSO) Guideline for Adult Respiratory Failure Managed with Venovenous ECMO (VV ECMO) states that common indications for adult venovenous ECMO include one or more of the following: 1) hypoxemic respiratory failure, after optimal medical management, including, in the absence of contraindications, a trial of prone positioning; 2) hypercapnic respiratory failure, despite optimal conventional mechanical ventilation; and 3) ventilatory support as a bridge to lung transplantation or primary graft dysfunction following lung transplant. Specific clinical condition indications for ECMO include: acute respiratory distress syndrome (e.g., viral/bacterial pneumonia and aspiration); acute eosinophilic pneumonia; diffuse alveolar hemorrhage or pulmonary hemorrhage; severe asthma; thoracic trauma (e.g., traumatic lung injury and severe pulmonary contusion); severe inhalational injury; large bronchopleural fistula; and peri-lung transplant (e.g., primary lung graft dysfunction and bridge to transplant). A 2021 ELSO Interim Guidelines for Venoarterial Extracorporeal Membrane Oxygenation (VA ECMO) in Adult Cardiac Patients states, “Cardiogenic shock suitable for ECMO is generally characterized by systemic systolic pressure less than 90, urine output < 30 ml/hour, lactate over 2, SVO2 less than 60%, altered conscious state for 6 hours unresponsive to optimal treatment. The goal is to maintain systemic oxygen delivery at least 3 times oxygen consumption (the DO2:VO2 ratio is >3) (normal is 5, shock is 2): O2 delivery is arterial oxygen content (normal 20 ml/dl) times cardiac output (normal 30 dl/m2/min). In VA ECMO access, addressing the goal is easy because the cardiac output is the ECMO flow and the arterial hemoglobin saturation is 100%, so content is easily calculated, knowing the hemoglobin concentration (normal 15 g/dl). In VA ECMO, the drainage blood saturation (the SVO2) measures the DO2:VO2 ratio, and SVO2 is measured continuously. If the arterial saturation is 100% and the venous sat is 80%, the ratio is 5:1. So, adjusting flow and hemoglobin to maintain SVO2 over 66% assures that the goal of DO2/VO2 > 3 is met.” ELSO published a disclaimer for

their VA ECMO guideline, stating, “This guideline for venoarterial extracorporeal membrane oxygenation in adult cardiac patients is intended for educational use to build the knowledge of physicians and other health professionals in assessing the conditions and managing the treatment of patients undergoing ECLS / ECMO and describe what are believed to be useful and safe practice for extracorporeal life support (ECLS, ECMO) but these are not necessarily consensus recommendations.”

POSITION STATEMENT:

The use of extracorporeal membrane oxygenation (ECMO) in adults **meets the definition of medical necessity** for the management of acute respiratory failure when **ALL** of the following criteria are met:

- Age 18 or older
- Respiratory failure is due to a potentially reversible etiology[1]
- Respiratory failure is severe, as determined by the Murray score* or other respiratory failure severity criteria**

AND

NONE of the following contraindications are present:

- High ventilator pressure (peak inspiratory pressure >30 cm H2O) or high fraction of inspired oxygen (>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 less than 6 months
- A do-not-resuscitate directive
- Cardiac decompensation in a person who has already been declined for ventricular assist device or transplant
- Known neurologic devastation without potential to recover meaningful function
- Determination of care futility***

[1]The reversibility of the underlying respiratory failure is best determined by the treating physicians, ideally physicians with expertise in pulmonary medicine and/or critical care. Some underlying causes of respiratory failure, which are commonly considered reversible, are:

- Acute respiratory distress syndrome (ARDS)
- Acute pulmonary edema
- Acute chest trauma
- Infectious and noninfectious pneumonia
- Pulmonary hemorrhage
- Pulmonary embolism

- Asthma exacerbation
- Aspiration pneumonitis

The use of ECMO in adults **meets the definition of medical necessity** as a bridge to heart, lung, or combined heart-lung transplantation for the management of respiratory, cardiac, or combined cardiorespiratory failure refractory to optimal conventional therapy.

The use of ECMO in adults for management of cardiogenic shock refractory to standard therapy **meets the definition of medical necessity** when both of the following are met:

- When shock is thought to be due to a potentially reversible condition (e.g., ST elevation acute myocardial infarction, acute myocarditis, peripartum cardiomyopathy, or acute rejection in a heart transplant)
- There is reasonable expectation for recovery

The use of ECMO in adults is considered **experimental or investigational** when the above criteria are not met, including as an adjunct to cardiopulmonary resuscitation (ECPR).

BILLING/CODING INFORMATION:

CPT Coding:

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
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)
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
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
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)
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)

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)
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
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
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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

*Murray Lung Injury Score

Scale	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	PaO2/FIO2 >300 mm Hg	0
	PaO2/FIO2 225-299 mm Hg	1
	PaO2/FIO2 175-224 mm Hg	2
	PaO2/FIO2 100-174 mm Hg	3
	PaO2/FIO2 ≤100 mm Hg	4
PEEP score (when ventilated)	PEEP ≤ 5 cm H2O	0
	PEEP 6-8 cm H2O	1
	PEEP 9-11 cm H2O	2
	PEEP 12-14 cm H2O	3
	PEEP ≥15 cm H2O	4
Respiratory system compliance score (when available)	Compliance >80 mL/cm H2O	0
	Compliance 60-79 mL/cm H2O	1
	Compliance 40-59 mL/cm H2O	2
	Compliance 20-39 mL/cm H2O	3
	Compliance ≤19 mL/cm H2O	4

****Other Respiratory Failure Severity Criteria**

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

- Uncompensated hypercapnia with a pH less than 7.2, or
- Partial pressure of oxygen in arterial blood (Pao2)/fraction of inspired oxygen (Fio2) of <100 mmHg on Fio2 >90%, or
- Inability to maintain airway plateau pressure (Pplat) <30 cm H2O despite a tidal volume of 4 to 6mL/kg ideal body weight (IBW), or
- Oxygenation Index >30: Oxygenation Index = FIO2 x 100 x 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)

Berlin Definition of Acute Respiratory Distress Syndrome

Criteria	
Timing	Within 1 week of a known clinical insult or new or worsening respiratory symptoms
Chest imaging (CT or CXR)	Bilateral opacities-not fully explained by effusions, lobar/lung collapse, or nodules
Origin of edema	Respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (eg, echocardiography) to exclude hydrostatic edema if no risk factors present.
Oxygenation, mild	200 mm Hg < Pao2/Fio2 <300 mm Hg with PEEP or CPAP >5 cm H2O
Oxygenation, moderate	100 mm Hg < Pao2/Fio2 ≤200 mm Hg with PEEP or CPAP ≥5 cm H2O
Oxygenation, severe	Pao2/Fio2 ≤100 mmHg with PEEP or CPAP ≥5 cm H2O

*****Assessment of ECMO Futility**

Adults 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 computed tomography, electroencephalography, 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)

RELATED GUIDELINES:

Total Artificial Hearts and Ventricular Assist Devices, 02-33000-25

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/28/25.

GUIDELINE UPDATE INFORMATION:

06/15/17	New Medical Coverage Guideline.
06/15/18	Scheduled review. Added criteria for cardiogenic shock and guideline for respiratory failure reversibility. Updated references.
06/15/19	Scheduled review. Revised description, maintained position statement and updated references.
06/15/20	Scheduled review. Revised description. Maintained position statement and updated references.
07/15/21	Scheduled review. Added Berlin Definition of Acute Respiratory Distress Syndrome table. Updated references.
11/15/22	Scheduled review. Maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
10/15/24	Scheduled review. Revised description, maintained position statement and updated references.
09/15/25	Scheduled review. Maintained position statement and updated references.