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).
EXTRACORPOREAL MEMBRANE OXYGENATION FOR ADULT RESPIRATORY FAILURE (cont.)

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. $\text{PaO}_2/\text{FiO}_2$ of $<100 \text{ mm Hg}$ on fraction of inspired oxygen ($\text{FiO}_2$) >90%
     c. Inability to maintain airway plateau pressure (Pplat) $<30 \text{ cm H}_2\text{O}$ despite a tidal volume of $4 - 6 \text{ mL/kg ideal body weight (IBW)}$
     d. Oxygenation Index $>30$: $\text{Oxygenation Index} = \text{FiO}_2 \times 100 \times \text{MAP}/\text{PaO}_2 \text{ mm Hg}$. [$\text{FiO}_2 \times 100 = \text{FiO}_2$ as percentage; MAP = mean airway pressure in cm H$_2$O; $\text{PaO}_2$ = partial pressure of oxygen in arterial blood]
     e. $\text{CO}_2$ retention despite high Pplat ($>30 \text{ cm H}_2\text{O}$)
EXTRACORPOREAL MEMBRANE OXYGENATION FOR ADULT RESPIRATORY FAILURE (cont.)

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)
EXTRACORPOREAL MEMBRANE OXYGENATION FOR ADULT RESPIRATORY FAILURE (cont.)

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 06/20/17. 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.

EXTRACORPOREAL MEMBRANE OXYGENATION FOR ADULT RESPIRATORY FAILURE (cont.)

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/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: Díi kwe’ é atah nílłíniłí Blue Cross Blue Shield of Arizona haada yilt’éego bíná’idílikidgo éí doddago Háida bítí aniyeeedígi tí’áádoó le’é yina’idílikidgo beehaz’áaní hóó díí t’áá hazaak’éhí háká a’doowolgo beez’a doo bąbh ilíngóó. Aта’ halné’égli koj’ bíchj’’ hodiilíiní 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关插入项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权免费以您的母语得到帮助和讯息。洽询一位翻译员，电话号码 此处插入数字 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 người dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدته أسلحة بخصوص وسرية، يمكنك الحصول على المساعدة والمعلومات من Blue Cross Blue Shield of Arizona. إنك حق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم أصل ب 877-475-4799.
EXTRACORPOREAL MEMBRANE OXYGENATION FOR ADULT RESPIRATORY FAILURE (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyon wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통해서 귀하에게 877-475-4799로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様が親に相談する場合でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

اغذر شما، یا کسی که شما به او کمک می‌کنید، سوال در مورد اطلاعاتی که با انگیزه و به درجه‌بندی دریافت شده‌اند 877-475-4799 می‌تواند از شما داشته باشد.

Assyrian:

Blue Cross Blue Shield of Arizona که شما به او کمک می‌کنید، سوال در مورد اطلاعاتی که با انگیزه و به درجه‌بندی دریافت شده‌اند 877-475-4799 می‌تواند از شما داشته باشد.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณหรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถโทรศัพท์มาสอบถามข้อมูลได้ โทร 877-475-4799.