ANALYSIS OF HUMAN DNA IN STOOL SAMPLES AS A TECHNIQUE FOR COLORECTAL CANCER SCREENING

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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ANALYSIS OF HUMAN DNA IN STOOL SAMPLES AS A TECHNIQUE FOR COLORECTAL CANCER SCREENING (cont.)

Description:
Detection of DNA abnormalities associated with colorectal cancer in stool samples has been proposed as a screening test for colorectal cancer. This technique is another potential alternative to currently available screening approaches such as fecal occult blood testing, fecal immunochemical testing (FIT) or colonoscopy. The currently available stool DNA test combines FIT and DNA analysis (FIT-DNA).

Several cellular genetic alterations have been associated with colorectal cancer. Tumor-associated gene mutations and epigenetic markers can be detected in exfoliated intestinal cells in stool specimens. Since cancer cells are spread into the stool, tests have been developed that detect these genetic alterations in DNA from shed colorectal cancer cells isolated from stool samples.

Cologuard™ was FDA approved August, 2014 as an automated fecal DNA testing product. Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer or advanced adenoma and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at average risk for colorectal cancer. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Other stool DNA tests have been evaluated in studies and previously marketed including the PreGen-Plus™ and ColoSure™. The PreGen-Plus has not been cleared by the FDA and ColoSure was offered as a laboratory-developed test and is not subject to FDA regulation.

Screening:
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. Screening can be used to predict risk or potential risk for the individual or their offspring.
ANALYSIS OF HUMAN DNA IN STOOL SAMPLES AS A TECHNIQUE FOR
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Criteria:

➢ DNA analysis of stool samples is considered *medically necessary* as a screening technique for colorectal cancer in individuals at average risk of colorectal cancer.

➢ DNA analysis of stool samples for all other indications not previously listed or if above criteria not met 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.

These tests include, *but are not limited to*:

- ColoSure (Vimentin Gene Methylation Assay)
- PreGen-Plus

Resources:

Literature reviewed 11/08/16. 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.

Resources prior to 03/18/14 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


2. American Cancer Society. Colorectal Cancer Prevention and Early Detection. 06/24/16.

ANALYSIS OF HUMAN DNA IN STOOL SAMPLES AS A TECHNIQUE FOR COLORECTAL CANCER SCREENING (cont.)

Resources: (cont.)


11. UpToDate. Screening for Colorectal Cancer: Strategies in Patients at Average Risk. Last updated 08/01/16.
ANALYSIS OF HUMAN DNA IN STOOL SAMPLES AS A TECHNIQUE FOR COLORECTAL CANCER SCREENING (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/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 níldííjíí Blue Cross Blue Shield of Arizona haída ylt’éego bíná’ídilkidgo éi doodago Háída bíjá aniyeedííjí t’aadoo le’e yíná’ídilkidgo beehaz’áníí hóoló díí t’a hazaad’ehí háká a’dóowolgo bee haz’á doo baáh ilínígóó. Atá’ halnééjííjí koj’í bíchí’jí hodilííhin 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 nói chuyện với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona الادوية، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.
ANALYSIS OF HUMAN DNA IN STOOL SAMPLES AS A TECHNIQUE FOR COLORECTAL CANCER SCREENING (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, 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 makaasap 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 도움을 받아야 할 어떤 부담이 없을 수 있는 권리가 있습니다. 그렇게 동역어와 매개하기 위해서는 877-475-4799로 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についてご質問があれば、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まで電話ください。

Farsi:
این شما، یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعات به زبان خود را به مطور رایگان دریافت نمایید 877-475-4799.

Assyrian:
کۆکێکی نۆک و ئەمەبەبەیەکان تەنەوەیە تەنەوەیەکان بۆ Blue Cross Blue Shield of Arizona بە مەنەیە بۆ یەکە لە ڕێگەیەکە نەوەیەکە بۆ 877-475-4799.


Thai: ท่านหรือผู้ที่ได้รับความช่วยเหลือจาก Blue Cross Blue Shield of Arizona ท่านมีสิทธิ์ที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคณะให้โดยไม่มีค่าใช้จ่าย โปรดโทรมาที่ 877-475-4799.