Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Facet Arthroplasty

Policy #: 367
Latest Review Date: April 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

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:

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 PubMed database. The most recent literature update was performed through February 21, 2023.

Summary of Evidence

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of an otherwise unpublished randomized controlled trial (RCT), a planned interim analysis of an ongoing 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 completed in October 2017, have been identified to date. Interim results from a pivotal randomized trial of the

Total Posterior-element System (TOPS) indicated substantial improvement over transforaminal lumbar interbody fusion (TLIF) in multiple patient-reported outcomes related to functional status and symptoms up to 2 years post-operatively; the results further suggested relatively preserved range of motion at the treated vertebral level with TOPS versus TLIF, without increased risk of adverse events. 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; results without statistical analysis were posted on ClinicalTrials.gov but have not been published in the peer-reviewed literature. A Phase III trial of the Total Facet Arthroplasty System® (TFAS®, Archus Orthopedics) was discontinued.

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 column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine

REFERENCES:

1. ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020.
2. Coric D, Nassr A, Kim PK, et al. Prospective, randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis. J Neurosurg Spine. Jan 01 2023; 38(1): 115-125.
3. Goodwin ML, Spiker WR, Brodke DS, et al. Failure of facet replacement system with metal-on-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases. J Neurosurg Spine. Jul 2018; 29(1): 81-84.
4. Gu BJ, Blue R, Yoon J, et al. Posterior Lumbar Facet Replacement and Arthroplasty. Neurosurg Clin N Am. Oct 2021; 32(4): 521-526.
5. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
6. Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. BMJ. Jan 04 2016; 352: h6234.
7. 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.
8. 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. July 2011; 11(7):e15-9.
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. Oct 04 2019: 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
Medical Policy Group: April 2022
Medical Policy Group, April 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.

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.