BlueCross BlueShield of Alabama

Name of Policy:
Facet Arthroplasty

Policy #: 367
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

Background:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts to have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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.

Policy:

Total facet arthroplasty does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate 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.

Key Points:

This policy has been updated regularly with searches of the MEDLINE database. The most recent update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be

relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Facet Arthroplasty
A report by Palmer et al indicated that the U.S. Food and Drug Administration–regulated multicenter investigational device exemption trial (NCT00418197) of the Total Facet Arthroplasty System was discontinued due to financial reasons. Two of 10 Total Facet Arthroplasty System implants performed at the authors' institution experienced stem fracture after total facet replacement.

An abstract reported by Myer et al in conference proceedings provided interim 2- and 4-year results for 243 patients from a phase 3 multicenter randomized trial of the ACADIA Facet Replacement System (NCT00401518; see Table 1). The study, which was completed in late 2017, enrolled 390 subjects with lumbar spinal stenosis, and compared facet arthroplasty with the ACADIA system to spinal fusion. Submission of trial data to the U.S. Food and Drug Administration is expected.

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 randomized controlled trial. 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 the effects of the technology on health outcomes.

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, Hopkinton, MA) is currently being evaluated as part of an ongoing FDA-regulated investigational device exemption (IDE) Phase III trial. The Phase III trial of the Total Facet Arthroplasty System® (TFAS®, Archus Orthopedics) has been discontinued. (Facet Solutions acquired Archus Orthopedics and all of their assets in 2009. In 2011, Globus Medical acquired substantially all of the assets of 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.
ITS: Home Policy provisions apply. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

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

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. 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.
5. 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.
6. 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.

Policy History:

Medical Policy Group, July 2009 **(1)**
Medical Policy Administration Committee, August 2009
Available for comment August 10-September 23, 2009
Medical Policy Group, July 2010 **(1)** Updated Key Points and Governing Bodies information
Medical Policy Group, July 2011 **(1)** Updated Key Points, Approved by Governing Bodies, References
Medical Policy Group, July 2012 **(1)** Update to Key Points, Approved by Governing Bodies, and References related to MPP update; no change in policy statement.
Medical Policy Panel, July 2013
Medical Policy Group, September 2013 **(2)** Policy updated with literature review through June 2013. Policy statement unchanged. Minor wording changed to Key Points.
Medical Policy Panel July, 2014
Medical Policy Group July, 2014 **(4):** Updated Key Points, added USPSTF section. There are no changes to the policy statement at this time.
Medical Policy Panel, July 2015
Medical Policy Group, July 2015 (**2**): 2015 Updates to Key Points and Key Words, no change to policy statement.
Medical Policy Panel, January 2017
Medical Policy Group, January 2017 **(7):** 2017 Updates to Key Points & References; no change to policy statement.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(7)**: 2018 Updates to Key Points; no change to policy statement.
