TITLE: LUMBAR SPINE SURGERIES

EFFECTIVE DATE: January 21, 2019

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. Please refer to the member’s plan document for 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 and Minnesota Health Care 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 about this Medica utilization management policy 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 reviewers in utilization management decision-making by providing the criteria that generally determines the medical necessity of lumbar spine surgeries. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND
I. Prevalence / Incidence
A. It is reported that the lifetime incidence of low back pain (LBP) in the general population within the United States is between 60% and 90%, with an annual incidence of 5%. According to a National Center for Health Statistics study (Patel, 2007), 14.3% of new patient visits to primary care physicians per year are for LBP. Also, approximately 13 million physician visits are related to complaints of chronic LBP.
B. More than 300,000 spinal fusion surgeries are performed annually in the United States. Degenerative disease is the most common reason for fusion surgery, with fusion often performed along with other spinal surgical procedures (e.g., disc decompression, decompression laminectomy). There are many variations on how spinal fusion is achieved, including different surgical approaches and techniques, and use of instrumentation or other available materials.

II. Definitions
A. Anterior lumbar spine surgery is performed by the surgeon approaching the spine from the front of the body. The surgical site can be approached by a traditional front midline incision (i.e., through the abdominal musculature and retroperitoneal cavity) or by lateral approaches from the front side of the body (e.g., eXtreme lateral interbody fusion [XLIF]; direct interbody fusion [DLIF]; oblique interbody fusion [OLIF]). The surgical site can be accessed by open incision approaches or through percutaneous routes usingimage guidance. Anterior surgeries for correction of lumbar disc disease include discectomy, corpectomy, fusion, and bone grafting.
B. Artificial lumbar 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 lumbar intervertebral discs that have received U.S. Food and Drug Administration
(FDA) approval include:
  i. Inmotion® Lumbar Artificial Disc system (formerly Charite™ Artificial Disc)
  ii. activL® Artificial Disc system
  iii. PRODISC®-L Total Disc Replacement system.

D. **Cauda equina syndrome** (CES) is a rare disorder characterized by impairment of the bundle of spinal nerve roots arising from the cauda equina (i.e. lumbar plexus) at the lower end of the spinal cord. CES may or may not be painful, but may result in numbness or tingling in the buttocks, perineum, genitalia and legs. Predominant symptoms include acute, rapidly progressive loss of bowel or bladder control or acute, sudden weakness and/or numbness in the leg (e.g., sudden foot drop/claudication and/or inability to stand). Cauda equina is usually a surgical emergency requiring immediate hospitalization.

E. **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.

F. **Corpectomy/hemicorpectomy** is removal of the entire vertebral body and removal of 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.

G. **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; osteophytectomy (i.e., bone spur removal); and corpectomy.

H. **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.

I. **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.”

J. **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.

K. 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.

L. **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.

M. **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 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.

N. **Laminotomy (hemilaminectomy; laminoforaminotomy)** is a surgical transection of vertebral lamina performed to decompress a nerve. It consists of partially removing 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.

O. **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. Lumbar disc disorder with
myelopathy refers to compression of the lowest portion of the spinal cord (conus medullaris).

P. **Oswestry Disability Index (ODI)** is a standard self-administered, low back pain disability questionnaire used by clinicians and researchers to measure a patient’s functional disability at a certain point in time.

Q. **OsteoAmp™ allogeneic morphogenic protein** is marketed for use for orthopedic indications. OsteoAmp is comprised of allogeneic bone (i.e., cadaver-derived) with BMP-2, BMP-7 and other endogenous growth factors derived from the allogeneic bone marrow. These other growth factors are additional proteins with osteoinductive, angiogenic, and mitogenic properties and are bound to the bone during the harvesting process. OsteoAmp is available in various forms, including a compressible sponge, putty for mixing with bone marrow or blood, and granules for incorporation with mineralized allograft bone chips.

R. **Post laminectomy syndrome**, also known as **failed back surgery syndrome** (FBSS), is characterized by persistent back and/or leg pain following otherwise successful back surgery, frequently 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 or FBSS is reserved for individuals who continue to suffer from a majority of their pain symptoms following surgery.

S. **Posterior lumbar spine surgery** is performed by the surgeon approaching the spine through the individual’s back. The surgical site can be approached by a traditional back midline incision or transfaraminally through the opening between two spinal vertebrae (i.e. the foramen) where the nerves leave the spinal canal to enter the body (i.e., transfaramil bone interbody fusion [TLIF]). The surgical site can be accessed by open incision approaches or through percutaneous routes using image guidance. Posterior surgeries for correction of lumbar disc disease include discectomy, corpectomy, foraminectomy/foraminotomy, laminectomy/laminotomy, fusion, and bone grafting.

T. **Pseudoarthrosis** (aka “false joint”) is a term that is used to describe the situation where the spinal segment does not grow together (i.e., non-union) after an attempted surgical fusion. Symptoms normally present as post-operative axial (neck or back) or radicular (arms or leg) pain. Surgery to correct a pseudoarthrosis is considered a repeat/revision fusion.

U. **Radiculopathy** (also called radiculitis) refers to a loss of sensory, motor, or reflex function or pain in a specific region as a result of irritation and/or compression of a spinal nerve root. Radiculopathy often presents clinically as pain traveling down the leg or arm, often accompanied by numbness and/or weakness in the limb.

V. **Recombinant human bone morphogenic protein-2 (rhBMP-2)** is FDA-approved and available for use in the United States. BMPs are proteins naturally found in the body and many types (i.e., 2, 4, 6, 7, 9) assist with bone formation. Unlike standard bone allografts and autografts, BMP-2 is synthetically manufactured using a technique called recombinant technology. BMP-2 is the active agent in the InFUSE™ Bone Graft/LT-CAGE™ system (Medtronic). InFUSE is comprised of recombinant human bone morphogenic protein-2, which is applied to an absorbable collagen sponge and insertion into the titanium LT-CAGE prior to placement between the affected discs.

W. **Scoliosis** (from the Greek word skoliōsis, meaning “crooked condition”) is a complex three-dimensional deformity in which the spine is curved laterally (i.e., from side to side) and twisted rotationally. Large curves can cause postural imbalance which lead to muscle fatigue and pain. With advanced curvature, scoliosis can interfere with breathing, cause nerve or spinal cord compression, and lead to arthritis of the spine (spondylosis). Most scoliosis is idiopathic with onset in adolescence, but in rare cases scoliosis can be congenital and present at birth or result from neurological conditions such as cerebral palsy or myelodysplasia.

X. **Skeletal (bone) maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of either the knee or the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.

Y. **Spinal fusion** (also known as spinal arthrodesis) is a procedure that permanently fuses two or more vertebrae. 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, decreasing pain, or correcting deformity.
Z. **Spinal instability** refers to loss of motion segment stiffness which 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 force applied to the painful spine segment produces abnormally excessive motion (e.g., flexion, extension, lateral angulation, translation) compared to the same force applied to a non-affected segment. Instability can also be demonstrated on radiographic images by seeing damage to the spine’s restraining structures (i.e., facet joint, spinous process, transverse process, disk, ligaments, and/or muscles). 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.

AA. **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 cages.

BB. **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.

CC. **Spondylolisthesis** can occur when one vertebra slips forward and out of alignment with the vertebra 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 **listhesis**.

DD. **Tethered spinal cord syndrome** is a stretch-induced condition which results in fixation (tethering) of inelastic tissue to the lower spine, usually in the caudal spinal region (e.g., the filum terminale). This results in limited movement. Symptoms usually begin in infancy or childhood, and progress as a child ages when increased tension is applied to the spine. Progression of neurological signs and symptoms are highly variable, and some individuals do not experience noticeable symptoms until adulthood. Tethered spinal syndrome can be reversible if surgically treated (e.g., laminectomy and cord release) in its early stages.

EE. **Tobacco/Nicotine products** can result in nicotine addiction and health problems, including a negative effect on bone 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), (4) 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 low back pain (LBP) arising from numerous etiologies are often treated with conservative medical management. Measures commonly used include:
   1. Behavior modification (e.g., smoking cessation, weight reduction)
   2. Cessation/modification of any identifiable inciting activity (e.g., sports injury)
   3. Epidural or facet injection therapy
   4. Lumbar bracing
   5. Medication (e.g., analgesics, anti-inflammatory, muscle relaxants, tricyclic antidepressants, anti-epileptics)
   6. Physical therapy regimen (e.g., exercise, manipulative therapy)
   7. Chiropractic care
   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. Acute cauda equina.

BENEFIT CONSIDERATIONS
1. Prior authorization is **required** for initial lumbar spinal surgery or combination surgery and for any subsequent surgery/combination surgery, as defined in the Medical Necessity Criteria section of the policy, including the following procedures (Please see the prior authorization list for product specific prior authorization requirements):
   a. Lumbar decompression surgery:
      i. Corpectomy/hemicorpectomy
      ii. Discectomy
      iii. Foraminectomy/foraminoplasty
      iv. Foraminotomy
      v. Laminectomy/laminoplasty
      vi. Laminotomy/laminoforaminotomy, hemilaminectomy
      vii. Osteophyte removal (bone spur removal)
   b. Lumbar fusion
   c. Lumbar intervertebral artificial disc replacement (arthroplasty)
   d. Lumbar fusion using recombinant human bone morphogenic protein (BMP).
      NOTE: Refer to coverage criteria in Medica's Coverage Policy, Bone Morphogenic Protein (BMP) for Spine and Orthopedic Applications, for further details.
2. Prior authorization is **not required** for tethered spinal cord syndrome in infants, children, and adults.
3. Prior authorization is **not required** for the type of access and associated instrumentation used to gain entry to the surgical site, including:
   a. Anterior access. Anterior access for lumbar fusion is referred to as anterior lumbar interbody fusion (ALIF) access.
   b. Lateral access. Lateral access for lumbar fusion is referred to as lateral LIF (LLIF) access.
   c. Posterior LIF (PLIF) access. Posterior access for lumbar fusion is referred to as posterior LIF (PLIF) access.
   d. Transforaminal access. Transforaminal access for lumbar fusion is referred to as transforaminal LIF (TLIF) access.
      Note: Exceptions are: (1) laparoscopic anterior lumbar interbody fusion (lap-ALIF) and (2) axial presacral lumbar interbody fusion (AxiaLIF®). These techniques have been determined to be investigative and therefore not covered.
4. Standard spinal instrumentation and/or tissue grafting materials are considered a covered benefit when all of the medical necessity criteria listed above are met, and not otherwise excluded according to terms in # 7, below.
5. Lumbar intervertebral artificial disc replacement (arthroplasty) is investigative and therefore not covered for all other indications not listed above, including but not limited to treatment at more than one contiguous level and at disc levels not FDA-approved for the device being used.
6. 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.
7. Lumbar spinal surgery otherwise meeting medical necessity criteria defined in this policy is not covered when performed in combination with any procedure Medica considers investigative and therefore not covered.
8. Examples of procedures considered **investigative and therefore not covered** include, but are not limited to: autologous blood-derived products; stem cell therapy for orthopedic applications; OsteoAmp™ allogenic morphogenic protein, motion preserving decompression/dynamic spine stabilization; axial presacral lumbar interbody fusion (AxiaLIF®); laparoscopic anterior lumbar interbody fusion (lap-ALIF); interspinous process...
decompression procedures; laser spine surgery; minimally invasive sacroiliac joint fusion; and selected percutaneous and minimally invasive lumbar spine procedures. See the following Medica coverage policies:

b. Stem Cell Therapy 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 rhBMP-2/InFUSE indications are covered services and others are non-covered services. Refer to coverage policy for details.
d. Motion Preserving Posterior Interspinous/Interlaminar Decompression/Stabilization Devices (e.g., X-Stop, Coflex, Dynesys, DIAM spinal stabilization, Wallis system, total facet joint replacement system)
e. mild® Procedure (mild® Device Kit)
f. Laser Spine Surgery
g. Minimally Invasive Sacroiliac Joint Fusion
h. Percutaneous Disc Decompression Procedures (Manual, Automated or Laser Discectomy, and Plasma Disc Decompression [PDD])
i. Percutaneous Radiofrequency and Laser Ablation/Denervation Procedures for Facet and Sacroiliac Joints. NOTE: Some procedures are covered services and others are non-covered services. Refer to coverage policy for details.

9. Coverage may vary according to the terms of the member’s plan document.
10. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.
11. If it appears that the Medical Necessity and Coverage Criteria are not met, the case will be reviewed by the medical director or an external reviewer for individual consideration. Practitioners are advised of the appeal 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: Lumbar decompression, stand-alone procedure
  NOTE: If fusion is also request, use appropriate sections III-VII, below.
- Section III: Lumbar fusion, standard
- Section IV: Lumbar fusion, post laminectomy syndrome
- Section V: Lumbar fusion using InFUSE™ Bone Graft/LT-Cage™ with recombinant human bone morphogenic protein-2 (rhBMP-2)
- Section VI: Lumber intervertebral artificial disc replacement (arthroplasty)
- Section VII: Lumber fusion, chronic discogenic pain alone.

I. Prior Authorization is not required when the procedure is emergent in nature. These indications include, but are not limited to:
A. Acute cauda equina syndrome (i.e., damage to the cauda equina causing loss of function in the lumbar plexus)
B. Acute, unremitting radicular pain resulting in severe rapid-onset/progression of neurological impairment arising from lumbar compression, nerve root compression, or stenosis and requiring emergent hospitalization within a few days post-onset/progression.
C. Idiopathic scoliosis over 40 degrees of curvature
D. Congenital scoliosis
E. Infection-related instability, nerve or spinal cord compression, vertebral destruction, instability, or pathologic fracture
F. Acute, traumatic spinal fracture or dislocation with neural compression and/or radiographic evidence of instability
G. Spinal tuberculosis
H. Tumor-related (benign or malignant) nerve or spinal cord compression, vertebral destruction, instability,
or pathologic fracture.

II. Prior authorization is required for initial and repeat/revision lumbar decompression as a stand-alone procedure.

NOTE: If lumbar decompression is being done in combination with lumbar fusion, medical necessity criteria for lumbar fusion apply. Refer to appropriate fusion criteria sections III-VII, below.

Lumbar decompression alone is considered medically necessary when all of the following criteria are met:

A. Individual is undergoing one of the following procedures:
   1. Discectomy
   2. Corpectomy
   3. Hemicorpectomy
   4. Foraminectomy/foraminoplasty
   5. Foraminotomy
   6. Laminectomy
   7. Laminoplasty
   8. Laminotomy (i.e., laminoforaminotomy, hemilaminectomy)
   9. Osteophytectomy (i.e., bone spur removal).

B. Individual has one of the following documented diagnoses, exclusive of those listed in I., above:
   1. Chronic radiculopathy with nerve root compression
   2. Spondylolisthesis, anterolisthesis, or retrolisthesis
   3. Symptomatic lumbar stenosis (e.g., pain, motor weakness, paresthesia, compromised neurological function)
   4. Post laminectomy syndrome
   5. Disc herniation, initial or recurrent (i.e., remaining disc material following initial lumbar discectomy).

C. Decompression surgery is not to exceed two lumbar levels.

An example of three lumbar levels would be L2-L3 & L3-L4 & L4-L5. See Appendix 1, below.

NOTE: If lumbar decompression is being requested at more than two levels, send for medical director review for medical necessity.

D. Skeletal maturity has been reached.

E. Failure of a minimum of three months of conservative medical management related to current episode and symptoms and all of the following criteria are met:
   1. Documentation of continued episodes of severe, radiating neurological pain and/or impairment (e.g., extremity weakness, foot drop, numbness and/or decreased sensation, bladder and/or bowel dysfunction) demonstrating compromised ability to perform routine activities of daily living (e.g., standing, walking, climbing steps, bathing/grooming, food preparation).
   2. Imaging studies/radiographic imaging (computed tomography; magnetic resonance imaging) documents spinal lesion(s) at a level correlating with clinical presentations mentioned in E.1. above.
   3. Documentation of the Oswestry Disability Index (ODI) scores at the conclusion of three months of conservative treatment (e.g., a physical therapy regimen, injection therapy, etc.) demonstrating one of the following:
      a. Less than 30% improvement in ODI score between first and last conservative treatment session.
      b. Continued ODI score of greater than or equal to 30% at the conclusion of conservative treatment and thereafter.
      c. If an individual has not had conservative treatment, of a documented ODI score of greater than or equal to 30% within one month prior to the date of the prior authorization request.
      d. For individuals unable to complete a minimum of three months conservative treatment, documentation of one of the following is required:
         i. ODI score of greater than or equal to 30% at the time conservative treatment is discontinued
         ii. Inability to perform routine activities of daily living, as defined in E.1., above
      e. Individual has documented myelopathy without pain.
III. Prior Authorization is required for initial and repeat/revision lumbar fusion, with or without accompanying decompression. Surgery is considered medically necessary when all of the following criteria are met:

NOTE: If lumbar fusion is being done for any of the following, refer to appropriate criteria sections, below:

- Section IV: fusion for post laminectomy syndrome (aka, failed back surgery syndrome)
- Section V: fusion in combination with recombinant human bone morphogenic protein-2 (rhBMP-2)
- Section VI: fusion via artificial disc replacement
- Section VII: fusion for chronic discogenic pain, alone (i.e., none of the following present: confirmed instability, deformity, or nerve root decompression at the surgical level).

A. Individual has one of the following documented diagnoses, exclusive of those listed in I., above.
   1. Spondylolisthesis, anterolisthesis, or retrolisthesis
   2. Non-acute radiculopathy (e.g., symptomatic lumbar stenosis, segmental scoliosis, 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 lumbar discectomy).

B. Skeletal maturity has been reached.

C. Surgery is not to exceed two lumbar levels. An example of three lumbar levels would be L2-L3 & L3-L4 & L4-L5. See Appendix 1, below.

NOTE: If either fusion or decompression is requested for more than two levels, send for medical director review

D. Documentation of osteoporosis status, as applicable, demonstrates one of the following:
   1. Significant anatomical and/or neurological compromise
   2. Bone structure has ability to support instrumentation.

E. BMI less than 40 at the time of the prior authorization request.

F. Documentation of continued episodes of severe, radiating neurological pain and/or impairment (e.g., extremity weakness, foot drop, numbness and/or decreased sensation, bladder and/or bowel dysfunction) demonstrating compromised ability to perform routine activities of daily living (e.g., standing, walking, climbing steps, bathing/grooming, food preparation).

G. Imaging studies/radiological evidence (computed tomography; magnetic resonance imaging) documents demonstrating lesion(s) at a level correlating with clinical presentations mentioned in F., above (e.g., damage/compromise to facet joint, spinous process, transverse process, disk, ligaments, and/or muscles).

H. Failure of a minimum of three months conservative medical management related to current episode and symptoms.

I. Documentation of an Oswestry Disability Index (ODI) score(s) at the conclusion of conservative treatment (e.g., a physical therapy regimen, injection therapy, etc.) demonstrating one of the following:
   1. Less than 30% improvement in ODI score between first and last conservative treatment session.
   2. Continued ODI score of greater than or equal to 30% at the conclusion of conservative treatment and thereafter.
   3. If an individual has not had conservative treatment, an ODI score of greater than or equal to 30% within one month prior to the date of the prior authorization request.
   4. For individual unable to complete a minimum of three months of conservative treatment, documentation of one of the following is required:
      a. ODI score of greater than or equal to 30% at the time conservative management is discontinued
      b. Inability to perform routine activities of daily living as defined in F., above.

NOTE: An ODI questionnaire with scoring/interpretation directions is found in Appendix 3, below.

J. Documentation of tobacco or nicotine status indicating one of the following:
   1. The individual is a non-tobacco or non-nicotine user
   2. The individual has been tobacco and nicotine free for a minimum of one month prior to the date of the prior authorization request.

K. Documentation indicates an FDA approved bone graft or fusion material is being used, as applicable.
NOTE: If use of recombinant human bone morphogenic protein-2 (rhBMP-2) is indicated, use section V: InFUSE™ Bone Graft/LT-CAGE™ using rhBMP-2, below.

NOTE: Medica considers any of the following to be standard graft material: (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) autologous blood-derive biologics (e.g., platelet-rich plasma, autologous conditioned serum, autologous whole blood), (2) stem cell therapy (e.g. AlloStem®, Cellentra™ VCBM, Osteocell® Plus, Trinity® Evolution™), and (3) OsteoAmp™ allogeneic morphogenic protein investigative and therefore not covered for orthopedic applications.

IV. Prior authorization is required for initial and repeat/revision lumbar fusion for treatment of documented post laminectomy syndrome (aka, failed back surgery syndrome). Surgery is considered medically necessary when all of the following criteria are met:

A. Individual meets criteria outlined in III.A.-K., above.
B. Documentation of disability and unremitting pain for a minimum of three months following initial procedure.
C. Documentation of preoperative psychiatric/psychological evaluation conducted within the past 12 months by a licensed psychologist or psychiatrist, or other licensed mental health professional who has an appropriate working knowledge of the psychosocial issues involved in management of chronic pain, including documentation of all of the following:
   1. Ability of the individual to understand the risks and goals of the surgical procedure
   2. Absence of unmanageable acute psychiatric illness and/or psychological distress, including but not limited to depression, drug abuse, or alcohol abuse
   3. Ability of the individual to understand the need to comply with long-term aftercare and with the behavioral changes expected after surgery.

V. Prior authorization is required for initial and repeat/revision lumbar fusion, with or without accompanying decompression, in combination with the InFUSE™ Bone Graft/LT-CAGE™. Surgery is considered medically necessary when all of the following criteria are met:

A. Individual meets criteria outlined in III.A.-K., above.
B. Recombinant human bone morphogenic protein-2 (rhBMP-2) is the bone graft component being employed.
   NOTE: Medica considers OsteoAmp™ allogeneic morphogenic protein investigative and therefore not covered for orthopedic applications.
C. Anterior-approach is documented.
D. Single level application is documented for insertion from the fourth lumbar vertebra to the first sacral vertebra (L4-S1).
E. Individual has been diagnosed with degenerative disc disease and has a specific risk factor for nonunion (e.g., poor nutrition; history of nicotine or alcohol use; endocrine disorder [e.g., diabetes]; prolonged NSAID use; metabolic abnormalities [e.g., poor vascular supply, infection, damaged muscle]; noncompliant brace wear).

VI. Prior authorization is required for initial and repeat/revision lumbar intervertebral artificial disc replacement (arthroplasty) for treatment of radiculopathy or myelopathy. Surgery is considered medically necessary when all of the following criteria are met:

A. Individual has documented symptomatic degenerative disc disease (DDD), with or without radicular pain, resulting in unremitting low back pain, exclusive of those listed in I., above.
   NOTE: Examples of associated underlying causes include, but are not limited to: (1) degenerative disc disease, (2) unstable spinal stenosis, (3) degenerative scoliosis, (4) segmental instability, (5) unstable failed back surgery syndrome (i.e., post-laminectomy syndrome), (6) unstable post-facetectomy syndrome.
B. Documentation of continued episodes of unremitting back pain demonstrating compromised ability to perform routine activities of daily living (e.g., standing, walking, sitting, climbing steps, bathing/grooming, food preparation).
C. Medical record does not indicate any of the following:
1. Moderate to severe facet joint arthritis
2. Localized or systemic infection.
3. Spinal tumor or other active malignancy
4. Osteoporosis
5. Spondylolisthesis.

D. Imaging studies/radiological evidence (computed tomography; magnetic resonance imaging) documents a DDD lesion at a level correlating with impaired ADLs as mentioned in B, above.

E. Skeletal maturity has been reached.

F. BMI is less than 40 at the time of the prior authorization request.

G. Documentation of insertion at one-level.

H. Procedure will be performed using an FDA-approved device for one of the following:
   1. From L4-S1 when using one of the following:
      a. Inmotion® Lumbar Artificial Disc system (formerly Charite™ Artificial Disc)
      b. activL® Artificial Disc system.
   2. From L3-S1 when using PRODISC®-L Total Disc Replacement system.

I. Documentation of failure of a minimum of six months of conservative medical management related to current episode/symptoms.

J. Documentation of an Oswestry Disability Index (ODI) score(s) at the conclusion of conservative treatment (e.g., a physical therapy regimen, injection therapy) demonstrating one of the following:
   1. Less than 30% improvement in ODI score between first and last conservative treatment session.
   2. Continued ODI score of greater than or equal to 30% at the conclusion of conservative treatment and thereafter.
   3. If the individual has not had conservative treatment an ODI score of greater than or equal to 30% within one month prior to the date of the prior authorization request.
   4. For an individual unable to complete a minimum of six months of conservative treatment, documentation of one of the following is required:
      a. ODI score of greater than or equal to 30% at the time conservative management is discontinued
      b. Inability to perform routine activities of daily living as defined in B, above.

NOTE: An ODI questionnaire with scoring/interpretation directions is found in Appendix 3, below.

VII. Prior authorization is required for initial and repeat/revision lumbar fusion when ordered for chronic discogenic pain, alone. Surgery is considered medically necessary when all of the following criteria are met:

A. Skeletal maturity has been reached.

B. Continued discogenic pain has persisted for a minimum of six months.

C. Spinal instability, deformity, and/or nerve root decompression is not present, as documented by one of the following:
   1. Imaging studies
   2. Physical examination (e.g., segmental instability testing).

D. Surgery is not to exceed two lumbar levels. An example of three lumbar levels would be L2-L3 & L3-L4 & L4-L5. See Appendix 1, below.

NOTE: If lumbar fusion is being requested at more than two levels, send for medical director review.

E. BMI less than 40 at the time of the prior authorization request.

F. Documentation of preoperative psychiatric/psychological evaluation conducted within the past 12 months by a licensed psychologist or psychiatrist, or other licensed mental health professional who has an appropriate working knowledge of the psychosocial issues involved in management of chronic pain, including documentation of all of the following:
   1. Ability of the individual to understand the risks and goals of the surgical procedure.
   2. Absence of unmanageable acute psychiatric illness and/or psychological distress, including but not limited to depression, drug abuse, or alcohol abuse.
   3. Ability of the individual to understand the need to comply with long-term aftercare and with the behavioral changes expected after surgery.

G. Failures of all of the following:
   1. Minimum of six months intensive medical management (e.g., active, organized and progressive therapy program addressing strength and flexibility).
   2. Anti-inflammatory medication and/or analgesics
3. Regimen of therapeutic injections.

H. Documentation, within one month prior to surgery, of the Oswestry Disability Index (ODI) scores demonstrating one of the following:
   1. Less than 30% improvement in ODI score between first and last conservative treatment session.
   2. Continued ODI score of greater than or equal to 40% at the conclusion of conservative treatment and thereafter.

   NOTE: An ODI questionnaire with scoring/interpretation directions is found in Appendix 3, below.

I. Documentation of tobacco or nicotine status indicating one of the following:
   1. The individual is a non-tobacco or non-nicotine user
   2. The individual has been tobacco and nicotine free for a minimum of six months prior to the date of the prior authorization request.

J. Documentation indicates an FDA approved bone graft or fusion material is being used, as applicable.

   NOTE: Medica considers any of the following to be standard graft material: (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) autologous blood-derive biologics (e.g., platelet-rich plasma, autologous conditioned serum, autologous whole blood), (2) stem cell therapy (e.g. AlloStem®, Cellentra™ VCBM, Osteocel® Plus, Trinity® Evolution™), and OsteoAMP™ allogeneic morphogenic protein investigative and therefore not covered.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>December 1, 2010</th>
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<tr>
<td>Administrative Updates</td>
<td>02/2017; 05/01/2017; 06/21/2018</td>
</tr>
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</table>

References:

Pre-11/2014 Medical Policy Committee (MPC) and Pre-09/2015 Medical Technology Assessment Committee (MTAC):

9. Deyo RA, Mirza SK, Martin BI, et al. Trends, major medical complications, and charges associated with surgery...


**09/2015 MTAC:**


56. Wei J, Song Y, Sun L, Lv C. Comparison of artificial total disc replacement versus fusion for lumbar degenerative

11/2016 MPC and 04/2016 & 10/2016 MTAC:


80. Saavedra-Pozo FM, Deusdara RA, Benzel EC. Adjacent segment disease perspective and review of the


Vertebrae Structure

- There are five vertebrae comprising the lumbar spine, L1 – L5.
- 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.

Causes of Lumbar Pain

- **Contained bulging disc:** the soft nucleus is protruding outward and compressing nerve root.
- **Extruded, ruptured disc:** the firm annulus has torn, letting the soft center squeeze through to compress nerve root.
- **Stenosis:** results when bone spurs (osteophytes) narrow the foramen or spinal canal. This also puts pressure on nerves.
- **Spondylolisthesis:** vertebrae become unstable and slip forward. Slippage can irritate nerves & joints, and can also worsen stenosis.


Examples of Disc Problems

- Normal Disc
- Degenerated Disc
- Bulging Disc
- Herniated Disc
- Thinning Disc
- Disc Degeneration with Osteophyte Formation

Appendix 2

Grades of Spondylolisthesis

The most common grading system for spondylolisthesis is the Meyerding grading system for severity of slip, with grade 1 being least advanced, and grade 5 being most advanced.

To determine the grade of spondylolisthesis, or slippage, the disc is divided in quarters. The grade is equal to the number of quarters of slippage. If there is no slippage, the grade is zero. If the slippage is equal to one quarter of the total width of the disc, the slippage is grade one. If the slippage is three quarters of the width of a disc, it is a grade three spondylolisthesis. If the slippage is more than four quarters (the whole disc space) then it is called a grade 5. In a grade 5 spondylolisthesis, the spine is completely dislocated.

Grading is calculated by measuring how much a vertebral body has slipped forward over the body beneath it. It is based upon measurements on lateral X-ray of the distance from the posterior edge of the superior vertebral body to the posterior edge of the adjacent inferior vertebral body. This distance is then reported as a percentage of the total superior vertebral body length:

<table>
<thead>
<tr>
<th>GRADE</th>
<th>Percentage of Total Superior Vertebral Body Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>2</td>
<td>50% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>3</td>
<td>75% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>4</td>
<td>100% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>5</td>
<td>Vertebral body completely fallen off (i.e., spondyloptosis)</td>
</tr>
</tbody>
</table>

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
\[
\text{score} = \frac{\text{total score}}{5 \times \text{number of questions answered}} \times 100
\]
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**
3. Official ODI Website - maintained by the original author, Jeremy Fairbanks.
   Available at: [http://www.orthosurg.org.uk/odi/](http://www.orthosurg.org.uk/odi/)
## Appendix 4

### Demineralized Bone (DBM) Matrix Products

2017 Availability / Not intended as all-inclusive list

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