BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Fetal Echocardiography and Magnetocardiography

Policy #: 231
Latest Review Date: September 2024
Category: OB/Radiology

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 **fetal echocardiography** as a **covered benefit** for use in cases where one of the following indications for high risk of congenital heart disease is present:

Fetal Risk Factors:

- Extracardiac abnormality (e.g., congenital lung lesions, diaphragmatic hernia);
- Chromosomal abnormality;
- Fetal cardiac arrhythmia;
- Non-immune hydrops;
- Question of cardiac anomaly on prior sonogram;
- Intrauterine growth retardation;
- Suspicion of twin-twin transfusion syndromes;
- Monochorionic twins.

Maternal Risk Factors:

- Family history of CHD (parent or sibling);
- Metabolic disorders (e.g., diabetes mellitus, phenylketonuria [PKU]);
- Teratogenic exposure (e.g. alcohol, amphetamines, anticonvulsives, lithium paroxetine (Paxil);
- Exposure to prostaglandin synthetase inhibitors (e.g., ibuprofen, salicylic acid, indomethacin);
- Maternal seizure disorder and not currently taking anti-seizure medication;
- Maternal autoimmune disorders (e.g., collagen vascular disease, systemic lupus erythremia [SLE], Sjögren's);
- Maternal infection (e.g. rubella);
- Familial inherited disorders (Ellisvan, Creveld, Marfan, Noonan's, etc);
- In vitro fertilization;
- Autoimmune antibodies (anti Ro/ Anti La).

Blue Advantage will treat **fetal echocardiography** as a **non-covered benefit** when there are no indications of a cardiac abnormality found on a routine antepartum ultrasound or the mother or fetus does not have one of the indications listed above.

Blue Advantage will treat **repeat fetal echocardiography** as a **covered benefit** for:

- Structural heart disease with potential hemodynamic compromise;
- Tachycardia other than sinus tachycardia;
- A ductus arteriosus dependent lesion.

Blue Advantage will treat **repeat fetal echocardiography** a **non-covered benefit** when done for an indication not listed above.

Fetal Magnetocardiography

Blue Advantage will treat **fetal magnetocardiography** as a **non-covered benefit** and as **investigational** in all situations.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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:

Fetal Echocardiography (FE)

General antepartum obstetrical ultrasound has become a standard part of gestational care and is commonly used for the determination of fetal age, size, gender or well-being and for the detection of congenital anomalies. A variety of maternal or fetal disorders may result in abnormality of the fetal cardiovascular system to a degree which requires evaluation at a level above and beyond that attainable with standard antepartum obstetrical ultrasound. In these circumstances, a fetal echocardiogram may be performed.

Fetal echocardiography is a non-invasive technique for diagnosing and assessing cardiac abnormalities in the fetus. It is performed using a two-dimensional (2-D) high-resolution ultrasound system, which usually also has other capabilities, including M-mode, pulsed Doppler and color doppler mapping.

The standard fetal echocardiographic examination utilizes all modalities of diagnostic ultrasound including 2-dimensional (B-mode) imaging, Doppler, and Doppler color flow mapping. Ultrasound energy expenditures increase with each modality used and are most intense when Doppler color flow mapping is applied to a small region of interest, as is commonly the case when examining the structures of the fetal heart. Hence special consideration should be given to the use of ultrasound energy in the developing fetus. While theoretical concerns exist, to date there have been no confirmed harmful effects detected. Those performing fetal echocardiography should be aware of these effects and should limit power output and time of exposure to no more than that which is absolutely necessary to complete the examination.

The optimal timing for performance of a transabdominal fetal echocardiogram is 18 to 22 weeks gestation. Images can be more difficult to obtain after 30 weeks gestation, as the ratio of fetal body mass-to-amniotic fluid increases. Acquiring images of the fetal heart at 15 to 18 weeks is possible; however, performing a comprehensive cardiac evaluation study at this age can be difficult.

Fetal Magnetocardiography (FM)

Fetal magnetocardiography is another non-invasive technique to assess a fetus' heart. FM converts electrical signals from the heart into magnetic signals that look similar to a traditional electrocardiogram. The recording allows the assessment of PQRST abnormalities thus possibly leading to decreased fetal death. It is proposed that this is a more effective method of assessing cardiac abnormalities than the FE; however, the equipment is not widely available and requires careful shielding and skilled technical experience.

KEY POINTS:

The most recent update was with a review of the literature through September 26, 2024.

Summary of Evidence

Fetal Echocardiography

For individuals who receive fetal echocardiography, the evidence consists of systematic reviews and prospective studies. Relevant outcomes are fetal morbidity and mortality and accuracy of echos. Fetal echocardiography (FE) has been shown to be medically important in several ways. First, the early diagnosis of CHD with FE has been shown to lead to the detection of associated extracardiac fetal anomalies. Second, the prenatal diagnosis of major CHD may have implications for the optimal route, location, or timing of delivery, and may bring critically ill infants to medical attention quicker than they would have been without a prenatal diagnosis. Many studies have suggested improved outcome in infants diagnosed prenatally with CHD in comparison with those not diagnosed until after birth. These studies suggest that early diagnosis can lead to improved preoperative hemodynamic status, less end-organ dysfunction, less preoperative morbidity and mortality, and less long-term morbidity. The evidence is sufficient to determine the effects of the technology on health outcomes.

Fetal Magnetocardiography (FM)

For individuals who receive fetal magnetocardiography, the evidence consists of systematic reviews, a retrospective review, and observational studies. Relevant outcomes are fetal morbidity, fetal mortality, and alterations in management of current pregnancy. One study stated that FM is a more effective method of assessing fetal well-being with a higher resolution compared to cardiotocography and FE; however, the authors conclude by stating FM is an experimental method. A retrospective study of 215 pregnancies reviewed FM tracings and identified 35 changes in pregnancy management. The equipment is not widely available, requires careful shielding and requires skilled technical support. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Society of Echocardiography

In 2023, The American Society of Echocardiography published Guidelines and Recommendations for Performance of the Fetal Echocardiogram. The recommendations include the following:

Potential indications for fetal echocardiography

	ASE 2023 recommendation	AUM 2020	AHA 2014
Maternal factors (absolute risk)			
Pre–gestational diabetes (3%-5%)	Is indicated	Is indicated	I (indicated)

Gestational diabetes diagnosed after second trimester (<1%)	Not indicated	Not indicated	III (no benefit)
Phenylketonuria (12%-14%)	Is indicated	Is indicated	I (indicated)
Autoimmune disease: SSA/SSB positive (1%-5%)	Is indicated	Is indicated	IIa (probably indicated)
In vitro fertilization (1.1%-3.3%)	May be considered	Is indicated	IIa (probably indicated)
Maternal infection: rubella (3%-4%)	Is indicated	Is indicated	I (indicated)
Family history of CHD: first-degree relative (3%-20%)	Is indicated	Is indicated	I (indicated)
Family history of CHD: second-degree or more distant relative (<2%)	Not indicated	May be considered	IIb (may be indicated)
Obesity (BMI > 30 kg/m2) (1-2%)	Not indicated	Not indicated	---
Retinoids (8%-20%)	Is indicated	Is indicated	I (indicated)
ACE inhibitors (3%)	May be considered	May be considered	IIa (probably indicated)
Paroxetine (3%)	May be considered	May be considered	IIb (may be indicated)
Other selective serotonin reuptake inhibitors (1%-2%)	Not indicated	Not indicated	III (no benefit)
Anticonvulsants (1%-2%)	Not indicated	May be considered	IIb (may be indicated)
Lithium (1%-2%)	Not indicated	May be considered	IIb (may be indicated)
Warfarin (<1%)	Not indicated	Not indicated	III (no benefit)

Fetal factors identified during screening (absolute risk)			
Fetal hydrops (15%-20%)	Is indicated	Is indicated	I (indicated)
Extracardiac anomaly (20%-45%)	Is indicated	Is indicated	I (indicated)
Chromosomal abnormalities (10%-90%)	Is indicated	Is indicated	I (indicated)
Monochorionic twinning (2%-10%)	Is indicated	Is indicated	I (indicated)
Nuchal translucency 3.0-3.4 mm (3%)	May be considered	May be considered	IIa (probably indicated)
Nuchal translucency =/>3.5 mm (6%-60%)	Is indicated	Is indicated	I (indicated)
Single umbilical artery in isolation (1.2%- 1.8%)	Not indicated	Not indicated	IIb (may be indicated)

American Institute of Ultrasound in Medicine
In 2019, the AIUM updated their practice parameter for fetal echocardiography. They state that "indications for fetal echocardiography are often based on a variety of parental and fetal risk factors for congenital heart disease…. For fetuses suspected of having an abnormal fetal heart at the time of a basic or detailed anatomic ultrasound examination, referral for fetal echocardiography is indicated, as the risk of significant disease is high. For low risk for CHD, cardiac screening ultrasound is primarily used to examine the fetal heart as a part of a standard second trimester obstetric ultrasound examination".

The following is a list of common fetal and maternal conditions associated with an increased risk of CHD:

1. Maternal Indications

- Pregestational diabetes regardless of the hemoglobin A1C level
- Gestational diabetes diagnosed in the first or early second trimester
- Autoimmune antibodies, anti-Ro (SSA)/anti-La (SSB)
- In vitro fertilization, including intracytoplasmic sperm injection
- Phenylketonuria (unknown status or a periconceptional phenylalanine level > 10 mg/dL)
- Autoimmune disease with anti-Sjogren syndrome– related antigen A antibodies and with a prior affected fetus
- First-degree relative of a fetus with CHD (parents, siblings, or prior pregnancy)
- First- or second-degree relative with disease of Mendelian inheritance and a history of childhood cardiac manifestations
- Retinoid exposure

- First-trimester rubella infection

2. Fetal Indications
    - Suspected cardiac structural anomaly
    - Suspected abnormality in cardiac function
    - Hydrops fetalis
    - Persistent fetal tachycardia (heart rate >180 bpm)
    - Persistent fetal bradycardia (heart rate <120 bpm) or suspected heart block
    - Frequent episodes or a persistently irregular cardiac rhythm
    - Major fetal extracardiac anomaly
    - Nuchal translucency of 3.5mm r greater or at or above the 99th percentile for gestational age
    - Fetal chromosomal anomaly
    - Monochorionic twins.

KEY WORDS:
Fetal echocardiography, complete heart block, fetal cardiovascular system, echocardiography, echocardiogram, congenital heart disease, CHD, fetal magnetocardiography

APPROVED BY GOVERNING BODIES:
In March 2016, the Echo fMCG™ (Tristan Technologies) received FDA 510(k) approval for use as a tool that non-invasively measures and displays the magnetic signals produced by the electric currents in the heart of human beings of any age or in the heart of a fetus in utero. It is used for magnetocardiography and echocardiography.

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

CURRENT CODING:
CPT codes

76825	Echocardiography, fetal, cardiovascular system, real time with image documentation (2-D) with or without M-mode recording;
76826	; follow-up or repeat study
76827	Doppler echocardiography, fetal, pulsed wave and/or continuous wave with spectral display; complete

76828	; follow-up or repeat study
93325	Doppler color flow velocity, mapping
93799	Unlisted cardiovascular service or procedure

PREVIOUS CODING:

0475T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other. (Deleted effective 12/31/22)
0476T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording, data scanning, with raw electronic signal transfer of data and storage (Deleted effective 12/31/22)
0477T	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result (Deleted effective 12/31/22)
0478T	Recording of fetal magnetic cardiac signal using at least 3 channels; review, interpretation, report by physician or other qualified health care professional (Deleted effective 12/31/22)

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POLICY HISTORY:

Adopted for Blue Advantage, August 2005
Available for comment August 30-October 13, 2005
Medical Policy Group, June 2008
Available for comment July 15-August 28, 2008
Medical Policy Group, June 2009
Available for comment July 6-August 19, 2009
Medical Policy Group, October 2017
Available for comment October 19 through December 2, 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated effective March 24, 2020.

Medical Policy Group, August 2021
Medical Policy Group, September 2022
Medical Policy Group, December 2022: Annual Coding Update. Moved deleted CPT codes 0475T-0478T from Current Coding to Previous Coding.
Medical Policy Group, September 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, September 2024

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.