Regence

Medical Policy Manual Surgery, Policy No. 171

Total Facet Arthroplasty

Effective: November 1, 2025

Next Review: July 2026
Last Review: September 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

This less invasive alternative to spinal fusion is intended to preserve more normal spinal motion.

MEDICAL POLICY CRITERIA

Total facet arthroplasty is considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Artificial Intervertebral Disc, Surgery, Policy No. 127
2. Ultrasound Guidance for Facet Joint Injection, Surgery, Policy No. 135
3. Dynamic Stabilization of the Spine, Surgery, Policy No. 143
4. Interspinous and Interlaminar Stabilization and Distraction Devices (Spacers), Surgery, Policy No. 155
5. Interspinous Fixation (Fusion) Devices, Surgery, Policy No. 172
6. Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176
7. Lumbar Spinal Fusion, Surgery, Policy No. 187

BACKGROUND

Facet arthroplasty implants are synthetic replacements for damaged posterior element structures in the lumbar spine for patients with facet arthrosis, spinal stenosis, and spondylolisthesis. Total facet arthroplasty is intended to replace the facet joints and excised posterior elements as an alternative to spinal fusion. The objective of facet arthroplasty is to stabilize the spine while retaining normal intervertebral motion of the surgically removed segment following neural decompression.

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 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. ACADIA Facet Replacement System is currently only available outside of the U.S.

EVIDENCE SUMMARY

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to establish the safety and efficacy of total facet arthroplasty compared with spinal fusion, the current standard of care for surgical treatment of degenerative disc disease (DDD). These comparisons are necessary to determine whether any beneficial treatment effects of total facet arthroplasty outweigh any risks and provide a significant advantage over conventional spinal fusion techniques.

Smorgick (2020) 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.[1] 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 one year interim safety analysis of the randomized, single-blind, multicenter FDA investigational device exemption (IDE) trial of the TOPS device was conducted by Pinter (2023).[2] 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 two year interim analysis of the randomized, single-blind, multicenter IDE TOPS trial were published by Coric (2022).[3]o 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.

Nassr (2024) reported an updated analysis of the TOPS IDE pivotal study with 2-year results of 113 patients who underwent arthroplasty with TOPS and 47 who received fusion (TLIF) per an interim analysis specified when at least 300 patients were randomized.[4] The primary outcome of clinical success was higher in the arthroplasty group (73.5% vs. 25.5%; difference, 47.9%; 95% CI, 33.0% to 62.8%; p<.001). The trial was stopped before all patients completed the 24-month follow-up due to the significant differences observed in the primary composite outcome. The fusion group had higher rates of new or progressive neurologic deficit (11.4% vs. 2.8%; p=.047) and fusion failure (43.09% vs. 1.0%; p<.001). A greater proportion of patients in the arthroplasty group achieved the MCID in the ODI (93.8% vs. 77.1%; p=.01) and in VAS back pain (84.4% vs. 61.8%; p=.01) at 24 months postoperatively. The study is limited by the reporting of only approximately 50% of the 321 randomized patients, the lack of blinding, and the relatively short follow-up period.

The remaining published studies are limited to ex vivo biomechanical studies on cadaver spines. Conclusions from these studies cannot be used to determine the outcomes of device implantation in living human subjects. The evidence is insufficient to permit conclusions about the benefits and safety of facet arthroplasty.There is no data available to determine the type and rate of complications or the rate of reoperations following facet joint replacement. Stem fractures have been reported in two cases.[5] According to a 2018 case report, two of five patients at one 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.[6]

PRACTICE GUIDELINE SUMMARY

No evidence-based clinical practice guidelines were identified which address total facet arthroplasty as a treatment for any condition.

SUMMARY

There is not enough research to show that total facet arthroplasty improves health outcomes for people with any indication. No clinical guidelines based on research recommend total facet arthroplasty. Therefore, total facet arthroplasty is considered investigational.

REFERENCES

1. Smorgick Y, Mirovsky Y, Floman Y, et al. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis. *Journal of neurosurgery Spine.* 2020;32(1):36-41. PMID: 31585417
2. 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.* 2023;36(2):E59-e69. PMID: 36191093
3. Coric D, Nassr A, Kim PK, et al. Prospective, randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis. *Journal of neurosurgery Spine.* 2023;38(1):115-25. PMID: 36152329
4. Nassr A, Coric D, Pinter ZW, et al. Lumbar Facet Arthroplasty Versus Fusion for Grade-I Degenerative Spondylolisthesis with Stenosis: A Prospective Randomized Controlled Trial. *J Bone Joint Surg Am.* 2024;106(12):1041-53. PMID: 38713762
5. 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. *The spine journal : official journal of the North American Spine Society.* 2011;11(7):e15-9. PMID: 21703940
6. 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. *Journal of neurosurgery Spine.* 2018;29(1):81-84. PMID: 29652237

CODES

Codes	Number	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	

Date of Origin: *January 2010*