



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 06/12/17
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

FETAL MAGNETOCARDIOGRAPHY

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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FETAL MAGNETOCARDIOGRAPHY (cont.)

Description:

Fetal magnetocardiography or fetal MCG (fMCG) is a non-invasive procedure. Fetal MCG measures and records a magnetic fetal cardiac signal using a device called a SQUID Biomagnetometer by Tristan Technologies, Inc., which received FDA 510k clearance March 15, 2016. Fetal MCG does not alter energy states or produce magnetic fields, making it safe to use in pregnancy. It is different from other magnetocardiography in that it receives signals from both the fetus and the mother and complex signal processing is used to separate them. In theory, this is similar to an EKG. Fetal MCG is complimentary to echocardiography for rhythm assessment and can detect conduction abnormalities that are not possible to diagnose prenatally with M-mode or pulsed Doppler ultrasound.

SQUID: Superconducting Quantum Interference Device is a sensitive magnetic flux detector, often referred to as a cryogenic magnetometer capable of measuring extremely small magnetic fields. Because of their superconducting nature, the SQUID sensor must be kept at cryogenic temperatures, usually in an insulating vessel.

Criteria:

- Fetal magnetocardiography 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.

FETAL MAGNETOCARDIOGRAPHY (cont.)

Resources:

Literature reviewed 06/19/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. Cuneo BF, Strasburger JF, Wakai RT. The natural history of fetal long QT syndrome. *Journal of electrocardiology*. Nov - Dec 2016;49(6):807-813.
2. Donofrio MT, Moon-Grady AJ, Hornberger LK, et al. Diagnosis and treatment of fetal cardiac disease: a scientific statement from the American Heart Association. *Circulation*. May 27 2014;129(21):2183-2242.
3. Escalona-Vargas D, Wu HT, Frasch MG, Eswaran H. A Comparison of Five Algorithms for Fetal Magnetocardiography Signal Extraction. *Cardiovascular engineering and technology*. Mar 26 2018.
4. Eswaran H, Escalona-Vargas D, Bolin EH, Wilson JD, Lowery CL. Fetal magnetocardiography using optically pumped magnetometers: a more adaptable and less expensive alternative? *Prenatal diagnosis*. Feb 2017;37(2):193-196.
5. Hrtankova M, Biringer K, Sivakova J, Sumichrastova P, Lukac P, Danko J. [Fetal magnetocardiography: a promising way to diagnose fetal arrhythmia and to study fetal heart rate variability?]. *Ceska gynekologie*. Jan 2015;80(1):58-63.
6. Lin L, Takahashi-Igari M, Kato Y, et al. Prenatal Diagnosis of Atrioventricular Block and QT Interval Prolongation by Fetal Magnetocardiography in a Fetus with Trisomy 18 and SCN5A R1193Q Variant. *Case reports in pediatrics*. 2017;2017:6570465.
7. Minai U, Gustafson K, Fiorentino R, Jongman A, Sereno J. Fetal rhythm-based language discrimination: a biomagnetometry study. *Neuroreport*. Jul 5 2017;28(10):561-564.
8. UpToDate. Atrial tachycardias in children. 07/12/2016.
9. UpToDate. Fetal cardiac abnormalities: Screening, evaluation, and pregnancy management. 09/25/2017.
10. UpToDate. Overview of the general approach to diagnosis and treatment of fetal arrhythmias. 01/04/2018
11. Wacker-Gussmann A, Strasburger JF, Cuneo BF, Wiggins DL, Gotteiner NL, Wakai RT. Fetal arrhythmias associated with cardiac rhabdomyomas. *Heart rhythm*. Apr 2014;11(4):677-683.



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FETAL MAGNETOCARDIOGRAPHY (cont.)

Resources: (cont.)

12. Wiggins DL, Strasburger JF, Gotteiner NL, Cuneo B, Wakai RT. Magnetophysiologic and echocardiographic comparison of blocked atrial bigeminy and 2:1 atrioventricular block in the fetus. *Heart rhythm*. Aug 2013;10(8):1192-1198.
13. Zhou KY, Hua YM. Autoimmune-associated Congenital Heart Block: A New Insight in Fetal Life. *Chinese medical journal*. Dec 5 2017;130(23):2863-2871.



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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/file/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: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 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 thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulongan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong 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 Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 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、またはお客様の身の回りの方でも、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:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 . [تماس حاصل نمایید.]

Assyrian:

Blue Cross Blue Shield of Arizona , ئه زۆر به بهیشت گهێت ئه بهێتێنێت . 877-475-4799 .

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: หากคน หรือคนที่คุณกำลังช่วยเหลือถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถที่จะได้รับความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไมเสียค่าใช้จ่าย โปรดถาม โทร 877-475-4799