IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY AND FOR RECURRENT SINUS 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 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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Implantable sinus stents have been investigated for use following endoscopic sinus surgery (ESS) for the maintenance of sinus opening patency in the postoperative period. These devices may also serve as a local drug delivery vehicle.

The Propel™ has received FDA premarket approval for use in individuals 18 years of age and older. It is a bioabsorbable, steroid-eluting sinus implant for use following ethmoid sinus surgery to reduce surgical edema and adhesions thereby reducing the need for post-operative interventions and the use of oral steroids. The Propel is designed to be inserted by a physician under endoscopic visualization and once inserted, the implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus.

The Propel Mini Sinus Implant has received FDA premarket approval for use in individuals 18 years of age and older. It is a shortened version of the Propel device. It is approved for use following ethmoid/frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening.

The Propel Contour Sinus Implant has received FDA premarket approval for use in individuals 18 years of age and older to maintain patency of the frontal and maxillary sinuses following sinus surgery and to deliver steroids to the sinus mucosa.

Criteria:

- Implantable sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis 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.

These implants include, but are not limited to:

- Propel
- Propel Mini
- Propel Contour
IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY AND FOR RECURRENT SINUS DISEASE (cont.)

Resources:

Literature reviewed 03/08/17. 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.


IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY AND FOR RECURRENT SINUS DISEASE (cont.)

Resources: (cont.)


Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus 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 nihíghíí Blue Cross Blue Shield of Arizona haada yit’éego bina’idiłkidgo éí doodago Háíída bijá aniyeedííi t’àadoo le’é vina’idiłkidgo beebe’az’ānii hólo díí t’àá hazaad’ēhí háká a’dooowolgo bee ha’z’a doo báah ilinígóó. Ata’ halné’iligí koj’í bíchí’jí hodinííí 877-475-4799.

Chinese: 如您需要服务，或您正在协助的对像，有关于插入项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费以您的母语得到帮助和讯息。请拨打我们的翻译员电话 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 viễn, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدته أسئلة بخصوص خدمات Blue Cross Blue Shield of Arizona غيرها من الأسئلة الأخرى، يمكنك الاتصال ب 877-475-4799.
IMPLANTABLE SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY AND FOR RECURRENT SINUS DISEASE (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katarungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuhang tulog at impormasyon sa iyong wika ng walang gastos. Upang makuasa ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돌고 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 매니저가 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。通訳とお話しされる場合、877-475-4799までお電話ください。

Farsi: اگر شما یا کسی که شما به آن کمک می کنید، سوال در مورد خدمات بهترین خدمت را به طور رایگان دریافت کنید 877-475-4799.

Assyrian: Blue Cross Blue Shield of Arizona یاری کننده به شما و نیازمندی می‌شود. درخواست دارید 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 prevodilicom, nazovite 877-475-4799.

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