

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
End-Tidal Carbon Monoxide Measurement (ETCOC)

Policy #: 196

Latest Review Date: May 2023

Category: Laboratory

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;*
- 2. Not experimental or investigational*;*
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - Furnished in a setting appropriate to the patient's medical needs and condition;*
 - Ordered and furnished by qualified personnel;*
 - One that meets, but does not exceed, the patient's medical need; and*
 - At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **end-tidal carbon monoxide measurement as an index of bilirubin production and/or hemolysis** as a **non-covered** benefit and as **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

The measurement of ETCOc corrected for background carbon monoxide (CO) in the breath represents a new technology that is said to detect the rate of hemolysis and/or assist in the tracking of hemolytic conditions. The technology is said to also measure end-tidal carbon dioxide (ETCO₂) and respiratory rate simultaneously. The test is non-invasive, does not require the cooperation of the patient, and the results are available immediately.

The catabolism of hemoglobin (Hgb) results in the equimolar formation of CO and Bilirubin. ETCOc is an indicator of the rate of hemolysis and bilirubin production. Elevation of breath CO may be indicative of pathological process in the newborn.

Administration of the test involves placement of a catheter into a patient's nostril, secured to the lip with tape; insertion of filter cartridge to analyzer port; and sampling of patient's breath with background air check for base levels. An elevated ETCOc is said to indicate that the infant is at high risk for development of hyperbilirubinemia. The cause of the hemolysis should be identified, appropriate treatment should be initiated, and the patient should be monitored closely.

Jaundice is probably the most common medical issue in newborns, affecting 60% to 70% of children within the first week of life. It is one of the most common diagnoses for readmission of newborns. Although all babies have levels higher than adults do, neonatal hyperbilirubinemia is considered when total serum bilirubin (TSB) level is >5 mg/dL. Bilirubin is formed from the breakdown of hemoglobin and hemoproteins. There is equimolar production of carbon monoxide (which is exhaled) and bilirubin (which is excreted in the GI tract). Bilirubin excess occurs due to overproduction, decreased conjugation, or impaired excretion/increased reabsorption.

The examining clinician who notices jaundice or scleral icterus often first detects hyperbilirubinemia. Jaundice typically begins in the face and spreads to the chest and the extremities. Visual examination (largely dependent on experience, skin tone, and lighting) may not be reliable. Jaundice within the first 24 hours is pathologic and requires immediate evaluation and therapy. More typically, jaundice appears on day of life 2 to 4 and is often idiopathic.

The diagnosis of hyperbilirubinemia is based on TSB. Transcutaneous bilimeters offer advantages in ease, cost, and comfort to the patient. The newer models may not be as dependent on skin pigmentation, which is the biggest obstacle in using these devices. End tidal carbon monoxide levels is said to help assess for increased production of bilirubin, but this method has not been shown to be clinically superior to hour-specific bilirubin levels in the prediction of hyperbilirubinemia.

KEY POINTS:

The most recent update with literature review covers the period through August 10, 2021.

Summary of Evidence

While measurement of end-tidal carbon monoxide levels, an index of bilirubin production can provide information about the presence or absence of hemolysis, additional research is needed to quantify the risks, benefits, and costs of these measurements. Until such information is available, the American Association of Pediatrics practice guidelines represent a good approach for most infants.

KEY WORDS:

End-tidal carbon monoxide levels, ETCOc, hyperbilirubinemia, serum bilirubin, bilirubin, hemolysis, jaundice, transcutaneous bilimeters

APPROVED BY GOVERNING BODIES:

Not applicable.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

84999	Unlisted chemistry procedure
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PREVIOUS CODING:

0043T	Carbon monoxide, expired gas analysis (e.g., ETCOc/hemolysis breath test) (Code deleted effective January 1, 2009)
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REFERENCES:

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15. U.S. Preventive Services Task Force (USPSTF). Screening of infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy. Agency for Healthcare Research and Quality, October 2009, www.ahrq.gov/clinic/uspstf09/hyperbilirubinemia/hyperbsum.htm.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005

Available for comment May 12-June 27, 2005

Medical Policy Group, August 2006

Medical Policy Group, August 2008

Medical Policy Group, August 2010

Medical Policy Group, September 2012: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Medical Policy Group, August 2019

Medical Policy Group, August 2021

Medical Policy Group, May 2022: There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, May 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.