Medical Policy Manual

Topic:  Total Facet Arthroplasty  Date of Origin:  January 2010
Section:  Surgery  Last Reviewed Date:  July 2014
Policy No:  171  Effective Date:  October 1, 2014

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

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:

- 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 (TOPSTM, Impliant Ltd./Premia Spine) is in development.
**MEDICAL POLICY CRITERIA**

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

**SCIENTIFIC EVIDENCE**

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both of these 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 in order 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.

**Clinical Practice Guidelines**

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

**Literature Appraisal**

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, short-term case series.[1] 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.[2]

**Summary**

The current published evidence is insufficient to determine whether facet arthroplasty is as effective or as safe as spinal fusion, the current standard for surgical treatment of degenerative disc disease. In addition, no devices have received approval from the U.S. Food and Drug Administration for use outside the clinical trial setting. Therefore, total facet arthroplasty is considered investigational.

**REFERENCES**


**CROSS REFERENCES**

- [Artificial Intervertebral Disc](#), Surgery, Policy No. 127
- [Lumbar Dynamic Stabilization](#), Surgery, Policy No. 143
- [Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)](#), Surgery, Policy No. 155
- [Interspinous Fixation (Fusion) Devices](#), Surgery, Policy No. 172
- [Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis](#), Surgery, Policy No. 176

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<thead>
<tr>
<th>CODES</th>
<th>NUMBER</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>CPT</td>
<td>0202T</td>
<td>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</td>
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<td>HCPCS</td>
<td>None</td>
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