Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Artificial Intervertebral Disc Replacement

Policy Number: PG0027
Last Reviewed Date: 01/01/2025
Revised Date: 1/01/2025

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Artificial Disc Replacement (ADR), also known as, total disc replacement (TDR) or total disc arthroplasty, uses advanced surgical techniques to remove damaged intervertebral discs within the lumbar or cervical spine and replaces them with a state-of-the-art prosthesis. The goal of total disc replacement is to recreate normal dynamic function of the spine and eliminate back pain. By implanting an entirely new prosthetic disc in place of a degenerated one, ADR restores the spine's ability to move dynamically without compromising mobility, unlike spinal fusion, whose purpose is to limit movement by removing spinal discs entirely and locking vertebrae together. Spinal fusion alters the function of the spine and can potentially lead to premature disc degeneration at adjacent spinal levels.

Artificial discs may consist of two cobalt-chromium endplates that are attached to the vertebrae and a polyethylene disk that is inserted between the metal endplates, may be metal on metal, metal on plastic, ceramic on ceramic or titanium on polyurethane. Discs are implanted through an anterior approach and are attached to vertebrae with screws, teeth, ridges, or pins.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Cervical artificial disc replacement at one level from C3-C7 (22856) does not require prior authorization.**
- **Cervical artificial disc replacement at two contiguous levels (22858) requires prior authorization.**
- **Lumbar artificial disc replacement at one level (22857) requires prior authorization.**
- **Lumbar artificial disc replacement at more than one level (0164T, 0165T) is non-covered.**
- **A total lumbar disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, (22860) is covered with a prior authorization for the Commercial Plans and non-covered for the Medicare Plans.**
- **Removal and/or revision of artificial disc replacement (22861, 22862, 22864, 22865, 0095T, 0098T) does not require prior authorization.**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount considers an FDA-approved **cervical artificial intervertebral disc replacement**, for symptomatic degenerative disc disease or herniated disc, at one level or two contiguous levels for the treatment of skeletally mature persons medically necessary from C3-C7 when ALL the following criteria are met:

1. Individual is skeletally mature and between the ages of 18 and 60; and
2. All other reasonable sources of pain and/or neurological deficit have been ruled out; and
3. Member has signs or symptoms of neural compression (radiculopathy, neurogenic claudication, myelopathy) associated with the levels being treated; and
4. Imaging studies (e.g., CT or MRI) indicate:
   - Nerve root or spinal cord compression at the level corresponding with the clinical findings; or
   - Central/lateral recess or foraminal stenosis graded as moderate, moderate to severe, or severe (not mild or mild to moderate); or
   - Visible loss of disc height as compared to adjacent levels; and
5. There is no radiologic evidence of segmental instability; and
6. Member has failed at least 6 consecutive weeks of conservative therapy under the direction of a healthcare professional within the past 12 months with ALL the following:
   a. Modification of pain-inducing activities; and
   b. Nonsteroidal anti-inflammatory drugs (NSAIDs) if medically appropriate and not contraindicated; and
   c. Oral glucocorticoids if medically appropriate and not contraindicated; and
   d. Physical therapy (PT) including a home exercise program); and
   e. Where appropriate, identification and management of associated anxiety and depression; and
7. Member's activities of daily living are limited by symptoms of neural compression.
8. None of the following is present:
   a) Active systemic infection or infection at the operating site; or
   b) Allergy or sensitivity to implant materials; or
   c) Osteopenia or osteoporosis (bone density T-score -2.5 or lower measured by dual energy x-ray absorptiometry [DEXA]); or
   d) Moderate to advanced spondylosis characterized by any bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of >50% of its normal height.
   e) Marked cervical instability on imaging (e.g., signs of subluxation >3.5 mm or angulation of the disc space >11º greater than adjacent segments); or
   f) Severe facet joint arthropathy; or
   g) Significant cervical anatomical deformity or compromised vertebral bodies at the index level due to systemic disease, diffuse idiopathic skeletal hyperostosis, ankylosing spondylitis , degeneration, trauma, and surgery related trauma; or
   h) Significant kyphotic deformity, significant reversal of lordosis significant spondylolisthesis; or
   i) Symptoms necessitating surgical treatment at > 2 cervical level; or
   j) Congenital stenosis; or
   k) Previous surgery at the involved level; or
   l) Spinal metastases; or
   m) Current medical condition requires long-term use of medications affecting bone quality and fusion rates (e.g., systemic corticosteroids); or
   n) Medical-surgical clearance not obtained from appropriate specialty provider(s).

Note: not all cervical artificial discs have FDA labeling for contiguous two-level degenerative disc disease. Only cervical artificial discs FDA labeled for contiguous two-level disease are proven and medically necessary for this indication.

Paramount considers cervical artificial disc replacement at three or more levels (22899) experimental/investigational as the safety and long-term outcomes are still unclear.

Paramount has determined **thoracic artificial intervertebral disc replacement**, implantation, removal and revision have not demonstrated equivalence or superiority to currently accepted standard means of treatment. Paramount considers thoracic artificial disc replacement, implantation, removal and revision (22899)

investigational and not eligible for reimbursement.

Paramount covers the surgical implantation of an FDA–approved **lumbar artificial intervertebral disc replacement** ~~(22857)~~ medically necessary for the treatment of lumbar degenerative disc disease when ALL the following criteria are met:

1. Individual is skeletally mature and between the ages of 18 and 60
2. Device is FDA approved for lumbar disc replacement
3. Spondylolisthesis at the involved level per the FDA-approved artificial disc specific limits
4. Diagnosis of single level lumbar degenerative disc disease with intractable radiculopathy and/or myelopathy at L3-4, L4-L5 or L5-S1 and confirmed with imaging studies
5. Symptoms of unremitting back and/or leg pain, resulting in disability and/or neurological deficit that is refractory to six months or more of standard medical management including ALL the following unless contraindicated:
    a. Modification of pain-inducing activities; and
    b. Nonsteroidal anti-inflammatory drugs (NSAIDs) if medically appropriate and not contraindicated; and
    c. Oral glucocorticoids if medically appropriate and not contraindicated; and
    d. Physical therapy (PT) including a home exercise program); and
    e. Where appropriate, identification and management of associated anxiety and depression; and
6. The planned implant will be used in the reconstruction of a lumbar disc in only one vertebral level between L-3 to S-1, following single-level discectomy
7. Candidate for single-level lumbar decompression and interbody fusion
8. None of the following is present:
    a) Active systemic infection or infection at the operating site; or
    b) Allergy or sensitivity to implant materials; or
    c) Osteopenia or osteoporosis (bone density T-score -2.5 or lower measured by dual energy x-ray absorptiometry [DEXA]); or
    d) Moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of >50% of its normal height; or
    e) Marked lumbosacral instability on imaging (e.g., signs of subluxation >3.5 mm or angulation of the disc space >11º greater than adjacent segments); or
    f) Severe facet joint arthropathy; or
    g) Significant lumbosacral anatomical deformity or compromised vertebral bodies at the index level due to systemic disease, diffuse idiopathic skeletal hyperostosis, ankylosing spondylitis , degeneration, trauma, and surgery related trauma.
    h) Significant kyphotic deformity, significant reversal of lordosis, or significant spondylolisthesis; or
    i) Symptoms necessitating surgical treatment at > 1 lumbosacral level; or
    j) Congenital stenosis; or
    k) Previous surgery at the involved level; or
    l) Spinal metastases; or
    m) Nerve root compression; or
    n) Stenosis; or
    o) Current medical condition requires long-term use of medications affecting bone quality and fusion rates (e.g., systemic corticosteroids); or
    p) Medical-surgical clearance not obtained from appropriate specialty provider(s).

Paramount considers lumbar artificial disc replacement at more than one level (0164T, 0165T) experimental/investigational as the safety and long-term outcomes are still unclear.

Paramount considers a total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (22860) non-covered for the Medicare members over 60 years of age.

Revision or Replacement of a Cervical and Lumbar Artificial Intervertebral Disc

Paramount covers revision or replacement of a cervical and lumbar artificial intervertebral disc, at the same level as the previous surgery when ALL the following criteria are met:

- Original surgery was performed with an FDA-approved device, and in accordance with those approved indications; and
- Imaging studies confirm implanted device mechanical failure (e.g., dislodgement, implanted device breakage, infection loosening, vertebral body fracture); and
- Symptoms were relieved by original procedure, but reoccurred upon failure of the implanted device

The requirement for a trial of conservative measures may be waived in *any* of the following situations indicating need for urgent intervention:

- Spinal cord compression (this does not include nerve root compression);
- Stenosis causing myelopathy;
- Stenosis causing severe weakness of the muscle(s) innervated by nerves at the requested surgical level(s) (graded 4 minus or less on MRC scale (see Appendix)) (Note: 4 minus strength describes muscle activation that is beyond antigravity (3/5) and produces motion against only slight resistance and fails against moderate resistance);
- Progressive neurological deficit on serial examinations;
- Severe stenosis associated with instability (dynamic excursion with flexion/extension); or
- A discharge note from a physical therapist documenting lack of utility of further physical therapy.

Artificial intelligence-based (AI) augmented reality (AR) guidance and computer spinal navigation systems including, but not limited to, the Caduceus S, HOLO Portal System, Stryker Q Guidance System and Surgalign ARAI System are considered integral to the primary procedure and not separately reimbursable.

When the planned artificial intervertebral disc replacement procedure includes the combined use of a prosthesis and spinal fusion (i.e., hybrid surgery) it is considered experimental/investigation and therefore non-covered.

Required Medical Record Documentation, when applicable:

- Diagnosis
- Specific requested procedure
- History of the medical condition(s) requiring treatment or surgical intervention, including:
    - Level(s) of motor deficit
    - Level(s) of sensory deficit
    - Extremity weakness, numbness, pain, or loss of dexterity including unilateral or bilateral
    - Gait disturbance, including investigation for other etiologies
    - Bowel or bladder dysfunction, including investigation for other etiologies
- History or signs of infection, malignancy, facet arthritis or spine instability at the level of disc replacement request
- Documentation of signs and symptoms; including onset, duration, and frequency
- Physical exam; include spasticity, including investigation for other etiologies
- Relevant medical history, including:
    - Osteoporosis or osteopenia
    - Spondylosis, including severity and level
    - Ankylosing spondylitis
    - Rheumatoid arthritis
    - Ossification of the posterior longitudinal ligament
- Documentation supporting specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, x-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images
- Treatments tried, failed, or contraindicated; include the dates, duration of treatment, and reason for discontinuation
- Current medications used to treat condition, including start date
- Reports of all recent imaging studies and applicable diagnostics, including:

- Results of imaging including number of pathology level(s)
- Physician treatment plan

- For lumbar surgery, in addition to the above, provide medical notes documenting the following, when applicable:
  - Provide psychological face to face evaluation
  - Documentation of instability (listhesis, spondylolisthesis, and grade)
  - Provide the surgical technique to be used and the number of levels involved and their location

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
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)
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure) [Not Covered for Medicare plans]
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, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22899	Unlisted procedure, spine
CPT Category III Code(s)	
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure) [Not Covered]
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure) [Not Covered]

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 07/25/2005

Date	Explanation & Changes
01/01/2006	• Code revision
01/01/2007	• 0091T, 0094T and 0097T have been deleted and replaced with 22857, 22865 and 22862 • These services will remain experimental and will be denied
01/01/2009	• 0090T, 0093T and 0096T have been deleted and replaced with 22856, 22864 and 22861 • These services will remain experimental and will be denied
01/01/2011	• Updated codes

03/21/2014	• Changed title of policy from Disc Arthroplasty to Artificial Intervertebral Disc Replacement • Single-Level Cervical Artificial Intervertebral Disc Replacement (22856, 22864) covered with prior authorization per TAWG committee's review • Policy reviewed and updated to reflect most current clinical evidence • Policy approved per the Technology Assessment Working Group (TAWG) as revised
12/19/2014	• Added new 2015 CPT codes 22858 and 0375T and deleted code 0092T • Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
05/21/2015	• Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
07/22/2016	• PPO now requires prior authorization for cervical artificial disc replacement at one level from C3-C7 (22856, 22864) • Cervical artificial disc replacement at two contiguous levels (22858) is now covered with prior authorization for all product lines (Procedure 22858 is now covered for Advantage per ODM Appendix DD.) • Lumbar artificial disc replacement at one level (22857) is now covered with prior authorization for HMO, PPO, Individual Marketplace, & Elite • Elite members must be 60 years of age or younger per CMS guidelines • Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
06/23/2017	• Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
08/25/2017	• Cervical artificial disc replacement at one level from C3-C7 (22856) no longer requires prior authorization for all product lines per the Technology Assessment Working Group (TAWG)
05/24/2018	• Lumbar artificial disc replacement at one level (22857) is now covered with prior authorization for Advantage per ODM guidelines effective 07/01/18 • Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
12/18/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/01/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
01/01/2024	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Added non-covered code 22860 • Removed deleted code 0375T
02/01/2024	• Medical policy placed on the new Paramount Medical Policy Format
01/01/2025	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Effective 01/01/2025 procedure 22860 is covered with a prior authorization for the Commercial plans, per InterQual criteria. Maintain procedure 22860 as noncovered for the Medicare Plans. • Removed deleted procedure 0163T

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

Centers for Medicare & Medicaid Services. Lumbar Artificial Disc Replacement (LADR) (150.10). Version number 2. Effective date August 14, 2007.

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/

Hayes, Inc., https://www.hayesinc.com/

Hayes, Inc., (November 18,2021) Comparative Effectiveness Review Of Lumbar Total Disc Replacement For Degenerative Disc Disease, Annual update January19 2024.
Hayes, Inc., (August 21, 2017) Single-Level Artificial Disc Replacement for Cervical Degenerative Disc Disease. Annual update January19 2024.
Hayes, Inc., (October 03,2017) Multilevel Artificial Disc Replacement for Cervical Degenerative Disc Disease. Annual update January19 2024.
Hayes, Inc., (April 1,2019) Lumbar Total Disc Replacement for Degenerative Disc Disease. Annual update January19 2024.

Industry Standard Review

International Society for the Advancement of Spine Surgery. (2020). Position Statement on Cervical and Lumbar Disc Replacements. Retrieved from: https://www.isass.org/position-statement-on-cervical-and-lumbar-discreplacements-2019/. Accessed November 22, 2021. Updated Search (January 19,2024)