ASURIS NORTHWEST HEALTH

Medicare Advantage Policy Manual **Policy ID:** M-SUR171

Total Facet Arthroplasty

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

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, to stabilize the spine while retaining normal intervertebral motion of the surgically removed segment following neural decompression.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for total facet arthroplasty. Therefore, the health plan's medical policy is applicable.* Total Facet Arthroplasty, Surgery, Policy No. 171 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

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 include the following:

- 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 (TOPS™; Premia Spine) is in development, currently available in Europe.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not

establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Dynamic Stabilization of the Spine, Surgery, Policy No. M-143

Interspinous Fixation (Fusion) Devices, Surgery, Policy No. M-172

Image-Guided Minimally Invasive Spinal Decompression (IGMSD) for Spinal Stenosis, Surgery, Policy No. M-176

REFERENCES

None

CODING

Codes	Number	Description
CPT	0202T	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
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*