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# Corporate Medical Policy

## Total Facet Arthroplasty

File Name: total\_facet\_arthroplasty

**Origination:** 10/2009 **Last Review:** 10/2023

#### **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 individuals 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). The ACADIA<sup>TM</sup> 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 3 trial of the Total Facet Arthroplasty System® (TFAS®, Archus Orthopedics) was discontinued. Another implant design, the Total Posterior-element System (TOPS<sup>TM</sup>, Premia Spine), is currently available in Europe.

#### Related policies:

Artificial Intervertebral Disc Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) Lumbar Spine Procedures Cervical Spine Procedures

\*\*\*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.

#### **Policy**

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

#### **Benefits Application**

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

Not applicable.

### When Total Facet Arthroplasty is not covered

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

#### **Policy Guidelines**

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 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 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. 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.

### Billing/Coding/Physician Documentation Information

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. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0202T

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**

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/12/2012

Specialty Matched Consultant Advisory Panel – 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/11/2013

Specialty Matched Consultant Advisory Panel – 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/10/2014

Specialty Matched Consultant Advisory Panel – 10/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 7/9/2015

Specialty Matched Consultant Advisory Panel – 10/2015

Specialty Matched Consultant Advisory Panel – 10/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 1/12/2017

Specialty Matched Consultant Advisory Panel – 10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 4/12/2018

Specialty Matched Consultant Advisory Panel – 10/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 4/8/2019

Specialty Matched Consultant Advisory Panel – 10/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 4/16/2020

Specialty Matched Consultant Advisory Panel – 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.120, 4/8/2021

Specialty Matched Consultant Advisory Panel – 10/2021

Specialty Matched Consultant Advisory Panel – 10/2022

Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. BMJ. Jan 04 2016; 352: h6234. PMID26727925

Gu BJ, Blue R, Yoon J, et al. Posterior Lumbar Facet Replacement and Arthroplasty. Neurosurg Clin N Am. Oct 2021; 32(4): 521-526. PMID 34538478

ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020.

Specialty Matched Consultant Advisory Panel – 10/2023

Medical Director review- 10/2023

#### **Policy Implementation/Update Information**

- 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)
- 9/4/12 Regulatory Status section updated. Reference added. (btw)
- 11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. Policy Guidelines updated. No change to policy intent. (btw)
- 8/27/13 Reference added. (btw)
- 11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to policy. (btw)
- 12/9/14 Reference added. Specialty Matched Consultant Advisory Panel review 10/28/2014. Policy Guidelines updated. No change to Policy statement. (sk)
- 9/1/15 Reference added. (sk)
- 11/24/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. (sk)
- 11/22/16 Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)
- 3/31/17 Reference added. Policy Guidelines updated. (sk)
- 11/10/17 Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
- 7/13/18 Reference added. (sk)
- 11/9/18 Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
- 7/1/19 Reference added. Regulatory Status updated. (sk)
- 11/26/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)

8/25/20	Reference added. (sk)
11/10/20	Specialty Matched Consultant Advisory Panel review 10/21/2020. (sk)
3/31/22	Reference added. Specialty Matched Consultant Advisory Panel review 10/20/2021. (sk)
5/2/23	Policy review. Specialty Matched Consultant Advisory Panel review 10/19/2022. (sk)
11/7/23	Added and updated title of one Related Policy. Updated Regulatory Status. Policy Guidelines updated. No change to policy intent. References updated. Specialty Matched Consultant Advisory Panel review 10/2023. Medical Director review 10/2023. (ldh)

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.