Name of Policy: Facet Arthroplasty

Policy #: 367       Latest Review Date: July 2014
Category: Surgery   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 for degenerative disc disease 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:
Searches of the MEDLINE database, most recently performed through June 2014, identified a report indicating that the U.S. Food and Drug Administration (FDA)-regulated multicenter investigational device exemption (IDE) trial (NCT00418197) of the Total Facet Arthroplasty System® (TFAS®) was discontinued due to financial reasons. (Facet Solutions acquired Archus Orthopedics and all of their assets in November 2009). Two out of 10 TFAS procedures performed at the authors’ institution had stem fracture after total facet replacement.

Identified from the EMBASE database was a conference proceeding of interim results in 100 patients from the U.S. multicenter, randomized trial of the ACADIA™ Facet Replacement System (NCT00401518). The study began in 2006, is expected to enroll around 300 subjects with lumbar spinal stenosis, and compares facet arthroplasty with the ACADIA™ system to posterior spinal fusion. Information posted in April 2012 on the online site ClinicalTrials.gov
indicates that recruitment is ongoing. Study completion with a 24-month follow-up is expected in October 2014.

A search of ClinicalTrials.gov in June 2014 showed a prospective, multicenter clinical study to assess the Implant TOPSTM system (NCT00405691), this study is listed as completed as of May 2011. The study began in 2006 with an estimated enrollment of 450 subjects with back and leg pain resulting from moderate/severe lumbar spinal stenosis at a single vertebral level between L3 to L5. The objective of the study is to compare the safety and effectiveness of the TOPS System to a control group of patients undergoing posterior spinal fusion with pedicle screws and local autograft bone.

As of June 2014, an industry-sponsored postmarketing study of the TOPSTM system (NCT01933607) is not yet open for recruitment. There is an estimated enrollment of 10 subjects in this single-arm study. Study completion is expected December 2016.

Facet arthroplasty refers to the implantation of a spinal prosthesis to restore posterior element structure and function as an adjunct to neural decompression. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received FDA approval; therefore, facet arthroplasty is considered investigational.

U.S. Preventative Services Task Force Recommendations
Facet arthroplasty is not a preventive service.

Key Words:
Total facet arthroplasty, facet arthroplasty, TFAS

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 (TOPSTM, Implant Ltd., Israel), is in development and has restarted enrollment in a FDA-regulated Phase III trial in 2011 after design and manufacturing changes. Premia Spine acquired Implant in 2011.

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. 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:**


**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.

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.