OPTICAL ENDOMICROSCOPY

▪ Confocal Laser Endomicroscopy (CLE)
▪ Probe-Based Confocal Laser Endoscopy (pCLE)

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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OPTICAL ENDOMICROSCOPY (cont.)

Description:

Optical endomicroscopy, also known as confocal fluorescent endomicroscopy and confocal laser endomicroscopy (CLE) allows in vivo microscopic imaging of cells during endoscopy. Optical endomicroscopy has been investigated for a variety of purposes, especially as a real-time alternative to biopsy/polypectomy and histopathologic analysis during colonoscopy and for targeting areas to undergo biopsy in individuals with inflammatory bowel disease and Barrett’s esophagus. Optical endomicroscopy has been investigated for a variety of indications, including but not limited to:

- Assessing the adequacy of endoscopic treatment of gastrointestinal lesions
- Atrophic gastritis
- Barrett’s esophagus associated neoplasia
- Breast surgery
- Cholangiocarcinoma
- Colonoscopy
- Colorectal lesions (e.g., colorectal neoplasms, colorectal polyps, inflammatory bowel disease)
- Duodenal polyps
- Esophageal cancer
- Gastric cancer
- Head and neck cancer
- Lung Cancer
- Pancreatic cysts
- Pancreaticobiliary strictures
- Transurethral resection of bladder tumors

Confocal laser endomicroscopy (CLE) devices with FDA-clearance include, but are not limited to:

- Cellvizio® with Confocal Miniprobe™ (Mauna Kea Technologies)
- CranioFlex™ Confocal Miniprobe (Mauna Kea Technologies)
- EC-3S7OCILK Confocal Video Colonoscope (Pentax Medical Company)

Criteria:

- Optical endomicroscopy for all indications 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.
OPTICAL ENDOMICROSCOPY (cont.)

Resources:

Literature reviewed 12/18/18. 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.


OPTICAL ENDOMICROSCOPY (cont.)

Resources: (cont.)


OPTICAL ENDOMICROSCOPY (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 nílínígíí Blue Cross Blue Shield of Arizona haada yit’éego bina’idilkidí éi doodago Háida bijá anilyeedigíí t’àadoo le’é yína’idilkidí beehaz’áaníi hólo díí t’àá hazaadk’ehjí háká a’dowolgo be haz’á doo baq’ ilínígó. Atá’ haine’ígí kojí bích’íí 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 nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تساعده أسألة باللغة العربية، Blue Cross Blue Shield of Arizona ممتنين للتحدث مع مترجمنصب. 877-475-4799.
OPTICAL ENDOMICROSCOPY (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinitulungan, 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 무료없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하시십시오.

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:

امکان حاصل نمی‌باشید. [Blue Cross Blue Shield of Arizona] اطلاعات به زبان خود را به طور رایگان دریافت نمایید.

Assyrian:

إن شاكركم كيماكي كه ما وار كمك ميكيند، سوال در مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 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: หากคุณ หรือคนที่คุณช่วยเหลือจ่ายค่าใช้จ่ายของ Blue Cross Blue Shield of Arizona คุณสมควรจะได้รับความช่วยเหลือและข้อมูลภาษา ของคุณได้โดยไม่ค่าใช้จ่าย ที่ 877-475-4799.