



Spinal Arthroplasty, Surgical 35

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Effective Date 1/2011

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<u>Coverage Policy</u> Surgical 35

<u>Version</u> 7

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details **_.

Purpose:

This policy addresses the medical necessity of Spinal Arthroplasty.

Description & Definitions:

Spinal arthroplasty is a procedure that replaces a worn-out disc or facet joint in the spine with a device that moves like a natural disc or joint. The artificial disc or facet joint can also be called a disc prosthetic or disc arthroplasty device or a facet joint arthroplasty/replacement.

Criteria:

Spinal arthroplasty is considered medically necessary for 1 or more of the following:

- Cervical artificial intervertebral disc placement may be considered medically necessary with **all of the** following are present and will be approved as ambulatory (outpatient) unless additional criteria are met as noted by MCG's Ambulatory Surgery or Procedure criteria located at the bottom of this section:
 - Device being used is FDA approved (including, but not limited to: Bryan Cervical Disc, M6-C Artificial Cervical Disc, MOBI-C, the Prestige Cervical Disc, ProDisc-C Total Disc Replacement, Secure-C Artificial Cervical Disc)
 - Individual is skeletally mature
 - Individual has 1 or more of the following:
 - Cervical degenerative disc disease or disc herniation at 1 to 2 contiguous levels from C3 to C7 causing debilitating, intractable cervical radicular pain or myelopathy (weakness, sensory deficit, reflex change, gait disturbance, sphincter disturbance) associated with the cervical level to be treated and refractory to at least 6 weeks of conservative treatment (e.g. analgesics, neuropathic medications, physical therapy)
 - Nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment
- Cervical artificial intervertebral disc placement at a second contiguous level simultaneously for all of the following
 are present and will be approved as ambulatory (outpatient) unless additional criteria are met as noted by MCG's
 Ambulatory Surgery or Procedure criteria located at the bottom of this section:
 - Individual is skeletally mature
 - Individual has 1 or more of the following:

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- Cervical degenerative disc disease or disc herniation at 1 to 2 contiguous levels from C3 to C7 causing debilitating, intractable cervical radicular pain or myelopathy (weakness, sensory deficit, reflex change, gait disturbance, sphincter disturbance) associated with the cervical level to be treated and refractory to at least 6 weeks of conservative treatment (e.g. analgesics, neuropathic medications, physical therapy)
- Nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment
- o The device being used is FDA-approved for 2 levels (i.e., Mobi-C, Prestige LP)
- Subsequent cervical artificial intervertebral disc placement at an adjacent level with all of the following are
 present and will be approved as ambulatory (outpatient) unless additional criteria are met as noted by MCG's
 Ambulatory Surgery or Procedure criteria located at the bottom of this section:
 - Individual is skeletally mature
 - Individual has 1 or more of the following:
 - Cervical degenerative disc disease or disc herniation at 1 to 2 contiguous levels from C3 to C7 causing debilitating, intractable cervical radicular pain or myelopathy (weakness, sensory deficit, reflex change, gait disturbance, sphincter disturbance) associated with the cervical level to be treated and refractory to at least 6 weeks of conservative treatment (e.g. analgesics, neuropathic medications, physical therapy)
 - Nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment
 - The device being used is FDA-approved for 2 levels
 - The initial artificial disc placement has fully healed
 - The planned subsequent procedure is at a different cervical level than the initial artificial disc placement
- Lumbar disc arthroplasty is considered medically necessary when **1 or more** of the following criteria are present and will be approved as ambulatory (outpatient) unless additional criteria are met as noted by MCG's Ambulatory Surgery or Procedure criteria located at the bottom of this section:
 - o Initial treatment
 - Individual is between the age of 18 and 60 years
 - Axial pain determined to be of discogenic origin is the primary complaint
 - At least 6 months of symptoms which have not responded to a multifaceted program of conservative management.
 - MRI and plain radiographs demonstrating moderate to severe degeneration of the disc with Modic changes (peridiscal bone signal above and below the disc space inquestion) with presence of single or dual (when using 2-level FDA-approved implant) level, advanced disc disease at L3-L4, L4-L5, or L5-SI.
 - Individual reports moderate pain and disability ideally documented by a visual analog scale (VAS) pain score of 40 or higher (out of 100, or 4 out of 10) and individualhas functional limitation of one or more IADL
 - Any individual with underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
 - Absence of symptomatic degenerative disc disease at all other lumbar levels, as documented by normal X-rays, and MRI confirms no abnormalities or mild degenerative changes
 - Implant device is FDA-approved
 - Revision of lumbar artificial intervertebral disc maybe considered medically necessary if imaging (x-ray, CT scan, MRI) shows failure of the implanted device (e.g., loosening, dislodgement, fracture, infection).

As noted in MCG's Ambulatory Surgery or Procedure GRG PG-AS (ISC GRG):

This surgery or procedure will be traditionally approved ambulatory (outpatient), but may receive initial approval for Inpatient Care when **one or more of the following** are met:

- Inpatient care needed for clinically significant disease or condition identified preoperatively, as indicated by one or more of the following:
 - Severe infection
 - Altered mental status
 - Dangerous arrhythmia
 - Hypotension
 - Hypoxemia

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- o Complex surgical approach or situation anticipated, as indicated by 1 or more of the following:
 - Prolonged airway monitoring required (eg, severe obstructive sleep apnea, open neck procedure)
 - Other aspect or feature of procedure that indicates a likely need for prolonged postoperative care or monitoring
- o High patient risk identified preoperatively, as indicated by **1 or more** of the following:
 - American Society of Anesthesiologists class IV or greater <u>American Society of Anesthesiologists</u>
 (ASA) Physical Status Classification System
 - Severe frailty
 - Severe valvular disease (eg, severe aortic stenosis)
 - Symptomatic coronary artery disease, or heart failure
 - Symptomatic chronic lung disease (eg, COPD, chronic lung disease of prematurity)
 - Severe renal disease (eg, glomerular filtration rate (GFR) less than 30 mL/min/1.73m² (0.5 mL/sec/1.73m²) or on dialysis) eGFR Adult Calculator
 - Morbid obesity (eg, body mass index greater than 40 BMI Calculator) with hemodynamic or respiratory problems (eg, severe obstructive sleep apnea, hypoventilation)
 - Complex chronic condition in children (eg, ventilator-dependent, neuromuscular, genetic, or immunologic disease)
 - Other patient condition or finding that places patient at increased anesthetic risk such that prolonged postoperative inpatient monitoring or treatment is anticipated
- Presence of drug-related risk identified preoperatively, as indicated by 1 or more of the following:
 - Procedure requires discontinuing medication (eg, antiarrhythmic medication, antiseizure or anticoagulant medication), which necessitates preoperative or prolonged postoperative inpatient monitoring or treatment.
 - Preoperative use of drugs that may interact with anesthetic (eg, cocaine, amphetamines, monoamine oxidase inhibitor) such that prolonged postoperative monitoring or treatment is needed

Spinal Arthroplasty is not covered for any of the following:

- ACADIA Facet Replacement System (Facet Solutions/Globus Medical)
- Artificial intervertebral disc placement for 1 or more of the following:
 - Hybrid fusion with artificial disc replacement
 - Individual has 1 or more of the following:
 - Absence of neck and/or arm pain
 - Active infection or malignancy
 - Auto-immune disease (Rheumatoid arthritis, Ankylosing Spondylitis)
 - Facet joint disease/degeneration which is moderate to severe
 - Had a prior surgery at the requested spinal level
 - Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia, Paget's disease)
 - Neck or arm pain of unknown etiology
 - Progressive neurological deficit or deterioration
 - Scoliosis
 - Spinal fracture
 - Spinal instability (spondylolisthesis of Grade 2 or greater in the lumbar spine and >11 degree angular or >3.5 mm subluxation in the cervical spine) is noted on lateral or flexion/extension x-rays
 - Request is for combined artificial disc placement and fusion

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- Request is for disc placement at more than two levels in the cervical spine and more than one level in the lumbar spine
- Facet joint implantation (Total Posterior-element System (TOPS) (Premia Spine)
- Lumbar and cervical partial disc prosthetics (e.g., Nubac, DASCOR Disc Arthoplasty System)
- Non FDA-approved cervical and lumbar disc prosthesis
- Posterior Vertebral (facet) Joint Replacement
- Total Facet Arthroplasty System (TFAS) for the treatment of spinal stenosis
- Lumbar disc arthroplasty is **NOT COVERED** for **ALL** of the following:
 - Disc replacement at more than one spinal level (unless FDA approved for more than one level, e.g., prodisc® L Total Disc Replacement)
 - o Individual has history of prior lumbar fusion
 - Individual with isolated radicular compression syndromes, especially due to disc herniation
 - Hybrid lumbar total disc arthroplasty/lumbar fusion (lumbar total disc arthroplasty at one level at the same time as lumbar fusion at a different level)
 - Arthroplasty using devices that are not FDA approved, or use of an FDA approved device in a manner not intended by FDA requirements.
- Individual requires significant facet arthropathy at the index level
- Depending on FDA-approved levels of diseases above L3-L4 or L4-L5
- Bony lumbar spinal stenosis
- Pars defect
- Prior fusion at intended level
- Individual with poorly managed psychiatric disorder
- Chronic radiculopathy (unceasing pain with leg pain symptoms greater than back pain symptoms for a minimum of one year)
- Clinically compromised vertebral bodies at affected level due to current or past trauma
- Lytic spondylolisthesis or degenerative spondylolisthesis of grade greater than 1
- Individual with allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- Presence of infection or tumor
- Osteopenia or osteoporosis (defined as DEXA bone density measured T-score less than or equal to -1.0)

Coding:

Medically necessary with criteria:

Coding	Description
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)
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

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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, 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

Coding	ot Medically Necessary: Description
County	Boomption
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (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)
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)
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)

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0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: July
- 2020: August (Unarchived)
- 2016: April
- 2015: February, May, September
- 2014: January, April, June (Archived and added to Surgical 78), August, November
- 2012: January
- 2011: May, June

Reviewed Dates:

- 2024: August Annual review completed criteria updated, exceptions clarified and updated. Title changed and coding updated.
- 2023: August
- 2022: August
- 2021: September
- 2018: November
- 2017: December
- 2016: May
- 2013: January

Effective Date: January 2011

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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LCD Lumbar Artificial Disc Replacement (L37826). (2021, Jun 17). Retrieved Jul 23, 2024, from Centers for Medicare and Medicaid Services: <a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37826&ver=21&keyword=disc%20replacement&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

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Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

SHP Artificial Disc Replacement and Treatment, SHP Surgical 35, Cervical artificial intervertebral disc, Bryan Cervical Disc, M6-C Artificial Cervical Disc, MOBI-C, the Prestige Cervical Disc, ProDisc-C Total

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Disc Replacement, Secure-C Artificial Cervical Disc, Cervical degenerative disc disease, Nerve root compression, spinal cord compression, Lumbar artificial intervertebral disc placement,

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