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Policy Effective Date	**12/15/2024**

Facet Arthroplasty

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Facet arthroplasty, by any method, including but not limited to the Total Facet Arthroplasty System®, whether performed inpatient or outpatient, or as part of another procedure, **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

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.

Background

Spinal fusion is a common surgical treatment following surgical decompression when conservative treatment fails. (1) 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. (2) 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). (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 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. (4) ACADIA Facet Replacement System is currently only available outside of the U.S.

Rationale

Medical policies 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.

Facet Arthroplasty

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 policy.

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.

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, 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.

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 interim analysis of the randomized, single-blind, multicenter IDE TOPS trial were published by Coric et al. (2022). (7) Adults aged 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 that the FDA-regulated multicenter IDE 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)

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), 2 planned interim analyses 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 October 2017, have been identified to date. Interim results from a pivotal randomized trial of the Total Posterior Spine (TOPS) System indicated substantial improvement compared to baseline at 1 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.

Practice Guidelines and Position Statements
No guidelines or statements were identified as of March 2024.

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 Number	Trial Name	Planned Enrollment	Completion Date (Status)
Unpublished			
NCT03012776[a]	A Clinical Study to Assess the Safety and Effectiveness of the Premia Spine TOPS™ System	305	Jun 2023 (Completed)
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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0202T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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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

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2024	Document updated with literature review. Coverage unchanged. References 3, 6, and 8 added.
12/15/2023	Document updated with literature review. Coverage unchanged. References 1-3 and 8 added.
10/15/2022	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2021	Reviewed. No changes.
09/15/2020	Document updated with literature review. Coverage unchanged. References 3 and 4 added.

08/01/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged. Reference 2 added, one reference removed.
06/01/2017	Reviewed. No changes.
09/15/5016	Document updated with literature review. Coverage unchanged.
10/01/2015	Reviewed. No changes.
04/01/2014	Document updated with literature review. Coverage unchanged.
07/01/2011	New medical document. Facet arthroplasty, by any method, including but not limited to the Total Facet Arthroplasty System, whether performed inpatient or outpatient, or as part of another procedure, is considered experimental, investigational and unproven.