Bright HealthCare™

**Medical Policy**

| Lumbar Spine Surgery | |
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| **MEDICAL POLICY NUMBER** | MED_Clin_Ops-007 |
| **ORIGINAL EFFECTIVE DATE** | 8/1/2018 |
| **CURRENT VERSION EFFECTIVE DATE** | 6/16/2022 |
| **APPLICABLE PRODUCT AND MARKET** | *Individual Family Plan:* All<br>*Small Group*: All<br>*Medicare Advantage*: N/A |

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## PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for lumbar spine surgery.

## POLICY

### *Clinical Review Criteria*

Prior Authorization is NOT required when the lumbar spine surgery is emergent in nature.

### I. LUMBAR DECOMPRESSION

A. **Prior authorization is required for elective lumbar decompression** as a stand-alone procedure. If lumbar decompression is being done in combination with lumbar fusion, authorization requirements for lumbar fusion also apply (see section II below).

B. Lumbar decompression alone may be authorized when **ALL** the following criteria are met:

1) A physical examination, including a neurologic examination, has been performed by or reviewed by the operating surgeon.
2) Individual is undergoing **ONE** of the following procedures:
    i. Corpectomy/hemicorpectomy.
    ii. Discectomy.
    iii. Foraminectomy/foramioplasty.
    iv. Formainotomy.
    v. Laminectomy/laminoplasty.
    vi. Laminotomy (e.g., laminoforamonotomy, hemiliaminectomy).
    vii. Osteophyte removal (e.g., bone spur removal)
3) Individual has **ONE** of the following documented diagnoses:
    i. Chronic radiculopathy with nerve root compression noted on clinical exam that significantly hinders activities of daily living.
    ii. Spondylolisthesis, anterolisthesis, or retrolisthesis.
    iii. Symptomatic lumbar stenosis (e.g., pain, motor weakness, paresthesia, compromised neurological function).
    iv. Post laminectomy syndrome.
    v. Disc herniation, initial or recurrent.
4) Decompression surgery is not to exceed two (2) lumbar levels.
5) Skeletal maturity has been reached.
6) 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) and demonstrating compromised ability to perform routine activities of daily living for at least twelve (12) weeks duration.
7) Imaging studies (computed tomography or magnetic resonance imaging) document spinal lesion(s) at a level correlating exactly with clinical presentation.
8) Successful completion of an active, organized, and progressive strength and flexibility program and appropriate conservative therapy that includes **ALL** of the following:
    i. Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders. If opioids are being used, a plan to wean from opioid dependence should be in place.
    ii. Conservative therapy must include **ALL** of the following:

a. Formal physical therapy is required; at least four (4) visits over a six (6) week course and must include active muscle conditioning, or there must be an explicit statement in the clinical documents that explains why such physical therapy is contraindicated.

b. The requirement for physical therapy will not be met if there is a failure to initiate or complete prescribed physical therapy for non-clinical reasons.

c. Documentation of formal physical therapy is confirmed with the physical therapist's notes, including documentation of compliance with plan of conservative therapy.

9) If the program of non-operative treatment fails, with failure of a minimum of six (6) weeks of intensive conservative medical management, operative treatment is indicated when at least **ONE** of the following has occurred:

i. Improvement of the symptoms has plateaued or failed to occur and the residual symptoms of pain and functional disability are unacceptable at the end of six (6) weeks of active treatment.

ii. Frequent recurrences of symptoms cause serious functional limitations. Operative treatment may be considered even if a non-operative active treatment program provides satisfactory relief of symptoms and restoration of function on each recurrence.

iii. Progressive nerve compression resulting in an acute motor neurologic deficit sensory or motor due to herniated disc. The neurological deficits should be significant: 02/5 on the motor function scale for L5 or S1 roots; 0-3/5 for L3 or L4 roots.

10) Documentation of a visit with a primary care provider or with another provider appropriate to manage patient's co-morbid conditions in the judgement of the surgeon within six (6) weeks prior to the date of the prior authorization request.

11) BMI less than 35 at the time of the prior authorization request. A BMI of less than 35 should be obtained prior to surgery unless the surgeon's judgment dictates otherwise in cases of severe or progressive bone loss, deformity, or the symptoms progress/worsen in the face of active interventions.

12) Documentation in the medical record of tobacco and nicotine status indicating the **ONE** of the following:

i. The individual is a non-tobacco and non-nicotine user.

ii. The individual has been tobacco-free for a minimum of six (6) weeks prior to the date of the prior authorization request.

12) No medical contraindications are present (see section III below)

## II. LUMBAR FUSION

A. **Prior Authorization is required for elective lumbar fusion**, with or without accompanying decompression.

B. Lumbar Fusion surgery may be authorized when **ALL** the following criteria are met:

1) A physical examination, including a neurologic examination, has been performed by or reviewed by the operating surgeon.

2) Individual has **ONE** of the following documented diagnoses:

i. Spondylolisthesis, anterolisthesis, or retrolisthesis.

ii. Non-acute radiculopathy (e.g. symptomatic lumbar stenosis, segmental scoliosis, osteophytes) causing continued pain, motor weakness, paresthesia, compromised neurological function indicative of nerve root compression.

iii. Post-laminectomy syndrome.

iv. Recurrent disc herniation (i.e. remaining disc material following initial lumbar discectomy).

3) Fusion surgery is not to exceed two (2) lumbar levels.

4) Skeletal maturity has been reached.

5) Documented unremitting pain, disability, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for at least six (6) months duration.

6) Imaging studies (computed tomography or magnetic resonance imaging) document spinal lesion(s) at a level correlating exactly with clinical presentation.

7) Successful completion of an active, organized, and progressive strength and flexibility program and appropriate conservative therapy that includes **ALL** of the following:

i. Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders. If opioids are being used a plan to wean from opioid dependence should be in place.

ii. Conservative therapy must include **ALL** of the following**:**

a) Formal physical therapy is required, at least four (4) visits over a six (6) week course and must include active muscle conditioning, or there must be an explicit statement in the clinical documents that explains why such physical therapy is contraindicated.

b) The requirement for physical therapy will not be met if there is a failure to initiate or complete prescribed physical therapy for non-clinical reasons.

c) Documentation of formal physical therapy is confirmed with the physical therapist's notes, including documentation of compliance with plan of conservative therapy.

8) If the program of non-operative treatment fails, with failure of a minimum of twelve (12) weeks of intensive conservative medical management, operative treatment is indicated when **ONE** of the following has occurred:
    i. Improvement of the symptoms has plateaued or failed to occur and the residual symptoms of pain and functional disability are unacceptable at the end of twelve (12) weeks of active treatment;
    ii. Frequent recurrences of symptoms cause serious functional limitations. Operative treatment may be considered even if a non-operative active treatment program provides satisfactory relief of symptoms and restoration of function on each recurrence.
    iii. Progressive nerve compression resulting in an acute motor neurologic deficit sensory or motor due to herniated disc. The neurological deficits should be significant: 02/5 on the motor function scale for L5 or S1 roots; 0-3/5 for L3 or L4 roots.
9) Documentation of a visit with a primary care provider or with another provider appropriate to manage patient's co-morbid conditions in the judgement of the surgeon within six (6) weeks prior to the date of the prior authorization request.
10) BMI less than 35 at the time of the prior authorization request. A BMI of less than 35 should be obtained prior to surgery unless the surgeon's judgment dictates otherwise in cases of severe or progressive bone loss, deformity, or the symptoms progress/worsen in the face of active interventions.
11) Documentation in the medical record of tobacco and nicotine status: indicating the **ONE** of the following:
    i. The individual is a non-tobacco and non-nicotine user.
    ii. The individual has been tobacco-free for a minimum of six (6) weeks prior to the date of the prior authorization request.
12) If includes use of recombinant human bone morphogenic protein-2 (rhBMP-2) InFUSE™ Bone Graft/LT-CAGE™ **ALL** the following must be met:
    i. Anterior-approach is documented;
    ii. Single level only application is documented for insertion from the fourth lumbar vertebra to the first sacral vertebra (L4–S1); **AND**
    iii. 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; diabetes; prolonged NSAID use; poor vascular supply, infection, damaged muscle).
13) No medical contraindications are present (see section III below)

## III. CONTRAINDICATIONS

Lumber spine surgery will not be authorized if there are medical contraindications present. Medical contraindications to surgery include **ANY** of the following:

A. Congestive Heart Failure and NYHA functional class III or IV.

B. Coronary artery disease at least **ONE** of the following

   i. Myocardial Infarction less than 1 year ago.

   ii. Stent placed less than 1 year ago.

   iii. Uncontrolled angina.

C. Uncontrolled Hypertension (HTN) as defined by at least **ONE** of the following:

   i. systolic measurement greater than 160.

   ii. diastolic measurement great than 100.

D. Chronic Obstructive Pulmonary Disease (COPD) patients with mMRC Grade 3 and 4. (mMRC: Modified Research Council dyspnea scale).

E. Cardiovascular Disease patients with acute Cerebrovascular Accident less than 6 months ago.

F. Cardiovascular Disease patients post-acute Cerebrovascular Accident with significant deficits that affect activities of daily living.

G. Chronic kidney disease stage G4-G5.

H. Decompensated cirrhosis.

I. Current alcohol abuse.

J. Neurological and musculoskeletal conditions that might preclude recovery (i.e., Parkinson disease).

K. Generally frail patients.

L. Non-ambulatory patients.

M. Moderate to severe dementia.

N. Anemia, as defined by;

   1. Hb less than normal range (female less than 12 g $dl^{-1}$, male less than 13 g $dl^{-1}$)

O. Malnutrition, as defined by at least **ONE** of the following:

   i. BMI less than 18.

   ii. Recent unintentional weight loss.

   iii. Low serum Albumin (below normal range for a lab).

P. Active urinary tract infection.

Q. Active dental infection.

R. Systemic infection.

S. Skeletal immaturity.

IV. **EXCLUSIONS**

**A.** Bright Health considers the following procedures to be investigative or experimental. The procedures listed below will not be authorized**:**

1) Procedures that include use of lumbar intervertebral artificial disc replacement. There is insufficient evidence in the published medical literature to show that this service is as safe as standard services and provides better long-term outcomes than current standard services.
2) Autologous blood-derive biologics (e.g., platelet-rich plasma, autologous conditioned serum, autologous whole blood).
3) Stem cell therapy (e.g. AlloStem®, Cellentra™ VCBM, Osteocel® Plus, Trinity® Evolution™).
4) OsteoAmp™ allogeneic morphogenic protein.
5) Motion preserving decompression/dynamic spine stabilization; axial presacral lumbar interbody fusion (AxiaLIF®).
6) Laparoscopic anterior lumbar interbody fusion (lap-ALIF).
7) Interspinous process decompression procedures.
8) Motion Preserving Posterior Interspinous/Interlinear Decompression/Stabilization Devices (e.g., X-Stop, Coflex, Dynesys, DIAM spinal stabilization, Wallis system, total facet joint replacement system).
9) mild® Procedure (mild® Device Kit).
10) Laser Spine Surgery.
11) Percutaneous Disc Decompression Procedures (Manual, Automated or Laser Discectomy, and Plasma Disc Decompression)/
12) Percutaneous Radiofrequency and Laser Ablation/Denervation Procedures for Facet and Sacroiliac Joints.
13) Sacroiliac Joint Fusion.
14) Intradiscal Electrothermal annuloplasty (IDEA) or more commonly called IDET (Intradiscal Electrothermal therapy).
15) Nucleus Pulpous Replacement.
16) PreSacral Fusion.
17) Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement.
18) Lumbar Artificial Disc Replacement.
19) Staged, multi-session* spinal fusions are considered not authorized for fusion involving fewer than three (3) levels, unless being performed for treatment of severe scoliosis or other spinal deformities. *Multi-session is defined as procedures occurring on different days or requiring an additional anesthesia session.

**B.** Exceptions to any of the criteria above MAY be considered on a case-by-case basis when the submitted medical/clinical documentation supports the exception.

## BACKGROUND

Back pain affects 80% of Americans at some time in their lives. Over $80 billion is spent annually in American to treat chronic back pain. Progressive back pain is more likely to occur when the person is in their most productive period in life, between the years of 30 and 50. The total age-adjusted percentages per 100,000 people who reported severe (pain that lasted a whole day or more) low back pain in the prior three (3) months were: 27.4% and neck pain 14.7%. Uncontrolled pain remains one of the greatest healthcare crises affecting Americans to date. Pain is the major cause of disability, a leading reason for physician office visits, and the most frequent indication for diagnostic studies, including MRIs and X-rays and is purported to cost Americans upwards of $100 billion annually in direct health care costs.

Lumbar decompression procedures, performed alone or in combination with spinal fusion, are designed to relieve symptoms of neural compression. Lumbar discectomy involves removal of the disc, in whole or part. Foraminotomy and laminotomy involve removal of a portion of the Bony arch, or lamina, on the dorsal surface of a vertebra. These are typically performed to access the disc space and relieve pressure on the nerve roots and spinal cord.

Lumbar fusion is one of the most commonly performed procedures in spinal surgery, and a well- established treatment for spinal instability resulting from a variety of conditions. In most of techniques, a bone graft is utilized to join two or more adjacent vertebral bodies into a single unit, which permanently immobilizes the involved section of the spine. Techniques to achieve lumbar spinal fusion are numerous, and include different surgical approaches (anterior, posterior, lateral) to the spine, different areas of fusion (intervertebral body (interbody), transverse process (posterolateral), different fusion materials (bone graft and/or metal instrumentation), and a variety of ancillary techniques to augment fusion. Lumbar fusion has been widely used to treat back pain associated with degenerative disc disease and spinal stenosis in the absence of instability. Many fusion operations are also performed for nonspecific low back pain which has not responded to standard treatment. Evidence to support the efficacy of fusion in treating these common conditions has been inconsistent, and many experts agree that the procedure is overused.

Spine surgery is a complex area of medicine, and this document breaks out the clinical indications by surgical type. Operative treatment is indicated only when the natural history of an operatively treatable problem is better than the natural history of the problem without operative treatment. Choice of surgical approach is based on anatomy, the patient's pathology, and the surgeon's experience and preference. All operative interventions must be based on a positive correlation with clinical findings, the natural history of the disease, the clinical course, and diagnostic tests or imaging results.

## DEFINITIONS

1. **Artificial intervertebral disc replacement** (arthroplasty) - is a surgical procedure in which

an 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.

2. **Authorization -** a decision by Bright Health that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary or meets other member contract terms. Sometimes called prior authorization, prior approval or precertification. Bright Health requires preauthorization for certain services before a member receives them, except in an emergency. Authorization isn't a promise Bright Health will cover the cost.

3. **Cauda equina syndrome** (CES) - is a rare disorder characterized by impairment of the bundle of spinal nerve roots arising from the cauda equine (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.

4. **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.

5. **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.

6. **Pseudoarthrosis -** is a term that is used to describe the situation where the spinal segment does not grow together after an attempted surgical fusion. It occurs more frequently in people who use nicotine products.

7. **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, and 9) assist with bone formation. Unlike standard bone allografts and autografts, BMP-2 is synthetically manufactured by using a technique called recombinant technology. BMP-2 is the active agent in the InFUSE™ Bone Graft/LTCAGE™ 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.

8. **Tobacco/Nicotine -** products can result in nicotine addiction and health problems, including a negative effect on bone healing. This includes delayed unions, non-unions and other complications (e.g., decreased blood flow; wound complications). Products containing nicotine include, but are not limited to;
   - Smoked tobacco (e.g., cigarettes, cigars, cigarillos, pipe tobacco).
   - Smokeless tobacco (e.g., chewing tobacco, snuff).

- Nicotine replacements (e.g., patches, gum, nasal spray, inhalers).

## CODING CPT CODES

22533, 22558, 22612, 22630, 22633, 22533, 22534, 22558, 22585, 22612, 22614, 22630, 22632, 22633, 22634, 63030, 63035, 63005, 63012, 63017, 63042, 63044, 63047, 63048, 63056, 63057, 63030, 6303522857, 0163T, 22862, 0164T, 22865, 0165T, 0221T, 0222T

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Detection, evaluation, and management of preoperative anemia in the elective orthopaedic surgical patient: NATA guidelines

L. T. Goodnough, A. Maniatis, P. Earnshaw, G. Benoni, P. Beris, E. Bisbe, D. A. Fergusson, H. Gombotz, O. Habler, T. G. Monk: *BJA: British Journal of Anaesthesia*, Volume 106, Issue 1, 1 January 2011, Pages 13–22, https://doi.org/10.1093/bja/aeq361

## POLICY HISTORY Month Day, Year

| | |
|---|---|
| Original Effective Date | August 2, 2018 |
| Revised Date | **December 18, 2018** – Updated to include 2019 markets<br>**July 2019** – Annual Review<br>**February 1, 2020** – Updated policy to include 2020 markets<br>**June 18, 2020** – Annual review; updated policy boilerplate language and medical contraindications<br>**December 20, 2020** – Small Group added as applicable product<br>**June 17, 2021** – Annual review<br>**June 16, 2022** – Annual review |
| UM Committee Endorsement | July 31, 2018 |

Approved by UM Committee
June 16, 2022