LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE

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 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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LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE (cont.)

Description:

Inflammatory Bowel Disease (IBD) can be subdivided into Crohn's disease (CD) and ulcerative colitis (UC). Both present with symptoms of diarrhea and abdominal pain. It can be difficult to differentiate between CD and UC, but the definitive diagnosis can usually be established by a combination of radiographic, endoscopic and histologic criteria.

Serologic, genetic, and inflammation markers have been investigated as a means to differentiate between IBD versus non-IBD and CD versus UC. Serum markers associated with IBD are anti-neutrophilic cytoplasmic antibodies (ANCA), which is relatively specific for ulcerative colitis, and anti-Saccharomyces cerevisiae (ASCA) antibodies, which is relatively specific for Crohn's disease. ANCA and ASCA have also been investigated as a means to predict response to therapy, to monitor individuals with IBD and to identify susceptibility to IBD among family members of an affected individual.

The PROMETHEUS® IBD sgi Diagnostic™ test combines serologic, genetic and inflammation marker testing to aid in the differentiation of IBD versus non-IBD and CD versus UC. This test is a panel of 17 serologic (n=8), genetic (n=4) and inflammatory biomarkers (n=5), and includes testing for ASCA and ANCA.

Criteria:

Diagnosis of Inflammatory Bowel Disease:

- The following laboratory procedures to diagnose inflammatory bowel disease (IBD) versus non-IBD or to distinguish Crohn's disease from ulcerative colitis 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 as much as, or more than, established alternatives.

These laboratory procedures include, but are not limited to:

- ANCA tests
- ASCA tests
- IBD sgi Diagnostic tests
LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE (cont.)

Criteria: (cont.)

Management of Inflammatory Bowel Disease:

- The following laboratory procedures for the management or monitoring of inflammatory bowel disease 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 as much as, or more than, established alternatives.

These laboratory procedures include, but are not limited to:

- ANCA tests
- ASCA tests
- IBD sgi Diagnostic tests

Resources:

Literature reviewed 05/06/15. 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.


LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE (cont.)

Resources: (cont.)


11. Prometheus® Therapeutics and Diagnostics.


LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE (cont.)

Resources: (cont.)


20. UpToDate, . Immune and microbial mechanisms in the pathogenesis of inflammatory bowel disease. 06/02/2016, 07/31/2013.
LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE (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 níilníi gií Blue Cross Blue Shield of Arizona haada yiít’éego bína’ildíikíi go éí doodago Háída bijá aniyeedííi t’áadoo le’é yína’ildíikíí go beehaz’aanii hóół díí t’áa hazaad’ehi háká a’dóowolgo bée hax’á doo báqah ilínígóó. Ata’ halné’ilgii koj’ bích’í’ hodilíihí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插件項目的名稱 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 thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تسانده أسئلة بخصوص الضرورية بلغتك من دون أي تكلفة للتحدث مع متجم. اتصل ب 877-475-4799.
LABORATORY TESTS FOR THE DIAGNOSIS AND MANAGEMENT OF INFLAMMATORY BOWEL DISEASE (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tutuulanang, 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 Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 메시하기 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 Doimetscher 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 آنکه می‌گویید، سوال در مورد اطلاعاتی که از پزشک را به طور رایگان دریافت نمایید، 877-475-4799 می‌گوید.

Assyrian: حیثیت به شما یا کسی که شما به آنکه می‌گویید، سوال در مورد اطلاعاتی که از پزشک را به طور رایگان دریافت نمایید، 877-475-4799 می‌گوید.


Thai: หากคุณหรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่ต้องเสียค่าใช้จ่าย โปรดโทรถาม โทร 877-475-4799.