Kansas City

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Facet Arthroplasty

Policy Number: 7.01.120
Origination: 9/2009
Last Review: 9/2014
Next Review: 3/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for total facet arthroplasty. This is considered investigational.

When Policy Topic is covered

Total facet arthroplasty is considered **investigational**.

When Policy Topic is not covered

Not Applicable

Description of Procedure or Service

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.

Background

Spinal fusion is a common surgical treatment for degenerative disc disease 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 policy 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.

Regulatory Status

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA) at this time. The Total Facet Arthroplasty System® (TFAS®, Archus Orthopedics) and ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA) are currently being evaluated as part of ongoing FDA-regulated investigational device exemption (IDE) Phase III trials. (Facet Solutions acquired Archus Orthopedics and all of their assets in 2009. In 2011, Globus Medical acquired substantially all of the assets of Facet Solutions.) Another implant design, the Total Posterior-element System (TOPS™, Impliant Ltd., Israel), is in development and has restarted enrollment in a FDA-regulated Phase III trial in 2011 after design and manufacturing changes. Premia Spine acquired Impliant in 2011.

Rationale

Searches of the MEDLINE database, most recently performed through June 3, 2014, identified a report indicating that the U.S. Food and Drug Administration (FDA)-regulated multicenter investigational device exemption (IDE) trial (NCT00418197) of the Total Facet Arthroplasty System® (TFAS®) was

discontinued due to financial reasons. (1) (Facet Solutions acquired Archus Orthopedics and all of their assets in November 2009). Two of 10 TFAS procedures performed at the authors' institution had stem fracture after total facet replacement.

Identified from the EMBASE database was a conference proceeding of interim results in 100 patients from a Phase III U.S. multicenter randomized trial of the ACADIA™ Facet Replacement System (NCT00401518). (2) The study began in 2006, is expected to enroll around 300 subjects with lumbar spinal stenosis, and compares facet arthroplasty with the ACADIA™ system to posterior spinal fusion. Information posted on online site ClinicalTrials.gov indicates that recruitment is ongoing. Study completion with 24-month follow-up is expected in October 2014.

A search of ClinicalTrials.gov in June 2014 showed the following trials:

- A prospective, multicenter clinical study to assess the Impliant TOPS™ system (NCT00405691), this study is listed as completed as of May 2011. The study began in 2006 with an estimated enrollment of 450 subjects with back and leg pain resulting from moderate/severe lumbar spinal stenosis at a single vertebral level between L3 to L5.
- As of June 2014, an industry-sponsored postmarketing study of the TOPS™ system (NCT01933607) is not yet open for recruitment. There is an estimated enrollment of 10 subjects in this single-arm study. Study completion is expected December 2016.

Summary

Facet arthroplasty refers to the implantation of a spinal prosthesis to restore posterior element structure and function as an adjunct to neural decompression. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received FDA approval. Therefore, facet arthroplasty is considered investigational.

U.S. Preventative Services Task Force Recommendations

Facet arthroplasty is not a preventive service.

Medicare National Coverage

There is no national coverage determination.

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 2011; 11(7):e15-9.
2. Dryer RF, Regan JJ, Hartjen CA et al. Prospective US IDE trial: Interim results for the treatment of symptomatic lumbar spinal stenosis with facet replacement in 100 patients enrolled at 15 centers. Spine J 2010; 10(9 SUPPL 1):90S.

Billing Coding/Physician Documentation Information

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

0219T Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone grafts(s) or synthetic device(s), single level; cervical

0220T Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone grafts(s) or synthetic device(s), single level; thoracic

0221T Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone grafts(s) or synthetic device(s), single level; lumbar

0222T Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone grafts(s) or synthetic device(s), single level; each additional vertebral

segment (List separately in addition to code for primary procedure)

Additional Policy Key Words

N/A

Policy Implementation/Update Information

9/1/09	New policy; considered investigational.
3/1/10	No policy statement changes.
9/1/10	No policy statement changes.
1/1/11	Coding updated.
3/1/11	No policy statement changes.
9/1/11	No policy statement changes.
3/1/12	No policy statement changes.
9/1/12	No policy statement changes.
3/13/13	No policy statement changes.
9/1/13	No policy statement changes.
3/1/14	No policy statement changes.