PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING

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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PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Description:

Affected Individual:
An individual displaying signs or symptoms characteristic of a suspected or specific inherited disorder.

Genetic Testing and Counseling:
Genetic testing is the analysis of DNA, RNA, chromosomes, proteins and certain metabolites in order to detect alterations related to an inherited disorder. Genetic counseling provides interpretation of genetic tests and information about courses of action that are available for the care of an individual with a genetic disorder or for future family planning.

Infertility:
Inability of a couple to conceive after one year of unprotected intercourse.

Screening:
Screening is the testing of an individual with no symptoms for the presence of disease or infection. Genetic screening is the testing of an individual with no symptoms for a specific inherited disorder to determine if the individual carries an abnormal gene. Genetic screening can be used to predict risk or potential risk for the individual or their offspring.

Unaffected Individual:
An individual who displays no signs or symptoms characteristic of a suspected or specific inherited disorder.

Definitions:

Expanded Carrier Screening (ECS):
ECS is a non-targeted approach to carrier screening genetic panels and has been investigated as a new technology to screen for mutations in many genes more efficiently than testing mutations in a single gene or a small number of population-specific mutations in several genes. There is no standardization in the makeup of these genetic panels.

Single Disease Carrier Testing:
Single disease carrier tests for cystic fibrosis include CFnxt Cystic Fibrosis and HerediT™ Cystic Fibrosis Carrier Screen. Carrier tests for spinal muscular atrophy include SMAngt spinal muscular atrophy and HerediT Spinal Muscular Atrophy Carrier Screen.
PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Criteria:

MATERNITY COVERAGE IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER’S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

Other BCBSAZ Medical Coverage Guidelines may exist for diagnosis not addressed in this guideline.

For genetic testing for invasive prenatal fetal testing, amniocentesis and chorionic villous sampling, see BCBSAZ Medical Coverage Guideline #O939, “Genetic Testing With Invasive Prenatal (Fetal) Diagnostic Testing”.

For genetic testing for Fanconi anemia, see BCBSAZ Medical Coverage Guideline #O941, “Genetic Testing for Fanconi Anemia”.

➢ If benefit coverage for maternity is available, the following standard screening tests of a pregnant woman are considered medically necessary:

1. Alpha-fetoprotein (AFP)
2. Glucose
3. Group B Streptococcus culture
4. Hemoglobin and hematocrit
5. Hepatitis B
6. Human Immunodeficiency Virus (HIV)
7. Rh factor
8. Rubella immunity
9. Sexually transmitted diseases (e.g., chlamydia, gonorrhea, syphilis)
10. Ultrasounds
11. Urinary tract infections

➢ If benefit coverage for maternity is available, chromosome testing of products of conception following a spontaneous abortion is considered medically necessary. Chromosome testing of parents is considered not medically necessary.
PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Criteria: (cont.)

➢ If benefit coverage for maternity is available, expanded carrier screening genetic panels are 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.

Tests include, but are not limited to:

▪ AJPnxt Basic and Expanded
▪ Ashkenazi Jewish Panel Carrier Screen
▪ Counsyl™ Family Prep Screen
▪ GoodStart Select™
▪ Inherigen™
▪ Inheritest™
▪ Natera One™ Disease Panel
▪ Natera Horizon™
▪ PreTRM™

➢ Except as expressly described as covered in this guideline, preconception or prenatal and/or infertility genetic testing and/or counseling of an unaffected individual, regardless of risk factors is considered screening and not eligible for coverage.

Examples include, but are not limited to:

▪ A pregnant woman and/or her partner as part of a routine screening maternity assessment or infertility workup except as previously identified
▪ Bloom syndrome
▪ Canavan disease
▪ CFTR gene to determine the G551D mutation for cystic fibrosis in a fetus
▪ Cystic fibrosis screening of an infant
▪ Familial dysautonomia
▪ Gaucher disease
▪ Niemann-Pick
▪ Tay-Sachs disease screening, e.g. HEXA gene analysis
PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Criteria: (cont.)

- Preconception or prenatal and/or infertility genetic testing and/or counseling of an affected individual to confirm a disease when confirmation of the diagnosis would not impact the care and/or management is considered not medically necessary and not eligible for coverage.

Resources:

Literature reviewed 09/12/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Resources: (cont.)


PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Resources: (cont.)


PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

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/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 niliñíí Blue Cross Blue Shield of Arizona haada yít’éego bina’dílkidogo éí doodago Háida bìjá aniiyeeédíí t’àadoo le’é yina’dílkidogo bee haazh’ááníí hólo díí t’àá hazaadk’ehí hákà a’dooowolgo bee ha’z’á doo báq’áh ilinvígó. Atá’ halne’ilígíi kojí bich’í’ hodilínih 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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để đổi chuyển với một thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.
PRECONCEPTION, NONINVASIVE PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang ibang tulongan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang 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 Arizona에 관해서 질문이 있다면 귀하의 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화해주시기 바랍니다.

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て、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 آن کمک می‌کنید، سوال در مورد اطلاعات به زبان خود را به طور رایگان دریافت کنید. لطفاً به شماره 877-475-4799 تماس حاصل شاگرد.

Assyrian: Blue Cross Blue Shield of Arizona, سەنسەیە یەکەیە کە دەدەستیە بۆ ژیانەکانی کە ڕاوەیەکی بۆ سەسەرەکەیە وەکو بۆ ئەپەرەیەکەیە. لە لەسە کە دەگەیە بۆ سەسەرەکەیە، بەردەوام بۆ 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 dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: ถ้าคุณหรือที่มีต่อไปยังมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถจะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่ต้องจ่ายค่าธรรมเนียม โทร 877-475-4799.