7.01.120	Facet Arthroplasty		
Original Policy Date:	May 18, 2012	**Effective Date:**	June 1, 2024
Section:	7.0 Surgery	**Page:**	Page 1 of 9

Policy Statement

I. Total facet arthroplasty in individuals with lumbar spinal stenosis undergoing spinal decompression is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
See the Codes table for details.

Description

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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).[3,] 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.[4,]ACADIA Facet Replacement System is currently only available outside of the U.S.

Rationale

Background

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. 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 (RCT) 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these

groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 was used to select literature to inform this review.

Population

The relevant population of interest is 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.

Comparator

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, quality of life, and adverse events related to the surgical procedure. These outcomes should be measured over months to years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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.[5,] 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).[6,] 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±12.4 to 22.1±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±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±24.4 preoperatively to 12.7±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±13.2 preoperatively to 11.5±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).[7,] 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.[3,] 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.[8,] 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 TILF with lumbar spinal decompression.

Unapproved or Off-Label Use Devices

A report by Palmer et al (2011) indicated the FDA -regulated multicenter investigational device exemption trial (NCT00418197) of the Total Facet Arthroplasty System was discontinued due to financial reasons.[9,] 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 (NCT00401518) was completed in October 2017 but results have not yet been fully published; results without statistical analysis are posted on ClinicalTrials.gov.[4,] 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.[10,] 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.[11,]

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified as of March 2024.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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 (Status)
Ongoing			
NCT03012776[a]	A Clinical Study to Assess the Safety and Effectiveness of the Premia Spine TOPS™ System	305	June 2027 (Active, not recruiting)
Unpublished			
NCT00401518[a]	The Investigational Plan for the Evaluation of the ACADIA® Facet Replacement System	390	Oct 2017 (Completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

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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 March 5, 2024.
4. ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020. Accessed March 5, 2024.
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
8. 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. Accessed March 4, 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

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
05/18/2012	BCBSA Medical Policy adoption
09/30/2014	Policy revision without position change
01/01/2017	Policy revision without position change
03/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2021	Annual review. No change to policy statement. Literature review updated.
07/01/2022	Annual review. No change to policy statement. Literature review updated.
06/01/2023	Annual review. Policy statement and literature review updated.
06/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Facet Arthroplasty 7.01.120 **Policy Statement:** I. Total facet arthroplasty is considered **investigational** in individuals with lumbar spinal stenosis undergoing spinal decompression.	**Facet Arthroplasty 7.01.120** **Policy Statement:** I. Total facet arthroplasty in individuals with lumbar spinal stenosis undergoing spinal decompression is considered **investigational**.