Total Artificial Disc Replacement for the Spine (for Indiana Only)

Policy Number: CS121IN.01
Effective Date: April 1, 2021

Instructions for Use

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Related Policies

- Bone or Soft Tissue Healing and Fusion Enhancement Products
- Surgical Treatment for Spine Pain

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the Indiana Surgical Services Provider Reference Module.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	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)
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)

CPT Code	Description
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
22899	Unlisted procedure, spine

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Lumbar

The following lumbar disc replacement products (product code MJO) have received FDA approval:

- The activL® Artificial Disc (Aesculap Implant Systems, LLC) received FDA Premarket Approval on June 11, 2015. It is indicated for people who have fully formed and fully grown bones (are skeletally mature), have low back pain due to a problem with one lumbar disc (as determined by a doctor), have been diagnosed as having degenerative disc disease (DDD) in only one lumbar disc at either level L4/L5 or L5/S1 (as determined by a doctor), and have gone through at least six months of non-surgical treatment without relief. The device is designed to help stabilize the operated spinal level and allow motion at the level. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120024A.pdf. (Accessed July 1, 2020)
- The Charite® intervertebral disc (DePuy Spine, Inc., Raynham, MA) received FDA Premarket Approval on October 26, 2004. It is approved for use in patients who have single-level degenerative disc disease (L4-S1) of the lumbar spine and who have had no relief from low back pain after at least six months of nonsurgical treatment. Removed from the market in 2012.
- The ProDisc-L® Total Disc Replacement received FDA Premarket Approval on August 14, 2006 for use in patients who have single-level degenerative disc disease of the lumbar spine (L3-S1) and who have had no relief from low-back pain after at least 6 months of nonsurgical treatment. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010A.pdf. (Accessed July 1, 2020)

Cervical

The following cervical disc replacement products (product code MJO) have received FDA approval:

- M6-C™ Artificial Cervical Disc Prosthesis received premarket approval on February 6, 2019 (P170036). The M6 has two titanium outer plates with keels for anchoring the disc into the bone of the vertebral body. These outer plates are coated with a titanium plasma spray that promotes bone growth into the metal plates, providing long term fixation and stability of the disc in the bone. The M6-C™ Artificial Cervical Disc is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3–C7. Degenerative cervical radiculopathy is defined as arm pain and/or a neurological deficit (numbness, weakness, deep tendon reflexes changes) with or without neck pain due to disc herniation and/or osteophyte formation and confirmed by radiographic imaging (CT, MRI, x-rays). The M6-C™ Artificial Cervical Disc is implanted via an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or exhibit progressive neurological symptoms which could lead to permanent impairment prior to implantation of the M6-C™ Artificial

Cervical Disc. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/p170036a.pdf. (Accessed July 1, 2020)

- Mobi-C® Cervical Disc Prosthesis received premarket approval on August 7, 2013. (P110002). The Mobi-C® Cervical Disc Prosthesis consists of two metal (cobalt-chrome alloy2) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc that is causing arm pain and/or weakness or numbness. The Mobi-C® Cervical Disc Prosthesis is intended for skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc at only one spinal level. The device should help stabilize the operated spinal level. Unlike a fusion procedure7, the Mobi-C® Cervical Disc Prosthesis is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002a.pdf. (Accessed July 1, 2020)
- Mobi-C® Cervical Disc Prosthesis (two-level) received premarket approval of August 23, 2013. (P110009). The Mobi-C® Cervical Disc Prosthesis consists of two metals (cobalt-chrome endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc at two adjacent levels that are causing arm pain and/or weakness or numbness. The Mobi-C® Cervical Disc Prosthesis is intended for skeletally mature patients (people who have stopped growing) to replace two adjacent cervical discs in the neck (from C3-C7) following removal of the discs for conditions that result from diseased or bulging discs at two adjacent spinal levels. The two devices should help stabilize the operated spinal levels. Unlike a fusion procedure the Mobi-C® Cervical Disc Prosthesis is designed to allow motion at the operated spinal levels. The effects of removing the diseased discs should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110009a.pdf. (Accessed July 1, 2020)
- ProDisc-C® Total Disc Replacement received premarket approval on December 17, 2007 (P070001). The device is indicated for skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes) and/or loss of disc height. The ProDisc-C® total disc replacement is implanted via an open anterior approach. Patients receiving the ProDisc-C® total disc replacement should have failed at least six weeks of non-operative treatment prior to implantation. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070001a.pdf. (Accessed July 1, 2020)
- Prestige® LP Cervical Disc received premarket approval on July 24, 2014. Indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and./ r a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, x-ray): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. In July 2016, the Prestige® LP received FDA approval for implantation at 2 levels. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029c.pdf. (Accessed July 1, 2020)
- Prestige® Cervical Disc System received premarket approval on July 16, 2007 (P060018). The device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation. The safety and effectiveness of the device has not been established in patients who have not undergone at least six weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060018. (Accessed July 1, 2020)
- Bryan® Cervical Disc received premarket approval on May 12, 2009 (P060023). The device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The Bryan® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT and/or magnetic resonance imaging (MRI). Patients receiving the Bryan® Cervical Disc should

have failed at least six weeks of non-operative treatment prior to implantation. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060023. (Accessed July 1, 2020)

- SECURE®-C Artificial Cervical Disc received premarket approval on September 28, 2012 (P100003). The SECURE®-C Artificial Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy3 or myelopathy4) at only one level. The device should help stabilize the operated disc in the neck. Unlike a fusion procedure5, the SECURE®-C Artificial Cervical Disc is designed to allow motion at the operated disc. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100003. (Accessed July 1, 2020)
- PCM® Cervical Disc System received premarket approval on October 26, 2012 (P100012). The PCM Cervical Disc consists of two metal (cobalt-chrome alloy) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (vertebrae) to replace a diseased cervical disc2 that is causing arm pain and/or weakness or numbness. The PCM Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc from C3-C7 following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy3 or myelopathy4) at only one level. The device should help stabilize the operated disc in the neck (spinal level). Unlike a fusion procedure5, the PCM Cervical Disc is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100012. (Accessed July 1, 2020)

Policy History/Revision Information

Date	Summary of Changes
04/01/2021	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.