Sentara Health Plans

Medicaid

Spinal Arthroplasty, Surgical 35

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Implementation	7/1/2025
Next Review Date	4/2026
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

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 **ALL of the following**:

- Procedure is indicated 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:

- 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 (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
- ~~o~~ 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:
  - ▪ Initial treatment and **ALL of the following:**
    - 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-Sl.
    - 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).

- Individual smoking requirement meets **1 or more** of the following:
  - Single level Anterior Cervical Discectomy and Fusion or posterior Foraminotomy may be performed in patients that smoke.
  - The individual must be a nonsmoker and in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery and 6 weeks after the surgery.
  - If individual is a smoker, cessation must be confirmed by a negative urine nicotine test, prior to surgery approval.

<u>Spinal Arthroplasty is not covered for any of the following:</u>

- 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 previous fusion surgery at any other spinal level
        - 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
    - 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)
    - 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)

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
    - 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
    - High patient risk identified preoperatively, as indicated by **1 or more** of the following:
        - American Society of Anesthesiologists class IV or greater American Society of Anesthesiologists (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/1.73m^2 (0.5 mL/sec/1.73m^2) 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

Document History:

Revised Dates:

- 2025: April – Implementation date of July 1, 2025. Added criteria for absence of smoking or cessation to Single level Anterior Cervical Discectomy and Fusion or posterior Foraminotomy. Updated to new format.
- 2024: August – Annual review completed – criteria updated, exceptions clarified and updated. Title changed and coding updated.
- 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:

- 2023: August
- 2022: August
- 2021: September
- 2018: November
- 2017: December
- 2016: May
- 2013: January

Effective Date: January 2011

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
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

Considered Not Medically Necessary:

Coding	Description
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)
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.

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement.

Special Notes: *

- Coverage: See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to Products: Policy is applicable to Sentara Health Plan Medicaid products.
- Authorization Requirements:
    - Pre-certification by the Plan is required.
- Special Notes:
    - Medicaid
        - This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.
        - 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.
        - The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health

problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

- Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2024, Mar 14). Retrieved Jul 23, 2024, from MCG 28th Edition: https://careweb.careguidelines.com/ed28/index.html

(2024). Retrieved Jul 23, 2024, from Department of Medical Assistance Services - MES Public Portal: https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=spinal%20surgery&gsc.sort=

Chou, R. (2023, Sep 27). Subacute and chronic low back pain: Surgical treatment. Retrieved Jul 24, 2024, from UpToDate: https://www.uptodate.com/contents/subacute-and-chronic-low-back-pain-surgical-treatment?search=lumbar%20disc%20replacement&sectionRank=1&usage_type=default&anchor=H5&source=machineLearning&selectedTitle=1%7E3&display_rank=1#H15

CLINICAL GUIDELINES. (2024). Retrieved Jul 23, 2024, from North American Spine Society: https://www.spine.org/Coverage

Comparative Effectiveness Review Of Lumbar Total Disc Replacement For Degenerative Disc Disease. (2022, Mar 24). Retrieved Jul 23, 2024, from Hayes: https://evidence.hayesinc.com/report/htb.linx2659

Kothari, M., & Chuang, K. (2023, Feb 28). Treatment and prognosis of cervical radiculopathy. Retrieved Jul 24, 2024, from UpToDate: https://www.uptodate.com/contents/treatment-and-prognosis-of-cervical-radiculopathy?search=cervical%20disc%20replacement&source=search_result&selectedTitle=1%7E3&usage_type=default&display_rank=1#H17

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

LCD: Cervical Disc Replacement (L38033). (2023, Apr 27). Retrieved Jul 23, 2024, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38033&ver=13&

NCD Lumbar Artificial Disc Replacement (LADR) (150.10). (2007, Aug 14). Retrieved Jul 22, 2024, from Centers for Medicare and Medicaid Services: https://careweb.careguidelines.com/editionless/mcr/ncd0313v02b01.htm

prodisc C SK, prodisc C Nova, and prodisc C Vivo Instruments. (2024, Jul 22). Retrieved Jul 23, 2024, from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221848

Spine Surgery. (2024, Apr 01). Retrieved Jul 23, 2024, from Carelon Medical Benefits Management: https://guidelines.carelonmedicalbenefitsmanagement.com/spine-surgery-2024-01-01/

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