



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Facet Arthroplasty

Policy #: 367
Category: Surgery

Latest Review Date: April 2021
Policy Grade: B

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after March 24, 2020:

Blue Advantage will treat **total facet arthroplasty** as a **non-covered** benefit and as **investigational**.

Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCD L34555.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **total facet arthroplasty** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Facet arthroplasty refers to the implantation of a spinal prosthesis to restore posterior element structure and function as an adjunct to neural decompression. This procedure is proposed as an alternative to posterior spinal fusion for patients with facet arthrosis, spinal stenosis, and spondylolisthesis.

Spinal fusion is a common surgical treatment following surgical decompression when conservative treatment fails. However, spinal fusion alters the normal biomechanics of the back, which may potentially lead to premature disc degeneration at adjacent levels. A variety of implants have been investigated as alternatives to rigid interbody or posterolateral intertransverse spinal fusion. This policy addresses the implantation of prostheses intended to replace the facet joints and excised posterior elements, termed facet arthroplasty. The objective of facet arthroplasty is to stabilize the spine while retaining normal intervertebral motion of the surgically removed segment following neural decompression. It is proposed that facet arthroplasty should also maintain the normal biomechanics of the adjacent vertebrae. If normal motion patterns are achieved by artificial joints in the spine, the risk of adjacent-level degeneration thought to be associated with fusion may be mitigated.

KEY POINTS:

This policy has been updated regularly with searches of the MEDLINE database. The most recent update was performed through January 11, 2021.

Summary of Evidence

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of a RCT and a few case series studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Interim results from a pivotal trial of the ACADIA Facet Replacement System were reported in 2012. No additional publications from this trial, which was expected to be completed October 2015, have been identified to date. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received U.S. Food and Drug Administration approval. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

No guidelines were identified.

U.S. Preventative Services Task Force Recommendations

Not applicable.

KEY WORDS:

Total facet arthroplasty, facet arthroplasty, TFAS, ACADIA® Facet Replacement System.

APPROVED BY GOVERNING BODIES:

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA) at this time. The ACADIA™ Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) was being evaluated in an FDA regulated investigational device exemption phase 3 trial which was completed in October 2017, but has not been published. A Phase III trial of the Total Facet Arthroplasty System® (TFAS®, Archus Orthopedics) has been discontinued. (Facet Solutions acquired Archus Orthopedics in 2009. In 2011, Globus Medical acquired Facet Solutions.)

Another implant design, the Total Posterior-element System (TOPS™, Premia Spine), is currently available in Europe.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

0202T	Posterior vertebral joint(s) arthroplasty (e.g. facet joint[s] replacement) including facetectomy, laminectomy, foraminectomy and vertebral with or without injection of bone cement, including fluoroscopy, single level, lumbar spine
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REFERENCES:

1. Blue Cross Blue Shield Association. Total facet arthroplasty. Medical Policy Reference Manual, July 2012.
2. ClinicalTrials.gov. Safety and effectiveness study of the TOPS System, a total posterior arthroplasty implant designed to alleviate pain resulting from moderate to severe lumbar stenosis. clinicaltrials.gov/ct2/show/NCT00405691?term=NCT00405691&rank=1.
3. Dryer RF, Regan JJ, Hartjen CA et al. Prospective US IDE trial: Interim results for the treatment of symptomatic lumbar spinal stenosis with facet replacement in 100 patients enrolled at 15 centers. *Spine J* 2010; 10(9 SUPPL 1):90S.
4. Goodwin, MM, Spiker, WW, Brodke, DD, Lawrence, BB. Failure of facet replacement system with metalon-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases.. *J Neurosurg Spine*, 2018 Apr 14;29(1).
5. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
6. Myer J, Youssef JA, Rahn KA, et al. ACADIA facet replacement system IDE clinical trial: Preliminary outcomes at two-and four-years postoperative. *Spine J*. 2014; 11(SUPPL. 1):S160-161.
7. Palmer DK, Inceoglu S, Cheng WK. Stem fracture after total facet replacement in the lumbar spine: a report of two cases and review of the literature. *Spine J* 2011; 11(7):e15-9.
8. Phillips FM, Tzermiadianos MN, Voronov LI, et al. Effect of the Total Facet Arthroplasty System after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments. *Spine J*, January-February 2009; 9(1): 96-102.
9. Smorgick Y, Mirovsky Y, Floman Y et al. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis. *J Neurosurg Spine*. 2019 Oct;1-6:1-6.

POLICY HISTORY:

Adopted for Blue Advantage, July 2009

Available for comment July 20-September 2, 2009

Medical Policy Group, July 2010

Medical Policy Group, July 2011

Medical Policy Group, July 2012

Medical Policy Group, August 2013

Medical Policy Group, August 2014

Medical Policy Group, July 2015
Medical Policy Group, January 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, April 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.