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.

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.
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.)


FDA Premarket Approval Database for X STOP Interspinous Process Decompression System:

- **FDA-approved indication:** Approval for the X STOP interspinous process decompression system. The device is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with x-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months on nonoperative treatment. The X STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

FDA Premarket Approval Database for coflex Interlaminar Technology:

- **FDA-approved indication:** Approval for the coflex Interlaminar Technology. This device is indicated for use in one- or two-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 month of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).
INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES
(SPACERS) (cont.)

**Resources:** (cont.)

FDA Premarket Approval Database for Superion Interspinous Spacer:

- **FDA-approved indication:** Approval for the Superion Interspinous Spacer (ISS): This device is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, mri and/or ct evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The superion® iss is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The superion iss may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from l1 to l5. For this intended use, moderate degenerative lumbar spinal stenosis was defined as follows:1) 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:a) evidence of thecal sac and/or cauda equina compression;b) evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements; andc) evidence of hypertrophic facets with canal encroachment. 2) and associated with the following clinical signs:a) presents with moderately impaired physical function (pf) defined as a score of >= 2. 0 of the zurich claudication questionnaire (zcq); andb) ability to sit for 50 minutes without pain and to walk 50 feet or more
MEDICAL COVERAGE GUIDELINES

SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/07/12
LAST REVIEW DATE: 05/09/17
LAST CRITERIA REVISION DATE: 05/09/17
ARCHIVE DATE:

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 nilingiií Blue Cross Blue Shield of Arizona haadá yit’éego bíina’dííkíddgo éí doocdao Háida bijá aniyeedíígi t’áadoó le’é yina’dííkíddgo beehaz’ááníi hóó díí t’áá hazaak’ehii háká a’dooowolgo bee haz’a doo baą́h nilingóó. Ata’ halne’iligí‘ kojí bíchí’i’ hodiliinh 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 có vụ việc, hay người nhà vụ việc đang gặp khó, có câu hỏi về Blue Cross Blue Shield of Arizona vụ việc sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thống dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو أدى شخص تساؤله أسئلة بخصوص

الضرورة بلغتك من دون أي تكلفة. للتحدث مع مترجم، اتصل ب 877-475-4799.
INTERSPINOUS 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 Arizona에 관해서 질문이 있다면 귀하의 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 얘기하기 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。通訳とお話される場合、877-475-4799までお電話ください。

Farsi: 
آگر شما، یا کسی که شما او یا کمک می‌کنید، سوال در مورد اطلاعاتی که درباره Blue Cross Blue Shield of Arizona باید پرسیده شود، با کمک و 877-475-4799 تماس حاصل نمایید.

Assyrian: 

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: หากคุณหรือบุคคลอื่นต้องการที่จะสอบถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถจะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่ต้องใช้ค่าใช้จ่าย โปรดโทรมาที่ 877-475-4799.