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## Medical Policy



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of the Blue Cross and Blue Shield Association

**Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.**

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**\*Current Policy Effective Date: 3/1/25**  
**(See policy history boxes for previous effective dates)**

### **Title: Facet Arthroplasty**

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#### **Description/Background**

Spinal fusion is a common surgical treatment following surgical decompression when conservative treatment fails.<sup>1</sup> 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 evidence review 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.<sup>2</sup> 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.

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#### **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).<sup>3</sup> 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 patients 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 a 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.<sup>4</sup>

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**Medical Policy Statement**

The insertion of posterior intrafacet implants is experimental and investigational. It has not been scientifically demonstrated to be as safe and effective as conventional surgical approaches for the treatment of painful spinal facet joints.

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**Inclusionary and Exclusionary Guidelines**

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

**Established codes:**

N/A

**Other codes (investigational, not medically necessary, etc.):**

0202T	0219T	0220T	0221T	0222T	0219T
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**Rationale**

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.

### **Clinical Context and Therapy Purpose**

The purpose of facet arthroplasty in individuals who have lumbar spinal stenosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** were used to select literature to inform this review.

### **Populations**

The relevant population of interest are individuals with lumbar spinal stenosis.

### **Intervention**

The therapy being considered is facet arthroplasty. A variety of implants have been investigated as alternatives to rigid interbody or posterolateral intertransverse spinal fusion. This evidence review 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.

### **Comparators**

The following practice is currently being used to treat lumbar spinal stenosis: lumbar spinal decompression with spinal fusion. 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. Lumbar spinal stenosis may also be treated with nerve ablation techniques.

### **Outcomes**

The general outcomes of interest are pain, function, QOL, and adverse events related to the surgical procedure.

### **Review of Evidence**

#### **U.S. Food and Drug Administration Approved Devices**

Smorgick et al (2019) initially reported 11-year outcomes of 10 individuals from a single center in Israel who received the Total Posterior Spine (TOPS; Premia Spine) System as an adjunct to decompression to treat neurogenic claudication of at least 12 weeks' duration due to spinal stenosis with single-level grade 1 L4 to L5 degenerative spondylolisthesis.<sup>5</sup> In this study, 6-week improvements in leg pain, back pain, disability, and quality of life were generally maintained at 11 years. In terms of adverse events, there was 1 case of implant failure at 12 weeks that involved a damaged polycarbonate urethane component that led to internal locking of the device; no other instances of screw loosening or breakages, spontaneous fusion, or progression of the spondylolisthesis were observed. These results contributed to breakthrough device status being granted in October 2020 by the U.S. Food and Drug Administration (FDA).

A planned 1 year interim safety analysis of the randomized, single-blind, multicenter FDA investigational device exemption (IDE) trial of the TOPS device was conducted by Pinter et al (2023).<sup>6</sup> This interim analysis only evaluated patients who had undergone implementation of the TOPS device and compared postoperative results to baseline characteristics. At the time of analysis, 153 patients had undergone implantation of the TOPS device. Characteristics of patients are described below, by Coric et al (2022). Postoperative complications occurred in 11/153 (7.2%) patients, including 2 neurological deficits, 2 dural tears, 2 retained drains, 1 pair of misplaced pedicle screws, 1 screw loosening, 1 infection, 1 seroma, and 1 hematoma. The 2 patients who reported new neurological deficits experienced full recovery within one year after surgery. Of the 153 patients enrolled, 105 patients (69%) reached 1-year follow-up by the time of interim analysis and were included in analysis of patient-reported outcomes. From baseline, mean Oswestry Disability Index (ODI) scores improved from  $56.9 \pm 12.4$  to  $22.1 \pm 17$  at 6 weeks postoperatively ( $p < .001$ ), and were maintained at 3, 6, and 12 months postoperatively. At 1 year, mean ODI scores were  $11.5 \pm 14.9$  and 93.2% of patients had achieved a minimally clinically important difference (MCID) ( $p < .001$ ). Pain scores were reported via visual analog scale (VAS). Mean VAS scores for low back pain improved from  $67.2 \pm 24.4$  preoperatively to  $12.7 \pm 21.8$  at 12 months postoperatively, and 83% of patients had achieved a MCID ( $p < .001$ ). Additionally, VAS scores for worst leg pain also improved from  $83.9 \pm 13.2$  preoperatively to  $11.5 \pm 22.7$  at 12 months postoperatively ( $p < .001$ ), and more than 90% of patients achieved a MCID in VAS worst leg pain at all postoperative time points. This interim analysis of the TOPS device demonstrated safety and efficacy compared to baseline at 12 months post-implantation.

Efficacy results of a planned 2-year interim analysis of the randomized, single-blind, multicenter IDE TOPS trial were published by Coric et al (2022).<sup>7</sup> Adults age 35 to 80 years with grade I spondylolisthesis with symptomatic stenosis despite at least 6 months of conservative therapy (such as physical therapy, systemic pain management, or local injections or nerve block) were randomized 2:1 to undergo surgical decompression followed by either stabilization with TOPS or transforaminal lumbar interbody fusion (TLIF). The primary endpoint is a composite clinical success rate, defined as improvement of at least 15 points from baseline in the ODI without new or worsening neurological deficit or treatment failure (need for surgical reintervention or radiographic evidence of device breakage or disassembly), analyzed at 24-month post-operative follow-up. The interim analysis compared the primary endpoint in 170 patients randomized to TOPS and 79 patients randomized to control (total N=249; planned minimum sample size for final analysis is 300). While the authors stated the primary endpoint was not being tested for superiority or noninferiority in this interim analysis and the analysis was descriptive, statistical comparisons were reported; adjustment for increased risk of type I error was not reported. Composite clinical success at 24 months was reported in 85% of the TOPS arm and 64% of the TLIF arm ( $p = .0138$ ). Proportions of patients in the TOPS and TLIF groups who reported a minimum 15-point improvement in ODI were 93.1% and 80.6%, respectively; new or worsening neurological deficit was reported in 3.4% and 12.1%, respectively. Device removal, revision, or supplementation was reported in 2.9% and 6.3% and surgical reintervention occurred in 5.8% and 8.8% of TOPS and TLIF patients, respectively. Improvements by at least 20 points from baseline in patient-reported VAS scores for back pain were reported in 83.5% of TOPS patients and 65.8% of TLIF patients at 6 weeks post-operatively ( $p = .004$ ); at 24-month follow-up, 87% of the TOPS group and 64% of the TLIF group reported at least 20-point VAS improvement from baseline ( $p = .015$ ). Improvements of at least 20 points from baseline in VAS scores for leg pain were comparable between TOPS and TLIF patients at both 6 weeks (92% and 93%, respectively) and 24 months (90% vs. 88%, respectively). Radiographically-assessed range of motion for flexion/extension of the treated vertebral level in the TOPS and TLIF groups at 24-month follow-up were 3.76 (vs. 3.75 at baseline) and 1.21 degrees (vs. 4.39 at baseline), respectively; range of motion for left/right

lateral bending of the treated vertebral level at 24 months were 3.75 (vs. 3.25 at baseline) and 0.88 degrees (vs. 0.88 at baseline), respectively. In June 2023, the TOPS System was approved by the FDA via the premarket approval (PMA) process based on 24-month interim results.<sup>3</sup> The final results of the TOPS IDE pivotal study have yet to be published, but 24-month results are detailed in the FDA summary of safety and effectiveness data (SSED) as part of the approval packet.<sup>8</sup> The results within the SSED differ slightly from those reported by Coric et al (2022) in the interim analysis.

Clarity is needed on the trial's final results to determine if adjustments for the increased risk of type 1 error were made and to compare the results presented in the published trial to those presented in the SSED. Additionally, continued follow-up of the TOPS IDE trial is ongoing, per Clinicaltrials.gov (NCT03012776), which will shed light on the longer-term safety profiles of TOPS versus TLIF with lumbar spinal decompression.

### **Unapproved or Off-Label Use Devices**

A report by Palmer et al (2011) 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.<sup>9</sup> Two of 10 Total Facet Arthroplasty System implants performed at the authors' institution experienced stem fracture after total facet replacement.

A phase 3 multicenter randomized trial of the ACADIA® Facet Replacement System was completed in October 2017 but results have not yet been fully published, results without statistical analysis are posted on ClinicalTrials.gov.<sup>4</sup> The trial enrolled 390 subjects with lumbar spinal stenosis, and compared facet arthroplasty with the ACADIA® system to spinal fusion. An abstract reported by Myer et al (2014) in conference proceedings provided interim 2- and 4-year results for 243 patients.<sup>10</sup> According to a 2018 case report, 2 of 5 patients at 1 institution who received the ACADIA® Facet Replacement System as part of the trial experienced a return of neurological symptoms, local tissue reaction, and development of cobalt allergy.<sup>11</sup>

## **SUMMARY OF EVIDENCE**

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of an otherwise unpublished randomized controlled trial (RCT), a planned interim analysis of an ongoing RCT, 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 in 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. 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.

## **SUPPLEMENTAL INFORMATION**

## PRACTICE GUIDELINES AND POSITION STATEMENTS

No guidelines or statements were identified.

## ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently ongoing trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT03012776 <sup>a</sup>	A Clinical Study to Assess the Safety and Effectiveness of the Premia Spine TOPS™ System	305	Jun 2027
<b>Unpublished</b>			
NCT00401518 <sup>a</sup>	The Investigational Plan for the Evaluation of the ACADIA® Facet Replacement System	390	Oct 2017

NCT: national clinical trial

<sup>a</sup> Denotes industry sponsored or cosponsored trial.

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## Government Regulations

### National/Local:

There is no specific NCD or LCD for this procedure. The LCD (L35490) listed not medically necessary T codes in the past but no longer lists them.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

- Interspinous Distraction Devices
- Spinal Surgery-Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD, MELD) for Lumbar Stenosis
- Spinal Surgery-Percutaneous, Endoscopic, Laser and/or Radiofrequency Decompression

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## References

1. Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. BMJ. Jan 04 2016; 352: h6234. PMID 26727925
2. 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
3. U.S. Food and Drug Administration. Premarket Approval (PMA): TOPS System. June 15, 2023.<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P220002>. Accessed October 2024.
4. ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020. Accessed November 2023.

5. Smorgick Y, Mirovsky Y, Floman Y, et al. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis. J Neurosurg Spine. Oct 04 2019; 1-6. PMID 31585417
6. 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
7. 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
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[https://www.accessdata.fda.gov/cdrh\\_docs/pdf22/P220002B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220002B.pdf). Accessed October 2024
9. 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. Jul 2011; 11(7): e15-9. PMID 21703940
10. Myer J, Youssef JA, Rahn KA, et al. ACADIA facet replacement system IDE clinical trial: Preliminary outcomes at two-and four-years postoperative [abstract]. Spine J. 2014;11(Suppl. 1):S160-161.
11. Goodwin ML, Spiker WR, Brodke DS, et al. Failure of facet replacement system with metal-on-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases. J Neurosurg Spine. Jul 2018; 29(1): 81-84. PMID 29652237  
Hayes Prognosis Overview. Total Facet Arthroplasty System (TFAS®). Lansdale, PA: HAYES, Inc., September 2009. Last updated September 2009. Archived.
12. Blue Cross Blue Shield Association. Facet Arthroplasty. MPRM 7.01.120. Published July 2009. Last updated May 2024.

*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2024, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

<b>Policy Effective Date</b>	<b>BCBSM Signature Date</b>	<b>BCN Signature Date</b>	<b>Comments</b>
9/1/10	7/22/10	6/15/10	Joint policy established
9/1/12	6/12/12	6/19/12	Routine update; policy formatted on new template. Reference added. No change in policy status.
1/1/15	10/24/14	11/3/14	Routine update of non-established service. Rationale and references reviewed and updated. No change in policy status.
3/1/16	12/10/15	12/10/15	Routine maintenance, updated references & rationale. No change in policy status.
3/1/17	12/13/16	12/13/16	Updated regulatory, clinical trial and government sections. No change in policy status.
3/1/18	12/12/17	12/12/17	Routine policy maintenance. No change in policy status.
3/1/19	12/13/18		Routine policy maintenance. Change in policy title. No change in policy status.
3/1/20	12/17/19		Routine policy maintenance. No change in policy status.
3/1/21	12/15/20		Routine policy maintenance. No change in policy status.
3/1/22	12/14/21		Routine policy maintenance. No change in policy status.
3/1/23	12/20/22		Routine policy maintenance, no additional updated literature. No change in policy status.
3/1/24	12/19/23		Routine policy maintenance, added code 0202T as E/I. No change in policy status. Vendor managed: Turning Point (ds)
3/1/25	12/17/24		Routine policy maintenance, no change in policy status. Vendor managed: Turning Point (ds)

Next Review Date: 4<sup>th</sup> Qtr. 2025



**BLUE CARE NETWORK BENEFIT COVERAGE**  
**POLICY: FACET ARTHROPLASTY**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered.
<b>BCNA (Medicare Advantage)</b>	See government section.
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

N/A