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## SHP Artificial Disc Replacement and Treatment

MCG Health Ambulatory Care 25th Edition

AUTH: SHP Surgical 35 v2 (AC)

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#### Coverage

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See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

## **Application to Products**

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Policy is applicable to all products.

### **Authorization Requirements**

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Pre-certification by the Plan is required.

### **Description of Item or Service**

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An artificial disc is replacement that can be inserted into the spine. Artificial disc can also be called a disc prosthetic or disc arthroplasty device.

### **Exceptions and Limitations**

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- For Optima Commercial Plan or Optima Virginia Medicaid Plan there is insufficient scientific evidence to support the medical necessity of the following as they are not shown to improve health outcomes upon technology review:
  - · Artificial intervertebral disc placement for 1 or more of the following:
    - Hybrid fusion with artificial disc replacement
    - Individual with 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
- · Lumbar and cervical partial disc prosthetics (e.g., Nubac, DASCOR Disc Arthoplasty System)
- · Non FDA-approved cervical and lumbar disc prosthesis
- For Optima Medicare Plan There is insufficient scientific evidence to support the medical necessity of the following as they are not shown to improve health outcomes upon technology review:
  - Cervical Disc Replacement Revision for individual with **1 or more** of the following:
    - Combined use of artificial cervical disc and fusion
    - Disc replacement at 2 non-contiguous levels or 3 or more levels
    - Individual with **1 or more** of the following:
      - Any anatomical deformity (eg, ankylosing spondylitis, trauma)
      - · Any autoimmune disease or rheumatoid arthritis
      - Chronic renal failure
      - Malignancy
      - Metabolic bone disease (eg, osteoporosis, Paget's disease, osteomalacia, osteogenesis imperfecta) or taking medications known to potentially interfere with bone/soft tissue healing (eg, steroids)
      - · Moderate to severe facet joint arthropathy at involved level
      - · Previous fusion at another level
      - Prior surgery at treated level
  - · Lumbar artificial intervertebral disc placement
- There is insufficient scientific evidence to support the medical necessity of Artificial Disc Replacement and Treatment for uses other than those listed in the clinical indications for procedure section.

## **Clinical Indications for Procedure**

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- Artificial disc replacement is considered medically necessary for **1 or more** of the following:
  - Individual has Optima Commercial Plan or Optima Virginia Medicaid Plan and request is for 1 or more of the following:
    - Cervical artificial intervertebral disc placement may be considered medically necessary with ALL of the following:
      - Device being used is FDA approved (including, but not limited to: Bryan Cervical Disc, M6-C Artificial Cervical Disc, M0BI-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:
      - · 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:
       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 artificial intervertebral disc placement with ALL of the following:
  - Device being used is FDA approved
  - Individual is skeletally mature
  - Individual has **1 or more** of the following:
    - Single level lumbar degenerative disc disease from L3 to S1 causing debilitating, intractable low back pain associated with the lumbar level to be treated and refractory to at least 6 months of conservative treatment (e.g. analgesics, physical therapy, exercise, lifestyle modification, muscle relaxers, epidural steroid injections)
    - 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 has Optima Medicare Plan and request is for **1 or more** of the following:
  - Cervical Disc Replacement may be covered for **ALL** of the following:
    - Appropriate procedure, as indicated by 1 or more of the following:
      - Single-level procedure and **ALL** of the following:
        - Cervical disc replacement (CDR) device is approved by FDA
        - Individual is skeletally mature
        - Individual with **1 or more** of the following:
          - Intractable cervical radicular pain or myelopathy which has failed at least 6 weeks of conservative non-operative treatment including physician-directed pain management (eg, pharmacotherapy addressing neuropathic pain and physical therapy)
          - Severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical intervention
        - Clinical evidence of corresponding nerve root or spinal cord compression, as documented by 1 or more of the following:
          - Computed tomography (CT)
          - Myelography
          - Magnetic resonance imaging (MRI)
        - Cervical degenerative disc disease from C3 to C7
        - Individual is free from absolute contraindications to cervical disc replacement (CDR), as indicated by ALL of the following:
          - Individual is without extreme obesity (BMI  $\ge$  40 kg/m2)
          - · Individual is without significant cervical anatomical deformity
          - Individual is without allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
          - · Individual is without active systemic infection or infection at operating site
          - · Individual is without osteoporosis or osteopenia
          - Individual is without marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or greater than 11 degree angular difference to that of either level adjacent the treated level
          - Individual is without severe spondylosis
          - Individual is without clinically compromised vertebral bodies at affected level
      - $\circ~$  Two-level procedure and ALL of the following:
        - Cervical disc replacement (CDR) device is FDA-approved for 2 levels
        - Individual is skeletally mature
        - Individual with **1 or more** of the following:
          - Intractable cervical radicular pain or myelopathy which has failed at least 6 weeks of conservative non-operative treatment including physician-directed pain management (eg, pharmacotherapy addressing neuropathic pain and physical therapy)
          - Severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical intervention
        - Clinical evidence of corresponding nerve root or spinal cord compression, as documented by 1 or more of the following:
          - Computed tomography (CT)
          - Myelography
          - Magnetic resonance imaging (MRI)
        - Cervical degenerative disc disease from C3 to C7
        - Individual is free from absolute contraindications to cervical disc replacement (CDR), as indicated by ALL of the following:
          - Individual is without extreme obesity (BMI ≥ 40 kg/m2)

- Individual is without significant cervical anatomical deformity
- Individual is without allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- · Individual is without active systemic infection or infection at operating site
- · Individual is without osteoporosis or osteopenia
- Individual is without marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or greater than 11 degree angular difference to that of either level adjacent the treated level
- · Individual is without severe spondylosis
- · Individual is without clinically compromised vertebral bodies at affected level
- Objective clinical evidence of radiculopathy, myelopathy, or spinal cord compression at 2 corresponding contiguous levels
- Provider performing cervical disc replacement (CDR) is licensed qualified physician, as evidenced by ALL
  of the following:
  - Physician trained and acquired expertise within framework of accredited residency or fellowship
    program in applicable specialty/subspecialty (eg, neurosurgery, orthopedic spine) or must reflect
    equivalent education, training, and expertise endorsed by academic institution in spine surgery or by
    applicable specialty/subspecialty society.
  - Physician has ability to provide evidence of proficiency in performance and management of cervical disc replacement and cervical degenerative disc disease.
- For Optima Commercial Plan or Optima Virginia Medicaid Plan artificial disc replacement is **NOT COVERED** for **ANY** of the following:
  - 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
  - · Lumbar and cervical partial disc prosthetics (e.g., Nubac, DASCOR Disc Arthoplasty System)
  - Non FDA–approved cervical and lumbar disc prosthesis
- · For Optima Medicare artificial disc replacement is NOT COVERED for ANY of the following:
  - Cervical Disc Replacement Revision for **1 or more** of the following:
    - Combined use of artificial cervical disc and fusion
    - Disc replacement at 2 non-contiguous levels or 3 or more levels
    - Individual with 1 or more of the following:
      - Any anatomical deformity (eg, ankylosing spondylitis, trauma)
        - · Any autoimmune disease or rheumatoid arthritis
      - Chronic renal failure
      - Malignancy
      - Metabolic bone disease (eg, osteoporosis, Paget's disease, osteomalacia, osteogenesis imperfecta) or taking medications known to potentially interfere with bone/soft tissue healing (eg, steroids)
      - · Moderate to severe facet joint arthropathy at involved level
      - Previous fusion at another level
      - Prior surgery at treated level
  - Lumbar artificial intervertebral disc placement

### **Document History**

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Revised Dates:

- 2020: August (Unarchived)
- 2016: April
- 2015: February, May, September
- $\circ\,$  2014: January, April, June (Archived and added to Surgical 78), August, November
- 2012: January
- ∘ 2011: May, June
- Reviewed Dates:
  - 2022: August
  - 2021: September
  - 2018: November
  - 2017: December
  - 2016: May
  - 2013: January
- Effective Date: January 2011

# **Coding Information**

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- CPT/HCPCS codes covered if policy criteria is met:
  - CPT 0095T Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
  - CPT 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)
  - CPT 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
  - CPT 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
  - CPT 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)
  - CPT 22861 Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical)
  - CPT 22862 Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
  - CPT 22864 Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
  - CPT 22865 Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
- CPT/HCPCS codes considered not medically necessary per this Policy:
  - CPT 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)
  - CPT 0164T Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
  - CPT 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)

#### References

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References used include but are not limited to the following:

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#### Codes

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CPT® : 0095T, 0098T, 0163T, 0164T, 0165T, 22856, 22857, 22858, 22861, 22862, 22864, 22865

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