



## UTILIZATION MANAGEMENT POLICY

TITLE: CERVICAL SPINE SURGERIES

EFFECTIVE DATE: January 15, 2024

*This policy was developed with input from specialists in orthopedic spine surgery and endorsed by the Medical Policy Committee.*

### **IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**

*These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.*

*Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.*

### **PURPOSE**

To promote consistency between Utilization Management reviewers by providing the criteria that determine medical necessity.

### **BACKGROUND**

#### **I. Disease State**

- A. Cervical degenerative disease (CDD), aka cervical spondylosis, affects approximately ten percent of all adults who display some degree of neck pain at any given time. Less than one percent develop neurologic deficits. In the majority of cases, individuals recover following conservative treatment, and there remains a lack of consensus regarding use of surgical options and the prognostic factors associated with surgical treatment of CDD.
- B. Symptomatic CDD can result in axial neck pain, extremity pain, and/or neurological dysfunction. Causes of axial neck pain include cervical strain, internal disc disruption syndrome, cervical facet-mediated pain, cervical 'whiplash' syndrome, and myofascial pain.
- C. Cervical radiculopathy is a disorder that involves a combination of pain, numbness, tingling and/or weakness in a particular nerve distribution that correlates with imaging findings showing mechanical compression of the individual nerve by a soft disc herniation or osteophyte (bone spur). It can involve one or more nerves at a time.
- D. Cervical myelopathy is a disorder that is caused when a soft disc herniation, hypertrophic ligaments or osteophytes cause mechanical pressure on the spinal cord, which results in a continuum of symptoms ranging from subtle incoordination and spasticity to frank quadraparesis or quadriplegia.

#### **II. Definitions**

- A. **Anterior cervical spine surgery** is the most common method for cervical spine surgery. It is performed by the surgeon approaching the spine from the front of the body, through the throat area. Anterior approaches are performed for correction of CDD including cervical discectomy, corpectomy, fusion, and bone grafting.
- B. **Artificial cervical intervertebral disc replacement (arthroplasty)** is a surgical procedure in which a diseased or damaged intervertebral disc is replaced with an artificial device in individuals with symptomatic degenerative disc disease or herniated disc. They are intended to preserve/restore vertebral alignment, maintain spinal stability and flexibility, and alleviate pain. Surgery is performed in-patient and requires general anesthesia.
- C. **Artificial cervical intervertebral discs** that have received U.S. Food and Drug Administration (FDA) approval include:
  1. M6-C™ (Orthofix)

2. MOBI-C® Cervical Disc Prosthesis (LDR Spine USA)
  3. PCM® Cervical Disc System (NuVasive, Inc.)
  4. Prestige® Cervical Disc System (Medtronic Sofamor Danek)
  5. ProDisc™ C (Synthes, Inc.)
  6. Secure® C Artificial Disc System (Globus Medical)
  7. Simplify® (Simplify Medical, Inc).
- D. **Axial neck pain** is musculoskeletal, characterized as neck or soft tissue pain occurring solely along the spinal column. Whiplash, musculoligamentous strain and cervical spondylosis are three common causes. Non-operative treatment of isolated axial neck pain has been reported to benefit most patients.
- E. **Cervical spondylotic myelopathy** is due to compression of the spinal cord by spinal stenosis (e.g., osteophytes), extruded disk material (i.e., herniated disc), metastatic tumor, or fracture fragments. Myelopathy is more common in older individuals and is generally a slowly progressive condition. Symptoms include loss of dexterity in upper and lower extremities, and/or hand incoordination/heaviness. If the site of compression is applying pressure to nerves, pain at the segment site may be present.
- F. **Chronic discogenic pain** is severe, recurring or constant pain originating from the intervertebral disc that limits the individual's ability to function. The term is most frequently used when the patient has relatively mild pathology on imaging studies, and does not have significant spondylosis, instability, radicular or myelopathic findings. Surgery is rarely indicated to treat this condition.
- G. **Corpectomy/hemicorpectomy** is removal of the entire vertebral body and surrounding discs to relieve nerve and/or spinal cord impingement. When the pathology dictates that only a portion of the vertebral body be removed, the procedure is referred to as a hemicorpectomy.
- H. **Decompression surgery** is a general term that refers to various procedures intended to relieve symptoms caused by pressure, or compression, on the spinal cord and/or nerve roots. Bulging or collapsed disks, thickened joints, loosened ligaments and bony growths can narrow the spinal canal and the spinal nerve openings (foramen), causing irritation. Examples of procedures include: discectomy; laminotomy/laminectomy; foraminotomy; osteophylectomy (i.e., bone spur removal); and corpectomy.
- I. **Degenerative disc disease (DDD)** is a general term indicating a progressive drying out and degeneration of the intervertebral disc that leads to loss of spine flexibility and function. DDD is part of the normal aging process and develops over time. It can cause neck pain and stiffness.
- J. **Discectomy** is the surgical removal of the intervertebral disc. It can refer to removing the entire disc, as in an anterior discectomy and fusion, or simply a herniated portion of the nucleus pulposus (the central portion of the intervertebral disc), which is pressing on a nerve root or the spinal cord. Infrequently (i.e., 5% - 10% of discectomies), additional nuclear material may extrude through the same annular defect at any time after the primary discectomy surgery. This condition is termed "recurrent disc herniation."
- K. **Facet joints** are small joints that are located on the back of the spine, one on each side. Each vertebra is connected by facet joints. They provide stability to the spine by interlocking two vertebrae.
- L. **Facetectomy** is spine surgery to partially remove one or both of the facet joints on a set of vertebrae in the spine. Facetectomy is intended to remove the pressure of the spinal nerve roots near the facet joint when conservative medical treatment fails.
- M. **Laminectomy** is a surgical procedure performed to remove the lamina. It is also referred to as decompression surgery. A laminectomy enlarges the spinal canal and is intended to relieve pressure on the spinal cord and surrounding nerves.
- N. The **lamina** is the flat area of bone between the superior process of the facet joint and the spinous process. The lamina is located on either side of the spinous process and forms the back of the central canal through which the spinal cord passes.
- O. **Laminoplasty** is also performed to relieve pressure on the spinal cord and nerve roots. However, instead of removing the lamina, the lamina is partially cut on one side, creating a hinge, and completely cut on the other side. The lamina is then opened slightly and held in place with the use of small bone plates and screws. An alternative method creates hinges on both side of the lamina and opens similar to a French-style door.
- P. **Laminotomy (hemilaminectomy; laminoforaminotomy)** is a surgical transection of vertebral lamina performed to decompress a nerve. It consists of partially removing of a portion of the lamina overlying the compressed nerve to access and remove a disc herniation or to remove osteophytes. The procedure can be done on one or both sides of the spinous process.
- Q. **Myelography** is radiographic imaging that involves injection of contrast material in the subarachnoid space around the spinal cord and nerve roots using a real-time form of x-ray called fluoroscopy. Following injection of the contrast media, the radiologist is able to view and evaluate the status of the spinal cord, the nerve roots, and the meninges. The radiologist tracks the flow of contrast material in real-time and also takes

- permanent radiographs to document findings. A myelogram is most often followed by computed tomography (CT) to further clarify the individual's anatomy.
- R. **Myelopathy** is due to compression of the spinal cord by spinal stenosis (e.g., osteophytes), extruded disk material (i.e. herniated disc), metastatic tumor, or fracture fragments. Myelopathy is more common in older individuals and is generally a slowly progressive condition. Symptoms include hand incoordination, heaviness in the legs, or numbness/tingling in the legs. If the site of compression is applying pressure to nerves, pain at the segment site may be present.
  - S. **Neck Disability Index (NDI) Score** was developed as a modification of the Oswestry Disability Index (ODI) for low back pain with the permission of the original author. The NDI is a standard self-administered, neck pain disability questionnaire used by clinicians and researchers to measure a patient's functional disability related to the neck pain at a certain point in time.
  - T. **Nerve conduction testing** measures how well and how fast the nerves can send electrical signals within the peripheral nervous system. They are performed mainly for evaluation of numbness, tingling (i.e., paresthesias), burning, and/or weakness of the arms and legs. The type of study performed depends on the symptoms presented.
  - U. **Post laminectomy syndrome** is characterized by persistent neck pain or neck and arm pain following otherwise successful cervical spine surgery, most often following a laminectomy. Following spine surgery, major pain relief is expected, but rarely is there total pain relief. A fraction of post-surgical pain is normal. However, the term post laminectomy syndrome is reserved for individuals who continue to suffer from a majority of their pain symptoms following surgery.
  - V. **Posterior surgical spine surgery** is performed by the surgeon approaching the spine through the back of the neck. Posterior approaches for correction of cervical conditions include laminectomy, foraminotomy, laminotomy, laminoplasty, and posterior fusion.
  - W. **Pseudarthrosis** is a term that is used to describe the situation where the spinal segment does not grow together after an attempted surgical fusion.
  - X. Cervical **radiculopathy** refers to a loss of sensory, motor or reflex function or pain in a specific region within the upper extremity secondary to irritation and/or compression of a spinal nerve root in the neck. Radiculopathy often presents clinically as pain traveling from the neck into the arm, forearm and/or hand. In many cases, this will be accompanied by numbness or weakness in the limb.
  - Y. **Skeletal (bone) maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of growth plates (i.e., epiphyses and apophyses). Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.
  - Z. **Spinal fusion** (also known as spinal arthrodesis) is a procedure that permanently causes two or more vertebrae to grow together. A bone graft (autograft, allograft, or synthetic graft) is placed between the vertebrae or facet joints to stimulate the growth of bone across the joint, with the intent of improving stability and decreasing pain.
  - AA. **Spinal instability** refers to loss of motion segment integrity that results in excessive motion within a spinal segment that could result in neurological deficit, deformity, or pain. Instability can be categorized as acute (e.g., spine fractures, spinal dislocations) or chronic (i.e., caused by degeneration of the joint through the normal aging process or diseases such as rheumatoid arthritis). Instability can be clinically simulated when movement of the painful spine segment produces abnormally excessive motion (e.g., flexion, extension, lateral angulation, translation) compared to the movement of a non-affected segment. Instability can also be demonstrated on radiographic images by seeing excessive angulation or malalignment of spinal segments (e.g., spinout processes, facet joints, or vertebral bodies). Conditions or diseases associated with spinal instability include, but are not limited to, trauma, tumors, infections, connective tissue disorders, congenital disorders, degenerative disorders, and postsurgical events.
  - BB. **Spinal instrumentation** refers to devices that surgeons implant in the spine during spinal surgery, often made of titanium, titanium-alloy, stainless steel, or plastic. These implants are available in many shapes and sizes and include rods, hooks, braided cable, plates, screws, and interbody prostheses and devices.
  - CC. **Spinal stenosis** is a reduction in the diameter of the spinal canal caused by bone spur formation, disc herniation, hypertrophic (thickened) ligaments, or traumatic displacement of bone or soft tissue. Some individuals are born with small or stenotic spinal canals. Stenosis often results in pressure on the spinal cord and/or nerve root compression leading to significant pain and nerve-related symptoms or paralysis.
  - DD. **Spondylolisthesis** can occur when one vertebra slips forward and out of alignment with the vertebra lying below it. It is commonly seen in the fourth over the fifth lumbar vertebra or the fifth over the sacrum. The causes can be congenital, due to stress fractures, facet degeneration, injury, or after decompression

surgery. The condition may be asymptomatic, or cause significant pain and nerve-related symptoms. If the slippage occurs backwards, it is referred to as retrolisthesis and lateral slippage is called lateral listhesis.

EE. **Synthetic ceramic-based and bioactive glass bone substitutes/fillers** are synthetically produced bone substitutes/extenders and void fillers used to fill voids and gaps in bone structure including the spine. These products can be obtained as injectables, pastes, putties, solid matrices, and granules. Ceramic-based bone grafts are made up of collagen, calcium phosphate (CaP), calcium sulfate and one or more of the following products: Synthetic hydroxyapatite (HA), beta-tricalcium phosphates (B-TCP), biphasic calcium phosphate (BCP) (consists of both HA and B-TCP), and bioactive glass. These products have been proposed for use as stand-alone products or in combination with other bone substitutes and/or enhancement products.

FF. **Tobacco/Nicotine products** can result in nicotine addiction and health problems, including a negative effect on bone and tissue healing. This includes delayed unions, nonunions and other complications (e.g., decreased blood flow to the discs; wound complications). Products containing nicotine include, but are not limited to, (1) smoked tobacco (e.g., cigarettes, cigars, cigarillos, kreteks, pipe tobacco), (2) smokeless tobacco (e.g., chewing tobacco, snuff), (3) electronic cigarettes (E-cigarettes), (5) nicotine vaping, (5) dissolvable tobacco, and (6) nicotine patches. Nicotine or its primary metabolite, cotinine, is most often tested to evaluate use. Both can be measured qualitatively or quantitatively for determination of: (1) active use, (2) users who have recently quit, or (3) exposure in non-tobacco/nicotine users. Urine or blood testing is most commonly performed, although cotinine can also be measured in saliva.

### III. Medical Management

A. Individuals presenting with mild to moderate cervical pain are often treated with conservative medical management. Measures commonly used include, but are not limited to:

1. Activity modification adjustment to "low risk" activity levels
2. Anti-inflammatory medication regimen
3. Epidural steroid injections
4. Physical therapy
5. Chiropractic care
6. Cervical traction
7. Neck immobilization (e.g., cervical collar)
8. Transcutaneous electrical stimulation.

B. Conservative management is not recommended when there is evidence of:

1. Infectious condition of the spine
2. Significant or progressive neurological deficit
3. Progressive spinal deformity
4. Some degree of traumatic injury
5. Unstable fracture or dislocation
6. Evidence of myelopathy on imaging.

### BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for non-emergent cervical spinal surgery.
2. Beginning with January 01, 2023 dates of service for **Medica Medicare members only**, prior authorization **is required** for intraoperative neurophysiologic monitoring performed at the time of cervical spine surgery. See Medica's Utilization Management Policy, *Intraoperative Neurophysiologic Monitoring (IONM)*.
3. Prior authorization is **not required** for tethered spinal cord syndrome in infants, children, and adults.
4. Prior authorization is **not required** for the type of access and associated instrumentation used to gain entry to the surgical site.

NOTE: Exception is laparoscopic anterior spinal surgery (e.g., fusion), which has been determined to be investigative and therefore not covered.

5. Intervertebral cervical artificial disc replacement (arthroplasty) is *investigative and therefore not covered* for all other indications not listed in the Medical Necessity Criteria below, including but not limited to: (1) treatment in combination with concurrent cervical spinal fusion or (2) in an individual with a previous fusion at another cervical level.
6. Spinal instrumentation and/or tissue grafting are considered a covered benefit when all of the medical necessity criteria in the Medical Necessity Criteria section are met, and not otherwise excluded according to the terms in Benefit Considerations #6 and #7.
7. Cervical spine surgery otherwise meeting medical necessity criteria defined in this policy, including cervical artificial intervertebral disc replacement, is not covered when performed in combination with any cervical spine procedure Medica considers *investigative and therefore not covered*, including, but not limited to, treatment of

degenerative disc disease at more than one level or treatment in combination with cervical spinal fusion (e.g., concurrently or sequentially).

8. Examples of procedures considered *investigative and therefore not covered* include, but are not limited to: autologous blood-derived products; stem cell and cellular bone matrix products for orthopedic applications; OsteoAmp™ allogenic morphogenic protein; cervical use of recombinant human bone morphogenic protein-2 (rhBMP-2)/InFUSE; synthetic ceramic-based and bioactive glass bone substitutes/fillers, i-Factor™ bone graft; interspinous process decompression procedures; laparoscopic anterior interbody fusion; laser spine surgery; and selected percutaneous and minimally invasive disc decompression procedures. See the following Medica coverage policies.
  - a. *Autologous Blood-Derived Products (Platelet-Rich Plasma, Autologous Conditioned Serum, Autologous Whole Blood)*.
  - b. *Stem Cell and Cellular Bone Matrix Products for Orthopedic Applications* (i.e., concentrated, engineered or expanded stem cells, as well as allograft bone products containing stem cells).
  - c. *Recombinant Human Bone Morphogenic Protein-2 (rhBMP-2)/InFUSE and Allogeneic Morphogenic Protein (e.g., OsteoAMP™)*. NOTE: Some indications are covered services and others are non-covered services, Refer to the coverage policy for details.
  - d. *Synthetic Ceramic-Based and Bioactive Glass Bone Substitutes/Fillers*
  - e. *Laser Spine Surgery*.
  - f. *Percutaneous Disc Decompression Procedures (Manual, Automated or Laser Discectomy, and Plasma Disc Decompression [PDD])*.
9. See related utilization management policy, *Facet Injections and Percutaneous Denervation Procedures (Radiofrequency and Laser Ablation) for Facet-Mediated Joint Pain (III-SUR.45)*.
10. If medical necessity criteria are not met as defined in this policy, any associated procedures (e.g., instrumentation, device implantation) will not be covered. This includes, but is not limited to, facility and anesthesia services, professional fees, and associated supplies.
11. Coverage may vary according to the terms of the member's plan document.
12. If the Medical Necessity Criteria and Benefit Consideration are met, Medica will authorize benefits within the limits in the member's plan document.
13. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer for individual consideration. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

#### MEDICAL NECESSITY CRITERIA

Refer to the section below which corresponds with the surgical procedure(s), initial or repeat/revision, being requested:

- Section I: Emergent surgical need
- Section II: Decompression, stabilization, or fusion
- Section III: Cervical intervertebral artificial disc replacement (arthroplasty)

NOTE: Beginning with January 01, 2023 dates of service for **Medica Medicare members only**, prior authorization **is required** for intraoperative neurophysiologic monitoring performed at the time of cervical spine surgery. See Medica's Utilization Management Policy, *Intraoperative Neurophysiologic Monitoring (IONM)*.

- I. Prior authorization **is not required** when the procedure is **emergent in nature**. These indications include, but are not limited to:
  - A. Acute traumatic cervical spine fracture or dislocation with neural compression and/or radiographic evidence of instability
  - B. Acute, unremitting radicular pain resulting in severe rapid-onset/progression of neurological impairment arising from cervical cord compression, stenosis, or nerve root compression and requiring emergent hospitalization within a few days post-onset/progression
  - C. Tumor-related nerve or spinal cord compression, vertebral destruction, instability, or pathologic fracture
  - D. Infection-related instability, nerve or spinal cord compression, vertebral destruction, instability, or pathologic fracture
  - E. Spinal tuberculosis
  - F. Significant cervical spine instability putting the individual at risk of spinal cord injury.
  - G. Acute, unremitting severe cervical myelopathy.

- II. Prior Authorization **is required** for **initial and repeat/revision cervical decompression, stabilization, or fusion** for treatment of radiculopathy or myelopathy and is considered medically necessary when documentation in the medical record shows that **all of the following** criteria are met:
- A. Individual is undergoing **one of the following** procedures:  
**NOTE:** Use Section III if cervical artificial disc replacement is being done.
1. Cervical decompression surgery employing at least **one of the following** procedures:
    - a. Corpectomy/hemicorpectomy
    - b. Discectomy
    - c. Facetectomy
    - d. Foraminectomy/foraminoplasty
    - e. Foraminotomy
    - f. Laminectomy/laminoplasty
    - g. Laminotomy (i.e., laminoforaminotomy, hemilaminectomy)
    - h. Osteophyte removal (i.e., bone spur removal).
  2. Cervical fusion.
- B. Individual has **one of the following** diagnoses:
1. Spondylolisthesis, anterolisthesis, or retrolisthesis
  2. Radiculopathy (e.g., symptomatic cervical foraminal stenosis; osteophytes) causing continued pain, motor weakness, paresthesia, and/or compromised neurological function indicative of nerve root compression.
  3. Post laminectomy syndrome
  4. Recurrent disc herniation (i.e., remaining disc material following initial cervical discectomy)
  5. Progressive neurologic deficit or myelopathy demonstrated on imaging (e.g., central cervical spinal stenosis causing spinal cord compression).
- C. Member does not present with any of the emergent diagnoses identified in section I.
- D. Skeletal maturity has been reached.
- E. If osteoporosis is identified in the medical history or imaging, documentation of osteoporosis status demonstrates **one of the following**:
1. Significant anatomical and/or neurological compromise necessitating surgical intervention despite presence of osteoporosis
  2. Bone structure has ability to support instrumentation.
- F. Documentation of tobacco or nicotine status for individuals undergoing spinal fusion (only) indicating **one of the following**:
1. The individual is a non-tobacco or non-nicotine user
  2. The individual has been tobacco-free and nicotine free for a **minimum of one month** prior to date of the prior authorization request.
- G. Documentation of continued episodes of severe, radiating, neurological pain and/or impairment (e.g., extremity weakness or stiffness, lack of arm and/or hand coordination, numbness and/or decreased sensation, back and/or lower extremity involvement) demonstrating compromised ability to perform routine activities of daily living (e.g., writing and other small motor skills, household maintenance, bathing/grooming, food preparation).
- H. Radiologic or electrodiagnostic testing documenting **one of the following**:
1. For central myelopathy only, radiographic imaging (computed tomography; magnetic resonance imaging) demonstrating spinal cord compression at a level correlating with clinical presentations. H
  2. For persistent radiculopathy, **one of the following** is met:
    - a. Radiographic imaging (computed tomography; magnetic resonance imaging) demonstrating persistent nerve root compression at a level correlating with clinical presentations mentioned in H., above.
    - b. Radiographic imaging (computed tomography; magnetic resonance imaging; myelography) and electrodiagnostic testing (e.g., electromyogram; nerve conduction testing) when no objective evidence of radiculopathy is identified and documented during physical examination.
- I. Individual meets **one of the following**:
1. Completion of a minimum of six weeks conservative management, including physical therapy or spinal manipulation by a chiropractor, and documentation of **one of the following**:
    - a. An increase on the disability index (DI) scores documenting progression of pain/disability indicating a DI score of at least moderate disability (i.e., NDI score of at least 15; ODI score of at least 40%).
    - b. Continued DI score indicating at least moderate disability (i.e., NDI score of at least 15; ODI score of at least 40%).

2. For individuals who have not attempted or are unable to complete a minimum of 6 weeks conservative management, including physical therapy or spinal manipulation by a chiropractor, documentation of a continued NDI score of at least 15; ODI score of at least 40% **and** documentation of **one of the following** is required:
  - a. Assessment by the individual's physical therapist or spine surgeon stating the clinical reasons why conservative management is contraindicated.
  - b. Assessment by the individual's physical therapist stating the clinical reasons (e.g., causes of progressively debilitating pain and/or disability) why physical therapy could not be completed.
3. Neurologic impairment (e.g., weakness on physical examination; bowel or bladder dysfunction).

**NOTE:** An NDI and ODI questionnaire with scoring and interpretation directions are found in Appendix 2 and 3.

J. Graft/fusion documentation indicates **one of the following**:

1. An FDA approved bone graft or fusion material is being used.
2. Bone graft or fusion material is not being used (e.g., fusion is not being performed).

NOTE: Certain materials (e.g., blood-derived biologics) are not subject to standard FDA approval.

NOTE: Medica considers any of the following to be standard graft material following FDA approved indications, if applicable: (1) autograft (i.e., bone from individual) or cadaver-derived bone allograft or (2) demineralized bone matrices (DBMs). See Appendix 4, Demineralized Bone Matrix (DBM) Products, following, for available DBMs and FDA approved uses.

NOTE: Medica considers (1) recombinant human bone morphogenic protein-2 (rhBMP-2)/InFUSE™ Bone Graft/LT-CAGE™ for cervical spine indications, (2) OsteoAmp™ allogenic morphogenic protein (3) autologous blood-derive biologics (e.g., platelet-rich plasma, autologous conditioned serum, autologous whole blood), (4) stem cell and cellular bone matrix products (e.g. AlloStem®, Cellentra™ VCBM, Osteocel® Plus, Trinity® Evolution™), (5) synthetic ceramic-based and bioactive glass bone substitutes/fillers, and (6) i-Factor™ bone graft *investigative and therefore not covered*.

III. Prior authorization **is required** for **initial or repeat/revision cervical intervertebral artificial disc replacement (arthroplasty)** for treatment of radiculopathy or myelopathy and is considered medically necessary when documentation in the medical record indicates that **all of the following** criteria are met:

- A. Individual has documented symptomatic degenerative disc disease (DDD) resulting in persistent symptoms (e.g., pain or neurologic impairment).
- B. Member **does not** present with any of the emergent diagnoses identified in section I.
- C. Procedure will be performed using an FDA-approved device according to the FDA-approved indications (e.g., Prestige® Cervical Disc Systems; ProDisc™ C; Bryan® Cervical Disc; Secure® C Artificial Disc System; Simplify® Cervical Artificial Disc, PCM® Cervical Disc System; MOBI- C® Cervical Disc Prosthesis; M6-C Artificial Cervical Disc).

NOTE: The MOBI-C® Cervical Disc Prosthesis (LDR USA), the Prestige LP Cervical Disc (Medtronic), and the Simplify Cervical Artificial Disc (Simplify Medical, Inc.) are the only artificial discs FDA approved for use at both one and two contiguous levels. Two-level arthroplasty using a device other than Mobi-C, Prestige LP, or Simplify is considered investigative.

D. Individual does not present with **any of the following**:

1. Spinal instability
2. Severe facet arthritis
3. Localized or systemic infection
4. Prior fusion.
5. Spinal tumor or other active malignancy.

E. Procedure will be performed at one or two contiguous levels from C3 to C7. Note: Two level replacements using a device other than the MOBI-C, Prestige LP Cervical Disc, or Simplify Cervical Artificial Disc is considered investigative and therefore not covered. See C, above.

F. Individual has reached skeletal maturity.

G. Individual meets **one of the following**:

1. Completion of a minimum of six weeks conservative management, including physical therapy or spinal manipulation by a chiropractor, documenting one of the following
  - a. An increase on the disability index (DI) scores documenting progression of pain/disability indicating a DI score of at least moderate disability (i.e., NDI score of at least 15; ODI score of at least 40%).

- b. Continued DI score indicating at least moderate disability (i.e., NDI score of at least 15; ODI score of at least 40%).
  2. For individual who have not attempted or are unable to complete a minimum of six seek conservative management, including physical therapy or spinal manipulation by a chiropractor, documentation of a continued DI score indicating at least moderate disability (i.e., NDI score of at least 15; ODI score of at least 40%) **and** documentation of **one of the following** is required:
    - a. Assessment by the individual's physical therapist or spine surgeon stating the clinical reasons why conservative management is contraindicated.
    - b. Assessment by the individual's physical therapist stating the clinical reasons (e.g., causes of progressively debilitating pain and/or disability) why physical therapy could not be completed.
  3. Neurologic impairment (e.g., weakness on physical examination; bowel or bladder dysfunction).
- NOTE: An NDI and ODI questionnaire with scoring and interpretation directions are found in Appendix 2 and 3.

#### CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: <https://www.cms.gov/medicare-coverage-database/search.aspx>

#### MINNESOTA HEALTH CARE PROGRAMS (MHCP)

- For MHCP members, refer to [https://www.dhs.state.mn.us/main/idcplg?IdcService=GET\\_DYNAMIC\\_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id\\_000094#](https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_000094#)
- No MHCP policy found as of 10/03/2024.

#### DOCUMENT HISTORY

Original Effective Date	September 1, 2013
MPC Endorsement Date(s)	09/2013, 11/2013, 11/2014, 11/2015, 11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023
Administrative Updates	02/2017; 05/01/2017, 09/20/2021, 01/17/2023, 04/17/2023

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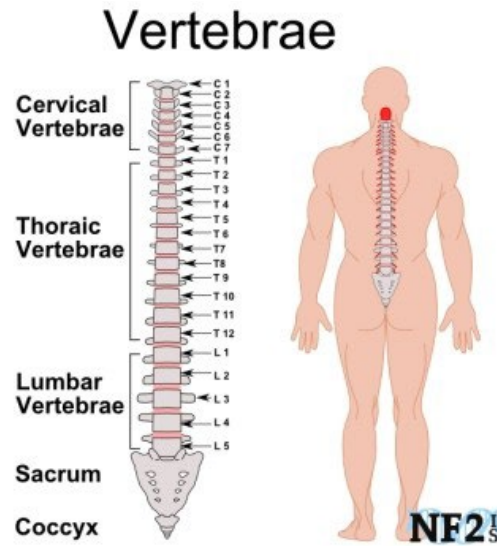
**11/2022 MPC:**

No new references.

**11/2023 MPC:**

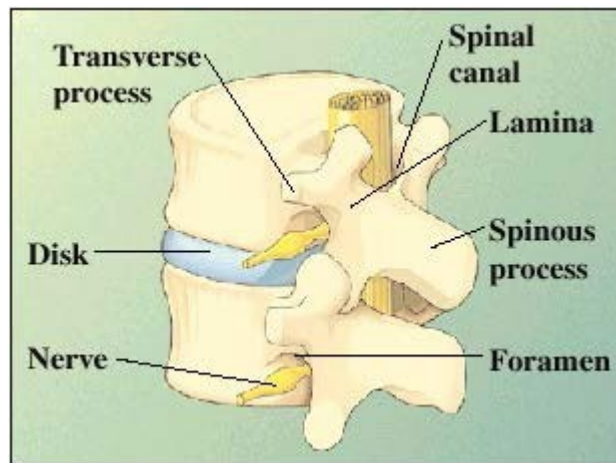
No new references.

Appendix 1



Source:  
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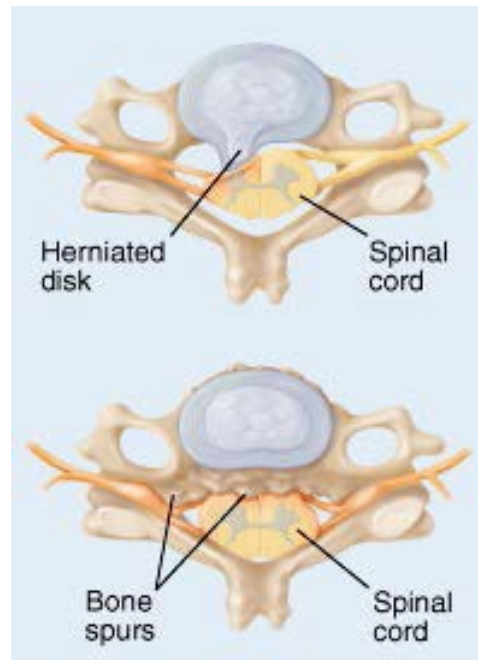
### Vertebrae Structure



- There are seven vertebrae comprising the cervical spine, C1 – C7.
- The lamina of each vertebra forms the back of the spinal canal.
- A foramen is a small opening. This is where a nerve leaves the spinal canal.
- The transverse process is the wing of bone on either side of each vertebra.
- The spinous process is the part of each vertebra you can feel through your skin.
- A disk lies between each of the vertebrae.

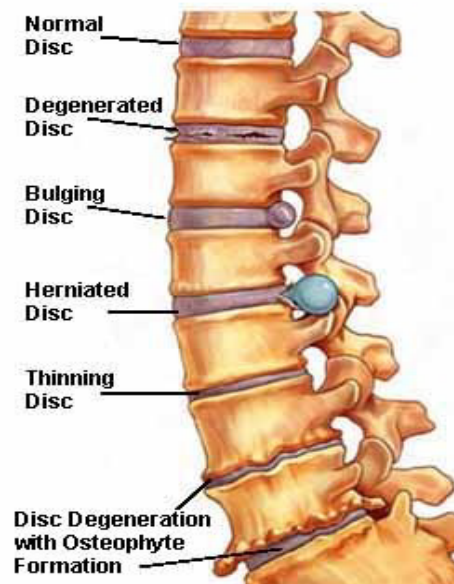
Source: University of Minnesota. <http://www.uofmmedicalcenter.org/HealthLibrary/Article/84747>. May 2, 2013.

### Cervical Spine Problems



Source: University of Minnesota. <http://www.uofmmedicalcenter.org/HealthLibrary/Article/84755> May 2, 2013.

### Examples of Disc Problems



Source: <http://www.spineuniverse.com/conditions/neck-pain/degenerative-cervical-spine-disorders>

**Appendix 2**

**Neck Disability Index**

<p><b>Section 1 – Pain Intensity</b>  <input type="checkbox"/> I have no pain at the moment. (0)  <input type="checkbox"/> The pain is very mild at the moment. (1)  <input type="checkbox"/> The pain is moderate at the moment. (2)  <input type="checkbox"/> The pain is fairly severe at the moment. (3)  <input type="checkbox"/> The pain is very severe at the moment. (4)  <input type="checkbox"/> The pain is the worst imaginable at the moment. (5)</p>	<p><b>Section 7 – Work</b>  <input type="checkbox"/> I can do as much work as I want to. (0)  <input type="checkbox"/> I can do my usual work, but no more. (1)  <input type="checkbox"/> I can do most of my usual work, but no more. (2)  <input type="checkbox"/> I cannot do my usual work. (3)  <input type="checkbox"/> I can hardly do any work at all. (4)  <input type="checkbox"/> I cannot do any work at all. (5)</p>
<p><b>Section 2 – Personal Care (Washing, Dressing, etc.)</b>  <input type="checkbox"/> I can look after myself normally without causing extra pain. (0)  <input type="checkbox"/> I can look after myself normally but it causes extra pain. (1)  <input type="checkbox"/> It is painful to look after myself and I am slow and careful. (2)  <input type="checkbox"/> I need some help but manage most of my personal care. (3)  <input type="checkbox"/> I need help every day in most aspects of self care. (4)  <input type="checkbox"/> I do not get dressed, I wash with difficulty and stay in bed. (5)</p>	<p><b>Section 8 – Driving</b>  <input type="checkbox"/> I can drive my car without any neck pain. (0)  <input type="checkbox"/> I can drive my car as long as I want with slight pain in my neck. (1)  <input type="checkbox"/> I can drive my car as long as I want with moderate pain in my neck. (2)  <input type="checkbox"/> I cannot drive my car as long as I want because of moderate pain in my neck. (3)  <input type="checkbox"/> I can hardly drive at all because of severe pain in my neck. (4)  <input type="checkbox"/> I cannot drive my car at all. (5)</p>
<p><b>Section 3 – Lifting</b>  <input type="checkbox"/> I can lift heavy weights without extra pain. (0)  <input type="checkbox"/> I can lift heavy weights but it gives extra pain. (1)  <input type="checkbox"/> Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table. (2)  <input type="checkbox"/> Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned. (3)  <input type="checkbox"/> I can lift very light weights. (4)  <input type="checkbox"/> I cannot lift or carry anything at all. (5)</p>	<p><b>Section 9 – Sleeping</b>  <input type="checkbox"/> I have no trouble sleeping. (0)  <input type="checkbox"/> My sleep is slightly disturbed (less than 1 hour sleepless). (1)  <input type="checkbox"/> My sleep is mildly disturbed (1-2 hours sleepless). (2)  <input type="checkbox"/> My sleep is moderately disturbed (2-3 hours sleepless). (3)  <input type="checkbox"/> My sleep is greatly disturbed (3-5 hours sleepless). (4)  <input type="checkbox"/> My sleep is completely disturbed (5-7 hours sleepless). (5)</p>
<p><b>Section 4 – Reading</b>  <input type="checkbox"/> I can read as much as I want to with no pain in my neck. (0)  <input type="checkbox"/> I can read as much as I want to with slight pain in my neck. (1)  <input type="checkbox"/> I can read as much as I want with moderate pain in my neck. (2)  <input type="checkbox"/> I cannot read as much as I want because of moderate pain in my neck. (3)  <input type="checkbox"/> I can hardly read at all because of severe pain in my neck. (4)  <input type="checkbox"/> I cannot read at all. (5)</p>	<p><b>Section 10 – Recreation</b>  <input type="checkbox"/> I am able to engage in all my recreation activities with no neck pain at all. (0)  <input type="checkbox"/> I am able to engage in all my recreation activities, with some pain in my neck. (1)  <input type="checkbox"/> I am able to engage in most, but not all, of my usual recreation activities because of pain in my neck. (2)  <input type="checkbox"/> I am able to engage in a few of my usual recreation activities because of pain in my neck. (3)  <input type="checkbox"/> I can hardly do any recreation activities because of pain in my neck. (4)  <input type="checkbox"/> I cannot do any recreation activities at all. (5)</p>
<p><b>Section 5 – Headaches</b>  <input type="checkbox"/> I have no headaches at all. (0)  <input type="checkbox"/> I have slight headaches that come infrequently. (1)  <input type="checkbox"/> I have moderate headaches which come infrequently. (2)  <input type="checkbox"/> I have moderate headaches which come frequently. (3)  <input type="checkbox"/> I have severe headaches which come frequently. (4)  <input type="checkbox"/> I have headaches almost all the time. (5)</p>	<p><b>Evaluation:</b>  <b>0-4 No disability</b>  <b>5-14 Mild disability</b>  <b>15-24 Moderate disability</b>  <b>25-34 Severe disability</b>  <b>&gt; 35 Complete disability</b></p>
<p><b>Section 6 – Concentration</b>  <input type="checkbox"/> I can concentrate fully when I want to with no difficulty. (0)  <input type="checkbox"/> I can concentrate fully when I want to with slight difficulty. (1)  <input type="checkbox"/> I have a fair degree of difficulty in concentrating when I want to. (2)  <input type="checkbox"/> I have a lot of difficulty in concentrating when I want to. (3)  <input type="checkbox"/> I have a great deal of difficulty in concentrating when I want to. (4)  <input type="checkbox"/> I cannot concentrate at all. (5)</p>	<p>Adapted from: Vernon H, Mior S. The Neck Disability Index: A Study of Reliability and Validity. <i>Journal of Manipulative and Physiological Therapeutics</i>. 1991;17(&amp;):409-415.</p>

**Scoring and Interpretation:**

- Each of the 10 items is scored from 0 - 5. The maximum raw score is therefore 50. The obtained score can be multiplied by 2 to produce a percentage score. Occasionally, a respondent will not complete one question or another. The average of all other items is then added to the completed items.
- Interpretation, as follows:
  - 0 - 4 = no disability
  - 5 - 14 = mild
  - 15 - 24 = moderate
  - 25 - 34 = severe
  - Above 34 = complete disability.

Source: Vernon, H. and Mior, S. The Neck Disability Index: A study of reliability and validity. *Journal of Manipulative and Physiological Therapeutics*, 1991, 14, 409-415.

### Appendix 3

## Oswestry Disability Index (ODI)

Version 2.1a

**This questionnaire is designed to provide information as to how your back (or leg) trouble affects your ability to manage in everyday life.**

**Please answer every section. Mark one box only in each section that most closely describes you today.**

### Section 1 - Pain intensity

- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.

### Section 2 - Personal care (washing, dressing, etc.)

- I can look after myself normally without causing extra pain.
- I can look after myself normally but it is very painful.
- It is painful to look after myself and I am slow and careful.
- I need some help but manage most of my personal care.
- I need help every day in most aspects of self care.
- I do not get dressed, wash with difficulty and stay in bed.

### Section 3 - Lifting

- I can lift heavy weights without extra pain.
- I can lift heavy weights but it gives extra pain.
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- I can lift only very light weights.
- I cannot lift or carry anything at all.

### Section 4 - Walking

- Pain does not prevent me walking any distance.
- Pain prevents me walking more than one mile.
- Pain prevents me walking more than a quarter of a mile.
- Pain prevents me walking more than 100 yards.
- I can only walk using a stick or crutches.
- I am in bed most of the time and have to crawl to the toilet.

### Section 5 - Sitting

- I can sit in any chair as long as I like.
- I can sit in my favourite chair as long as I like.
- Pain prevents me from sitting for more than 1 hour.
- Pain prevents me from sitting for more than half an hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.

### Section 6 - Standing



I can stand as long as I want without extra pain.  
I can stand as long as I want but it gives me extra pain.  
Pain prevents me from standing for more than 1 hour.  
Pain prevents me from standing for more than half an hour.  
Pain prevents me from standing for more than 10 minutes.  
Pain prevents me from standing at all.

**Section 7 - Sleeping**

My sleep is never disturbed by pain.  
My sleep is occasionally disturbed by pain.  
Because of pain I have less than 6 hours sleep.  
Because of pain I have less than 4 hours sleep.  
Because of pain I have less than 2 hours sleep.  
Pain prevents me from sleeping at all.

**Section 8 - Sex life (if applicable)**

My sex life is normal and causes no extra pain.  
My sex life is normal but causes some extra pain.  
My sex life is nearly normal but is very painful.  
My sex life is severely restricted by pain.  
My sex life is nearly absent because of pain.  
Pain prevents any sex life at all.

**Section 9 - Social life**

My social life is normal and causes me no extra pain.  
My social life is normal but increases the degree of pain.  
Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.  
Pain has restricted my social life and I do not go out as often.  
Pain has restricted social life to my home.  
I have no social life because of pain.

**Section 10 - Travelling**

I can travel anywhere without pain.  
I can travel anywhere but it gives extra pain.  
Pain is bad but I manage journeys over two hours.  
Pain restricts me to journeys of less than one hour.  
Pain restricts me to short necessary journeys under 30 minutes.  
Pain prevents me from travelling except to receive treatment.

Scoring & Interpretation:

The 6 statements are scored from 0 to 5 with the first statement scoring 0 through to the last at 5. If more than one box is marked in each section, take the highest score.

The ODI score (index) is calculated as  $(\text{total score} / (5 \times \text{number of questions answered})) \times 100$

The disability scores are interpreted as follows: 0 to 20%, minimal disability; 20 to 40%, moderate disability; 40 to 60%, severe disability; 60 to 80%, crippled; and 80 to 100%, total incapacitation.

References

1. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy*. 1980. 66(8):271-3.
2. Fairbank J, Pynsent P. The Oswestry Disability Index. *Spine*. 2000;25:2940-2953.

Official ODI Website - maintained by the original author, Jeremy Fairbanks. Available at: <http://www.orthosurg.org.uk/odi/>



**Appendix 4**

**Demineralized Bone (DBM) Matrix Products**

Not intended as all-inclusive list

<b>Source Company</b>	<b>DMB Product Name</b>	<b>Available Forms</b>	<b>FDA Addressed Uses</b>
Allosource®	AlloFuse®	Putty, gel, paste	Bone void filler, bone graft extender in extremities, pelvis, and spine.
Baceterin International, Inc./XTANT Medical	OsteoSelect® Osteosponge®	Putty Block, disc, strip, filler	Bone void filler in extremities, pelvis, and posterolateral spine. Non 510(k) regulated – nonmanipulated substance
Lattice Biologics, Ltd	H-GENIN™	Putty, crush-mix, spongy blocks, powder	Non 510(k) regulated – nonmanipulated substance
Biomet/Zimmer Biomet	InterGro DBM®	Putty	Bone void filler in extremities, pelvis, and spine, bone graft extender in spine
Integra™ Orthobiologics/IsoTis Orthobiologics	Accel Connexus®	Putty	Bone void filler in extremities and pelvis, bone graft extender in extremities, pelvis and spine
	Accel Evo3™	Putty	Bone void filler in extremities, pelvis and posterolateral spine, bone graft extender in extremities, pelvis, and spine
	Accel TBM®	Strip	Bone void filler in extremities and pelvis, bone graft extender in extremities, pelvis, and spine
	DynaGraft™	Putty, gel	Bone void filler in extremities and pelvis, bone graft extender in extremities, pelvis, and spine
	OrthoBlast™ II	Putty, paste	Bone void filler in extremities and pelvis, bone graft extender in extremities, pelvis, and spine
LifeNet Health®	Optium®	Putty, gel	Bone void filler in extremities, pelvis, and spine
Medtronic	Progenix Putty	Putty	Bone void filler in extremities, pelvis, and spine
	DBX	Putty, paste, mix, strip	Bone void filler in extremities and pelvis
	GRAFTON®	Gel, flex, putty, matrix, CRUNCH®, orthoblend, strips, paste	Bone void filler and bone graft extender in extremities, pelvis, and spine
	Magnifuse DMB Matrix	DBM fibers and surface-demineralized chips	Bone void filler in Bone void filler in extremities and pelvis
RTI Surgical®, Inc.	BioSet DMB	Paste, strip, disc, with or without cancellous chips	Bone void filler in extremities, pelvis, and spine
Wright™ Medical Technology	ALLMATRIX®	Putty, provided in powder form	Bone void filler in extremities and pelvis, bone graft extender in spine
Zimmer	Puros® DBM	Putty, putty with cortico-cancellous chips	Non 510(k) regulated – nonmanipulated substance

Source: Shehadi JA, Elzein SM. Review of commercially available demineralized bone matrix products for spinal fusions: A selection paradigm. *Surg Neurol Int.* 2017;8:203[GMA1].