



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 03/31/15
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO) FOR ADULT RESPIRATORY FAILURE

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Extracorporeal membrane oxygenation (ECMO) provides extracorporeal circulation and physiologic gas exchange for temporary cardiorespiratory support in cases of severe respiratory and cardiorespiratory failure. ECMO can be used in the adult population for acute, potentially reversible respiratory failure due to a variety of causes, as a bridge to lung transplant and has been investigated in potentially reversible cardiogenic shock and as an adjunct to cardiopulmonary resuscitation (ECMO-assisted CPR).



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Definitions:

Adult: Age 18 years and older

Criteria:

- Extracorporeal membrane oxygenation (ECMO) for the management of adults with acute respiratory failure is considered **medically necessary** with documentation of **ALL** of the following:
 1. Respiratory failure is the result of **ONE** of the following potentially reversible conditions when there is reasonable expectation for recovery:
 - These indications include, *but are not limited to*:
 - a. Acute respiratory distress syndrome (ARDS)
 - b. Acute chest trauma
 - c. Acute pulmonary edema
 - d. Aspiration pneumonitis
 - e. Asthma exacerbation
 - f. Infectious and noninfectious pneumonia
 - g. Pulmonary hemorrhage
 - h. Pulmonary embolism
 2. Respiratory failure is severe, as determined by **ONE** of the following:
 - A standardized severity instrument such as the Murray score
 - **ONE** or more of the following:
 - a. Uncompensated hypercapnea with pH <7.2
 - b. PaO₂/FiO₂ of <100 mm Hg on fraction of inspired oxygen (FiO₂) >90%
 - c. Inability to maintain airway plateau pressure (Pplat) <30 cm H₂O despite a tidal volume of 4 – 6 mL/kg ideal body weight (IBW)
 - d. 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]
 - e. CO₂ retention despite high Pplat (>30 cm H₂O)



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Criteria: (cont.)

- Extracorporeal membrane oxygenation (ECMO) for the management of adults with acute respiratory failure is considered **medically necessary** with documentation of **ALL** of the following: (cont.)

3. The following contraindications are **not** documented:

- 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 (i.e., before onset of need for ECMO) diagnosis of a terminal condition with expected survival <6 months
- Do-not-resuscitate (DNR) directive
- Cardiac decompensation in an individual already declined for ventricular assist device (VAD) or transplant
- KNOWN neurologic devastation without potential to recover meaningful function
- Determination of care futility documents the following:

- a. Neurological devastation defined by consensus from two attending physicians that there is no likelihood of an outcome better than “persistent vegetative state” at 6 months, 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

- b. Inability to provide aerobic metabolism defined as **ONE** of the following:

- Refractory hypotension and/or hypoxemia
- Evidence of profound tissue ischemia based on creatine phosphokinase (CPK) or lactate levels, lactate-to-pyruvate ratio, or near-infrared spectroscopy (NIRS)
- Presumed end-stage cardiac or lung failure without “exit” plan (i.e., declined for assist device and/or transplantation)



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Criteria: (cont.)

- The use of ECMO is 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 adults for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Acute and refractory cardiogenic shock
- As an adjunct to cardiopulmonary resuscitation

Resources:

Literature reviewed 06/19/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 8.01.60 BCBS Association Medical Policy Reference Manual. Extracorporeal Membrane Oxygenation for Adult Conditions. Re-issue date 05/04/2018, issue date 01/15/2015.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

