No review or update is scheduled on this Medical Policy as it is unlikely that further published literature would change the policy position. There were no claims being received for the service at the time of archiving. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, your professional or institutional relations representative, or submit a predetermination request.

Medical Policy

BlueCross BlueShield of Kansas
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Title: Total Facet Arthroplasty

Professional
Original Effective Date: June 23, 2009
Revision Date(s): August 17, 2010; October 13, 2015; June 11, 2019
Current Effective Date: August 17, 2010
Archived Date: June 11, 2019

Institutional
Original Effective Date: September 16, 2010
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Current Effective Date: September 16, 2010
Archived Date: June 11, 2019

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Populations	Interventions	Comparators	Outcomes
Individuals: • With lumbar spinal stenosis	Interventions of interest are: • Lumbar spinal decompression with facet arthroplasty	Comparators of interest are: • Lumbar spinal decompression with spinal fusion	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

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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.

Objective

The objective of this evidence review is to determine whether facet arthroplasty as an adjunct to neural decompression improves the net health outcome in patients with lumbar spinal stenosis.

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.

POLICY

Total facet arthroplasty is considered **experimental / investigational**.

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent update was performed through February 5, 2019.

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?

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The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are 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 arthroplastyis 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 therapies/tools/rules/practices are currently being used to make decisions about facet arthroplasty.

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. Facet arthropathy may also be treated with nerve ablation techniques.

Outcomes
The general outcomes of interest are pain, function, QOL, and adverse events related to the surgical procedure.

Timing
Pain, function, and QOL outcomes should be measured over the long-term.

Setting
Facet replacement is a surgical procedure requiring inpatient hospitalization.

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 ten Total Facet Arthroplasty System implants performed at the authors' institution experienced stem fracture after total facet replacement.

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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,]

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 randomized controlled trial. The relevant outcomes are symptoms, functional outcomes, QOL, 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 October 2015, have been identified to date. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received U.S. Food and Drug Administration approval. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently 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
Unpublished			
NCT01933607[a]	Post-market Study of the TOPS™ System (TOPS)	10	Dec 2016
NCT02234154[a]	Post-market Study of the TOPS™ System (TOPS)	10	May 2017
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.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

0202T Posterior vertebral joint(s) arthroplasty (eg facet joint[s] replacement) including facetectomy, laminectomy, foraminectomy and vertebral column fixation injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine

- There is a CPT Category III code specific to this procedure: 0202T.

DIAGNOSIS

Experimental / investigational for all diagnoses related to this medical policy.

REVISIONS

08-17-2010	Policy added to the bcbsks.com web site. No change in policy language.
10-13-2015	Description section updated
	Rationale section updated
	In Coding section: ▪ Updated nomenclature for CPT Code: 0202T ▪ Updated Coding notations.
	References updated
06-11-2019	Description section updated
	Rationale section updated
	References updated
	Policy Archived

REFERENCES

1. 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):e15-19. 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, MM, Spiker, WW, Brodke, DD, Lawrence, BB. Failure of facet replacement system with metal-on-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases. J Neurosurg Spine, 2018 Apr 14;29(1). PMID 29652237