Medical Policy

BlueCross BlueShield of Kansas
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Title: Total Facet Arthroplasty

Professional
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Revision Date(s): August 17, 2010
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Institutional
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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.

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.

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) is currently being evaluated as part of an ongoing FDA-approved investigational device exemption (IDE) protocol (Facet Solutions acquired Archus Orthopedics and all of their assets in November 2009. Facet Solutions is developing the ACADIA™ Facet Replacement System). The objective of the IDE trial is to evaluate the efficacy and safety of TFAS™ for the stabilization of spinal segments in skeletally mature patients as an adjunct to neural decompression with facetectomy in the treatment of the following acute or chronic instabilities or deformities of the lumbar spine at levels L3-L4 or L4-L5, single level only: degenerative disease of the facets, degenerative disease of the facets with instability, Grade I degenerative spondylolisthesis with objective evidence

of neurologic impairment, central or lateral stenosis. Another implant design, the Total Posterior-element System (TOPS, Impliant, Israel) are currently in development.

POLICY

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

RATIONALE

A search of the MEDLINE database in June 2009 and 2010 identified several ex vivo biomechanical assessments in cadaver spine. For example, Phillips et al. reported a manufacturer-sponsored study that assessed the kinematics of implanted and adjacent lumbar segments in 9 human lumbar spines (L1 to sacrum). (1) No clinical trial results were found.

A search of ClinicalTrials.gov in June 2010 showed 2 active phase III clinical trials, both sponsored by the device developers. NCT00401518 is an actively recruiting U.S. multi-center randomized trial of the ACADIA™ Facet Replacement System (Facet Solutions, Inc) compared with posterior spinal fusion. The study began in 2006, is expected to enroll around 300 subjects, and has an estimated completion of 24-month primary outcome data in 2013.

A randomized trial of the Total Facet Arthroplasty System® (TFAS®, NCT00418197) is listed as active, but not currently recruiting. The study is designed for patients with moderate to severe lumbar spinal stenosis requiring neural decompression with facetectomy at L3-L4 or L4-L5 at a single level to treat central or lateral stenosis, Grade I degenerative spondylolisthesis with objective evidence of neurologic impairment, and degenerative disease of the facets, with or without instability. Specific inclusion criteria are patients between 50 and 85 years of age with degenerative spinal stenosis, central or lateral, at spinal levels L3-L4 or L4-L5, with persistent leg symptoms, including pain, numbness, burning or tingling that are refractory to at least 6 months of conservative treatment, no greater than Grade I degenerative spondylolisthesis at the index level, and no more than three levels of degenerative lumbar spinal stenosis requiring decompression. Study participants will be randomized in a 2:1 ratio into treatment with the investigational artificial facet replacement device (TFAS™) or with standard posterior instrumented fusion. The posting indicates an estimated enrollment of 450 subjects beginning in 2005. The information on ClinicalTrials.gov was last updated in February 2009 (Facet Solutions acquired Archus Orthopedics and all of their assets in November 2009). A search of the FDA site shows one adverse event report in the MAUDE database for new back pain in a patient following implantation of the investigational device (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=889455).

No device has received FDA approval; therefore, this is considered investigational.

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 (e.g. facet joint[s] replacement) including facetectomy, laminectomy, foraminectomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine (new code effective 7/1/09)

DIAGNOSIS

Experimental / investigational for all diagnoses.

REVISIONS

08-17-2010	Policy added to the bcbsks.com web site. No change in policy language.

REFERENCES

1. Phillips FM, Tzermiadianos MN, Voronov LI, et al. Effect of the Total Facet Arthroplasty System after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments. Spine J 2009; 9(1):96-102.
2. http://clinicaltrials.gov/ct2/show/NCT00418197