BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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ARCHIVE DATE:

INTERSPINOUS FIXATION (FUSION) DEVICES

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.

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.

Description:

Interspinous fixation (fusion) devices are being investigated to aid in the stabilization of the spine. They are being evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices are also being evaluated for stand-alone use in individuals with spinal stenosis.

Devices include:

- Affix™ (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx)
- Avenue L Lateral Lumbar Cage System® (LDR)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec)
- Coflex-F® (Paradigm Spine)
- Inspan™ (Spine Frontier)

INTERSPINOUS FIXATION (FUSION) DEVICES (cont.)

Description: (cont.)

- PrimaLOK™ (OsteoMed)
- Octave™ (Life Spine)
- Spire™ (Medtronic)
- SP-Fix™ (Globus)

Criteria:

- Interspinous fixation (fusion) devices for the following indications 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.

  These indications include, *but are not limited to*:

  - Used in combination with interbody fusion
  - Used alone for decompression in individuals with spinal stenosis

Resources:

1. 7.01.138 BCBS Association Medical Policy Reference Manual. Interspinous Fixation (Fusion) Device. Issue date 09/12/2013.

FDA Premarket Approval Database for LDR Spine USA Avenue® L Interbody Fusion System:

- FDA-approved indication: Intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with or without integrated fixation and must be used in conjunction with posterior supplementation fixation (e.g., pedicle screws). The device is intended to be used with autograft to facilitate fusion.

INTERSPINOUS FIXATION (FUSION) DEVICES (cont.)

Resources: (cont.)

Affix is a trademark of NuVasive, Inc., an independent corporation that is not affiliated with BCBSAZ.
Aileron and Octabe is a trademark of Life Spine, Inc., an independent corporation that is not affiliated with BCBSAZ.
Aspen is a trademark of Lanx, Inc., an independent corporation that is not affiliated with BCBSAZ.
Avenue L Lateral Lumbar Cage System is a registered trademark of LDR, an independent corporation that is not affiliated with BCBSAZ.
Axle is a trademark of X-Spine, Inc., an independent corporation that is not affiliated with BCBSAZ.
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