



An Independent Licensee of the Blue Cross Blue Shield Association

**EVIDENCE-BASED CRITERIA
SECTION: SURGERY**

**ORIGINAL EFFECTIVE DATE: 09/12/22
LAST REVIEW DATE: 06/04/24
CURRENT EFFECTIVE DATE: 06/04/24
LAST CRITERIA REVISION DATE: 06/06/23
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NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

AXIAL LUMBOSACRAL INTERBODY FUSION

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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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AXIL LUMBOSACRAL INTERBODY FUSION

Description:

Axial lumbosacral interbody fusion (also called presacral, transsacral, or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

FDA approved anterior spinal intervertebral body fixation orthoses devices include, *but are not limited to:*

- TranS1® AxiaLIF™ System
- TranS1® AxiaLIF® II System
- TranS1® AxiaLIF® 2L System
- TranS1® AxiaLIF® Plus System

Definitions:

Interbody fusion is a surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in individuals with spinal stenosis and instability, spondylolisthesis, scoliosis, following a discectomy, or for adjacent-level disc disease.

Criteria:

- Axial lumbosacral interbody fusion is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 06/04/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 06/04/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

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11. U.S. Food and Drug Administration. Premarket Notification [510(K)] Summary. TranS1 AxiaLIF II System. Accessed March 10, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf7/K073643.pdf
12. Whang PG, Sasso RC, Patel VV, Ali RM, Fischgrund JS. Comparison of axial and anterior interbody fusions of the L5-S1 segment: a retrospective cohort analysis. *J Spinal Disord Tech*. Dec 2013;26(8):437-43. doi:10.1097/BSD.0b013e318292aad7



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13. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. *Clin Interv Aging*. 2013;8:1063-9. doi:10.2147/CIA.S49802

Coding:

CPT: 22586, 22899

History:

Date:

Activity:

Medical Policy Panel	06/04/24	Review with revisions
Medical Policy Panel	06/06/23	Review with revisions
Medical Policy Panel	08/16/22	Approved guideline (Effective 9/19/22)
Medical Director (Dr. Deering)	07/08/22	Development

Policy Revisions:

06/04/24	Updated:	Resources section
06/06/23	Added:	“Insufficient evidence to support improvement of the net health outcome; or”, and “Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or” to experimental or investigational criteria.
06/06/23	Revised:	“Insufficient evidence to support improvement outside the investigational setting” from #3 to #5 in experimental or investigational criteria.
06/06/23	Updated:	Definitions section, Resources section.



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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 nilinígíí Blue Cross Blue Shield of Arizona haada yit’éeego bina’idíílkidgo éí doodago Háida bíjá anilyeedígíí t’áadoo le’é yina’idíílkidgo beehaz’ánii hólo díí t’áa hazaadk’ehjí háká a’doowołgo bee haz’ą doo baqah ilínígóó. Ata’ halne’ígíí kojí’ bich’j’ hodíilnih 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 thêm 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 لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

