

## Corporate Medical Policy

### Total Facet Arthroplasty

**File Name:** total\_facet\_arthroplasty  
**Origination:** 10/2009  
**Last Review:** 10/2024

#### 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 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

In June 2023, the Total Posterior Spine (TOPS™; Premia Spine) System was approved by the U.S. Food and Drug Administration (FDA) via the premarket approval (PMA) process (PMA: P220002). Per the approval order statement, "the TOPS System is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The TOPS system is intended to stabilize the spine following a lumbar decompression without rigid fixation. The TOPS System is indicated for individuals between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade 1, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or of the scarring facet joint capsule at one level from L3 to L5."

TOPS System was previously granted breakthrough device status through the FDA in October 2020. The TOPS System has been marketed outside of the U.S. since 2012, and is commercially available in several European Union countries, in Australia, and in several Asian countries. FDA Product Code: QWK.

Other products are currently under review. 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. ACADIA Facet Replacement System is currently only available outside of the U.S.

# Total Facet Arthroplasty

## **Related policies:**

Artificial Intervertebral Disc  
Interspinous and Interlaminar Stabilization/Distraktion 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**

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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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For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of an unpublished randomized controlled trial (RCT), two planned interim analysis of an ongoing RFT, 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 Spine (TOPS) System (TOPS) indicated substantial improvement compared to baseline at one-year and 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. Based on 24-month results, the TOPS System received U.S. Food and Drug Administration approval in June 2023; the final trial results have not yet been published. While the interim results are promising, clarity is needed on the final results of the trial to determine if adjustments for increased risk of type 1 error were made and to evaluate other strengths and limitations of the trial. Additionally, continued follow-up of the TOPS trial is ongoing, which will shed light on longer-term safety profiles of TOPS versus TLIF with lumbar spinal decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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## **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*

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

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

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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

Pinter ZW, Freedman BA, Nassr A, et al. A Prospective Study of Lumbar Facet Arthroplasty in the Treatment of Degenerative Spondylolisthesis and Stenosis: Results from the Total Posterior Spine System (TOPS) IDE Study. *Clin Spine Surg*. Mar 01 2023; 36(2): E59-E69. PMID 36191093

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. PMID 36152329

U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED): TOPS System. June 15, 2023. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf22/P220002B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220002B.pdf)

Specialty Matched Consultant Advisory Panel – 10/2024

Medical Director review- 10/2024

## 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)

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- 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)
- 11/13/24 Updated Regulatory Status. Policy Guidelines updated. No change to policy intent. References updated. Specialty Matched Consultant Advisory Panel review 10/2024. Medical Director review 10/2024. (ldh)

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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.