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## **1.0 Definition of the Procedure**

Mechanical cardiopulmonary support goes by many names under the general heading of extracorporeal life support. When the heart/lung machine is used in venoarterial mode to provide total support of heart and lung function to facilitate cardiac operations, the technique is commonly called cardiopulmonary bypass (CPB). When used with extrathoracic cannulation for respiratory support, it is called extracorporeal membrane oxygenation (ECMO), extracorporeal lung assist (ECLA), extracorporeal life support (ECLS), and extracorporeal CO<sub>2</sub> removal (ECCOR). The abbreviations ECMO and ECLS are used synonymously to mean prolonged extracorporeal circulation with mechanical devices.

ECMO exists in two varieties: veno-arterial (VA), and veno-venous (VV). The VA ECMO partially supports cardiac output, and the VV ECMO does not support circulation. ECLS management, indications, and results are quite different for cardiac and respiratory support and also different for neonatal, pediatric, and adult patients. In general, ECLS is indicated in acute severe reversible respiratory or cardiac failure, when the risk of dying from the primary disease is high despite optimal treatment.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

### **2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination\*\* (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**\*\*EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

*Basic Medicaid Billing Guide:* <http://www.ncdhhs.gov/dma/medbillcaguide.htm>

**EPSDT provider page:** <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>

### 3.0 When the Procedure Is Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage. The N.C. Medicaid program covers covers ECMO and ECLS related to the following disease processes.

### 3.1 ECMO in Neonates

Must meet *all* of the following criteria:

- a. Any of the following diagnoses:
  1. Hyaline membrane
  2. Congenital diaphragmatic hernia
  3. Respiratory distress syndrome
  4. Cardiac anomaly
  5. Persistent fetal circulation
  6. Meconium aspiration
- b. Gestational age of at least 34 weeks
- c. Birth weight of 2000 grams or more
- d. No more than 10 days old

### 3.2 ECMO/ECLS in Children and Adults

Must meet *any* of the following criteria:

- a. As a short-term (hours to a few days) bridge to heart transplant, once transplant has been approved
- b. Acute Respiratory Distress Syndrome (ARDS)
- c. Reversible causes of cardiac failure, myocarditis, and cardiomyopathy
- d. Pulmonary contusion
- e. Non-necrotizing bacterial or viral pneumonia

## 4.0 When the Procedure Is Not Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

The N.C. Medicaid program does not cover ECMO or ECLS for any of the following. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

#### 4.1 ECMO in Neonates

- a. Any severe diagnosis that decreases the probability of survival (such as severe and irreversible brain damage)
- b. Intracerebral hemorrhage
- c. Multiple congenital abnormalities
- d. Age more than 10 days
- e. Contraindication to systemic anticoagulation

#### 4.2 ECMO/ECLS in Children and Adults

- a. 60 years of age or greater
- b. Necrotizing pneumonia
- c. Multiple organ failure
- d. Metastatic disease
- e. Major CNS injury
- f. More than 10 days on mechanical ventilation prior to start of ECMO/ECLS
- g. Non-reversible respiratory or cardiac failure
- h. Contraindication to systemic anticoagulation
- i. History of or active substance abuse—must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

**Note:** To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

- j. Psychosocial history that would limit the ability to comply with medical care pre and post transplant
- k. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

### 5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

Prior approval for procedures provided to **neonatal recipients who are not candidates or potential candidates for transplants** must be requested through DMA's fiscal agent.

Prior approval for procedures provided to **recipients who are candidates or potential candidates for transplants** must be requested from DMA.

## 6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

## 7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized for ECMO or ECLS.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** January 1, 1994

### Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

### A. Claim Type

Physicians bill professional services on the CMS-1500 claim form.

Hospitals bill for services on the UB-92 or UB-04 claim form.

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

### C. Procedure Codes

Codes that are covered under ECMO include

36822	33960	33961
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### D. Reimbursement

Providers must bill their usual and customary charges.