INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS)

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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**INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS) (cont.)**

**Description:**

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves.

Interlaminar spacers are implanted to provide dynamic stabilization following decompressive surgery or as an alternative to decompressive surgery. These implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically, enlarges the neural foramen and decompresses the cauda equine in individuals with spinal stenosis and neurogenic claudication.

FDA-approved devices include the X-STOP® Interspinous Process Decompression (IPD®) System, the coflex® Interlaminar Technology implant previously called the Interspinous U and the Superion® Interspinous Spacer (ISS). In 2015, Medtronic discontinued sales and distribution of the X-STOP device.

**Criteria:**

For interspinous fixation (fusion) devices (e.g., coflex-F®), see BCBSAZ Medical Coverage Guideline #O661, “Interspinous Fixation (Fusion) Devices”.

- **Interspinous** or interlaminar distraction devices as a stand-alone procedure for the treatment of spinal stenosis 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.

- Use of interlaminar stabilization device following decompressive surgery 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.
INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS) (cont.)

Resources:

Literature reviewed 05/09/17. 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.


3. Bae HW, Davis RJ, Laurysen C, Leary S, Maislin G, Musacchio M, Jr. Three-Year Follow-up of the Prospective, Randomized, Controlled Trial of Coflex Interlaminar Stabilization vs


INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS) (cont.)

Resources: (cont.)


INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS) (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 níiłígíí Blue Cross Blue Shield of Arizona haada yit’éego bína’díílígíí íí’ doodago Háída bíí áníiyeedííí t’áadoo le’é yína’díílígíí beehaz’áaníí hóló díí t’áá hazaad’éehjí háká a’dooowolgo bee haz’á díí bąqą‘h ilinígóó. Atá’ halne’ilígíí kojí’ bíchí’ ho’díílííníh 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. Đenegro chuyển với một thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو تأثر شخص تستأثر أسئلة بخصوص Blue Cross Blue Shield of Arizona، فهذا الحق في الحصول على المساعدة والموارد الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.
INTERSPINOSIS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS) (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 iyang 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 Arizona 의 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 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 Dozetscher 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て、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 آن کمک می‌کنید، سوالی در مورد اطلاعات به بیان خود را به طور رایگان دریافت نمایید؟ 877-475-4799

Assyrian: Blue Cross Blue Shield of Arizona حکمه، که معلولین، معلولین، معلولین، معلولین، معلولین، معلولین، معلول

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

Thai: หากคุณ หรือคุณช่วยเหลือของคุณมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสมควรจะติดต่อกับทีมนักกฎหมายและทีมฝ่ายกฎหมายของคุณได้โดยไม่เสียค่าใช้จ่าย โปรดติดต่อ โทร 877-475-4799