Artificial Intervertebral Disc Replacement

Humana®

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Line of Business: Commercial

Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies

None

Description

Artificial intervertebral disc replacement is an alternative to cervical and lumbar spinal fusion surgery for an individual suffering from back or neck pain due to degenerative disc disease (DDD). The artificial disc was designed to restore normal disc height, to preserve spinal flexibility and decrease degeneration of adjacent discs, which can occur as a result of DDD.

Examples of US Food & Drug Administration (FDA) devices approved for ***single-level*** cervical spine intervertebral disc replacement include, but may not be limited to:

- **M6-C** cervical disc
- **MOBI-C** cervical disc
- **PCM** cervical disc
- **Prestige LP** cervical disc system
- **ProDisc C, ProDisc C Novo, ProDisc C SK, ProDisc C Vivo** total disc replacement
- **SECURE-C** artificial cervical disc
- **Simplify** cervical artificial disc

Examples of FDA-approved devices for ***single- or two-level*** cervical spine intervertebral disc replacement include, but may not be limited to:

- **MOBI-C** cervical disc
- **Prestige LP** cervical disc system
- **Simplify** cervical artificial disc

Examples of FDA-approved devices for the lumbar spine include, but may not be limited to:

- **activL** artificial disc (FDA approved for only a single level)
- **ProDisc L** total disc replacement (FDA-approved for one or two levels)

Coverage Determination

Services provided by a psychiatrist, psychologist or other behavioral health professionals are subject to the provisions of the applicable behavioral health benefit.

Cervical

Commercial Plan members: requests for *revision and/or replacement* of a cervical artificial intervertebral disc require review by a medical director.

Humana members may be eligible under the Plan for the use of an FDA-approved **cervical artificial intervertebral disc(s) replacement at a single level or two contiguous levels from C3 to C7**[29,31] when **ALL** of the following criteria are met:

- Radiographic confirmation (eg, computed tomography [CT] scan, magnetic resonance imaging [MRI]) of any of the following[42-45,47,48]:
    - Herniated nucleus pulposus; **OR**
    - Spondylosis (defined as presence of osteophytes); **OR**
    - Visible loss of disc height as compared to adjacent levels; **AND**
- Absence of contraindications; **AND**
- Documentation of skeletal maturity*[41-45,47,48]; **AND**
- Failure of at least 6 weeks of conservative treatment[31,41-45,47,48] under the direction of a healthcare professional within the past 12 months with **ALL** of the following:
    - Modification of pain-inducing activities; **AND**
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)[29] if medically appropriate and not contraindicated; **AND**

- Oral glucocorticoids if medically appropriate and not contraindicated; **AND**

- Physical therapy (PT)[29] including a home exercise program (HEP)(for information regarding coverage determination/limitations, please refer to Physical Therapy and Occupational Therapy Medical Coverage Policy); **AND**

- Implantation via an anterior approach[41-45,47,48]**;**

AND ONE of the following:

- Intractable neck pain; **OR**
- Progressive radicular arm pain; **OR**
- Progressive functional neurological deficit (eg, motor weakness, sensory deficit)

Revision or Replacement of a Cervical Artificial Intervertebral Disc

Humana members may be eligible under the Plan for **revision or replacement** of a cervical artificial intervertebral disc *at the same level(s) as the previous surgery* when **ALL** of 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 (eg, dislodgement, implanted device breakage, infection loosening, vertebral body fracture); **AND**

- Symptoms were relieved by original procedure, but reoccurred upon failure of the implanted device

Lumbar

Commercial Plan members: requests for *revision and/or replacement* of a lumbar artificial intervertebral disc require review by a medical director.

Humana members may be eligible under the Plan for the use of FDA-approved (activL, ProDisc L) **lumbar artificial intervertebral disc for replacement at *one* level[32] from L3 to S1** when **ALL** of the following criteria are met:

- Degenerative disc disease confirmed by a complex imaging study[40,46] (eg, CT, MRI, positive concordant discography); **AND**

- Absence of contraindications; **AND**

- Documentation of skeletal maturity*****[40,46]; **AND**

- Failure of at least 6 months of conservative treatment[32,40,46] under the direction of a healthcare professional within the past 12 months with **ALL** of the following:
    - Epidural steroid injections if medically appropriate and not contraindicated[32] (for information regarding coverage determination/limitations, please refer to Injections for Chronic Pain Conditions Medical Coverage Policy); **AND**
    - Modification of pain-inducing activities[32]; **AND**
    - NSAIDs if medically appropriate and not contraindicated[32]; **AND**
    - PT including a home exercise program (HEP)[32] (for information regarding coverage determination/limitations, please refer to Physical Therapy and Occupational Therapy Medical Coverage Policy); **AND**
- No more than grade I spondylolisthesis at the involved level[40,46]; **AND**
- Presurgical psychological evaluation conducted by a qualified behavioral health provider to identify surgical readiness and potential postoperative challenges that may contribute to a poor postoperative outcome; **AND**
- Unremitting low back pain and functional impairment**

*Skeletally mature refers to a system of fused skeletal bones which occurs when bone growth ceases.

**Functional impairment is defined as a direct and measurable reduction in physical performance of an organ or body part limiting the ability to perform activities of daily living such as bathing, dressing and mobility (eg, sit, stand, walk) due to illness or pain.

Revision or Replacement of a Lumbar Artificial Intervertebral Disc

Humana members may be eligible under the Plan for **revision or replacement** of a lumbar artificial intervertebral disc *at the same level as the previous surgery* when **ALL** of 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 (eg, dislodgement, implanted device breakage, infection loosening, vertebral body fracture); **AND**
- Symptoms were relieved by original procedure, but reoccurred upon failure of the implanted device

Coverage Limitations

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.

Cervical

Humana members may **NOT** be eligible under the Plan for **cervical artificial intervertebral disc replacement** for any indications other than those listed above including, but may not be limited to:

- Cervical disc replacement at 2 noncontiguous levels; **OR**
- Cervical disc replacement at *3 or more* levels[31]; **OR**
- Planned procedure includes combined use of a cervical artificial intervertebral disc replacement adjacent to a spinal fusion (also referred to as hybrid surgery); **OR**
- Prior fusion at an adjacent or any other cervical level; **OR**
- Prior surgery at the planned treatment level[29]

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **cervical artificial intervertebral disc replacement** for any of the following contraindications[41-45,47,48]:

- Active or chronic infection, systemic or infection localized to the operative site; **OR**
- Allergy or sensitivity to the implant materials (eg, aluminum, ceramic, chromium, cobalt, ethylene oxide, hydroxyapatite, molybdenum, PEEK, polyethylene, polyurethane, stainless steel, titanium, vanadium); **OR**
- Compromised vertebral bodies at the affected level(s) due to the following:
    - Current or previous trauma to the cervical spine (eg, radiographic appearance of fracture callus, malunion or nonunion; **OR**
    - Significant cervical anatomical deformity or disease (eg, ankylosing spondylitis, malignancy, rheumatoid arthritis); **OR**
- Congenital stenosis; **OR**

- Marked cervical instability on neutral resting lateral and/or flexion/extension radiographs, with greater than 3 millimeters (mm) translation or greater than 11 degrees of angular difference to that of either adjacent level or either level adjacent to the two treated levels; **OR**

- Moderate or severe spondylosis at the level to be treated, characterized by any of the following:

    - Absence of motion less than 2 degrees; **OR**
    - Bridging osteophytes; **OR**
    - Loss of greater than 50% normal disc height; **OR**

- Osteoporosis or osteopenia, defined as dual energy X-ray absorptiometry (DEXA) bone density measured T-score less than or equal to negative 1.0; **OR**

- Severe facet (zygapophyseal) disease or degeneration; **OR**

- Significant kyphotic deformity or severe symptoms (impaired breathing, significant pain, severe functional impairment) or significant reversal of lordosis (eg, curve is running in the wrong direction, loss of normal curve in neck)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Lumbar

Humana members may **NOT** be eligible under the Plan for **artificial intervertebral disc replacement for the lumbar spine** for any indications other than those listed above including, but may not be limited to:

- Multilevel lumbar disc replacement[32]; **OR**

- Planned procedure includes combined use of a lumbar artificial intervertebral disc replacement adjacent to a spinal fusion (also referred to as hybrid surgery); **OR**

- Prior spinal fusion surgery at the planned treatment level[32]

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **lumbar artificial intervertebral disc replacement** for any of the following contraindications[40,46]:

- Abdominal pathology precluding an anterior retroperitoneal approach; **OR**

- Active or chronic infection, systemic or infection localized to the operative site; **OR**
- Allergy or sensitivity to the implant materials (eg, calcium phosphate, cobalt, chromium, molybdenum, polyethylene, tantalum or titanium); **OR**
- Bony lumbar stenosis; **OR**
- Chronic radiculopathy over a period of at least 1 year; **OR**
- Clinically compromised vertebral bodies at the affected level due to current or past disease (eg, ankylosing spondylitis) or trauma (eg, fracture); **OR**
- Extruded disc material with sequestrum (free disc fragment); **OR**
- Facet ankylosis or facet joint degeneration; **OR**
- Involved vertebral endplate dimensionally smaller than 31 mm for activL or 34.5 mm for ProDisc L in the medial lateral and/or 26 mm for activL or 27 mm for ProDisc L in the anterior posterior directions; **OR**
- Isolated lumbar radiculopathy, especially due to herniated disc; **OR**
- Myelopathy; **OR**
- Osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than or equal to negative 1.0; **OR**
- Pars defect; **OR**
- Preoperative remaining disc height less than 3 mm; **OR**
- Scoliosis; **OR**
- Spondylolisthesis (degenerative, isthmic or lytic) greater than grade I or segmental instability

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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**
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	**Medical Director Review Required**
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	**Medical Director Review Required**
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	
CPT® Category III Code(s)	**Description**	**Comments**
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)	**Medical Director Review Required**
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**

HCPCS Code(s)	Description	Comments
No code(s) identified		

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Appendix

Appendix A
Spondylolisthesis Grades[11]
In this system the slip grade is calculated by determining the ratio between the anteroposterior diameter in the top of the first sacral vertebra and the distance the L5 has slipped anteriorly.

Grade I	25% or less displacement
Grade II	Between 25% and 50% displacement

Grade III	Between 50% and 75% displacement
Grade IV	More than 75% displacement
Grade V	L5 vertebra positioned completely below the top of the sacrum

Change Summary

- 03/28/2024 Annual Review, Coverage Change.