Intervertebral Artificial Disc Arthroplasty

State(s):	LOB(s):
☒ Idaho ☒ Montana ☒ Oregon ☒ Washington ☐ Other:	☒ Commercial ☒ Medicare ☒ Medicaid

Enterprise Policy

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Artificial Cervical Disc Arthroplasty is a surgical strategy indicated for the treatment of Degenerative Disc Disease (DDD) or herniated disc at a single level resulting in symptomatic cervical nerve compression. The procedure is designed to surgically secure an artificial disc into a prepared cervical intervertebral space. The intended outcomes are to relieve pain by reducing pressure on cervical spinal nerves, restoration of disc height and normal spinal curvature, and motion preservation with reduced risk of adjacent-level DDD.

Artificial Lumbar Disc Arthroplasty is a surgical strategy for reconstruction of the disc at one level of the lumbar spine with symptomatic DDD and no more than Grade 1 spondylolisthesis at the involved level. The procedure is designed to surgically secure an artificial disc into a prepared lumbar intervertebral space. The intended outcomes are to relieve pain by reducing pressure on spinal nerves, restoration of disc height and normal spinal curvature, and motion preservation with reduced risk of adjacent-level DDD.

Criteria

Commercial

Prior authorization is required.

A. Artificial Cervical Disc Arthroplasty

PacificSource covers surgical implantation of **FDA–approved** cervical intervertebral disc (IVD) prosthesis for degenerative cervical disc disease with intractable radiculopathy and/or myelopathy as medically necessary when there are no contraindications and **ALL** of the following criteria are met:

1. The individual is skeletally mature;

2. Documented use of an FDA-approved device, which can be located at https://www.fda.gov/Medical-Devices;
3. Implantation up to 2 adjacent/adjoining levels. More than 2 levels is E/I/U (see section below);
4. Tobacco/Nicotine Cessation:
    a. Does not apply to urgent/emergent cases; and
    b. Documentation of nicotine-free status by lab result (cotinine level) in patients who have been documented tobacco-users is required. Labs are to be performed after 6 weeks tobacco cessation. Ample time should be afforded to submit this confirmation and complete the prior authorization process.
5. Diagnosis must be **ONE** of the following:
    a. Cervical Radiculopathy and **ALL** of the following:
        - Patient has unremitting radicular pain or progressive weakness secondary to nerve root compression.
        - Presence of symptoms for at least three months;
        - Magnetic Resonance Imaging (MRI) or other neuroimaging finding correlates with clinical signs and symptoms and demonstrates spinal stenosis or nerve root compression at 1 or 2 adjoining levels from C3 to C7; and
        - Failure of at least three months physician-directed conservative medical management for this current episode of pain that includes the following:
            - Patient education;
            - Active physical therapy;
            - Medications (NSAIDS, acetaminophen, or tricyclic antidepressants); and
            - If applicable, identification/management of associated anxiety and depression.

    OR

    b. Cervical Spondylotic Myelopathy with treatment indicated by **ALL** of the following:
        - Signs or symptoms of myelopathy are present as indicated by **1 or more** of the following:
        - Upper limb weakness in more than single nerve root distribution;
        - Lower limb weakness in upper motor neuron distribution;
        - Loss of dexterity (e.g., clumsiness of hands);
        - Bowel or bladder incontinence;
        - Frequent falls;
        - Hyperreflexia;
        - Hoffmann sign;
        - Increased extremity muscle tone or spasticity;
        - Gait abnormality;
        - Positive Babinski sign; and/or
        - Alternative clinical signs or symptoms of myelopathy.

- MRI or other neuroimaging finding correlates with clinical signs and symptoms and demonstrates cord compression due to **1 or more** of the following at 1 or 2 adjoining levels from C3 to C7:
    - Herniated disk; and/or
    - Osteophyte.

6. Absence of contraindications which include:
    a. Osteoporosis, osteopenia or osteomalacia (e.g., T-score of -3.5 or -2.5, with associated compression fracture).
    b. Active or chronic infection that is localized at operative site or is systematic.
    c. Allergy or sensitivity to implant materials.
    d. Paget disease, osteomalacia, osteoporosis or any other metabolic bone disease.
    e. Rheumatoid arthritis or other autoimmune disease.
    f. Progressive neurological deficit or deterioration due to another disease process.
    g. There is radiological evidence of **ANY** of the following:
        - Clinically significant cervical instability, such as kyphotic deformity or spondylolisthesis (e.g., > 3 mm subluxation or > 11 degrees angulation);
        - Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma); or
        - Spinal metastases.

B. Artificial Lumbar Disc Arthroplasty

PacificSource covers surgical implantation of **FDA–approved** lumbar intervertebral disc prosthesis for treating single level lumbar Degenerative Disc Disease (DDD) and is considered medically necessary when there are no contraindications and **ALL** of the following criteria are met:

1. DDD in only **ONE** level between L3 and S-1 confirmed by a complex imaging studies (e.g., computerized tomography (CT) scan, Magnetic Resonance Imaging (MRI), or positive concordant discography), which indicates either moderate to severe DD of Modic Changes;
2. Symptoms correlate with imaging findings;
3. Documentation of skeletal maturity;
4. Presence of symptoms for at least three months;
5. No more than Grade 1 Spondylolisthesis at the involved level;
6. Documentation use of FDA-approved lumbar/sacral implant to be utilized in accordance with FDA labeling and implanted using an anterior retroperitoneal approach; and
7. Failure of at least three months of conservative treatment prior to implantation of artificial disc. Conservative treatment shall include **ALL** of the following, unless contraindicated:
    a. Physical therapy;
    b. Anti-inflammatory medications;
    c. Analgesics;
    d. Muscle relaxants; and
    e. Epidural steroid injections.

8. Absence of contraindications, which include, but are not limited to the following:
    a. Moderate or severe facet arthopathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph.
    b. Lumbosacral spine fracture.
    c. Scoliosis of the lumbosacral spine.
    d. Active systemic infection or infection localized to the site of implantation.
    e. Allergy or sensitivity to implant materials.
    f. Tumor in the peritoneum, retroperitoneum or site of implantation.
    g. Osteoporosis or osteopenia as defined by recent, within one year of a DEXA scan.
    h. Isolated radicular compression syndromes, especially due to disc herniation.
    i. Spinal stenosis or radiculopathy.
    j. Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain.
    k. Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery.

Medicaid

PacificSource Community Solutions follows Guideline Note 101 of the OHP Prioritized List of Health Services for Artificial Disc Replacement.

Medicare

PacificSource Medicare follows local coverage determination (LCD) L38033 for Cervical Disc Replacement.

PacificSource Medicare follows local coverage determination (LCD) L37826 for Lumbar Artificial Disc Replacement along with National Coverage Determination (NCD) 150.10.

Experimental/Investigational/Unproven

The following procedures are not supported by sufficient evidence-based data or outcome studies to deem them a standard of care for coverage and are considered experimental/investigational or unproven according to PacificSource criteria:

- Thoracic artificial disc arthroplasty.
- The planned procedure includes the combined use of a prosthesis and spinal fusion (i.e., hybrid surgery).
- Intervertebral disc prosthesis implantation of more than 2 consecutive cervical spinal disc levels.
- History of any spinal surgery at operative level.
- Prior fusion at an adjacent cervical or lumbar level.
- Any prior cervical or lumbar artificial disc replacement at any level.
- Intervertebral disc prosthesis implantation at nonconsecutive cervical spine disc levels.
- Non FDA–approved cervical disc.
- FDA-approved disc prosthesis used for other than the FDA approved and intended manufacturer specific use of the device.

Coding Information

0095T Removal of total disc arthroplasty, anterior approach, each additional interspace

0098T Revision of total disc arthroplasty, anterior approach, each additional interspace.

0163T Total Disc Arthroplasty (Artificial Disc), Ant Approach, Inc. Discectomy, Lumbar, Each Additional Interspace

0164T Removal of Total Disc Arthroplasty, Anterior Approach, Lumbar, Each Additional Interspace

0165T Revision of Total Disc Arthroplasty, Anterior Approach, Lumbar, Each Additional Interspace

22856 Total Disc Arthroplasty, Anterior Approach, Including Discectomy with End Plate Preparation, Single Interspace, Cervical

22857 Total Disc Arthroplasty (Artificial Disc), Anterior Approach, Including Discectomy, Lumbar, Single Interspace

22858 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)

22861 Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

22862 Revision Including Replacement of Total Disc Arthroplasty (Artificial Disc) Anterior Approach, Lumbar, Single Interspace

22864 Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

22865 Removal of Total Disc Arthroplasty (Artificial Disc), Anterior Approach, Lumbar, Single Interspace

22899 Arthrodesis, Pre-Sacral Interbody Technique, Inc Instrumentation, Imaging, and Discectomy, Lumbar; Single Interspace

Definitions

Cervical Spondylotic Myelopathy – a condition in which facet joints in the neck become enlarged causing the ligaments around the spinal canal to thicken, bone spur formation and narrowing of the spinal canal resulting in compression of the spinal cord and nerve root.

Degenerative Disc Disease (DDD) – degeneration of the disc confirmed by patient history, physical examination, and radiographic studies resulting in back pain, paresthesia and/or weakness of one or both lower extremities.

Spondylolisthesis Grades

Grade 1	25% or less of vertebral body has slipped forward
Grade 2	Between 25% and 50% of vertebral body has slipped forward
Grade 3	Between 50% and 75% of vertebral body has slipped forward
Grade 4	More than 75% of vertebral body has slipped forward
Grade 5	L5 vertebra positioned completely below the top of the sacrum

Related Polices

Care of the Surgical Patient

Instrumented Spinal Surgery

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Appendix

Policy Number: [Policy Number]

Effective: 5/1/2020 **Next review:** 5/1/2022

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): Guideline Note 101 of the OHP Prioritized List of Health Services, LCD L38033, NCD 150.10 and LCD L37826

Commercial Ops: 5/2021

Government Ops: 5/2021