Cohere Medicare Advantage Policy - Facet Joint Allograft Arthroplasty

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 10, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Facet Joint Allograft Arthroplasty

Date of last literature review: 6/10/2024
Document last updated: 6/10/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Facet Joint Allograft Arthroplasty

Benefit Category

Not applicable.

Recommended Clinical Approach

Intrafacet allograft arthroplasty has been proposed as an alternative technique to surgical fusion. It involves the placement of an allograft dowel made from bone (from the femur or tibia) and placed surgically or via a minimally invasive procedure. The allograft, which is processed by licensed tissue banks, which must be compliant with FDA requirements for tissue processing, is not subject to FDA 510K clearance and can be marketed. There are no clinical trials that address the efficacy and safety of these implants. The report on six cases did not indicate efficacy.[1]

Intrafacet implants are an alternative to surgical fusion to treat facet joint pain (also referred to as lumbar spondylosis or zygapophyseal joint pain). The minimally invasive procedure involves placing an allograft dowel derived from the femur or tibia. The allograft must originate from an FDA-compliant, licensed tissue bank. No clinical trials address allograft implants' efficacy and safety.[2]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of facet joint allograft arthroplasty. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Inadequate management of facet joint pain due to inappropriate denials. If facet arthritis progresses this can result in decreased mobility, larger osteophtyes that can impinge on nerve roots, and disabling pain that may result in opioid dependence.

- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, anesthetic risk and need for repeat or additional procedures due to implant failure, progression of disease and ongoing pain. Pinter et al reported on the one year outcomes from 158 patients who underwent facet joint arthroplasty.[10] Mean surgical time was 187.8 minutes with a 3 day hospital stay. Visual pain scales improved for leg and back pain. At one year follow up 7.2% of patients had complications with 5.9% undergoing a reoperation with 0.6% related to device failure. Lumbar facet arthroplasty improves patient outcomes in the short term but longer term studies are needed.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to facet joint allograft arthroplasty procedures. At this time there is inconclusive evidence of the long term results of facet arthroplasty therefore it is not currently recommended as a treatment option for facet arthritis.
- Reduction in complications and adverse effects from unnecessary procedures. Facet arthroplasty has surgical complications which can include infection, bleeding requiring transfusion, failure to reduce pain, failure of the implant, anesthetic risk and need for revision surgeries. At this time there is insufficient evidence for this procedure.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Facet joint allograft arthroplasty** (e.g., facet joint allograft, NuFix™, TruFUSE® allograft) is considered appropriate if **ALL** of the following are **TRUE**[3]:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- ➔ **Facet joint allograft arthroplasty** (e.g., facet joint allograft, NuFix™, TruFUSE® allograft) is not considered appropriate if **ALL** of the following are **TRUE**:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Level of Care Criteria

None

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(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 graft(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 graft(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 graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)
22899	Unlisted procedure, spine

Medical Evidence

The **American Society of Interventional Pain Physicians (ASIPP)** published guidelines for *Facet Joint Interventions in the Management of Chronic Spinal Pain.* Citing weak evidence, the ASIPP does not recommend facet joint injections.[4]

The following organizations have published guidelines however, they do not address facet joint allograft injections:

- **American College of Occupational and Environmental Medicine (ACOEM)** - *Invasive Treatments for Low Back Disorders*[5]
- **American Society of Pain and Neuroscience (ASPN)** - *Interventional Treatments for Low Back Pain*[6]
- **American Society of Regional Anesthesia (ASRA)** - *Interventions for Cervical Spine (Facet) Joint Pain*[7]
- **American Society of Regional Anesthesia (ASRA)** - *Interventions for Lumbar Facet Joint Pain*[8]
- **North American Spine Society (NASS)** - *Diagnosis and Treatment of Low Back Pain*[9]

References

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Clinical Guideline Revision History/Information

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