

7.01.120	Facet Arthroplasty		
Original Policy Date:	May 18, 2012	Effective Date:	June 1, 2021
Section:	7.0 Surgery	Page:	Page 1 of 7

Policy Statement

Total facet arthroplasty is considered **investigational**.

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

Policy Guidelines

The following CPT Category III code is specific to this procedure:

- **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

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

- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration. The ACADIA™ Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) was being evaluated in an Food and Drug Administration-regulated investigational device exemption phase 3 trial which was completed in October 2017 but has not been published. A phase 3 trial of the Total Facet Arthroplasty System® (TFAS®; Archus Orthopedics) was discontinued. (Facet Solutions acquired Archus Orthopedics in 2009. In 2011, Globus Medical acquired Facet Solutions.)

Another implant design, the Total Posterior-element System (TOPS™; Premia Spine), is currently available in Europe.

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.

Clinical Context and Therapy Purpose

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

The question addressed in this evidence review is: Does facet arthroplasty improve the net health outcome in patients with lumbar spinal stenosis?

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. Facet replacement is a surgical procedure requiring inpatient hospitalization.

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

A report by Palmer et al (2011) indicated 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.¹ 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. 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.² 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.³

For the TOPS™ device, Smorgick et al (2020) reported 11-year outcomes of 10 individuals from a single center in Israel who received the TOPS™ device as an adjunct to decompression to treat neurogenic claudication of at least 12 weeks' duration due to spinal stenosis with single-level grade 1 L4-5 degenerative spondylolisthesis.⁴ 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. But, no other instances of screw loosening or breakages, spontaneous fusion, or progression of the spondylolisthesis were observed. Although these findings are encouraging, more rigorous evaluation of the TOPS™ device in large RCTs is still needed to determine its effects on health outcomes.

Summary of Evidence

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of a 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 expected to be completed in October 2015, have been identified to date. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received FDA approval. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

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 and unpublished 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	266	September 2023
Unpublished			
NCT01933607 ^a	Post-market Study of the TOPS™ System (TOPS)	10	Dec 2016 (Unknown)
NCT02234154 ^a	Post-market Study of the TOPS™ System (TOPS)	10	May 2017 (Unknown)
NCT00401518 ^a	A Pivotal Study of a Facet Replacement System (ACADIA®) to Treat Spinal Stenosis	390 (actual)	Oct 2017 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

- 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

2. 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.
3. 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
4. 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
5. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.120 (April 2021).

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.

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 (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.

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: Total facet arthroplasty is considered investigational .	Facet Arthroplasty 7.01.120 Policy Statement: Total facet arthroplasty is considered investigational .