02-20000-37

Original Effective Date: 11/15/09

Reviewed: 09/26/24

Revised: 10/15/24

Subject: Facet Arthroplasty

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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 those with facet arthrosis, spinal stenosis, and spondylolisthesis.

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.

Summary and Analysis of Evidence: 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. 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). 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. 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, 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). 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. Additionally, VAS scores for worst leg pain also improved from 83.9±13.2 preoperatively to 11.5±22.7 at 12 months postoperatively, 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). 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; 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. 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. 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.

POSITION STATEMENT:

Total facet arthroplasty (facet replacement) is considered **experimental or investigational** for **all** indications. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminectomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine **(investigational)**

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable

OTHER:

Index terms used for facet arthroplasty (facet replacement):

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

ACADIA™ Facet Replacement System

Total Posterior System (TOPS™)

REFERENCES:

1. AHRQ National Guideline Clearinghouse. NGC-8890. Cervical and thoracic spine disorders. Elk Grove Village (IL): American College of Occupational and Environmental Medicine (ACOEM); 2011. p. 1-332.
2. AHRQ National Guideline Clearinghouse. NGC-9327. Low back disorders. Elk Grove Village (IL): American College of Occupational and Environmental Medicine (ACOEM); 2011. p. 333-796.
3. AHRQ National Guideline Clearinghouse. NGC-6456. Low back disorders. Occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers. 2nd ed. Elk Grove Village (IL): American College of Occupational and Environmental Medicine (ACOEM); 2004. p. 286-326.
4. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.120 - Facet Arthroplasty, 05/24.
5. ClinicalTrial.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis. Information provided by Facet Solutions, Inc. Identification number: NCT0000401518.
6. ClinicalTrial.gov. Total Facet Arthroplasty System®(TFAS®) Clinical Trial. Information provided by Archus Orthopedics, Inc. Last updated February 4, 2009. Identification number: NCT00418197.
7. ClinicalTrials.gov. Safety and Effectiveness Study of the TOPS System, a Total Posterior Arthroplasty Implant Designed to Alleviate Pain Resulting from Moderate to Severe Lumbar Stenosis. Verified by Impliant, Ltd., February 2007. Last Updated: January 28, 2010. Identifier NCT00405691.
8. ClinicalTrials.gov. Study to Evaluate the Safety and Effectiveness of the TOPS™ SP System. Identification number: NCT03247166. Hillel Yaffe Medical Center (August 2017).
9. Coric D, Nassr A, Kim PK, Welch WC, Robbins S, DeLuca S, Whiting D, Chahlavi A, Pirris SM, Groff MW, Chi JH, Huang JH, Kent R, Whitmore RG, Meyer SA, Arnold PM, Patel AI, Orr RD, Krishnaney A, Boltes P, Anekstein Y, Steinmetz MP. Prospective, randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis. J Neurosurg Spine. 2022 Sep 23;38(1):115-125. doi: 10.3171/2022.7.SPINE22536.
10. First Coast Service Options, INc. (FCSO). Local Coverage Determination (LCD): Noncovered Services (L33777) (retired 07/01/20).
11. Florida Medicare Part B Local Coverage Determination. LCD for Non-Covered Services (L29288). Revised 08/05/13. (Retired 09/30/15).
12. Gu BJ, Blue R, Yoon J, Welch WC. Posterior Lumbar Facet Replacement and Arthroplasty. Neurosurg Clin N Am. 2021 Oct;32(4):521-526. doi: 10.1016/j.nec.2021.05.011. Epub 2021 Jul 29. PMID: 34538478.
13. Manchikanti, L, Boswell, MV, Singh V, Benyamin RM, Fellows B, Salahadin A, Buenaventur RM, Conn A, Datta S, Derby R, Falco FJE, Erhart S, Diwan S, Hayek SM, Helm S, Parr AT, Schultz DM, Smith HS, Wolfer LR, & Hirsch JA. Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain. Pain Physician 2009; 12;699-802.
14. North American Spine Society Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis. 2011.

15. Phillips FM, Tzermiadianos MN, Voronov LI, et al. Effect of the Total Facet Arthroplasty System after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments. Spine J 2009; 9(1): 96-102.
16. Pinter ZW, Freedman BA, Nassr A, Sebastian AS, Coric D, Welch WC, Steinmetz MP, Robbins SE, Ament J, Anand N, Arnold P, Baron E, Huang J, Whitmore R, Whiting D, Tahernia D, Sandhu F, Chahlavi A, Cheng J, Chi J, Pirris S, Groff M, Fabi A, Meyer S, Kushwaha V, Kent R, DeLuca S, Smorgick Y, Anekstein Y; TOPS Study Group. 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 Mar 1;36(2):E59-E69. doi: 10.1097/BSD.0000000000001365. Epub 2022 Aug 3.
17. Savigny P, Kuntze S, Watson P, Underwood M, Ritchie G , Cotterell M, Hill D, Browne N, Buchanan E, Coffey P, Dixon P, Drummond C, Flanagan M, Greenough,C, Griffiths M, Halliday-Bell J, Hettinga D, Vogel S, Walsh D. Low Back Pain: early management of persistent non-specific low back pain. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.
18. Sjovold SG, et al. Biomechanical evaluation of the Total Facet Arthroplasty System (TFAS): loading as compared to a rigid posterior instrumentation system. Eur Spine J (2012) 21:1660–1673.
19. Smorgick Y, Mirovsky Y, Floman Y, Rand N, Millgram M, Anekstein Y. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis [published online ahead of print, 2019 Oct 4]. J Neurosurg Spine. 2019;1-6. doi:10.3171/2019.7. SPINE19150.
20. U.S. Food & Drug Administration (FDA). U.S. Food & Drug Administration (FDA) Premarket Approval (PMA) P220002: The TOPS™ System (06/15/23).
21. U.S. Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): TOPS System. June 15, 2023. Accessed at https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220002B.pdf.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

11/15/09	New Medical Coverage Guideline.
11/15/10	Scheduled review. No change in position statement; references updated.
10/15/11	Scheduled review; no change in position statement. Updated description section and references.
10/15/12	Scheduled review; no change in position statement. Revised description section and updated references.
10/15/13	Scheduled review; no change in position statement. Revised description section and program exceptions section. Updated references.
02/15/19	Scheduled review. Revised MCG title, description, and program exceptions. Maintained position statement and updated references.
10/15/20	Scheduled review. Maintained position statement and updated references.
06/15/22	Scheduled review. Maintained position statement and updated references.
07/01/22	Quarterly CPT/HCPCS coding update. Added 0719T.
05/23/23	Update to Program Exceptions section.

01/01/24	Position statements maintained.
10/15/24	Scheduled review. Revised description. Deleted CPT 0719T (refer to MCG 09-A0000-03 Investigational Services). Maintained position statement and updated references.