Facet Arthroplasty

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.

OBJECTIVE

The objective of this evidence review is to determine whether facet arthroplasty as an adjunct to neural decompression improves the net health outcome in patients with lumbar spinal stenosis.

POLICY STATEMENT

Total facet arthroplasty is considered investigational.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
FDA REGULATORY STATUS

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration. The ACADIA™ Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) was being evaluated in an Food and Drug Administration-regulated investigational device exemption phase 3 trial which was completed in October 2017 but has not been published. A phase 3 trial of the Total Facet Arthroplasty System (TFAS; Archus Orthopedics) was discontinued. (Facet Solutions acquired Archus Orthopedics in 2009. In 2011, Globus Medical acquired Facet Solutions.)

Another implant design, the Total Posterior-element System (TOPS™; Premia Spine), is currently available in Europe.

RATIONALE

Summary of Evidence

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of a randomized controlled trial. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Interim results from a pivotal trial of the ACADIA Facet Replacement System were reported in 2012. No additional publications from this trial, which was expected to be completed October 2015, have been identified to date. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received U.S. Food and Drug Administration approval. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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