ENDOSCOPY BY VIDEO CAPSULE

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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
Endoscopy by Video Capsule (cont.)

Description:

Wireless capsule video endoscopy is performed using the PillCam™ Given® Diagnostic Imaging System, an ingestible endoscope the size of a large capsule which contains a camera, lights, transmitter and batteries. The capsule is swallowed and propelled through the digestive tract by natural muscular waves. The capsule transmits images of the esophagus and/or small intestine to a data recorder worn around the waist. The data is recorded and then transferred to a computer for processing and analysis. Capsule video endoscopy has also been investigated as a technique for evaluation of the colon.

The Given® AGILE Patency System is an accessory capsule to the PillCam system. It has been investigated as a device to verify adequate patency of the gastrointestinal tract before administration of the PillCam in individuals with known or suspected strictures. This capsule is made of lactose and barium and dissolves within 30 to 100 hours of entering the GI tract. It carries a tracer material that can be detected by a scanning device. Excretion of the intact capsule without symptoms (abdominal pain or obstruction) is reported to predict the uncomplicated passage of the wireless capsule.

The PillCam COLON has been investigated for detection of colon polyps in individuals after an incomplete colonoscopy with adequate preparation and a complete evaluation of the colon was not technically possible.
**ENDOSCOPY BY VIDEO CAPSULE** (cont.)

**Criteria:**

- Capsule video endoscopy as an adjunct¹ to other endoscopic and radiologic evaluations of the gastrointestinal system is considered **medically necessary** with documentation of **ANY** of the following:

  1. Suspected Crohn’s disease of the small bowel with negative upper and lower endoscopy and documentation of **ANY** of the following:
     - Abdominal pain, persistent
     - Bleeding
     - Diarrhea
     - Negative stool cultures
     - Weight loss

  2. In individuals with an established diagnosis of Crohn’s disease, when there are unexpected change(s) in the course of disease or response to treatment, suggesting the initial diagnosis may be incorrect and re-examination may be indicated.

  3. Suspected small bowel bleeding as evidenced by prior inconclusive upper and lower gastrointestinal bleeding endoscopic studies performed during the current episode of illness.

  4. Small bowel surveillance with documentation of **ANY** of the following hereditary gastrointestinal polyposis syndromes:
     - Familial adenomatous polyposis including but not limited to Gardner’s syndrome
     - Peutz-Jeghers syndrome
ENDOSCOPY BY VIDEO CAPSULE (cont.)

Criteria: (cont.)

- Capsule video endoscopy 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 indications include, *but are not limited to*:

  - Evaluation of the esophagus in individuals with gastroesophageal reflux disease (GERD) or other esophageal pathologies
  - Evaluation of other gastrointestinal diseases and conditions not presenting with gastrointestinal bleeding, including, *but not limited to*, celiac sprue, irritable bowel syndrome, Lynch syndrome, portal hypertensive enteropathy, small bowel neoplasm and unexplained chronic abdominal pain
  - Initial evaluation of acute upper gastrointestinal bleeding
  
- The patency capsule to evaluate patency of the gastrointestinal tract before wireless capsule endoscopy 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.

  Capsule video endoscopy must **not** be provided as a replacement for endoscopic or radiologic evaluation or as a first-line test for evaluation of obscure gastrointestinal bleeding. Other types of endoscopic or radiologic evaluations include colonoscopy, upper esophagastroduodenoscopy, small bowel follow through and enteroclysis.
ENDOSCOPY BY VIDEO CAPSULE (cont.)

Resources:

Literature reviewed 12/19/17. 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.

Resources prior to 12/19/17 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

ENDOSCOPY BY VIDEO CAPSULE (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 níliñííí Blue Cross Blue Shield of Arizona haadá yít’ éego bina’ idilkidgo éí doodago Háida bii’á anilyeedíííi t’áadoo le’ é yina’ idilkidgo bee hazaaz’ ánii hóóll díí t’áa hazaad’ ek’ éhi háká a’ doowolgo bee haza’ doo bááh ilínígóó. Atá’ halne’ilgíí kojj’ bich’í’ hodíílníí’ 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 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. Đệ nói chuyển với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدادى شخص تساعد أسلحة بخصوص Blue Cross Blue Shield of Arizona الخضوية ببعض اللغة من دون مجة للكل، للتحدث مع مرجم الحلة 877-475-4799.
ENDOSCOPY BY VIDEO CAPSULE (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuanan, ay mga katarungang tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuhang tulong at impormasyon sa iyong wika ng walang gastos. Upang makuasaap ang isang tagsalog, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하의 가족이 Blue Cross Blue Shield of Arizona에 관해 궁금한 점이 있다면 귀하의 통화를 통해 정보를 얻어보시기 바랍니다. 귀하의 대화를 지원하기 위해서는 877-475-4799로 전화해 주세요.

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 вы или лицо, которому вы помогаете, имеют 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:

انگلیسی: اگر شما یا یکی از افرادی که به شما کمک می‌کنید، سوالاتی در مورد اطلاعاتی هستند که به یک زبان خود را به طور رایگان دریافت نمی‌کنند، 877-475-4799 می‌تواند به شما کمک کند.

Assyrian:

عربي: إذا كنت أو شخصًا تقدم له مساعدة، فقد يكون لديك الحق في الحصول على المساعدة والتعليمات باللغة التي تفضلها بجانب الرسالة المجانية 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomazete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodociem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ที่จะขอความช่วยเหลือและข้อมูลภาษาของคนโดยไม่เสียเงิน ที่ 877-475-4799.