Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Fetal Magnetocardiography

Description/Background

Fetal cardiac activity is one of the important markers of fetal health. Fetal arrhythmias complicate 1 to 2 percent of pregnancies and have the potential to compromise fetal health. They are categorized according to their rhythm (irregular, regular) and rate (tachycardia, bradycardia).[1] Fetal ECG (fECG) recordings have been used to monitor cardiac activity, but are not widely used because the of the poor electrical conductivity of the vernix caseosa surrounding the fetus during the latter second trimester and most of the third trimester of pregnancy, which results in low fECG amplitude. This makes a real-time assessment of fetal arrhythmias difficult to determine using fECG.

At the present time, ultrasonography is the best modality for the evaluation of fetal arrhythmias. It is important to differentiate fetal arrhythmias, particularly intrapartum, from fetal heart rate (FHR) changes related to hypoxemia or other factors. Fetal M-mode and Doppler echocardiography can be used to study the rate and timing of atrial and ventricular mechanical events which occur briefly after their respective electrical depolarization. Fetal echocardiography does not give details about the morphology of electrical complexes (e.g., P-wave axis) nor on QRS- and QT-interval durations. Despite these limitations, with some ultrasound experience and a basic understanding of electrophysiological principles, it is almost always possible to correctly identify the arrhythmia mechanism based on characteristic echocardiographic pattern.

Fetal magnetocardiography (fMCG), on the other hand, has promising potential as a method of fetal cardiac surveillance, e.g., for online monitoring of fetal heart rhythm, diagnosis of fetal arrhythmia, growth and development of the autonomic nervous system, acidosis and fetal stress. Fetal magnetocardiography is a noninvasive technique for recording magnetic fields generated by the electrical activity of the fetal heart. Unlike fetal MRI, fMCG does not emit magnetic fields or energy. Magnetocardiography shifts the electrical signals into an evoked magnetic signal that can be processed to create a beat-to-beat magnetocardiogram that looks much like a traditional electrocardiogram (ECG). Continuous recordings can be performed for

relatively sustained periods and have permitted elegant demonstration of arrhythmia onset/offset and more direct observation of mechanisms. It is a passive and safe recording technique, similar to the ECG, utilizing the extremely high sensitivity Superconducting Quantum Interference Device (SQUID) sensors.[2] FMCG must be performed within a magnetically shielded room or mobile unit that excludes magnetic interference from environmental sources. At this time, fetal magnetocardiography is only available in a few centers world-wide and is mainly used as a research tool.

Regulatory Status

The Tristan Technologies Model 621/624 Biomagnetometer is intended for use as a tool that noninvasively 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 received a 510(k) premarket notification of intent to market the device on February 2, 2016 for the U. S. Food and Drug Administration.

Medical Policy Statement

Fetal magnetocardiography is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

93799

Rationale

Echocardiography remains the principal technique for assessing AV synchrony or arrhythmias in the fetus.[3]

Postnatally, the 12 lead electrocardiogram (ECG) recording is the gold standard for assessment and diagnosis of cardiac rhythm disturbance. During fetal life, however, it is difficult to extract the fetal ECG because of the distance of the fetus to the maternal skin,

possible insulating properties of vernix, and the small size of the fetus, all of which contribute to low voltages. Fetal movement, interference from the maternal heart rate and maternal muscular contraction further contribute to the difficulties in extracting a fetal ECG. Despite these limitations, this method has often been used to accurately record the fetal ECG.

An alternative technique, fetal magnetocardiography (MCG) has been developed to detect the magnetic fields caused by electrical signals in the fetal heart. This technique is used in a research setting and requires a magnetically-shielded setting to be feasible.

Quartero et al reported on a study done in 2002 to test the usefulness and reliability of fetal magnetocardiography as a diagnostic or screening tool, both for fetuses with arrhythmias as well as for fetuses with a congenital heart defect.[4] They included 21 pregnant women with either a fetal arrhythmia or a congenital heart defect discovered during prenatal evaluation by sonography. Four fetuses exhibited a complete atrioventricular block, two an atrial flutter, nine ventricular extrasystole, and one a complete irregular heart rate. Five fetuses were suspected to have a congenital heart defect. In all cases magnetocardiograms were recorded. Following the magnetocardiograms, nine fetuses with extrasystole showed a range of premature atrial contractions, premature junctional beats or premature ventricular contractions. Two fetuses with atrial flutter showed typical flutter waves and four fetuses with complete atrioventricular block showed an uncoupling of P-wave and QRS complex. One fetus showed a pattern suggestive of a bundle branch block. In three of four fetuses with confirmed congenital heart defects the magnetocardiogram showed abnormalities. The authors concluded that fetal magnetocardiography allows an insight into the electrophysiological aspects of the fetal heart, is accurate in the classification of fetal arrhythmias, and shows potential as a tool in defining a population at risk for congenital heart defects. However, no change in patient management was made based on the results of the test findings.

A 2004 article by Li et al used magnetocardiography to assess P and QRS amplitude in normal subjects and subjects with fetal arrhythmia.[5] The study cohort consisted of 68 normal fetuses and 25 with various arrhythmias: 9 reentrant supraventricular tachycardia (SVT), 2 ventricular tachycardia (VT), 2 sinus tachycardia, 2 blocked atrial bigeminy, 2 congenital second-degree atrioventricular (AV) block, and 8 congenital complete AV block. Subjects with congenital AV block, all presenting with bradycardia, showed large QRS amplitude, exceedingly large P-wave amplitude, and long P-wave duration. The 2 subjects with VT, both with poor ventricular function, also exhibited large P waves. SVT was associated with only moderate signal amplitude elevation. The authors concluded that AV block in utero is accompanied by hypertrophy, which is more pronounced for the atria than the ventricles. They hypothesized that the hypertrophy results from a compensatory response associated with regulation of cardiac output and is likely to be observable in other arrhythmias and disease states. They also hypothesized that magnetocardiography may be more sensitive than fetal echocardiography for detection of atrial hypertrophy in utero.

A 2005 individual case study was published by Schneider et al regarding the use of fetal magnetocardiography on a woman with a family history for a hereditary long QT syndrome presented at 30 weeks of her first pregnancy with fetal bradycardia and a narrow oscillation bandwidth on cardiotocography without structural abnormalities of the fetal heart.[6] Fetal magnetocardiography was performed with a *prototype* biomagnetometer/gradiometer device in a magnetically unshielded environment. The cardiac time intervals were determined in the averaged PQRST complex. The QT time and the frequency-corrected QTc showed a marked

prolongation to 380 ms and 0.52 s, respectively. The findings were confirmed in the postnatal electrocardiogram after spontaneous term delivery in a perinatal center. The causative mutation on chromosome 11 had been passed on to the newborn from his mother. The authors concluded that the bedside fetal magnetocardiography revealed the exact diagnosis of the long QT syndrome in a period of the gestation when the fetus was electrically isolated by the vernix caseosa that hinders electrocardiography. To patients at risk of fetal cardiac abnormalities, magnetocardiography can be offered as a non-invasive diagnostic bedside procedure. The diagnosis should trigger closer surveillance and delivery in a perinatal center.

Long QT syndrome (LQTS) and its signature rhythm, Torsades de Pointes (TdP), have been diagnosed in utero by fetal magnetocardiography (fMCG) and, in a few cases, successfully treated before birth. In a recent fetal MCG study, the electrophysiology of LQTS in utero was characterized for the first time in a sizeable cohort, consisting of 30 fetuses at risk of LQTS Yu et al)[7] Heart rate, waveform intervals, T-wave morphology, initiation/termination patterns of TdP, and TWA were assessed. Fetal MCG demonstrated high diagnostic and prognostic value. Based on assessment of QTc interval (QTc> 490 ms), fetal MCG was able to identify the fetuses that tested positive for LQTS with high accuracy (89%). Low-for-gestational age heart rate (< 3%) was also associated with fetal LQTS. Some fetuses diagnosed with LQTS had only low fetal heart rate and no family history of LQTS at the time of referral. In several such cases, LQTS was subsequently found in 1st degree relatives who underwent testing as a result of the fetal MCG diagnosis. The fetal MCG findings also showed high prognostic value. Subjects that had TdP as fetuses or newborns showed the longest values of QTc (>600ms). TdP was also associated with other rare findings, including 2nd-degree AV block, TWA, and QRS alternans. Lastly, definitive detection of TdP was critical for guidance of in-utero therapy, consisting of administration of magnesium and lidocaine, which was highly effective at controlling or abolishing TdP.

Case studies and small case series documenting postnatal follow-up present compelling evidence that fMCG provides prenatal information concordant with postnatal findings during persistent fetal arrhythmias. Although use of this technique may be reasonable in the assessment of cardiac conduction and rhythm in fetuses with known or suspected disease of the conduction system, fMCG currently has limited availability,

Study of fetuses with abnormal heart rates, arrhythmia, and ion-channel defects are currently underway. Assessment of fetal systolic electromechanical function via fMCG and echocardiography may provide a better understanding of the underlying processes that lead to poor systolic cardiac function and heart failure in the at-risk human fetus.[8] Well-designed clinical trials and development of treatment protocols after identification of at-risk fetuses need to be developed going forward.

Hrtankova et al (2015) analyzed literature in the field of fMCG.[30] The author states “compared to cardiotocography and fetal electrocardiography, this is a more effective method with a higher resolution. The signal obtained from the fetal heart is sufficiently precise and the quality allows an assessment of PQRST complex alterations, and to detect fetal arrhythmia. With early diagnosis of fetal arrhythmia, there is the possibility for appropriate therapeutic intervention and the reduction of unexplained fetal death in late gestation. fMCG with high temporal resolution also increases the level of clinical trials which record fetal heart rate (FHR) variability. According to the latest theories, FHR variability is a possible indicator of fetal status and enables the study of the fetal autonomic nervous system indirectly. fMCG is an

experimental method that requires expensive equipment. It is yet to be shown in the future, if this method will get any application in clinical practice."

Eswaran et al (2017) states "fetal magnetocardiography provides the requisite precision for diagnostic measurement of electrophysiological events in the fetal heart.[31] Despite its significant benefits, this technique with current cryogenic based sensors has been limited to few centers, due to high cost of maintenance. In this study, we show that a less expensive non-cryogenic alternative, optically pumped magnetometers, can provide similar electrophysiological and quantitative characteristics when subjected to direct comparison with the current technology. Further research can potentially increase its clinical use for fetal magnetocardiography."

According to Levine et al. (2022), magnetocardiography shifts the electrical signals into an evoked magnetic signal that can be processed to create a beat-to-beat magnetocardiogram that looks like a traditional electrocardiogram.[32] Continuous recordings can be performed for relatively sustained periods and have permitted elegant demonstration of arrhythmia onset/offset and more direct observation of mechanisms. The equipment is not widely available and requires careful shielding and skilled technical support, so the technology remains investigational.

Gussmann, Strasburger & Wakai (2022) studied to what extent fMCG contributed to the precision and accuracy of fetal arrhythmia diagnosis and risk assessment, and in turn, how this altered pregnancy management.[33] The authors reviewed fMCG tracings and medical records of 215 pregnancies referred to the Biomagnetism Laboratory, UW-Madison, over the last 10 years, because of fetal arrhythmia or risk of arrhythmia. They compared referral diagnosis and treatment with fMCG diagnosis using a rating scale and restricted the review to the 144 subjects from the tachycardia, bradycardia/AV block, and familial long QT syndrome categories. Additional fMCG findings beyond those of the referring echocardiogram, or an alternative diagnosis were seen in 117/144 (81%), and 81 (56%) were critical changes. Eight (5.5%) had resolution of arrhythmia before fMCG. At least moderate changes in management were seen in 109/144 (76%) fetuses, of which 35/144 (24%) were major. The most diverse fMCG presentation was long QT syndrome, present in all 3 referral categories. Four of 5 stillbirths were seen with long QT syndrome. Nine fetuses showed torsades de pointes ventricular tachycardia, of which only 2 were recognized before fMCG.

SUMMARY OF EVIDENCE

The part that fetal magnetocardiography will play in the care of women with high-risk pregnancies is still being refined. Efforts to bridge the critical care continuum from the fetal period into infancy for pregnant women nearing delivery needs further study. Clinical trials are currently under way. In conjunction with bringing forward new technologies for fetal rhythm diagnosis, advanced care strategies are essential. This will likely entail a new field of high-risk obstetrical electrophysiology. Just as primary care medical fields have given rise to subspecialty fields, the same will need to happen as fetal electrophysiology expands beyond its present state. A question remains as to whether high-risk obstetricians with training in advanced cardiology and electrophysiology will be able to acquire the skills needed to manage arrhythmia patients independently, or whether perinatal pediatric electrophysiologists with comprehensive training in fetal and neonatal electrophysiology will emerge to be an integral part of the care of these pregnant patients and their fetuses. Enhancing clinical research in the

area of fetal and neonatal electrophysiology and intensive care will be an essential part of developing these strategies.

Although physicians and researchers have begun to better understand the complexity of fetal atrioventricular block, future work is necessary to fully explain its pathogenesis, improve prenatal counseling, identify the pregnancy for which fetal intervention may be indicated, and facilitate development of more appropriate and effective perinatal and neonatal management strategies.

SUPPLEMENTAL INFORMATION:

American Heart Association (AMA)[9]

Fetal magnetocardiography (fMCG) is a noninvasive means of assessing electromagnetic characteristics of fetal cardiac conduction. Magnetometers used to perform fMCG use superconductor physics principles to measure magnetic fields. The studies must be performed within a magnetically shielded room that excludes magnetic interference from environmental sources. Unlike MRI, fMCG devices represent passive receivers that do not produce energy or alter magnetic energy states. Because of the requirement for specialized equipment and expertise, fMCG is currently performed in only a small (albeit increasing) number of centers worldwide.

FMCG provides heart rate trend analysis, raw rhythm recordings at gestations >17 to 24 weeks, and signal-averaged recordings. The fMCG captures the P wave, PR interval, QRS interval, ST-T waves, QT interval, and RR interval in most fetuses of >24 weeks' gestation and QRS and RR intervals in fetuses of >17 weeks' gestation, 340–343 With the use of fMCG, normative data for cardiac intervals, including gender-based intervals and those in multiple pregnancies, have been established. Compared with mechanical PR intervals derived from fetal pulsed Doppler, fMCG PR intervals were shorter than those obtained by pulsed Doppler. Similar to Holter monitoring, the fMCG can display uninterrupted segments of recorded time during normal rhythm or during arrhythmias. fMCG may therefore be especially useful for analyzing complex rhythm and rate patterns such as irregular, multiple, or transient arrhythmias and for providing a more accurate differential diagnosis of tachycardia and bradycardia. No other current method can detect repolarization abnormalities such as T-wave alternans. Over the past decade, fMCG has been reported in case series and has increased the understanding of the pathophysiology of life-threatening arrhythmias such as LQTS, CHB, and various tachyarrhythmias with or without Wolff-Parkinson-White syndrome. FMCG has led to modifications in medical therapy of arrhythmias in some cases.

Unlike fetal electrocardiography, fMCG allows raw signal analysis even in the presence of an irregular rhythm. FMCG holds an inherent advantage over fetal electrocardiography in signal-to-noise ratios because the conductance properties of magnetic signals are not affected by poor conductivity of fetal and maternal tissues. Only a limited number of studies have compared contemporaneous fetal electrocardiography and fMCG recordings. Case studies and small case series documenting postnatal follow-up present compelling evidence that fMCG provides prenatal information concordant with postnatal findings during persistent fetal arrhythmias. Although fMCG currently has limited availability, use of this technique is reasonable in the assessment of cardiac conduction and rhythm in fetuses with known or suspected disease of the conduction system. Current COR (Class of recommendation): IIa; Level of Evidence: B

Ongoing and Unpublished Clinical Trials

Three currently unpublished trials that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion date
Ongoing			
NCT03775954	Fetal electrophysiologic abnormalities in high-risk pregnancies associated with fetal demise	200	Apr 2025
NCT03047161	Electrophysiology of Fetal Arrhythmia (fMCG)	450	May 2028
Unpublished			
NCT02876380	Prospective Identification of Long QT Syndrome in Fetal Life (Fetal LQTS)	600	Dec 2021

* This study has suspended participant recruitment.
** It is hoped that the data from the study will support a Humanitarian Device Exemption (HDE) application for the subject device.

Government Regulations
National/Local:

There is no national or local coverage determination of fetal magnetocardiography. The codes 0475T-0478T have no fees assigned to them.

Codes 0475T-0478T were deleted effective 1/1/23 and replaced with NOC code 93799.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/17	8/15/17	8/15/17	Joint policy established
11/1/18	8/21/18	8/21/18	Routine policy maintenance. No change in policy status.
11/1/19	8/20/19		Routine policy maintenance. No change in policy status.
11/1/20	8/18/20		Routine policy maintenance. No change in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
11/1/22	8/16/22		Routine policy maintenance, no new literature found, no change in policy status.
11/1/23	8/15/23		Updated rationale, added references 30-32. Codes 0475T-0478T deleted effective 1/1/23, replaced with NOC code 93799. Vendor managed: N/A. (ds)
11/1/24	8/20/24		Removed last sentence from MPS, routine maintenance, added reference #33, no change in status. Vendor managed: N/A (ds)

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: FETAL MAGNETOCARDIOGRAPHY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A