The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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.

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 Protocol 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 ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA) 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. (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™, Implant 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 Implant in 2011.

Related Protocols:

Artificial Intervertebral Disc: Lumbar Spine
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
Corporate Medical Guideline

Total facet arthroplasty is considered investigational.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.
