

## Corporate Medical Policy

### Total Facet Arthroplasty

**File Name:** total\_facet\_arthroplasty  
**Origination:** 10/2009  
**Last CAP Review:** 11/2011  
**Next CAP Review:** 11/2012  
**Last Review:** 11/2011

#### Description of Procedure or Service

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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.

#### Regulatory Status

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA) at this time. The Total Facet Arthroplasty System™ (TFAS™, Archus Orthopedics) and ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA) are currently being evaluated as part of ongoing FDA-approved investigational device exemption (IDE) Phase III trials. (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™, Impliant 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 Impliant in 2011.

#### Related policies:

Artificial Intervertebral Disc  
Spinal Surgery Using Interspinous Distraction Technology  
Lumbar Spine Fusion Surgery

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

# Total Facet Arthroplasty

## Policy

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**Total facet arthroplasty is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Total Facet Arthroplasty is covered

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Not applicable.

## When Total Facet Arthroplasty is not covered

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Total facet arthroplasty is considered investigational. BCBSNC does not provide benefits for investigational services.

## Policy Guidelines

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Searches of the MEDLINE database, most recently performed through May 2011, identified several ex vivo biomechanical assessments in cadaver spine. For example, Phillips et al. reported a manufacturer-sponsored study that assessed the kinematics of implanted and adjacent lumbar segments in 9 human lumbar spines (L1 to sacrum). No clinical trial results were found.

A search of online site [ClinicalTrials.gov](http://ClinicalTrials.gov) in June 2011 showed 3 Phase III clinical trials, all sponsored by the device developers.

NCT00401518 is a U.S. multicenter, randomized trial of the ACADIA™ Facet Replacement System that is listed as actively recruiting as of May 17, 2011. 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. The estimated completion of the 24-month primary outcome data is in 2013.

No device has received FDA approval; therefore, facet arthroplasty is considered investigational.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 0202T*

# Total Facet Arthroplasty

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/9/09

Senior Medical Director Review - 9/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/8/10

Specialty Matched Consultant Advisory Panel – 11/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/14/2011

Medical Director – 8/2011

Specialty Matched Consultant Advisory Panel – 10/2011

## Policy Implementation/Update Information

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10/26/09 New policy implemented. BCBSNC will not provide coverage for total facet arthroplasty. It is considered investigational. BCBSNC does not provide benefits for investigational services. Reviewed with Senior Medical Director 9/30/09. (btw)

6/22/10 Policy Number(s) removed (amw)

12/21/10 Specialty Matched Consultant Advisory Panel review 11/21/2010. No change to policy intent. References added. (btw)

9/13/11 “Description” section updated. “Policy Guidelines” updated. Medical Director review 8/27/2011. Reference added. (btw)

12/20/11 Specialty Matched Consultant Advisory Panel review 11/30/2011. No change to policy intent. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.