

## ***Total Facet Arthroplasty***

**Effective:** November 1, 2020

**Next Review:** July 2021

**Last Review:** September 2020

### **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. There are no implants with FDA approval for marketing in the U.S. outside the clinical trial setting.

### **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

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA). Therefore, these implants may not be used in this country outside the setting of an FDA-approved clinical trial.

Investigational devices in development include the following:

The ACADIA™ Facet Replacement System (Facet Solutions/Globus Medical) is currently being evaluated as part of an ongoing FDA-regulated investigational device exemption (IDE) Phase III trial.

The Phase III trial of the Total Facet Arthroplasty System® (TFAS®, Archus Orthopedics) has been discontinued for financial reasons. However, it was noted that two out of the ten TFAS procedures performed at the authors' institution had stem fracture after total facet replacement.

The Total Posterior-element System (TOPS™, Impliant Ltd./Premia Spine) is in development and not currently cleared for marketing in the US.

## 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.

The evidence is insufficient to permit conclusions about the benefits and safety of facet arthroplasty.

The current published clinical trial evidence is limited to data from a single, small (n=29), short-term case series published in 2007 by McAfee.<sup>[1]</sup> While this preliminary data demonstrated feasibility and provided some direction for future clinical trials, this pilot study does not permit conclusions due to methodological limitations such as non-random allocation of treatment, short-term follow-up (12 months), small number of patients, and a lack of an appropriate comparison group.

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.

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.<sup>[2]</sup> 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.<sup>[3]</sup>

## 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. McAfee, P, Khoo, LT, Pimenta, L, et al. Treatment of lumbar spinal stenosis with a total posterior arthroplasty prosthesis: implant description, surgical technique, and a prospective report on 29 patients. *Neurosurg Focus*. 2007;22(1):E13. PMID: 17608334
2. 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 Jul;11(7):e15-9. PMID: 21703940
3. Goodwin, ML, Spiker, WR, Brodke, DS, Lawrence, BD. 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 Jul;29(1):81-4. PMID: 29652237
4. BlueCross BlueShield Association Medical Policy Reference Manual "Facet Arthroplasty." Policy No. 7.01.120

## 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