



# CLINICAL GUIDELINES

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## Spine Surgery

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Clinical guidelines for medical necessity review of spine surgery services.

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## Spine Surgery Guidelines

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**CMM-600: Preface to Spine Surgery Guidelines**

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## **CMM-600.1: Prior Authorization Requirements**

- Prior-authorization requests should be submitted at least two weeks prior to the anticipated date of an elective spinal surgery.
- Minimum documentation requirements needed to complete a prior authorization request for spinal surgery include **ALL** of the following:
  - ◆ CPT codes, disc level(s) or motion segments involved for planned surgery, and ICD-10 codes
  - ◆ Detailed documentation of the type, duration, and frequency of provider-directed non-surgical treatment (e.g. interventional pain management, medication management, physical therapy, chiropractic care, provider-directed active exercise program, etc.) and the response to each treatment
    - Detailed documentation explaining why a sufficient trial of non-surgical treatment was contraindicated if applicable
    - Detailed documentation of less than clinically meaningful improvement for each treatment.
  - ◆ Written reports/interpretations of the most recent advanced diagnostic imaging studies (e.g. CT, MRI, Myelography) by an independent radiologist. Clinically significant discrepancies in interpretations between the surgeon and the radiologist need to be reconciled in the documentation submitted for prior authorization.
    - Acceptable imaging modalities for purposes of the Spine Surgery guidelines are: CT, MRI, and Myelography.
    - Discography results will not be used as a determining factor of medical necessity for any requested procedure. Discography use is not endorsed.
  - ◆ For spinal fusion surgery requests: documentation of flexion-extension plain X-rays based upon indications for instability and/or other plain X-rays that document failure of instrumentation, fusion, etc.
  - ◆ Documentation of nicotine-free status as evidenced by **EITHER** of the following, unless this is an urgent/emergent request, for decompression only without fusion, disc arthroplasty, or when myelopathy is present:
    - Patient is a never-smoker
    - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
      - **Note:** In order to complete the prior authorization process for spinal fusion surgery, allow for sufficient time for submission of lab results performed after the 6-week cessation period.
  - ◆ Some procedures in the eviCore Spine Surgery Guidelines require a trial of epidural steroid injection(s) (ESIs)/selective nerve root blocks (SNRBs) unless there is a documented contraindication(s) to ESIs/SNRBs.;Contraindications to ESIs/SNRBs include the presence of **ANY** of the following:
    - Allergy to the medication to be administered
    - A significantly altered or eliminated epidural space (e.g. congenital anatomic anomalies or previous surgery)
    - Anticoagulation therapy

- Bleeding disorder
- Localized infection in the region to be injected
- Systemic infection
- Other co-morbidities which could be exacerbated by steroid usage (e.g. poorly controlled hypertension, severe congestive heart failure, diabetes, etc.)

### **CMM-600.2: Urgent/Emergent Requests**

- All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment in lieu of provider-directed non-surgical management and/or proof of smoking cessation. Confirmatory imaging studies are required.
- An urgent/emergent request is based on the 2019 NCQA standards for utilization management and is as follows:
  - ◆ A request for medical care or services where application of the time frame for making routine or non-life threatening care determinations:
    - Could seriously jeopardize the life or health of the member or the member's ability to regain maximum function, based on a prudent layperson's judgment, or
    - Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
    - In the opinion of a practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

### **CMM-600.3: References**

1. Akhavan S, Nguyen L, Chan V, Saleh et al. Impact of smoking cessation counseling prior to total joint arthroplasty. *Orthopedics* 2017; 40: e323-e328.
2. Brown CW, Orme TJ, Richardson HD. The rate of pseudarthrosis (surgical nonunion) in patients who are smokers and patients who are nonsmokers: a comparison study. 1986. 942-943.
3. Bydon M, Garza-Ramos R, Abt NB, et al. Impact of smoking on complication and pseudarthrosis rates after single- and 2-level posterolateral fusion of the lumbar spine. *SPINE*. 2014. 39 (21): 1765-70.
4. Canale ST, Kelly FB, Daugherty K. Smoking threatens orthopaedic outcomes: Negative effects should prompt orthopaedists to address the issue with patients. *AAOS Now* 2012; 1.
5. Greenhagen RM, Johnson AR, Bevilacqua NJ. Smoking cessation: The role of the foot and ankle surgeon. *Foot Ankle Spec* 2010; 3:21-28.
6. Khullar D, Maa J. The impact of smoking on surgical outcomes. *J Am Coll Surg* 2012; 215:418-426.
7. Lau D, Chou D, Ziewacz JE, et al. The effects of smoking on perioperative outcomes and pseudarthrosis following anterior cervical corpectomy. *J Neurosurg Spine*. 2014. 21: 547-558.
8. Lindström D, Sadr Azodi O, Wladis A, et al. Effects of a perioperative smoking cessation intervention on postoperative complications: A randomized trial. *Ann Surg* 2008; 248:739-745.
9. Macki M, Syeda S, Rajjoub KR, et al. The effect of smoking status on successful arthrodesis after lumbar instrumentation supplemented with rhBMP-2. *World Neurosurg*. 2017. 97: 459-64.
10. NCQA 2019 UM-CR-PN Accreditation Standards
11. Moller AM, Pedersen T, Villebro N, et al. Effect of smoking on early complications after elective orthopaedic surgery. *J Bone Joint Surg Br* 2003; 85: 178-181.
12. Phan K, Fadhil M, Chang N, et al. Effect of smoking status on successful arthrodesis, clinical outcome, and complications after anterior lumbar interbody fusion (ALIF). *World Neurosurg*. 2018; 110: e998-e1003.

13. Raja M, Garg A, Yadav P, et al. Diagnostic Methods for Detection of Cotinine Level in Tobacco Users: A Review. *J Clin Diagn Res.* 2016 Mar; 10(3): ZE04–ZE06.
14. Ratner PA, Johnson JL, Richardson CG, et al. Efficacy of a smoking-cessation intervention for elective-surgical patients. *Res Nurs Health* 2004; 27:148-161.
15. Sorensen LT, Karlsmark T, Gottrup F. Abstinence from smoking reduces incisional wound infection: A randomized controlled trial. *Ann Surg* 2003; 238:1-5.
16. Thomsen T, Tonnesen H, Moller AM. Effect of preoperative smoking cessation interventions on postoperative complications and smoking cessation. *Br J Surg* 2009; 96:451-461.
17. Walker NM, Morris SA, Cannon LB. The effect of pre-operative counselling on smoking patterns in patients undergoing forefoot surgery. *Foot Ankle Surg* 2009; 15: 86-89.

## **CMM-601: Anterior Cervical Discectomy and Fusion**

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## **CMM-601.1: General Guidelines**

- The determination of medical necessity for the performance of cervical fusion with and without discectomy is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Proof of smoking cessation
  - ◆ Recent (within 6 months) plain X-rays of the cervical spine
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for cervical fusion with and without discectomy include **ANY** of the following:
  - ◆ Acute/unstable traumatic spinal fractures or dislocations with or without neural compression
  - ◆ Central cord syndrome
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ Severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neurocompressive pathology
  - ◆ Epidural hematoma
  - ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis)
  - ◆ Myelopathy
  - ◆ Occipitocervical and/or Atlantoaxial (C1-C2) instability (non-traumatic) due to **ANY** of the following:
    - Rheumatoid arthritis
    - Congenital abnormality of occipitocervical/C1-C2 vertebrae
    - Os odontoideum
  - ◆ Neoplasms of the spine
  - ◆ Primary or metastatic neoplastic disease causing pathologic fracture, cord compression or instability
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated
  - ◆ Flexion-extension plain X-rays demonstrate instability and include **ANY** of the following:
    - >3.5 mm sagittal plane translation
    - >20% sagittal plane translation of vertebral body width
    - >11 degrees relative sagittal plane angulation



## **CMM-601.2: Initial Primary Anterior Cervical Discectomy and Fusion (ACDF)**

Initial primary anterior cervical discectomy and fusion (ACDF) is considered medically necessary when ALL of the following are met:

- Recent (within 6 months) plain X-rays of the cervical spine have been performed
- No previous surgeries on the disc(s) involved with the exception of posterior laminoforaminotomies or laminoplasty in a patient with myelopathy from ventral neurocompression
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity with or without concordant objective physical examination findings resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings
    - Documentation of nicotine-free status with **EITHER** of the following:
      - Patient is a never-smoker
      - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL

- ◆ Myelopathy when **ALL** of the following are met:
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand
  - Recent (within 6 months) MRI/CT findings that are concordant with the patient's symptoms and physical examination findings including **EITHER** of the following:
    - MRI/CT demonstrates cervical spinal cord compression
    - MRI/CT identifies cervical spinal stenosis

### **CMM-601.3: Repeat Anterior Cervical Discectomy and Fusion (ACDF) at the Same Level**

Requests for cervical fusion with a history of two (2) or more cervical fusions requires medical review.

Repeat anterior cervical discectomy and fusion (ACDF) at the same level is considered medically necessary for **ANY** of the following:

- Painful pseudarthrosis documented by confirmatory imaging that is unresponsive to 6 months of non-surgical treatment
- Recent (within 6 months) post-operative plain X-rays of the cervical spine including flexion/extension lateral views with radiographic evidence of implant/structural bone graft malposition or implant/structural bone graft failure
- Performed for **ANY** of the following conditions:
  - ◆ Unremitting neck pain when **ALL** of the following are met:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Greater than 6 months since prior anterior cervical discectomy and fusion (ACDF) procedure at the same level

- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Less than clinically meaningful improvement with **BOTH** of the following unless contraindicated:
  - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
- Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms and/or physical examination findings presenting post-operatively
- Documentation of nicotine-free status including **EITHER** of the following:
  - Patient is a never-smoker
  - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- ◆ Radiculopathy secondary to herniated disc or osteophyte when **ALL** of the following are met:
  - Initial relief of symptoms following previous disc decompression procedure at the same level
  - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
  - Greater than 6 weeks since the initial anterior cervical discectomy/fusion surgery
  - Subjective symptoms including **BOTH** of the following:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
  - Objective physical examination findings including **ANY** of the following:
    - Dermatomal sensory deficit
    - Motor deficit (e.g. biceps, triceps weakness)
    - Reflex changes
    - Shoulder Abduction Relief Sign
    - Nerve root tension sign (e.g. Spurling's maneuver)
    - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
  - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
    - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
    - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks

- Selective nerve root block(s) performed at the same level(s) as the requested ACDF or epidural steroid injection(s)
- Recent (within 6 months) post-operative confirmatory imaging including **EITHER** of the following that is concordant with the patient's symptoms and physical examination findings:
  - MRI /CT confirms evidence of neural structure compression (e.g. either retained disc material or a recurrent disc herniation)
  - CT documenting pseudarthrosis, no less than 6 months after initial fusion
- Documentation of nicotine-free status including **EITHER** of the following:
  - Patient is a never-smoker
  - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- ◆ Myelopathy when **ALL** of the following are met:
  - Initial relief of symptoms following previous disc decompression procedure at the same level
  - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand
  - Recent (within 6 months) post-operative confirmatory MRI/CT findings including **ANY** of the following:
    - MRI /CT confirms evidence of neural structure compression
    - MRI /CT identifies stenosis
    - CT scan documenting pseudarthrosis, no less than 6 months after initial fusion

### **CMM-601.4: Adjacent Segment Disease**

Anterior cervical discectomy and fusion (ACDF) for a degenerative spinal segment adjacent to a previous decompression or fusion procedure is considered **medically necessary** when **ALL** of the following are met:

- Recent (within 6 months) plain X-rays of the cervical spine including flexion/extension lateral views and advanced diagnostic imaging demonstrating successful decompression and/or fusion at the adjacent level
- The prior decompression or fusion procedure at an adjacent level was performed at least 6 months prior.
- No previous surgeries on the disc(s) involved
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms and physical examination findings
    - Documentation of nicotine-free status with **EITHER** of the following:
      - Patient is a never-smoker
      - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL

- ◆ Myelopathy when **ALL** of the following are met:
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand
  - Recent (within 6 months) MRI/CT findings that is concordant with the patient's symptoms or physical examination findings including **EITHER** of the following:
    - MRI/CT demonstrates cervical spinal cord compression
    - MRI/CT identifies cervical spinal stenosis

### **CMM-601.5: Failed Cervical Disc Arthroplasty Implant**

Anterior cervical decompression and fusion following failed cervical disc arthroplasty implant is considered **medically necessary** for **EITHER** of the following:

- Recent (within 6 months) post-operative imaging studies demonstrating failure of a cervical disc arthroplasty implant (i.e. subsidence, loosening, infection, dislocation, subluxation, vertebral body fracture, dislodgement)
- Performed for **ANY** of the following conditions:
  - ◆ Unremitting neck pain when **ALL** of the following are met:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Greater than 6 months since prior since prior cervical disc arthroplasty procedure at the same level
    - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
    - Less than clinically meaningful improvement with prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks unless contraindicated
    - Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms or physical examination findings
    - Documentation of nicotine-free status including **EITHER** of the following:
      - Patient is a never-smoker

- Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- ◆ Radiculopathy when **ALL** of the following are met:
  - Greater than 6 months since the prior cervical disc arthroplasty procedure
  - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
  - Subjective symptoms including **BOTH** of the following:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
  - Objective physical examination findings including **ANY** of the following:
    - Dermatomal sensory deficit
    - Motor deficit (e.g. biceps, triceps weakness)
    - Reflex changes
    - Shoulder Abduction Relief Sign
    - Nerve root tension sign (e.g. Spurling's maneuver)
    - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
  - Less than clinically meaningful improvement with any **TWO** of the following unless contraindicated:
    - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
    - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
    - Epidural steroid injection(s)/selective nerve root block(s)
  - Recent (within 6 months) post-operative MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms or physical examination findings
  - Documentation of nicotine-free status including **EITHER** of the following:
    - Patient is a never-smoker
    - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- ◆ Myelopathy when **ALL** of the following are met:
  - Greater than 6 months since the prior cervical disc arthroplasty procedure
  - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)

- New-onset bowel or bladder dysfunction due to a neurocompressive pathology
- Frequent falls
- Objective physical examination findings including at least **TWO** of the following:
  - Grip and release test
  - Ataxic gait
  - Hyperreflexia
  - Hoffmann sign
  - Pathologic Babinski sign
  - Tandem walking test
  - Inverted brachial radial reflex
  - Increased muscle tone or spasticity
  - Clonus
  - Myelopathic hand
- Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms or physical examination findings including **ANY** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

### **CMM-601.6: Non-Indications**

- Anterior cervical discectomy and fusion (ACDF) is **not medically necessary** for **EITHER** of the following:
  - ◆ Chronic non-specific neck or arm pain of unknown etiology
  - ◆ Cervical degenerative disc disease without radiculopathy or myelopathy



## **CMM-601.7: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

<b>CPT®</b>	<b>Code Description/Definition</b>
<b>22548</b>	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
<b>22551</b>	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2
<b>+22552</b>	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
<b>22554</b>	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
<b>+22585</b>	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
<b>+22840</b>	Posterior non-segmental instrumentation (e.g. Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
<b>+22845</b>	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
<b>+22846</b>	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
<b>+22853</b>	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
<b>+22854</b>	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
<b>+22859</b>	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
<b>63075</b>	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophylectomy; cervical, single interspace
<b>+63076</b>	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophylectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)
<b>63081</b>	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve roots(s); cervical, single segment
<b>+63082</b>	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve roots(s); cervical, single segment; cervical, each additional segment (List separately in addition to code for primary procedure)

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

## CMM-601.8: References

1. Albert TJ, Murrell SE. Surgical management of cervical radiculopathy. *J Am Acad Orthop Surg*. Nov-Dec 1999;7(6):368-376.
2. American Academy of Orthopaedic Surgeons (AAOS). Position statement: The effects of tobacco exposure on the musculoskeletal system.
3. American Academy of Orthopedic Surgeons (AAOS). Surgery and smoking. Last Reviewed Dec 2013.
4. An HS, Simpson HM, Glover JM, et al. Comparison between allograft plus demineralized bone matrix versus autograft in anterior cervical fusion: a prospective multicenter study. *Spine*. 1995; 20(20): 2211-16.
5. Anderson PA, Subach BR, Riw KD. Predictors of outcome after anterior cervical discectomy and fusion: a multivariate analysis. *Spine* 2009; 34: 161-6.
6. Bishop RC, Moore KA, Hadley MN. Anterior cervical interbody fusion using autogeneic and allogeneic bone graft substrate: a prospective comparative analysis. *J Neurosurg* 1996; 85: 206-10.
7. Bohlman HH, Emery SE, Goodfellow DB, et al. Robinson anterior cervical discectomy and arthrodesis for cervical radiculopathy. Long-term followup of one hundred and twenty-two patients. *J Bone Joint Surg Am* 1993; 75: 1298-307.
8. Brown MD, Malinin TI, Davis PB. A roentgenographic evaluation of frozen allografts versus autografts in anterior cervical spine fusions. *Clin Orthop Relat Res* 1976; 119: 231-6.
9. Buttermann, GR. Anterior Cervical Discectomy and Fusion Outcomes over 10 Years. *SPINE* 2018; 43(3): 207-214.
10. Carrier CS, Bono CM, Lebl DR. Evidence-based analysis of adjacent segment degeneration and disease after ACDF: a systematic review. *Spine J* 2013; 13: 1370-8.
11. Cauthen JC, Kinard RE, Vogler JB, et al. Outcome analysis of noninstrumented anterior cervical discectomy and interbody fusion in 348 patients. *Spine* 1998; 23: 188-92.
12. Daniels AH, et al. Adverse events associated with anterior cervical spine surgery. *Journal of the American Academy of Orthopedic Surgeons* 2008;16(12):729-738.
13. Eck JC, Humphreys SC, Hodges SD, et al. A comparison of outcomes of anterior cervical discectomy and fusion in patients with and without radicular symptoms. *J Surg Orthop Adv* 2006; 15: 24-6.
14. Emery SE, Bohlman HH, Bolesta MJ, et al. Anterior cervical decompression and arthrodesis for the treatment of cervical spondylotic myelopathy. Two to seventeen year follow-up. *J Bone Joint Surg Am* 1998; 80: 941-51.
15. Emery SE, Fisher JR, Bohlman HH. Three-level anterior cervical discectomy and fusion: radiographic and clinical results. *Spine* 1997; 22: 2622-4.
16. Epstein NE. Iliac Crest Autograft Versus Alternative Constructs for Anterior Cervical Spine Surgery: Pros, Cons and Costs. *Surg Neurol Int*. 2012; 3(Suppl3): S143-S156
17. Eubanks JD, Thorpe SW, Cheruvu VK, et al. Does smoking influence fusion rates in posterior cervical arthrodesis with lateral mass instrumentation? *Clinical Orthop Relat Res*. 2011; 469(3): 696-701.
18. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine*. 2018;43(15): 1089-94.
19. Floyd T, Ohnmeiss D. A meta-analysis of autograft versus allograft in anterior cervical fusion. *Eur Spine J* 2000; 9: 398-403.
20. Fountas KN, et al. Anterior cervical discectomy and fusion associated complications. *Spine* 2007;32(21):2310-7.
21. Raja M, Garg A, Yadav P, et al. Diagnostic Methods for Detection of Cotinine Level in Tobacco Users: A Review. *J Clin Diagn Res*. 2016 Mar; 10(3): ZE04–ZE06.
22. Garringer SM, Sasso RC. Safety of anterior cervical discectomy and fusion performed as outpatient surgery. *Journal of Spinal Disorders and Techniques* 2010;23(7):439-43.
23. Garvey TA, Transfeldt EE, Malcolm JR, et al. Outcome of anterior cervical discectomy and fusion as perceived by patients treated for dominant axial-mechanical cervical spine pain. *Spine* 2002; 27: 1887-95.
24. Glassman SD, Anagnost SC, Parker A, et al. The effect of cigarette smoking and smoking cessation on spinal fusion. *Spine (Phila Pa 1976)*. 2000;25(20):2608-15.
25. Goffin J, Geusens E, Vantomme N, et al. Long-term follow-up after interbody fusion of the cervical spin. *J Spinal Disord Tech* 2004; 17: 79-85.

26. Gore DR, Sepic SB. Anterior cervical fusion for degenerated or protruded discs. A review of one hundred and forty-six patients. *Spine* 1984; 9: 667-71.
27. Gore DR, Sepic SB. Anterior discectomy and fusion for painful cervical disc disease. A report of 50 patients with an average follow-up of 21 years. *Spine* 1998; 23: 2047-51.
28. Hermansen A, Hedlund R, Vavruch L, et al. A comparison between the carbon fiber cage and the cloward procedure in cervical spine surgery: a ten to thirteen year follow-up of a prospective randomized study. *Spine* 2011; 36: 919-25.
29. Hilibrand AS, Fye MA, Emery SE, et al. Impact of smoking on the outcome of anterior cervical arthrodesis with interbody or strut-grafting. *J Bone Joint Surg Am* 2001; 83-A: 668-73.
30. Hashimoto M, et al. C5 palsy following anterior decompression and spinal fusion for cervical degenerative diseases. *European Spine Journal* 2010;19(10):1702-10.
31. Ishihara H, Kanamori M, Kawaguchi Y, et al. Adjacent segment disease after anterior cervical interbody fusion. *Spine J* 2004; 4: 624-8.
32. Jung A, Schramm J. How to reduce recurrent laryngeal nerve palsy in anterior cervical spine surgery: a prospective observational study. *Neurosurgery* 2010;67(1):10-5; discussion 15.
33. Kalsi-Ryan, S, et al. Ancillary Outcomes Measures for Assessment of Individuals with Cervical Spondylotic Myelopathy. *Spine*, 38 (22S) Supplement 1, October 2013, p.S111-122.
34. Klein GR, Vaccaro AR, Albert TJ. Health outcome assessment before and after anterior cervical discectomy and fusion for radiculopathy: a prospective analysis. *Spine* 2000; 25: 801-3.
35. Kuri M, Nakagawa M, Tanaka H, et al. Determination of the duration of preoperative smoking cessation to improve wound healing after head and neck surgery. *Anesthesiology*. 2005;102(5): 892-96.
36. Kwon B, Kim Dh, Marvin A, et al. Outcomes following anterior cervical discectomy and fusion: the role of interbody disc height, angulation, and spinous process distance. *J Spinal Disord Tech* 2005; 18: 304-8.
37. Lau D, Chou D, Ziewacz JE, et al. The effects of smoking on perioperative outcomes and pseudarthrosis following anterior cervical corpectomy: clinical article. *J Neurosurg Spine*. 2014; 21(4): 547-58.
38. Lawrence BD, Hilibrand AS, Brodt ED, et al. Predicting the risk of adjacent segment pathology in the cervical spine: a systematic review. *Spine* 2012; 37 (22 suppl): S52-64.
39. Lee JC, Lee SH, Peters C, et al. Adjacent segment pathology requiring reoperation after anterior cervical arthrodesis: the influence of smoking, sex and number of operated levels. *Spine* 2015; 40: E571-7.
40. Liu JT, Briner RP, Friedman JA. Comparison of inpatient vs. outpatient anterior cervical discectomy and fusion: a retrospective case series. *BMC Surgery* 2009;9:3.
41. Luszczuk M, Smith JS, Fischgrund JS, et al. Does smoking have an impact on fusion rate in single-level anterior cervical discectomy and fusion with allograft and rigid plate fixation?: clinical article. *J Neurosurg Spine*. 2013; 19(5): 527-31.
42. Malloy KM, Hilibrand AS. Autograft versus allograft in degenerative cervical disease. *Clin Orthop Relat Res* 2002; 394: 27-38.
43. Matsumoto M, Okada E, Ichihara D, et al. Anterior cervical decompression and fusion accelerates adjacent segment degeneration: comparison with asymptomatic volunteers in a ten-year magnetic resonance imaging follow-up study. *Spine* 2010; 35: 36-43.
44. Matz PG, et al. Anterior cervical surgery for the treatment of cervical degenerative myelopathy. *Journal of Neurosurgery: Spine* 2009;11(2):170-3.
45. Matz PG, et al. Indications for anterior cervical decompression for the treatment of cervical degenerative radiculopathy. *Journal of Neurosurgery: Spine* 2009;11(2):174-82.
46. Matz PG, et al. Techniques for anterior cervical decompression for radiculopathy. *Journal of Neurosurgery: Spine* 2009;11(2):183-97.
47. Mills E, Eyawo O, Lockhart I, et al. Smoking cessation reduces postoperative complications: a systematic review and meta-analysis. *Am J Med*. 2011;124(2):144-54.
48. North American Spine Society, Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders, 2014.
49. Palit M, Schofferman J, Goldthwaite N, et al. Anterior discectomy and fusion for the management of neck pain. *Spine* 1999; 24: 2224-8.

50. Papadopoulos EC, Huang RC, Girardi FP, et al. Three-level anterior cervical discectomy and fusion with plate fixation: radiographic and clinical results. *Spine* 2006; 31: 897-902.
51. Patel CK, Fischgrund JS. Complications of anterior cervical spine surgery. *Instr Course Lect.* 2003;52:465-469.
52. Peolsson A, Peolsson M. Predictive factors for long-term outcome of anterior cervical decompression and fusion: a multivariate data analysis. *Eur Spine J* 2008; 17: 406-14.
53. Raaijmakers TH, Gore DR, Tang SJ, et al. Radiographic changes in the cervical spine following anterior arthrodesis: a long term analysis of 166 patients. *J Bone Joint Surg* 2016; 98: 1606-13.
54. Riley LH, Vaccaro AR, Dettori JR, Hashimoto R. Postoperative dysphagia in anterior cervical spine surgery. *Spine* 2010;35(9 Suppl):S76-85.
55. Samartzis D, Shen FH, Lyon C, et al. Does rigid instrumentation increase the fusion rate in on-level anterior cervical discectomy and fusion. *Spine J* 2004; 4: 636-43.
56. Shen FH, Samartzis D, Khanna N, et al. Comparison of clinical and radiographic outcome in instrumented anterior cervical discectomy and fusion with or without direct uncovertebral joint decompression. *Spine J* 2004; 4: 629-35.
57. Sorensen LT. Wound healing and infection in surgery: the pathophysiological impact of smoking, smoking cessation, and nicotine replacement therapy: a systematic review. *Ann Surg.* 2012;255(6): 1069-79.
58. Stieber JR, Brown K, Donald GD, Cohen JD. Anterior cervical decompression and fusion with plate fixation as an outpatient procedure. *Spine Journal* 2005;5(5):503-7.
59. Suchomel P, Barsa P, Buchavald P, et al. Autogenous versus allogenic bone grafts in instrumented anterior cervical discectomy and fusion: A prospective study with respect to bone union pattern. *Eur Spine J* 2004; 13: 510-5.
60. Tetreault, et al. The Practical Application of Clinical Prediction Rules: A Commentary Using Case Examples in Surgical Patients with Degenerative Cervical Myelopathy. *Global Spine Journal.* J 2015;5:457-465.
61. Tumialan LM, Gluf WM. Progressive vertebral body osteolysis after cervicomedial disc arthroplasty. *Spine (Phila Pa 1976).* Jun 15 2011;36(14):E973-978.
62. Van Eck CF, Regan C, Donaldson WF, et al. The revisions rate and occurrence of adjacent segment disease after anterior cervical discectomy and fusion: a study of 672 consecutive patients. *Spine* 2014; 39: 2143-7.
63. Villavicencio AT, Pushchak E, Burneikiene S, Thramann JJ. The safety of instrumented outpatient anterior cervical discectomy and fusion. *Spine Journal* 2007;7(2):148-53.
64. Wang JC, McDonough PW, Endow KK, et al. Increase fusion rates with cervical plating for two-level anterior cervical discectomy and fusion. *Spine* 2000; 25: 41-5.
65. Weinberg D, Chugh AJ, Gebhart JJ, et al. Magnetic resonance imaging of the cervical spine under-represents sagittal plane deformity in degenerative myelopathy patients. *Int J Spine Surg.* 2016;10:32. doi: 10.14444/3032.
66. White AA 3<sup>rd</sup>, Southwick WO, et al. Relief of pain by anterior cervical-spine fusion for spondylosis. A report of sixty-five patients. *J Bone joint Surg Am* 1973; 55: 525-34.
67. Wong J, Lam DP, Abrishami A, et al. Short-term preoperative smoking cessation and postoperative complications: a systematic review and meta-analysis. *Can J Anaesth.* 2012;59(3): 268-79.
68. Yue WM, Brodner W, Highland TR. Long-term results after anterior cervical discectomy and fusion with allograft and plating: a 5 to 11 year radiologic and clinical follow-up study. *Spine* 2005; 30: 2138-44.

**CMM-602: Cervical Total Disc Arthroplasty**

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## **CMM-602.1: General Guidelines**

- The determination of medical necessity for the performance of cervical total disc arthroplasty is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for cervical total disc arthroplasty include **ANY** of the following:
  - ◆ Myelopathy
  - ◆ Central cord syndrome
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ Severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neurocompressive pathology
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

## **CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty**

Initial primary cervical total disc arthroplasty is considered medically necessary when ALL of the following are met:

- The patient has degenerative cervical disc disease with intractable radiculopathy and/or myelopathy, producing symptomatic nerve root and/or spinal cord compression due to herniated disc and/or osteophyte formation.
- The patient is skeletally mature.
- An FDA approved implant is used in accordance with FDA labeling:
  - ◆ **ANY** of the following for single level cervical disc arthroplasty:
    - PRESTIGE ST™ / PRESTIGE LP® / PRESTIGE® Cervical Disc
    - ProDisc®-C
    - BRYAN® Cervical Disc
    - SECURE-C® Cervical Artificial Disc
    - Mobi-C®
    - PCM Cervical Disc
    - M6-C™ Artificial Cervical Disc
  - ◆ **EITHER** of the following for two level cervical disc arthroplasty:
    - Mobi-C®
    - PRESTIGE LP®
- No previous surgeries on the disc(s) involved

- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy.
- The patient is a candidate for single-level or two level anterior cervical decompression(s) and interbody fusion(s)
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Absence of clinically significant cervical instability on neutral resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings
  - ◆ Myelopathy when **ALL** of the following are met:
    - Subjective symptoms including **ANY** of the following:
      - Upper/lower extremity weakness, numbness, or pain
      - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
      - Urinary urgency
      - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
      - Frequent falls

- Objective physical examination findings including at least **TWO** of the following:
  - Grip and release test
  - Ataxic gait
  - Hyperreflexia
  - Hoffmann sign
  - Pathologic Babinski sign
  - Tandem walking test
  - Inverted brachial radial reflex
  - Increased muscle tone or spasticity
  - Clonus
  - Myelopathic hand
- Recent (within 6 months) MRI/CT findings that are concordant with the patient's symptoms and physical examination findings including **EITHER** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

### **CMM-602.3: Failed Cervical Total Disc Arthroplasty Implant**

Revision of a failed cervical total disc arthroplasty is considered medically necessary when the patient is a candidate for single-level or two level anterior cervical decompression(s) and interbody fusion(s) for **EITHER** of the following:

- Recent (within 6 months) post-operative imaging studies of the cervical spine including flexion/extension lateral views demonstrating failure of a cervical disc arthroplasty implant (i.e., subsidence, loosening, dislocation/subluxation, vertebral body fracture without instability, dislodgement)
- Performed for **ANY** of the following conditions:
  - ◆ Unremitting neck pain when **ALL** of the following are met:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Greater than 6 months since prior cervical disc arthroplasty procedure
    - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
    - Less than clinically meaningful improvement with prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks unless contraindicated
    - Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms or physical examination findings
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Greater than 6 months since the prior cervical disc arthroplasty procedure
    - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
    - Subjective symptoms including **BOTH** of the following:



- Significant level of pain on a daily basis defined as **EITHER** of the following:
  - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
  - Severe, disabling, crippling, or incapacitating pain
- Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
- Objective physical examination findings including **ANY** of the following:
  - Dermatomal sensory deficit
  - Motor deficit (e.g. biceps, triceps weakness)
  - Reflex changes
  - Shoulder Abduction Relief Sign
  - Nerve root tension sign (e.g. Spurling's maneuver)
  - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
- Less than clinically meaningful improvement with any **TWO** of the following unless contraindicated:
  - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - Epidural steroid injection(s)/selective nerve root block(s)
- Recent (within 6 months) post-operative MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms or physical examination findings
- ◆ Myelopathy when **ALL** of the following are met:
  - Greater than 6 months since the prior cervical disc arthroplasty procedure
  - Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand

- Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms or physical examination findings including **ANY** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

#### **CMM-602.4: Adjacent Segment Disease Secondary to Cervical Total Disc Arthroplasty**

Cervical total disc arthroplasty for adjacent segment disease secondary to cervical total disc arthroplasty is considered **medically necessary** when **ALL** of the following are met:

- The patient has degenerative cervical disc disease with intractable radiculopathy and/or myelopathy, producing symptomatic nerve root and/or spinal cord compression due to herniated disc and/or osteophyte formation.
- The patient is skeletally mature.
- An FDA approved implant is used in accordance with FDA labeling:
  - ◆ **EITHER** of the following for two level cervical disc arthroplasty:
    - Mobi-C®
    - PRESTIGE LP®
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy
- Recent (within 6 months) imaging studies of the cervical spine including flexion/extension lateral views demonstrating successful cervical total disc arthroplasty at the adjacent level
- The prior total disc arthroplasty procedure at an adjacent level was performed at least 6 months prior.
- No previous surgeries on the disc(s) involved
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)

- Reflex changes
- Shoulder Abduction Relief Sign
- Nerve root tension sign (e.g. Spurling's maneuver)
- Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - Epidural steroid injection(s)/selective nerve root block(s)
- Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms and physical examination findings
- ◆ Myelopathy when **ALL** of the following are met:
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand
  - Recent (within 6 months) MRI/CT findings that is concordant with the patient's symptoms or physical examination findings including **EITHER** of the following:
    - MRI/CT demonstrates cervical spinal cord compression
    - MRI/CT identifies cervical spinal stenosis

### **CMM-602.5: Non-Indications**

- Cervical total disc arthroplasty for degenerative disc disease as the sole indication is considered **not medically necessary**.
- Cervical total disc arthroplasty is considered **experimental, investigational, or unproven** when **ANY** of the following are present:
  - ◆ Patient is under age 18 or over age 60
  - ◆ The patient had prior surgery at the treated level
  - ◆ The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid construct)
  - ◆ The patient had a prior fusion at an adjacent cervical level (hybrid construct)
  - ◆ The planned procedure will lead to cervical total disc arthroplasty at more than two (2) levels
  - ◆ Decreased bone mineral density defined by **ANY** of the following:
    - DEXA bone mineral T-score equal to or worse than -3.5
    - T-score equal to or worse than -2.5 with history of a vertebral compression fracture
    - DEXA bone mineral density T-score  $\leq$  -1.0
  - ◆ Allergy or sensitivity to titanium, aluminum or vanadium
  - ◆ Chronic non-specific neck or arm pain of unknown etiology
  - ◆ Absence of radiculopathy or myelopathy
  - ◆
  - ◆ Active systemic infection
  - ◆ Revision of an infected cervical disc arthroplasty
  - ◆ Rheumatoid arthritis or other autoimmune disease
  - ◆ Paget's disease, osteomalacia or any other metabolic bone disease
  - ◆ Severe poorly controlled diabetes mellitus requiring insulin treatment
  - ◆ There is radiological evidence of **ANY** of the following:
    - Clinically significant cervical instability on neutral resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal of lordosis or spondylolisthesis (e.g. > 3.5 mm sublaxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
    - Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g. ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma)
    - Spinal metastases
    - Severe spondylosis at the level to be treated characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of greater than 50% of its normal height
    - Severe facet joint arthropathy
    - Ossification of the posterior longitudinal ligament (OPLL)

## **CMM-602.6: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

<b>CPT®</b>	<b>Code Description/Definition</b>
<b>22856</b>	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
<b>+22858</b>	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), second level, cervical (List separately in addition to code for primary procedure)
<b>22861</b>	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
<b>22864</b>	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
<b>+0095T</b>	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
<b>+0098T</b>	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

## **CMM-602.7: References**

1. Acosta FL, Ames CP. Cervical Disc Arthroplasty: General Information. *Neurosurg Clin N Am*. 2005; (16): 603-7.
2. Ahrens M, Tsanztrizos A, Donkersloot P, Martens F, Lauweryns P, Le Huec JC, et al. Nucleus replacement with the DASCOR disc arthroplasty device: interim two-year efficacy and safety results from two prospective, non-randomized multicenter European studies. *Spine (Phila Pa 1976)*. 2009 Jun 1;34(13):1376-84.
3. Ament JD, Yang Z, Nunley P, Stone MB, Kim KD. Cost-effectiveness of cervical total disc replacement vs fusion for the treatment of 2-level symptomatic degenerative disc disease. *JAMA Surg*. 2014 Dec; 149(12): 1231-9.
4. American Academy of Orthopaedic Surgeons. Technology Overview. Cervical Disc Arthroplasty. March 2010.
5. Anderson PA, Sasso RC, Riew KD. Comparison of adverse events between the Bryan artificial cervical disc and anterior cervical arthrodesis. *Spine*. 2008 May 20;33(12):1305-12.
6. Auerbach JD, Jones KJ, Fras CI, Balderston JR, Rushton SA, Chin KR. The prevalence of indications and contraindications to cervical total disc replacement. *Spine J*. 2008 Sep-Oct;8(5):711-6.
7. Bao Q-B, Yuan HA. Artificial disc technology. *Neurosurg Focus*. 2000;9(4): Article 14.
8. Barbagallo GM, Assietti R, Corbino L, Olindo G, Foti PV, Russo V, Albanese V. Early results and review of the literature of a novel hybrid surgical technique combining cervical arthrodesis and disc arthroplasty for treating multilevel degenerative disc disease: opposite or complementary techniques? *Eur Spine J*. 2009 Jun;18 Suppl 1:29-39.
9. Bartels RH, Donk R, Verbeek AL. No justification for cervical disk prostheses in clinical practice: a meta-analysis of randomized controlled trials. *Neurosurgery*. 2010 Jun;66(6):1153-60.
10. Bertagnoli R, Duggal N, Pickett GE, Wifgield CC, Gill SS, Karg A, Voigt S. Cervical total disc replacement, part two: clinical results. *Orthop Clin North Am*, 2005;36:355-62.

11. Boselie TF, Willems PC, van Mameren H, de Bie R, Benzel EC, van Santbrink H. Arthroplasty versus fusion in single-level cervical degenerative disc disease. *Cochrane Database Syst Rev.* 2012 Sep 12;9:CD009173. doi: 10.1002/14651858.CD009173.pub2.
12. BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Artificial vertebral disc replacement. TEC Assessment Program June 2007. Vol. 22, No, 2.
13. BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. TEC Assessment Program, November 2007 Vol. 22, No. 12. Republished August 2009, Vol. 24, No. 3. Accessed October 12, 2012.
14. Blumenthal SL, Ohnmeiss DD, Guyer RD, et al. Reoperations in cervical total disc replacement compared with anterior cervical fusion: results compiled from multiple prospective food and drug administration investigational device exemption trials conducted at a single site. *Spine* 2013; 38: 1177-82.
15. Blumenthal SL, Ohnmeiss DD, Guyer RD, Hochschuler SH. Prospective study evaluating total disc replacement: preliminary results. *J Spinal Disord Tech.* 2003 Oct;16(5):450-4.
16. Blumenthal SL, Ohnmeiss DD, Guyer R, Hochschuler S, McAfee P, Garcia R, Salib R, Yuan H, Lee C, Bertagnoli R, Bryan V, Winter R. Artificial intervertebral disks and beyond: a North American Spine Society Annual Meeting Symposium. *Spine Journal: Official Journal of the North American Spine Society.* Nov-Dec 2002;2(6):460-3.
17. Boselie TF, Willems PC, van Mameren H, de Bie R, Benzel EC, van Santbrink H. Arthroplasty versus fusion in single-level cervical degenerative disc disease. *Cochrane Database Syst Rev.* 2012 Sep 12;9:CD009173.
18. Boswell MV, Shah RV, Everett CR, et al. Interventional techniques in the management of chronic spinal pain: evidence-based practice guidelines. *Pain Phys* 2005;8:1-47.
19. Bryan VE. Cervical motion segment replacement. *Eur Spine J.* 2002 Oct;11 Suppl 2:S92-7. Epub 2002 Sep 12.
20. Burkus JK, Haid RW, Traynelis VC, Mummaneni PV. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. *J Neurosurg Spine.* 2010 Sep;13(3):308-18.
21. California Technology Assessment Forum (CTAF). Artificial disc replacement for degenerative disc disease of the cervical spine. Updated Oct 2009.
22. Cepoiu-Martin M, Faris P, Lorenzetti D, Prefontaine E, Noseworthy T, Sutherland L. Artificial cervical disc arthroplasty: a systematic review. *Spine (Phila Pa 1976).* 2011 Dec 1;36(25):E1623-33.
23. Chen J, Fan SW, Wang XW, Yuan W. Motion analysis of single-level cervical total disc arthroplasty: a meta-analysis. *Orthop Surg.* 2012 May;4(2):94-100.
24. Cheng L, Nie L, Hou Y. Fusion versus Bryan cervical disc in two-level cervical disc disease: a prospective, randomized study. *Int Orthop.* 2009 Oct;33(5):1347-51.
25. Coric D, Cassis J, Carew JD, Boltes MO. Prospective study of cervical arthroplasty in 98 patients involved in 1 of 3 separate investigational device exemption studies from a single investigational site with a minimum 2-year follow-up. *Clinical article. J Neurosurg Spine.* 2010 Dec;13(6):715-21.
26. Coric D, Nunley PD, Guyer RD, Musante D, Carmody CN, Gordon CR, Laurysen C, Ohnmeiss DD, Boltes MO. Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex|C artificial disc investigational device exemption study with a minimum 2-year follow-up: *clinical article. Neurosurg Spine.* 2011 Oct;15(4):348-58.
27. Cunningham MR, Hershman S, Bendo J. Systematic review of cohort studies comparing surgical treatments for cervical spondylotic myelopathy. *Spine* 2010;35(5):537-43.
28. Davis RJ, Nunley PD, Kim KD, et al. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. *J Neurosurg Spine.* 2015; 22(1):15-25.
29. Davis RJ, Kim KD, Hisey MS, et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial: *clinical article. J Neurosurg Spine.* 2013; 19(5):532-545. Delamarter RB, Bae HW, Pradhan BB. Clinical results of ProDisc-II lumbar total disc replacement: report from the United States Clinical Trial. *Orthop Clin N Am.* 2005;36:301-13.

30. Delamarter RB, Murrey D, Janssen ME, et al. Results at 24 months form the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. *SAS Journal* 4 (2010):122-128.
31. Delamarter R, Zigler JE, Balderston RA, Cammisa FP, Goldstein JA, Spivak JM. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. *J Bone Joint Surg Am*. 2011 Apr 20;93(8):705-15. Epub 2011 Mar 11.
32. Ding C, Hong Y, Liu H, Shi R, Hu T, Li T. Intermediate clinical outcome of Bryan Cervical Disc replacement for degenerative disk disease and its effect on adjacent segment disks. *Orthopedics*. 2012 Jun;35(6):e909-16.
33. Durbhakula MM, Ghiselli G. Cervical Total Disc Replacement, Part I: Rationale, Biomechanics, and Implant Types. *Orthop Clin North Am*. 2005 Jul;36(3):349-54.
34. ECRI Institute. Artificial intervertebral disc replacement (AIDR) for lumbar degenerative disc disease (DDD). Emerging Technology Evidence Report. Plymouth Meeting (PA): ECRI Institute; 2009a October 14.
35. ECRI Institute. Artificial intervertebral disc replacement for symptomatic cervical disc disease. Emerging Technology Evidence Report. Plymouth Meeting (PA): ECRI Institute; June 5, 2009b.
36. ECRI Institute. Artificial intervertebral disc replacement for cervical disc disease. Evidence report. September 2012. Plymouth Meeting (PA): ECRI Institute; September 2012.
37. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine*. 2018;43(15): 1089-94.
38. FDA Summary of Safety and Effectiveness Data Artificial Cervical Disc. M6-C™ Artificial Cervical Disc.
39. Food and Drug Administration (FDA). Prestige® LP Cervical Disc.
40. Fekete TF, Porchet F. Overview of disc arthroplasty-past, present and future. *Acta Neurochir (Wien)*. 2010 Mar;152(3):393-404.
41. Gandhi AA, Kode S, DeVries NA, Grosland NM, Smucker JD, Fredericks DC. Biomechanical Analysis of Cervical Disc Replacement and Fusion Using Single Level, Two Level and Hybrid Constructs. *Spine* 2015 Oct; 15 (40): 1578-85. doi:10.1097/BRS. 0000000000001044.
42. Garrido BJ, Taha TA, Sasso RC. Clinical outcomes of Bryan cervical disc arthroplasty a prospective, randomized, controlled, single site trial with 48-month follow-up. *J Spinal Disord Tech*. 2010 Aug;23(6):367-71.
43. Goffin J, van Loon J, Van Calenbergh F, Lipscomb B. A clinical analysis of 4- and 6-year follow-up results after cervical disc replacement surgery using the Bryan Cervical Disc Prosthesis. *J Neurosurg Spine*. 2010 Mar;12(3):261-9.
44. Gornet MF, Schranck FW, Copay AG, Kopjar B. The Effect of Workers' Compensation Status on Outcomes of Cervical Disc Arthroplasty. *J Bone Joint Surg Am*. 2016; 98:93-9
45. Grob D, Porchet F, Kleinstück FS, Lattig F, Jeszenszky D, Luca A, Mutter U, Mannion AF. A comparison of outcomes of cervical disc arthroplasty and fusion in everyday clinical practice: surgical and methodological aspects. *Eur Spine J*. 2010 Feb;19(2):297-306.
46. Heidecke V, Burkert W, Brucke M, Rainov NG. Intervertebral disc replacement for cervical degenerative disease--clinical results and functional outcome at two years in patients implanted with the Bryan cervical disc prosthesis. *Acta Neurochir (Wien)*. 2008 May;150(5):453-9; discussion 459. Epub 2008 Apr 20.
47. Heller JG, Sasso RC, Papadopoulos SM, Anderson PA, Fessler RG, Hacker RJ, Coric D, Cauthen JC, Riew DK. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. *Spine (Phila Pa 1976)*. 2009 Jan 15;34(2):101-7.
48. Huang RC, Girardi FP, Lim MR, Cammisa FP. Advantages and disadvantages of nonfusion technology in spine surgery. *Orthop Clin N Am*. 2005;36:263-9.
49. Huppert J, Beaurain J, Steib JP, Bernard P, Dufour T, Hovorka I, Stecken J, Dam-Hieu P, Fuentes JM, Vital JM, Vila T, Aubourg L. Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement. *Eur Spine J*. 2011 Sep;20(9):1417-26. Epub 2011 Feb 20.

50. International Society for the Advancement of Spine Surgery (ISASS). Position Statement: Cervical Total Disc Arthroplasty. Approved October 2009.
51. Jackson RJ<sup>1</sup>, et al. Subsequent surgery rates after cervical total disc replacement using a Mobi-C Cervical Disc Prosthesis versus anterior cervical discectomy and fusion: a prospective randomized clinical trial with 5-year follow-up. *J Neurosurg Spine*. 2016 Jan 22;1-12.
52. Janssen ME, Zigler JE, Spivak JM, et al. ProDisc-C total disc replacement versus anterior cervical discectomy and fusion for single-level symptomatic cervical disc disease: seven-year follow-up of the prospective randomized U. S. Food and Drug Administration investigational device exemption study. *J Bone Joint Surg Am* 2015; 97: 1738-47.
53. Jawahar A, Cavanaugh DA, Kerr EJ 3rd, Birdsong EM, Nunley PD. Total disc arthroplasty does not affect the incidence of adjacent segment degeneration in cervical spine: results of 93 patients in three prospective randomized clinical trials. *Spine J*. 2010 Dec;10(12):1043-8. Epub 2010 Sep 24.
54. Kalsi-Ryan, S, et al. Ancillary Outcomes Measures for Assessment of Individuals with Cervical Spondylotic Myelopathy. *Spine*, 38 (22S) Supplement 1, October 2013, p.S111-122.
55. Kim SW, Limson MA, Kim SB, Arbatin JJ, Chang KY, Park MS, Shin JH, Ju YS. Comparison of radiographic changes after ACDF versus Bryan disc arthroplasty in single and bi-level cases. *Eur Spine J*. 2009 Feb;18(2):218-31.
56. Kostuik JP. Intervertebral disk replacement. Experimental study. *Clinical Orthopaedics & Related Research*. 1997 Apr;337:27-41.
57. Kurtz SM, Pelozo J, Siskey R, Villarraga ML. Analysis of a retrieved polyethylene total disc replacement component. *Spine J*. 2005 May-Jun;5(3):344-50.
58. Kurtz SM, van Ooij A, Ross R, Malefit JdW, Pelozo J, Ciccarelli L, Villarraga ML. Polyethylene wear and rim fracture in total disc arthroplasty. *Spine J*. 2007;7:12-21.
59. Lafuente J, Casey ATH, Petzold A, Brew S. The Bryan cervical disc prosthesis as an alternative to arthrodesis in the treatment of cervical spondylosis. *J Bone Join Surg [Br]*. 2005;87(B):508-12.
60. Martin CW and the Work Comp Board (WCB) Evidence Based Practice Group. Artificial cervical and lumbar disc implants: a review of the literature. Apr 2005. .
61. McAfee PC, Reah C, Gilder K, Eisermann L, Cunningham B. A Meta-Analysis of Comparative Outcomes Following Cervical Arthroplasty or Anterior Cervical Fusion: Results from Four Prospective Multi-center Randomized Clinical Trials and up to 1226 Patients. *Spine (Phila Pa 1976)*. 2011 Oct 27.
62. Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick TA. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine*. 2007;6:198-209.
63. Murrey D, Janssen M, Delamarter R, Goldstein J, Zigler J, Tay B, Darden B. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J*. 2009 Apr;9(4):275-86.
64. Nabhan A, Ahlhelm F, Shariat K, Pitzen T, Steimer O, Steudel W-I, Pape D. The ProDisc-C Prosthesis: Clinical and radiological experience 1 year after surgery. *Spine* 2007;32(18):1935-41.
65. National Institutes for Health and Clinical Excellence (NICE). Prosthetic intervertebral disc replacement in the cervical spine. *Interventional Procedure Guidance* 341. May 2010.
66. National Institutes for Health and Clinical Excellence (NICE). *Interventional Procedure Guidance* 306. Prosthetic intervertebral disc replacement in the lumbar spine. Revised July 2009.
67. North American Spine Society (NASS) Coverage Policy Recommendations. Cervical Artificial Disc Replacement. 2014.
68. Nunley PD, Jawahar A, Kerr EJ 3rd, Gordon CJ, Cavanaugh DA, Birdsong EM, Stocks M, Danielson G. Factors affecting the incidence of symptomatic adjacent-level disease in cervical spine after total disc arthroplasty: 2- to 4-year follow-up of 3 prospective randomized trials. *Spine (Phila Pa 1976)*. 2012 Mar 15;37(6):445-51.
69. Ontario Health Technology Assessment Committee (OHTAC). OHTAC Recommendation: Updated Health Technology Policy Assessment (HPTA) on Artificial Disc Replacement for Lumbar and Cervical Degenerative Disc Disease. Updated Apr 2006. *Ont Health Technol Assess Ser*. 2006;6(10):1-98
70. Papadopoulos S. The Bryan Cervical Disc System. *Neurosurg Clin N Am*. 2005;16:629-36.
71. Peng-Fei A, Yu-Hua J. Cervical disc prosthesis replacement and interbody fusion—a comparative study. *Int Orthop*. 2006 Dec 16.



72. Peng-Fei S, Yu-Hua J. Cervical disc prosthesis replacement and interbody fusion: a comparative study. *Int Orthop*. 2008 Feb;32(1):103-6. Epub 2006 Dec 16.
73. Phillips FM, Garfin SR. Cervical Disc Replacement. *Spine*. 2005;30(17S):S27-33.
74. Phillips FM, Tzermiadianos MN, Voronov LI, Havey RM, Carandang G, Dooris A, et al. Effect of two-level total disc replacement on cervical spine kinematics. *Spine (Phila Pa 1976)*. 2009 Oct 15;34(22):E794-9.
75. Pickett GE, Rouleau JP, Duggal N. Kinematic Analysis of the Cervical Spine Following Implantation of an Artificial Cervical Disc. *Spine*. 2005;30(17):1949-54.
76. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus*. 2004;17(3): 36-43.
77. Pracyk JB, Traynelis VC. Treatment of the Painful Motion Segment: Cervical Arthroplasty. *Spine*. 2005;30(16S):S23-S32.
78. Quan GM, Vital JM, Hansen S, Pointillart V. Eight-year clinical and radiological follow-up of the Bryan cervical disc arthroplasty. *Spine (Phila Pa 1976)*. 2011 Apr 15;36(8):639-46.
79. Ren X, Wang W, Chu T, Wang J, Li C, Jiang T. The intermediate clinical outcome and its limitations of Bryan cervical arthroplasty for treatment of cervical disc herniation. *J Spinal Disord Tech*. 2011 Jun;24(4):221-9.
80. Riina J, Patel A, Dietz JW, Hoskins JS, Trammell TR, Schwartz DD. Comparison of single-level cervical fusion and a metal-on-metal cervical disc replacement device. *Am J Orthop*. 2008 Apr;37(4):E71-7.
81. Rihn JA, Harrod C, Albert TJ. Revision cervical spine surgery. *Orthopedic Clinics of North America* 2012;43(1):123-36
82. Robertson JT, Metcalf NH. Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study. *Neurosurg Focus*. 2004;17(3):69-71.
83. Robertson JT, Papadopoulos SM, Traynelis VC. Assessment of adjacent-segment disease in patients treated with cervical fusion or arthroplasty: a prospective 2-year study. *J Neurosurg Spine*. 2005;(3):417-23.
84. Ryu KS, Park CK, Jun SC, Huh HY. Radiological changes of the operated and adjacent segments following cervical arthroplasty after a minimum 24-month follow-up: comparison between the Bryan and Prodisc-C devices. *J Neurosurg Spine*. 2010 Sep;13(3):299-307.
85. Salari B, McAfee PC. Cervical total disk replacement: complications and avoidance. *Orthop Clin North Am*. Jan 2012;43(1):97-107, ix.
86. Sasso RC, Anderson PA, Riew KD, Heller JG. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *J Bone Joint Surg Am*. 2011 Sep 21;93(18):1684-92.
87. Sasso RC, Best NM. Cervical kinematics after fusion and BRYAN disc arthroplasty. *J Spinal Disord Tech*. 2008b Feb;21(1):19-22.
88. Sasso RC, Best NM, Metcalf NH, Anderson PA. Motion analysis of BRYAN cervical disc arthroplasty versus anterior discectomy and fusion: results from a prospective, randomized, multicenter, clinical trial. *J Spinal Disord Tech*. 2008a Aug;21(6):393-9.
89. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. *Spine*. 2007b Dec 15;32(26):2933-40; discussion 2941-2.
90. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Clinical Outcomes of BRYAN Cervical Disc Arthroplasty: A Prospective, Randomized, Controlled, Multicenter Trial With 24-month Follow-up. *J Spinal Disord Tech*. 2007a;20:481-91.
91. Schuessmann E, Aghayev E, Staub L, Moulin P, Zweig T, Röder C; SWISSspine Registry Group. SWISSspine: the case of a governmentally required HTA-registry for total disc arthroplasty: results of cervical disc prostheses. *Spine (Phila Pa 1976)*. 2010 Nov 15;35(24):E1397-405.
92. Sekhon LHS, Duggal N, Lynch JJ, Haid RW, Heller JG, Riew KD, et al. Magnetic Resonance Imaging Clarity of the Bryan®, Prodisc-C®, Prestige LP®, and PCM® Cervical Arthroplasty Devices.
93. Sharan AD, Goldstein JA. Cervical artificial disc replacement technologies. Updated Aug 2015.
94. Shim DA, Yi S, Yoon DH, Him KN, Shin HC. Artificial disc replacement combined with fusion versus two-level fusion in cervical two-Level disc disease. *Spine* 2009 May; 34 (11): 1153-9
95. Shim CS, Lee S-H, Shin H-- Versus ProDisc: A Comparative Study of a Minimum 3-Year Follow-up. *Spine*. 2007;32(9):1012-8.

96. Shriver MF, Lubelski D, Sharma AM, Stenimetz MP, Benzel EC, Mroz TE. Adjacent segment degeneration and disease following cervical arthroplasty: a systematic review and meta-analysis. *Spine J.* 2016 Feb; 16(2): 168-81.
97. Traynelis VC and Treharne RW. Use of the Prestige® LP Artificial Cervical Disc in the spine. *Expert Rev Med Devices.* 2007;4(4):437-40.
98. Upadhyaya CD, Wu JC, Trost G, Haid RW, Traynelis VC, Tay B, Coric D, Mummaneni PV. Analysis of the three United States Food and Drug Administration investigational device exemption cervical arthroplasty trials. *J Neurosurg Spine.* 2012 Mar;16(3):216-28. Epub 2011 Dec 23.
99. Uschold TD, Fusco D, Germain R, Tumialan LM, Chang SW. Cervical and Lumbar Spinal Arthroplasty: Clinical Review. *AJNR Am J Neuroradiol.* 2011 Oct 27. [Epub ahead of print].
100. U.S. Food and Drug Administration. Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. Nov 2002. Updated Nov 2002.
101. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). New Device Approval. ProDisc™ -C Total Disc Replacement – P070001/S001. Issued December 17, 2007.
102. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). New Device Approval. Charite™ Artificial Disc- P040006. Issued October 26, 2004. Updated March 9, 2005.
103. Walraevens J, Demaerel P, Suetens P, Van Calenbergh F, van Loon J, Vander Sloten J, Goffin J. Longitudinal prospective long-term radiographic follow-up after treatment of single-level cervical disk disease with the Bryan Cervical Disc. *Neurosurgery.* 2010 Sep;67(3):679-87; discussion 687.
104. Wang G. Health Technology Assessment: Artificial Disc Replacement. Washington State Department of Labor and Industries. Updated Nov 2004.
105. Weinberg D, Chugh AJ, Gebhart JJ, et al. Magnetic resonance imaging of the cervical spine under-represents sagittal plane deformity in degenerative myelopathy patients. *Int J Spine Surg.* 2016;10:32.doi: 10.14444/3032.
106. Willems PC, Elmans L, Anderson PG, van der Schaaf DB, de Kleuver M. Provocative Discography and Lumbar Fusion. *Spine.* 2007;32(10):1094-99Wu JC, Huang WC, Tsai TY, Fay LY, Ko CC, Tu TH, Wu CL, Cheng H. Multilevel Arthroplasty for Cervical Spondylosis: More Heterotopic Ossification at 3 Years of Follow-up. *Spine (Phila Pa 1976).* 2012 Sep 15;37(20):E1251-E1259.
107. Yajun W, Yue Z, Xiuxin H, Cui C. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease. *Eur Spine J.* 2010 Aug;19(8):1250-61. Epub 2010 Apr 4.
108. Yang YC, Nie L, Cheng L, Hou Y. Clinical and radiographic reports following cervical arthroplasty: a 24-month follow-up. *Int Orthop.* 2009 Aug;33(4):1037-42.
109. Yang S, Wu X, Hu Y, Li J, Liu G, Xu W, Yang C, Ye S. Early and intermediate follow-up results after treatment of degenerative disc disease with the Bryan cervical disc prosthesis: single- and multiple-level. *Spine.* 2008 May 20;33(12):E371-7.
110. Yang B, Li H, Zhang T, He X, Xu S. The incidence of adjacent segment degeneration after cervical disc arthroplasty (CDA): a meta analysis of randomized controlled trials. *PLoS One.* 2012;7(4):e35032.
111. Yi S, Kim KN, Yang MS, Yang JW, Kim H, Ha Y, Yoon do H, Shin HC. Difference in occurrence of heterotopic ossification according to prosthesis type in the cervical artificial disc replacement. *Spine (Phila Pa 1976).* 2010 Jul 15;35(16):1556-61.
112. Yi S, Lee DY, Ahn PG, Kim KN, Yoon do H, Shin HC. Radiologically documented adjacent-segment degeneration after cervical arthroplasty: characteristics and review of cases. *Surg Neurol.* 2009 Oct;72(4):325-9; discussion 329.
113. Zhao YB, Sun Y, Chen ZQ, Liu ZJ. Application of cervical arthroplasty with Bryan cervical disc: long-term X-ray and magnetic resonance imaging follow-up results. *Chin Med J (Engl).* 2010 Nov;123(21):2999-3002.
114. Zeller JL. Artificial spinal disk superior to fusion for treating degenerative disk disease. *JAMA.* 2006;296(22):2665-6.
115. Zhang X, Zhang X, Chen C, Zhang Y, Wang Z, Wang B, Yan W, Li M, Yuan W, Wang Y. Randomized, Controlled, Multicenter, Clinical Trial Comparing BRYAN Cervical Disc Arthroplasty with Anterior Cervical Decompression and Fusion in China. *Spine (Phila Pa 1976).* 2011 Jun 13.

116. Zigler JE, Delamarter R, Murrey D, Spivak J, Janssen M. ProDisc-C and ACDF as Surgical Treatment for Single Level Cervical Symptomatic Degenerative Disc Disease: Five-Year Results of an FDA Study. *Spine (Phila Pa 1976)*. 2012 Oct 17. [Epub ahead of print]
117. Zigler JE. Clinical results with ProDisc: European experience and U.S. Investigation Device Exemption Study. *Spine*. 2003;28(20S):S163-6.
118. Zindrick M, Harris MB, Humphreys SC, et.al. Cervical disc arthroplasty. *J Am Acad Orthop Surg*. Oct 2010;18(10):631-637.

## **CMM-603: Electrical and Low Frequency Ultrasound Bone Growth Stimulation (Spine)**

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### **CMM-603.1: General Guidelines**

- The determination of medical necessity for the performance of electrical bone growth stimulation is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.

### **CMM-603.2: Indications**

- Invasive (inserted at the time of surgery) or noninvasive (beginning at any time from the time of surgery until up to 6 months after surgery with the exception of this timeline for an urgent/emergent condition for spinal fusion surgery excluding primary or metastatic neoplastic disease) electrical bone growth stimulation may be considered **medically necessary** for spinal fusion surgery in patients at high risk for pseudarthrosis with **ONE or MORE** of the following risk factors for fusion failure when associated with an approved spinal fusion surgery:
  - ◆ Alcoholism
  - ◆ Body mass index (BMI) > 30
  - ◆ Diabetes, renal disease, or other metabolic diseases when bone healing is likely to be compromised
  - ◆ Glucocorticoid dependent
  - ◆ Grade III or worse lumbar/lumbosacral spondylolisthesis
  - ◆ Multi-level spinal fusion including three (3) or more vertebrae
  - ◆ Nutritional deficiency/malnutrition
  - ◆ One or more previously failed spinal fusion(s)
  - ◆ Osteoporosis defined as T-score of  $\leq -2.5$  on a recent (within one year) DEXA
  - ◆ Severe anemia
  - ◆ Smoking history
  - ◆ Immunocompromised status
- Noninvasive electrical bone growth stimulation is considered **medically necessary** as a treatment for patients with failed spinal fusion when **BOTH** of the following are met:
  - ◆ A minimum of 6 months has passed since the date of the original surgery
  - ◆ Serial plain X-rays or appropriate imaging studies confirm there is no evidence of progression of healing/consolidation of the spinal fusion for 3 months during the later portion of the 6 month post-fusion surgery period.
- Urgent/emergent conditions for spine fusion surgery are exceptions to the above timelines for invasive and noninvasive electrical bone growth stimulation excluding primary or metastatic neoplastic disease (See: CMM 601.1, 604.1, and 609.1)

### **CMM-603.3: Non-Indications**

- Invasive and noninvasive electrical bone growth stimulation is considered **experimental, investigational, or unproven** for **ALL** of the following:
  - ◆ Acute or chronic lumbar spondylolysis (pars interarticularis defect) with or without spondylolisthesis
  - ◆ Failed cervical or lumbar disc arthroplasty
  - ◆ Spinal malignancy
  - ◆ As nonsurgical treatment of an established pseudarthrosis
- Semi-invasive electrical bone growth stimulation and low-intensity ultrasound stimulation is considered **experimental, investigational, or unproven** for any spinal indication due to a lack of sufficient evidence of their effectiveness.

### **CMM-603.4: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

<b>CPT®</b>	<b>Code Description/Definition</b>
<b>20974</b>	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
<b>20975</b>	Electrical stimulation to aid bone healing; invasive (operative)
<b>20979</b>	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
<b>HCPCS Codes</b>	<b>Code Description/Definition</b>
<b>E0748</b>	Osteogenesis stimulator; electrical, noninvasive, spinal applications
<b>E0749</b>	Osteogenesis stimulator; electrical, surgically implanted
<b>E0760</b>	Osteogenesis stimulator; low intensity ultrasound, non-invasive

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

### **CMM-603.5: References**

1. Centers for Medicare and Medicaid Services (CMS). NCD for Osteogenic Stimulators, Manual Section Number 150.2.
2. EBI Medical. Implantable Spinal Fusion Stimulator.
3. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2007, Jan 29. Electrical bone growth stimulation to enhance cervical vertebrae fusion.
4. Foley KT, Mroz TE, Arnold PM et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J* 2008; 8(3):436-42
5. Hotta S. Electrical bone-growth stimulation and spinal fusion. Health technology assessment review No. 8. 1998. Agency for Health Care Policy and Research (AHCPR) Pub No. 94-0014.
6. Kaiser MG, Eck JC, Groff MW, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: Bone growth stimulators as an adjunct for lumbar fusion. *J Neurosurg Spine*. 2014;21(1):133-139.
7. Mooney V., A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields on interbody lumbar fusions. *Spine*. 1990; 15(7): 708-712.
8. Orthofix. Bone growth stimulators. Spinal Stim.
9. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg Spine*. 2005 Jun;2(6):737-40.
10. Simmons, JW Jr., Mooney, V, Thacker, I. Pseudarthrosis After Lumbar Spine Fusion: Nonoperative Salvage With Pulsed Electromagnetic Fields. *American Journal of Orthopaedics*. 2004 Jun: 27-30.
11. Stasinopoulos D. Treatment of spondylolysis with external electrical stimulation in young athletes: a critical literature review. *Br J Sports Med*. 2004 Jun;38(3):352-4.
12. Washington State Health Care Authority. Health Technology Assessment, Bone Growth Stimulators. July 2009.

## **CMM-604: Posterior Cervical Decompression (Laminectomy/Hemilaminectomy/ Laminoplasty) with or without Fusion**

<b>CMM-604.1: General Guidelines</b>	<b>41</b>
<b>CMM-604.2: Initial Primary Posterior Cervical Decompression (Laminectomy/Hemilaminectomy/Laminoplasty) with or without Posterior Fusion</b>	<b>42</b>
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## **CMM-604.1: General Guidelines**

- The determination of medical necessity for the performance of posterior cervical decompression with or without fusion is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Proof of smoking cessation
  - ◆ Recent (within 6 months) plain X-rays of the cervical spine
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for posterior cervical decompression with or without fusion include **ANY** of the following:
  - ◆ Acute/unstable traumatic spinal fractures or dislocations with or without neural compression
  - ◆ Central cord syndrome
  - ◆ Congenital cervical stenosis (AP canal diameter  $\leq$  10 mm)
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ Epidural hematoma
  - ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis)
  - ◆ Myelopathy
  - ◆ Occipitocervical and/or Atlantoaxial (C1-C2) instability (non-traumatic) and/or spinal cord compression due to **ANY** of the following:
    - Rheumatoid arthritis
    - Congenital abnormality of occipitocervical/C1-C2 vertebrae
    - Os odontoideum
  - ◆ Ossification of the posterior longitudinal ligament at three (3) or more levels
  - ◆ Primary or metastatic neoplastic disease causing pathologic fracture, cord compression or instability
  - ◆ Severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neurocompressive pathology
  - ◆ Vascular malformations (e.g. AVM)
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated
- Urgent/emergent conditions for posterior cervical fusion without decompression include:
  - ◆ Flexion-extension plain X-rays demonstrate instability and include **ANY** of the following:
    - $>3.5$  mm sagittal plane translation
    - $>20\%$  sagittal plane translation of vertebral body width
    - $>11$  degrees relative sagittal plane angulation

## **CMM-604.2: Initial Primary Posterior Cervical Decompression (Laminectomy/Hemilaminectomy/Laminoplasty) with or without Posterior Fusion**

Initial primary posterior cervical decompression (laminectomy/hemilaminectomy/laminoplasty) with or without posterior fusion is considered medically necessary when ALL of the following are met:

- Recent (within 6 months) plain X-rays of the cervical spine including flexion/extension lateral views have been performed
- No previous surgeries on the disc(s) involved
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **ANY** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings
    - Documentation of nicotine-free status with **EITHER** of the following, unless request is for decompression only:
      - Patient is a never-smoker

- Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- ◆ Myelopathy when **ALL** of the following are met:
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand
  - Recent (within 6 months) MRI/CT findings that are concordant with the patient's symptoms and physical examination findings including **EITHER** of the following:
    - MRI/CT demonstrates cervical spinal cord compression
    - MRI/CT identifies cervical spinal stenosis
- ◆ A concurrent stabilization procedure with corpectomy, laminectomy, or other procedure at the cervicothoracic junction (i.e., C7 and T1)
- ◆ A concurrent stabilization procedure with a laminectomy, especially at C2
- ◆ Subluxation and/or spinal cord compression in patients with rheumatoid arthritis or clinical conditions with an increased incidence of congenital and/or acquired cervical spinal instability (e.g. Down syndrome, mucopolysaccharidoses, spondyloepiphyseal dysplasia, pseudoachondroplasia, etc.)
- ◆ Multi-level spondylotic myelopathy without kyphosis
- ◆ Primary or metastatic tumor with associated cord compression and/or instability
- ◆ Other symptomatic instability or spinal cord/root compression requiring posterior fusion with **BOTH** of the following:
  - Patient unresponsive to a reasonable and medically appropriate course of conservative treatment (e.g. rest, medication, cervical collar)
  - Recent (within 6 months) imaging study demonstrating corresponding pathologic anatomy

### **CMM-604.3: Posterior Cervical Fusion without Decompression**

Posterior cervical fusion without decompression is considered medically necessary when ALL of the following criteria are met:

- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **ONE or MORE** of the following:
  - ◆ Symptomatic pseudarthrosis from a prior anterior or posterior fusion procedure
  - ◆ Symptomatic cervical spondylosis with instability as evidenced radiographically by **ONE or MORE** of the following:
    - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic flexion/extension lateral plain X-rays
    - Sagittal plane angulation of more than 11 degrees between adjacent spinal segments
    - More than 4 mm of motion (subluxation) between the tips of the spinous processes on flexion/extension lateral plain X-rays
  - ◆ Klippel-Feil syndrome
  - ◆ Cervical instability in patients with Down syndrome, skeletal dysplasia, or connective tissue disorders
- Documentation of nicotine-free status with **EITHER** of the following:
  - ◆ Patient is a never-smoker
  - ◆ Patient has refrained from smoking, use of tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL

### **CMM-604.4: Repeat Posterior Cervical Decompression with or without Posterior Cervical Fusion at the Same Level**

Repeat posterior cervical decompression with or without posterior cervical fusion at the same level is considered medically necessary when there is recent (within 6 months) post-operative plain X-rays or CT evidence of implant/instrumentation or structural bone graft malposition or failure OR when ALL of the following criteria are met:

- Recent (within 6 months) post-operative MRI /CT confirms evidence of neural structure compression e.g.
- Greater than 12 weeks since last posterior cervical decompression with or without fusion surgery
- Initial relief of symptoms following previous posterior cervical decompression procedure at same level
- Recent (within 6 months) post-operative plain X-rays of the cervical spine including flexion/extension lateral views instability as evidenced by **ONE or MORE** of the following:
  - ◆ Subluxation or translation of more than 3.5 mm on static lateral views or dynamic flexion/extension lateral plain X-rays

- ◆ Sagittal plane angulation of more than 11 degrees between adjacent spinal segments
- ◆ More than 4 mm of motion (subluxation) between the tips of the spinous processes on flexion/extension lateral plain X-rays
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) post-operative MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings
    - Documentation of nicotine-free status with **EITHER** of the following, unless request is for decompression only:
      - Patient is a never-smoker
      - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
  - ◆ Myelopathy when **ALL** of the following are met:
    - Subjective symptoms including **ANY** of the following:
      - Upper/lower extremity weakness, numbness, or pain
      - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
      - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
      - Frequent falls

- Objective physical examination findings including at least **TWO** of the following:
  - Grip and release test
  - Ataxic gait
  - Hyperreflexia
  - Hoffmann sign
  - Pathologic Babinski sign
  - Tandem walking test
  - Inverted brachial radial reflex
  - Increased muscle tone or spasticity
  - Clonus
  - Myelopathic hand
- Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms and physical examination findings including **EITHER** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

### **CMM-604.5: Failed Cervical Disc Arthroplasty Implant**

Posterior cervical decompression with or without posterior cervical fusion following failed cervical disc arthroplasty implant is considered medically necessary when there is a failed cervical disc arthroplasty implant diagnosed by recent (within 6 months) post-operative plain film, CT and/or CT myelogram (i.e., subsidence, loosening, infection, dislocation/subluxation, vertebral body fracture, dislodgement)

OR when ALL of the following criteria are met:

- Recent (within 6 months) post-operative MRI/CT findings that correlate with the patient's symptoms or physical examination findings demonstrating neural structure compression
- Greater than 12 weeks since the cervical disc arthroplasty
- Initial relief of symptoms following previous cervical disc arthroplasty at the same level
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:

- Dermatomal sensory deficit
- Motor deficit (e.g. biceps, triceps weakness)
- Reflex changes
- Shoulder Abduction Relief Sign
- Nerve root tension sign (e.g. Spurling's maneuver)
- Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - Epidural steroid injection(s)/selective nerve root block(s)
- Documentation of nicotine-free status with **EITHER** of the following, unless request is for decompression only:
  - Patient is a never-smoker
  - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- ◆ Myelopathy when **ALL** of the following are met:
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand

### **CMM-604.6: Non-Indications**

Posterior cervical decompression (laminectomy, hemilaminectomy, and laminoplasty) with or without posterior fusion is considered not medically necessary for ANY of the following sole indications:

- Signs and symptoms with no correlation to imaging studies
- Annular tears
- Disc bulge with no neural impingement or cord compression on imaging
- Concordant discography
- Degenerative disc disease
- Isolated facet fusion, with or without instrumentation, including allograft bone graft substitutes used exclusively as stand-alone stabilization devices (e.g. DTRAX<sup>®</sup> (cervical), TruFuse (any level), NuFix<sup>®</sup> (any level))

### **CMM-604.7: Procedure (CPT<sup>®</sup>) Codes**

This guideline relates to the CPT <sup>®</sup> code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.	
<b>CPT<sup>®</sup></b>	<b>Code Description/Definition</b>
<b>22590</b>	Arthrodesis, posterior technique, craniocervical (occiput-C2)
<b>22595</b>	Arthrodesis, posterior technique, atlas-axis (C1-C2)
<b>22600</b>	Arthrodesis, posterior or posterolateral technique, single level; cervical below C2 segment
<b>+22614</b>	Each additional vertebral segment (List separately in addition to code for primary procedure)
<b>+22841</b>	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
<b>+22842</b>	Posterior segmental instrumentation (e.g. pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
<b>+22843</b>	Posterior segmental instrumentation (e.g. pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
<b>63001</b>	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g. spinal stenosis), 1 or 2 vertebral segments; cervical
<b>63015</b>	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g. spinal stenosis), more than 2 vertebral segments; cervical
<b>63045</b>	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g. spinal or lateral recess stenosis]), single vertebral segment; cervical



<b>+63048</b>	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g. spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
<b>63050</b>	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments;
<b>63051</b>	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices (e.g. wire, suture, mini-plates), when performed)
<b>63265</b>	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
<b>63270</b>	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; cervical
<b>63275</b>	Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, cervical
<b>63280</b>	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, extramedullary, cervical
<b>63285</b>	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, cervical
<b>63290</b>	Laminectomy for biopsy/excision of intraspinal neoplasm; combined extradural-intradural lesion, any level
<b>+63295</b>	Laminectomy for biopsy/excision of intraspinal neoplasm; osteoplastic reconstruction of dorsal spinal elements, following primary intraspinal procedure (List separately in addition to code for primary procedure)
This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.	

### **CMM-604.8: References**

1. Campbell RM. Spine deformities in rare congenital syndromes: clinical issues. *Spine* 2009;34(17):1815-27.
2. Carette S, Fehlings MG. Clinical practice. Cervical radiculopathy. *New England Journal of Medicine* 2005;353(4):392-9.
3. Celestre PC, et al. Minimally invasive approaches to the cervical spine. *Orthopedic Clinics of North America* 2012;43(1):137-47.
4. Dvorak MF, et al. The surgical approach to subaxial cervical spine injuries: an evidence-based algorithm based on the SLIC classification system. *Spine* 2007;32(23):2620-9.
5. Raja M, Garg A, Yadav P, et al. Diagnostic Methods for Detection of Cotinine Level in Tobacco Users: A Review. *J Clin Diagn Res.* 2016 Mar; 10(3): ZE04–ZE06.
6. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine.* 2018;43(15): 1089-94.
7. Ghogawala Z, et al. Comparative effectiveness of ventral vs dorsal surgery for cervical spondylotic myelopathy. *Neurosurgery* 2011;68(3):622-30; discussion 630-1.
8. Grabowski G, Cornett CA, Kang JD. Esophageal and vertebral artery injuries during complex cervical spine surgery--avoidance and management. *Orthopedic Clinics of North America* 2012;43(1):63-74.
9. Guzman JZ, Feldman ZM, McAnany S, Hecht AC, Qureshi SA, Cho SK. Osteoporosis in Cervical Spine Surgery. *Spine* 2016; 41(8): 662-668.
10. Hankinson TC, Anderson RC. Craniovertebral junction abnormalities in Down syndrome. *Neurosurgery* 2010;66(3 Suppl):32-8.

11. Hecht AC, Koehler SM, Laudone JC, Jenkins A, Qureshi S. Is intraoperative CT of posterior cervical spine instrumentation cost-effective and does it reduce complications? *Clinical Orthopaedics and Related Research* 2011;469(4):1035-41.
12. Hsu WK. Advanced techniques in cervical spine surgery. *Journal of Bone and Joint Surgery. American Volume* 2011;93(8):780-8.
13. Komotar RJ, Mocco J, Kaiser MG. Surgical management of cervical myelopathy: indications and techniques for laminectomy and fusion. *Spine Journal* 2006;6(6 Suppl):252S-267S.
14. Krauss WE, Bledsoe JM, Clarke MJ, Nottmeier EW, Pichelmann MA. Rheumatoid arthritis of the craniovertebral junction. *Neurosurgery* 2010;66(3 Suppl):83-95.
15. Kwon BK, Vaccaro AR, Grauer JN, Fisher CG, Dvorak MF. Subaxial cervical spine trauma. *Journal of the American Academy of Orthopedic Surgeons* 2006;14(2):78-89.
16. Lawrence BD, Brodke DS. Posterior surgery for cervical myelopathy: indications, techniques, and outcomes. *Orthopedic Clinics of North America* 2012;43(1):29-40
17. Machino M, Yukawa Y, Ito K, Inoue T, Kobayakawa A, Matsumoto T, Ouchida J, Tomita K, Kato F. Risk Factors for Poor Outcome of Cervical Laminoplasty for Cervical Spondylotic Myelopathy in Patients with Diabetes. *J Bone Joint Surg Am.* 2014; 96: 2049-55
18. Manzano GR, Casella G, Wang MY, D ODCS, Levi AD. A Prospective, Randomized Trial Comparing Expansile Cervical Laminoplasty versus Cervical Laminectomy and Fusion for Multi-level Cervical Myelopathy. *Neurosurgery.* Aug 2, 2011.
19. Matz PG, et al. Cervical laminoplasty for the treatment of cervical degenerative myelopathy. *Journal of Neurosurgery: Spine* 2009;11(2):157-69.
20. Molina CA, Gokaslan ZL, Sciubba DM. Diagnosis and management of metastatic cervical spine tumors. *Orthopedic Clinics of North America* 2012;43(1):75-87
21. Mummaneni PV, et al. Preoperative patient selection with magnetic resonance imaging, computed tomography, and electroencephalography: does the test predict outcome after cervical surgery? *Journal of Neurosurgery: Spine* 2009;11(2):119-29.
22. Mummaneni PV, et al. Cervical surgical techniques for the treatment of cervical spondylotic myelopathy. *Journal of Neurosurgery: Spine* 2009;11(2):130-41
23. National Hospital Discharge Database Analysis, all payers, all applicable states, 2009-2010. [ Context Link 1, 2, 3 ]
24. Raizman NM, O'Brien JR, Poehling-Monaghan KL, Yu WD. Pseudarthrosis of the spine. *Journal of the American Academy of Orthopedic Surgeons* 2009;17(8):494-503.
25. Rao RD, Gourab K, David KS. Operative treatment of cervical spondylotic myelopathy. *Journal of Bone and Joint Surgery. American Volume* 2006;88(7):1619-40.
26. Sasso RC, Anderson PA, Riew KD, Heller JG. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *Orthopedics* 2011;34(11):889.
27. Sakaura H, Hosono N, Mukai Y, Ishii T, Iwasaki M, Yoshikawa H. Long-term outcome of laminoplasty for cervical myelopathy due to disc herniation: a comparative study of laminoplasty and anterior spinal fusion. *Spine (Phila Pa 1976).* Apr 1 2005;30(7):756-759
28. Shetty GM, Song HR, Unnikrishnan R, Suh SW, Lee SH, Hur CY. Upper cervical spine instability in pseudoachondroplasia. *Journal of Pediatric Orthopedics* 2007 Oct-Nov;27(7):782-7.
29. Shin JH, Steinmetz MP, Benzel EC, Krishnaney AA. Dorsal versus ventral surgery for cervical ossification of the posterior longitudinal ligament: considerations for approach selection and review of surgical outcomes. *Neurosurgical Focus* 2011;30(3):E8
30. Siemionow K1, Janusz P1, Phillips FM2, et al. Clinical and Radiographic Results of Indirect Decompression and Posterior Cervical Fusion for Single-Level Cervical Radiculopathy Using an Expandable Implant with 2-Year Follow-Up. *J Neurol Surg A Cent Eur Neurosurg.* 2016 Nov;77(6):482-488. Epub 2016 Jun 8.
31. Sun Q, et al. Do intramedullary spinal cord changes in signal intensity on MRI affect surgical opportunity and approach for cervical myelopathy due to ossification of the posterior longitudinal ligament? *European Spine Journal* 2011;20(9):1466-73.
32. Tracy JA, Bartleson JD. Cervical spondylotic myelopathy. *Neurologist* 2010;16(3):176-87.

33. Tretreault L, Tan G, Kopjar B, Cote P, Arnold P, Nugaeva N, Barbagallo G, Fehlings MG. Clinical and surgical predictors of complications following surgery for the treatment of cervical spondylotic myelopathy: results from the multicenter, prospective AOSpine International Study of 479 patients. *Neurosurgery*. 2015 Nov 25.
34. Turgut M. Klippel-Feil syndrome in association with posterior fossa dermoid tumour. *Acta Neurochirurgica* 2009;151(3):269-76.
35. Wang VY, Chou D. The cervicothoracic junction. *Neurosurgery Clinics of North America* 2007;18(2):365-71.
36. Weinberg D, Chugh AJ, Gebhart JJ, et al. Magnetic resonance imaging of the cervical spine under-represents sagittal plane deformity in degenerative myelopathy patients. *Int J Spine Surg*. 2016;10:32. doi: 10.14444/3032.
37. Wood GW II. Fractures, dislocations, and fracture-dislocations of the spine. In: Canale ST, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 11th ed. Philadelphia, PA: Mosby Elsevier; 2008:1761-850.
38. Zechmeister I, Winkler R, Mad P. Artificial total disc replacement versus fusion for the cervical spine: a systematic review. *European Spine Journal* 2011;20(2):177-84.

## **CMM-605: Cervical Microdiscectomy**

<b>CMM-605.1: General Guidelines</b>	<b>53</b>
<b>CMM-605.2: Initial Primary Cervical Microdiscectomy</b>	<b>53</b>
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### **CMM-605.1: General Guidelines**

- The determination of medical necessity for the performance of cervical microdiscectomy is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for cervical microdiscectomy include **ANY** of the following:
  - ◆ Myelopathy
  - ◆ Central cord syndrome
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ Severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neurocompressive pathology
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

### **CMM-605.2: Initial Primary Cervical Microdiscectomy**

Initial primary cervical microdiscectomy is considered medically necessary when ALL of the following are met:

- No previous surgeries on the disc(s) involved
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)

- Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective examination findings
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - Epidural steroid injection(s)/selective nerve root block(s)
- Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings
- ◆ Myelopathy when **ALL** of the following are met:
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign
    - Pathologic Babinski sign
    - Tandem walking test
    - Inverted brachial radial reflex
    - Increased muscle tone or spasticity
    - Clonus
    - Myelopathic hand
  - Recent (within 6 months) MRI/CT findings that are concordant with the patient's symptoms and physical examination findings including **EITHER** of the following:
    - MRI/CT demonstrates cervical spinal cord compression
    - MRI/CT identifies cervical spinal stenosis

### **CMM-605.3: Repeat Cervical Microdiscectomy at the Same Level**

Repeat cervical microdiscectomy at the same level is considered medically necessary when ALL of the following are met:

- Recent (within 6 months) post-operative MRI /CT confirms evidence of neural structure compression (e.g. either retained disc material or a recurrent disc herniation)
- Greater than 12 weeks since the initial primary cervical microdiscectomy
- Initial relief of symptoms following previous disc decompression procedure at the same level
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
  - ◆ Myelopathy when **ALL** of the following are met:
    - Subjective symptoms including **ANY** of the following:
      - Upper/lower extremity weakness, numbness, or pain
      - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
      - New-onset bowel or bladder dysfunction due to a neurocompressive pathology
      - Frequent falls

- Objective physical examination findings including at least **TWO** of the following:
  - Grip and release test
  - Ataxic gait
  - Hyperreflexia
  - Hoffmann sign
  - Pathologic Babinski sign
  - Tandem walking test
  - Inverted brachial radial reflex
  - Increased muscle tone or spasticity
  - Clonus
  - Myelopathic hand

### **CMM-605.4: Non-Indications**

Cervical microdiscectomy for ANY of the following sole indications is considered not medically necessary:

- Signs and symptoms with no correlation to imaging studies
- Annular tears
- Disc bulge with no neural impingement or cord compression on imaging
- Concordant discography
- Degenerative disc disease

### **CMM-605.5: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definition
<b>63020</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
<b>+63035</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
<b>63040</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
<b>+63043</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.



## **CMM-605.6: References**

1. Bono CM, et al. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. *Spine Journal* 2011;11(1):64-72.
2. Celestre PC, et al. Minimally invasive approaches to the cervical spine. *Orthopedic Clinics of North America* 2012;43(1):137-47.
3. Cervical spine surgery. A guide to preoperative and postoperative patient care. AANN Clinical Practice Guideline Series [Internet] American Association of Neuroscience Nurses. 2007
4. Cunningham MR, Hershman S, Bendo J. Systematic review of cohort studies comparing surgical treatments for cervical spondylotic myelopathy. *Spine* 2010;35(5):537-43.
5. Decker RC. Surgical treatment and outcomes of cervical radiculopathy. *Physical Medicine and Rehabilitation Clinics of North America* 2011;22(1):179-91. Grabowski G, Cornett CA, Kang JD. Esophageal and vertebral artery injuries during complex cervical spine surgery--avoidance and management. *Orthopedic Clinics of North America* 2012;43(1):63-74, viii.
6. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine*. 2018;43(15): 1089-94.
7. Heary RF, et al. Cervical laminoforaminotomy for the treatment of cervical degenerative radiculopathy. *Journal of Neurosurgery: Spine* 2009;11(2):198-202.
8. Hsu WK. Advanced techniques in cervical spine surgery. *Journal of Bone and Joint Surgery. American Volume* 2011;93(8):780-8.
9. Jagannathan J, Sherman JH, Szabo T, Shaffrey CI, Jane JA. The posterior cervical foraminotomy in the treatment of cervical disc/osteophyte disease: a single-surgeon experience with a minimum of 5 years' clinical and radiographic follow-up. *Journal of Neurosurgery: Spine* 2009;10(4):347-56
10. Lutz S, et al. Palliative radiotherapy for bone metastases: an ASTRO evidence-based guideline. *International Journal of Radiation Oncology, Biology and Physics* 2011;79(4):965-76.
11. Management of patients with oncologic or degenerative neurologic disorders. In: Smeltzer SC, Bare BG, Hinkle JL, Cheever KH, editors. *Brunner & Suddarth's Textbook of Medical-Surgical Nursing*. 12th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2010:1975-2005.
12. Miller J, et al. Manual therapy and exercise for neck pain: a systematic review. *Manual Therapy* 2010;15(4):334-54.
13. Molina CA, Gokaslan ZL, Sciubba DM. Diagnosis and management of metastatic cervical spine tumors. *Orthopedic Clinics of North America* 2012;43(1):75-87, viii-ix.
14. Mummaneni PV, et al. Cervical surgical techniques for the treatment of cervical spondylotic myelopathy. *Journal of Neurosurgery: Spine* 2009;11(2):130-41.
15. Mummaneni PV, et al. Preoperative patient selection with magnetic resonance imaging, computed tomography, and electroencephalography: does the test predict outcome after cervical surgery? *Journal of Neurosurgery: Spine* 2009;11(2):119-29.
16. Nikolaidis I, Fouyas IP, Sandercock PA, Statham PF. Surgery for cervical radiculopathy or myelopathy. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD001466
17. Rao RD, et al. Degenerative cervical spondylosis: clinical syndromes, pathogenesis, and management. *Journal of Bone and Joint Surgery. American Volume* 2007;89(6):1360-78.
18. Rueth N, et al. Management of cervical esophageal injury after spinal surgery. *Annals of Thoracic Surgery* 2010;90(4):1128-33. DOI: 10.1016/j.athoracsur.2010.06.045.
19. Surgical treatment of cervical spondylodiscitis: a review of 30 consecutive patients. *Spine* 2012;37(1):e30-6.
20. Tomaras CR, Blacklock JB, Parker WD, Harper RL. Outpatient surgical treatment of cervical radiculopathy. *Journal of Neurosurgery* 1997;87(1):41-3.
21. Tracy JA, Bartleson JD. Cervical spondylotic myelopathy. *Neurologist* 2010;16(3):176-87

## **CMM-606: Lumbar Microdiscectomy (Laminotomy, Laminectomy, or Hemilaminectomy)**

<b>CMM-606.1: General Guidelines</b>	<b>59</b>
<b>CMM-606.2: Initial Primary Lumbar Microdiscectomy (Laminotomy, Laminectomy or Hemilaminectomy)</b>	<b>59</b>
<b>CMM-606.3: Repeat Lumbar Microdiscectomy (Laminotomy or Laminectomy) at the Same Level</b>	<b>60</b>
<b>CMM-606.4: Non-Indications</b>	<b>62</b>
<b>CMM-606.5: Procedure (CPT®) Codes</b>	<b>62</b>
<b>CMM-606.6: References</b>	<b>63</b>

## **CMM-606.1: General Guidelines**

- The determination of medical necessity for the performance lumbar microdiscectomy and excision of extradural lesion other than neoplasm is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are NOT required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Recent (within 6 months) plain X-rays of the lumbar spine
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for lumbar microdiscectomy and excision of extradural lesion other than neoplasm include **ANY** of the following<sup>2</sup>:
  - ◆ Cauda equina syndrome (CES)
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ Epidural hematoma
  - ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis)
  - ◆ Primary or metastatic neoplastic disease causing pathologic fracture, cord compression or instability
  - ◆ Severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neurocompressive pathology
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

## **CMM-606.2: Initial Primary Lumbar Microdiscectomy (Laminotomy, Laminectomy or Hemilaminectomy)**

Initial primary lumbar microdiscectomy (laminotomy, laminectomy, or hemilaminectomy) is considered medically necessary when ALL of the following are met:

- Performed for **ANY** of the following:
  - ◆ Radiculopathy/neurogenic claudication secondary to herniated disc
  - ◆ Synovial cyst/arachnoid cyst
  - ◆ Central/lateral/foraminal stenosis
- No previous surgeries on the disc(s) involved
- All other sources of pain have been excluded
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Subjective symptoms including at least **TWO** of the following:
  - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
    - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as ≥ 7

- Severe, disabling, crippling, or incapacitating pain
  - ◆ Persistent radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative treatment as described below
  - ◆ Pain, cramping, weakness, or tingling in the lower back, buttock(s), and leg(s) brought about by walking or positions that cause thecal sac or nerve root compression (e.g. standing, extension)
- Objective physical examination findings including **EITHER** of the following:
  - ◆ Nerve root tension sign including **ANY** of the following:
    - Positive straight leg raise
    - Crossed straight leg raise
    - Femoral stretch test
  - ◆ Neurologic deficit including **ANY** of the following:
    - Dermatomal sensory deficit
    - Functionally limiting motor weakness (e.g. foot drop, quadriceps weakness)
    - Reflex changes
- Recent (within 6 months) MRI/CT identifies nerve root impingement and/or thecal sac impingement that is concordant with patient symptoms and physical examination findings and is caused by **ONE OR MORE** of the following:
  - ◆ Herniated disc(s)
  - ◆ Synovial cyst or arachnoid cyst
  - ◆ Central/lateral/foraminal stenosis
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - ◆ Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - ◆ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - ◆ Epidural steroid injection(s)/selective nerve root block(s)

### **CMM-606.3: Repeat Lumbar Microdiscectomy (Laminotomy or Laminectomy) at the Same Level**

Repeat lumbar microdiscectomy (laminotomy or laminectomy) at the same level is considered medically necessary when ALL of the following are met:

- Recent (within 6 months) post-operative MRI /CT confirms evidence of neural structure compression (e.g. either retained disc material or a recurrent disc herniation)
- Greater than 12 weeks since initial lumbar disc decompression surgery
- Initial relief of symptoms following previous disc decompression procedure at the same level unless recent (within 6 months) post-operative imaging demonstrates persistent significant neurologic compression at the surgical level
- Performed for **ANY** of the following:
  - ◆ Radiculopathy/neurogenic claudication secondary to herniated disc
  - ◆ Synovial cyst/arachnoid cyst

- ◆ Central/lateral/foraminal stenosis
- All other sources of pain have been excluded
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Subjective symptoms including at least **TWO** of the following:
  - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
    - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
    - Severe, disabling, crippling, or incapacitating pain
  - ◆ Persistent radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative treatment as described below
  - ◆ Pain, cramping, weakness, or tingling in the lower back, buttock(s), and leg(s) brought about by walking or positions that cause thecal sac or nerve root compression (e.g. standing, extension)
- Objective physical examination findings including **EITHER** of the following:
  - ◆ Nerve root tension sign including **ANY** of the following:
    - Positive straight leg raise
    - Crossed straight leg raise
    - Femoral stretch test
  - ◆ Neurologic deficit including **ANY** of the following:
    - Dermatomal sensory deficit
    - Functionally limiting motor weakness (e.g. foot drop, quadriceps weakness)
    - Reflex changes
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - Epidural steroid injection(s)/selective nerve root block(s)

### **CMM-606.4: Non-Indications**

- The performance of lumbar microdiscectomy (laminotomy, laminectomy, and hemilaminectomy) with laser technique is considered **not medically necessary**.
- Initial and repeat lumbar microdiscectomy (laminotomy, laminectomy, and hemilaminectomy) is considered **not medically necessary** for **ANY** of the following sole indications:
  - ◆ Subjective symptoms and objective physical examination findings that are not concordant with imaging
  - ◆ Predominate lower back pain associated with disc degeneration with or without annular tears in the absence of a disc herniation
  - ◆ Patients who are asymptomatic with a normal physical examination regardless of the size of the disc herniation
  - ◆ Disc bulge with no neural impingement or cord compression on imaging
  - ◆ Concordant discography
  - ◆ Isolated axial lower back pain in the presence of disc herniation
- Endoscopic and/or percutaneous laser disc decompression of spinal cord nerve root(s) is considered **experimental, investigational, or unproven**.

### **CMM-606.5: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.	
CPT®	Code Description/Definition
<b>62380</b>	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
<b>63030</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
<b>+63035</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
<b>63042</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar
<b>+63044</b>	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)
<b>63056</b>	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g. herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g. far lateral herniated intervertebral disc)
<b>+63057</b>	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g. herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)

<b>63267</b>	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
<b>63272</b>	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; lumbar
<b>63277</b>	Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, lumbar
<b>S2350</b>	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace
<b>+S2351</b>	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, each additional interspace (list separately in addition to code for primary procedure )
This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.	

### **CMM-606.6: References**

1. Arts, Mark P., Brand R, Elske vanden Akker, M, Koes, Bart W., Baretis, Ronald H. M. A., Peul, Wilco C. for the Leiden-The Hague Spine Intervention Prognostic Study Group(SIPS). Tubular Discectomy vs Conventional Microdiscectomy for Sciatica: A Randomized Controlled Trial. JAMA 2009; (302): 149-158.
2. Albert R, Lange M, Brawanski A, et al. Urgent discectomy: clinical features and neurological outcome. Surgical Neurol Int. 2016;7:17.
3. Best NM, Sasso RC. Success and safety in outpatient microlumbar discectomy. Journal of Spinal Disorders and Techniques 2006;19(5):334-7.
4. Boonstra, AM, Stewart RE, Koke AJA, Oosterwijk RFA, Swann JL, Schreurs KMG, Sciphorst Preuper HR. Cut-off Points for Mild, Moderate, and Severe Pain on the Numeric Rating Scale for Pain in Patients with Chronic Musculoskeletal Pain: Variability and Influence of Sex and Catastrophizing. Frontiers in Psychology September 2016: (7) 1466: 1-9.
5. Brouwer, Patrick A., Brand, Ronald, Elske van den Akker-van Marle, M, Jacobs, Wilco C. H., Schenk, Barry, van den Berg-Huijsmans, Aneete A., Koes, Bart W., van Buchem, M. A., Arts, Mark P., Peul, Wilco C. Percutaneous laser disc decompression versus conventional microdiscectomy in sciatica: a randomized controlled trial. The Spine Journal 2015: (15) 857-865.
6. Carragee, Eugene J. et al. 2009 ISSLS Prize Winner: Does Discography Cause Accelerated Progression of Degeneration Changes in the Lumbar Disc: A Ten-year Matched Cohort Study. Spine, 2009;34(21): 2338-2345.
7. Carragee, Eugene J. et al. A Gold Standard Evaluation of the "Discogenic Pain" Diagnosis as Determined by Provocative Discography. Spine 2006; 31(18):2115-2123.
8. Chou R, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Annals of Internal Medicine 2007;147(7):478-91
9. Chou R, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine 2009;34(10):1066-77.
10. Chou R, Huffman LH. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Annals of Internal Medicine 2007;147(7):505-14
11. Conn A, Buenaventura RM, Datta S, Abdi S, Diwan S. Systematic review of caudal epidural injections in the management of chronic low back pain. Pain Physician 2009;12(1):109-35
12. Desai A, et al. Outcomes after incidental durotomy during first-time lumbar discectomy. Journal of Neurosurgery: Spine 2011;14(5):647-53.
13. Eliyas JK, Karahalios D. Surgery for degenerative lumbar spine disease. Disease-a-Month 2011;57(10):592-606
14. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? Spine. 2018;43(15): 1089-94.
15. Gebara, NV, Meltzer DE. Extraspinal findings on lumbar spine MR imaging. Radiology Case. 2009 Aug; 3 (8): 5-13.

16. Gerbershagen HJ, Rothaug J, Kalkman CJ, Meissner W. Determination of moderate-to-sever postoperative pain on the numeric rating scale: a cut-off point analysis applying four different methods. *British Journal of Anaesthesia* June 2011; 107 (4): 619-26.
17. German JW, Adamo MA, Hoppenot RG, Blossom JH, Nagle HA. Perioperative results following lumbar discectomy: comparison of minimally invasive discectomy and standard microdiscectomy. *Neurosurgical Focus* 2008;25(2):E20.
18. Gibson JN, Waddell G. Surgical interventions for lumbar disc prolapse. *Cochrane Database of Systematic Reviews* 2007, (verified by Cochrane 2008 Oct), Issue 2. Art. No.: CD001350
19. Goldberg H, Firtch W, Tyburski M, Pressman A, Ackerson L, Hamilton L, Smith W, Carver R, Maratukulam A, Won LA, Carragee E, Avins AL. Oral Steroids for Acute Radiculopathy Due to a Herniated Lumbar Disk: A Randomized Clinical Trial. *JAMA* 2015; (313) 19: 1915-1923.
20. Hahne AJ, Ford JJ, McMeeken JM. Conservative management of lumbar disc herniation with associated radiculopathy: a systematic review. *Spine* 2010;35(11):E488-504
21. Harrington JF, French P. Open versus minimally invasive lumbar microdiscectomy: comparison of operative times, length of hospital stay, narcotic use and complications. *Minimally Invasive Neurosurgery* 2008;51(1):30-5.
22. Jacobs WC. et al. Surgery versus conservative management of sciatica due to a lumbar herniated disc: a systematic review. *European Spine Journal* 2011.
23. Jarvik JG, Hollingworth W, Heagerty PJ, et al. Three-year incidence of low back pain in an initially asymptomatic cohort: clinical and imaging risk factors. *Spine (Phila Pa 1976)* 2005; 30:1541.
24. Jarvik JJ, Hollingworth W, Heagerty P, et al. The Longitudinal Assessment of Imaging and Disability of the Back (LAIDBack) Study: baseline data. *Spine (Phila Pa 1976)* 2001; 26:1158.
25. Kanayama M, Hashimoto T, Shigenobu K, Oha F, Togawa D. Effective prevention of surgical site infection using a Centers for Disease Control and Prevention guideline-based antimicrobial prophylaxis in lumbar spine surgery. *Journal of Neurosurgery: Spine* 2007;6(4):327-9.
26. Koc Z, Ozcakar S, Sivrioglu K, Gurbet A, Kucukoglu S. Effectiveness of physical therapy and epidural steroid injections in lumbar spinal stenosis. *Spine*. 2009;34(10):985-9.
27. Lequin MI B, Verbaan D, Jacobs, WCH., Brand R, Bouma GJ, Vandertop WP, Peul, WC for the Leiden-The Hague Spine Intervention Prognostic Study Group. Surgery versus prolonged conservative treatment for sciatica: 5-year results of a randomized controlled trial. *BMJ Open* 2013; 3: e002534.
28. Low back pain. ACR Appropriateness Criteria® [Internet] American College of Radiology (ACR). Date of Origin: 1996. Last Review: 2015. Accessed on May 22, 2018.
29. Lurie JD, Tosteson TD, Tosteson ANA, Zhao W, Morgan TS, Abdu WA, Herkowitz H, Weinstein JN. Surgical versus Non-Operative Treatment for Lumbar Disc Herniation: Eight-Year Results for the Spine Patient Outcomes Research Trial (SPORT). *Spine* Jan 2014.; 39(1): 3-16.
30. McGill, C.M. Industrial back problems. *Journal of Occupational Medicine*, 10, 1740-1748. 1968.
31. Munter FM, Wasserman BA, Wu HM, Yousem DM. Serial MR Imaging of Annular Tears in Lumbar Intervertebral Disks. *AJNR Am J Neuroradiol* 2002; 23:1105.
32. NASS Coverage Policy Recommendations, Lumbar Discectomy, 2014.
33. NASS Coverage Policy Recommendations, Endoscopic Discectomy, 2014.
34. NASS Coverage Policy Recommendations, Laser Spine Surgery, 2014.
35. NASS Coverage Policy Recommendations, Lumbar Laminotomy
36. Peul W.C. et al. Prolonged conservative care versus early surgery in patients with sciatica caused by lumbar disc herniation: two year results of a randomised controlled trial. *BMJ*. 2008 336(7657):1355-8.
37. Peul WC, et al. Surgery versus prolonged conservative treatment for sciatica. *New England Journal of Medicine* 2007;356(22):2245-56.
38. Podichetty VK, Spears J, Isaacs RE, Booher J, Biscup RS. Complications associated with minimally invasive decompression for lumbar spinal stenosis. *Journal of Spinal Disorders and Techniques* 2006;19(3):161-6.
39. Rampersaud YR, et al. Intraoperative adverse events and related postoperative complications in spine surgery: implications for enhancing patient safety founded on evidence-based protocols. *Spine* 2006;31(13):1503-10.



40. Thomas JG, Hwang SW, Whitehead WE, Curry DJ, Luerssen TG, Jea A. Minimally invasive lumbar microdiscectomy in pediatric patients: a series of 6 patients. *Journal of Neurosurgery. Pediatrics* 2011;7(6):616-9.
41. Tran de QH, Duong S, Finlayson RJ. Lumbar spinal stenosis: a brief review of the nonsurgical management. *Canadian Journal of Anaesthesia* 2010;57(7):694-703. DOI: 10.1007/s12630-010-9315-3. 15. Fallah A, et al. Admission and acute complication rate for outpatient lumbar microdiscectomy. *Canadian Journal of Neurological Sciences* 2010;37(1):49-53.
42. Weinstein JN, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). *Spine* 2008;33(25):2789-800.
43. Weinstein JN. Et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA*; 2006; 296:22441-2450.
44. Weinstein JN, et al. Surgical vs Nonoperative Treatment for Lumbar Disk Herniation: The Spine Patient Outcomes Research Trial (SPORT) Observational Cohort. *JAMA* Nov 2006; 296(20): 2451-2459.
45. Williams KD, Park AL. Lower back pain and disorders of intervertebral discs. In: Canale ST, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 11th ed. Philadelphia, PA: Mosby Elsevier; 2008:2159-236
46. Winters ME, Klutz P, Zilberstein J. Back pain emergencies. *Med Clin North Am*. 2006;90(3):505-523.
47. Young K, Brown R, Kaufmann L. Clinical inquiries. When is discectomy indicated for lumbar disc disease? *Journal of Family Practice* 2011;60(8):490.

## **CMM-607: Primary Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) and Sacroplasty**

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## **CMM-607.1: General Guidelines**

- The determination of medical necessity for the performance of vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) and sacroplasty is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
- Urgent/emergent conditions for vertebral augmentation procedure include **EITHER** of the following:
  - ◆ Primary or metastatic neoplastic disease causing pathologic fracture
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

## **CMM-607.2: Indications**

Vertebral augmentation (injection of methylmethacrylate cement under imaging guidance) is considered medically necessary when ALL of the following are met:

- Performed for **ANY** of the following conditions which is concordant with recent (within 6 months) confirmatory imaging:
  - ◆ Osteolytic or osteoporotic vertebral compression fracture with persistent and debilitating pain
  - ◆ Osteolytic metastases including destruction of a vertebral body by multiple myeloma
  - ◆ Primary malignant neoplasm of bone or bone marrow
  - ◆ Painful and/or aggressive space occupying lesions of a vertebral body (hemangioma/eosinophilic granuloma)
  - ◆ Pre-surgical stabilization of a vertebral body to facilitate a fusion operation
  - ◆ Painful osteonecrotic (i.e., Kummel disease) vertebral compression fracture
  - ◆ Steroid induced vertebral compression fracture
- Persistent debilitating pain including **BOTH** of the following:
  - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
    - Visual Analog Scale (VAS)/Number Rating Scale (NRS) ≥ 7
    - Severe, disabling, crippling, or incapacitating pain
  - ◆ Clinically significant functional impairment (e.g. inability to perform household chores, prolonged standing or essential job functions)
- **EITHER** of the following:
  - ◆ Acute (0-6 weeks) axial back pain that persists at a level which prevents independent transfers and/or ambulation and correlates with the level of the fracture
  - ◆ Subacute (> 6 weeks) axial pain in the thoracic/lumbar spine for at least 4 weeks including the following:

- Less than clinically meaningful improvement with **BOTH** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 4 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 4 weeks
- Documentation of a recent (within 6 months) compression fracture with **ANY** of the following:
  - ◆ Uptake on a nuclear medicine bone scan
  - ◆ Increased intensity on fluid sensitive MRI sequences
  - ◆ Plain x-ray
  - ◆ CT
- Performed at no more than 2 levels of the T5-L5 spine on the same date of service

### **CMM-607.3: Non-Indications**

Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) is considered not medically necessary for EITHER of the following:

- The presence of **ANY** of the following contraindications:
  - ◆ Allergy to materials used in the procedure
  - ◆ Uncorrected coagulation disorders or anticoagulation therapy
  - ◆ Myelopathy associated with a bone fragment in the spinal canal or cord compression from a tumor
  - ◆ Extensive vertebral destruction
  - ◆ Burst fracture associated with widened pedicles and/or retropulsed bone fragments
  - ◆ Potential space occupying lesions causing cord compression (tumor, bone fragment)
  - ◆ Collapse of vertebral body to less than the level of the vertebra plana
  - ◆ The use of Norian XR cement and Norian SRS cement products is prohibited because they are not FDA approved
  - ◆ Radiculopathy from a herniated intervertebral disc
  - ◆ Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators
  - ◆ Unstable fracture or requirement for stabilization procedure in the same or adjacent spinal region
  - ◆ Septicemia and any active infection (including urinary tract infection [UTI])
  - ◆ Active osteomyelitis of the target vertebra
  - ◆ Severe cardiopulmonary disease
  - ◆ Lack of credentialed spine surgeon to perform an urgent laminectomy in the event of cement extravasation into the spinal canal
  - ◆ Applications in the cervical spine
- The presence of **ANY** of the following alternative causes of axial back pain:
  - ◆ Lumbar/thoracic radiculopathy or facet disease
  - ◆ Lumbar/thoracic/sacral trigger points
  - ◆ Sacral insufficiency fractures

Primary Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) is considered experimental, investigational, or unproven for EITHER of the following:

- Percutaneous vertebral augmentation for **ANY** of the following:
  - ◆ Non-painful/non-aggressive vertebral hemangioma
  - ◆ Vertebrae of the cervical spine and thoracic levels T1-T4
  - ◆ Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty)
  - ◆ Prophylactic treatment for osteoporosis of the spine
  - ◆ Prophylactic treatment for chronic back pain of longstanding duration (>6 months), even if associated with old compression fracture(s)
- Spinoplasty (e.g. OptiMesh® 1500E Polyethylene Terephthalate (PET) mesh pouch)

### **CMM-607.4: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

<b>CPT®</b>	<b>Code Description/Definitions</b>
<b>22510</b>	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
<b>22511</b>	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
<b>+22512</b>	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)
<b>22513</b>	Percutaneous Vertebral Augmentation, Including Cavity Creation (Fracture Reduction and Bone Biopsy Included When Performed) Using Mechanical Device, (e.g. Kyphoplasty); 1 Vertebral Body, Unilateral or Bilateral Cannulation, Inclusive Of All Imaging Guidance; Thoracic
<b>22514</b>	Percutaneous Vertebral Augmentation, Including Cavity Creation (Fracture Reduction and Bone Biopsy Included When Performed) Using Mechanical Device, (e.g. Kyphoplasty); 1 Vertebral Body, Unilateral or Bilateral Cannulation, Inclusive Of All Imaging Guidance; Lumbar
<b>+22515</b>	Percutaneous Vertebral Augmentation, Including Cavity Creation (Fracture Reduction and Bone Biopsy Included When Performed) Using Mechanical Device, (e.g. Kyphoplasty); 1 Vertebral Body, Unilateral or Bilateral Cannulation, Inclusive Of All Imaging Guidance; Each Additional Thoracic or Lumbar Vertebral Body (List Separately in Addition to Code for Primary Procedure)

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

## CMM-607.5: References

1. American Academy of Orthopaedic Surgeons (AAOS). The treatment of symptomatic osteoporotic spinal compression fractures. September 24, 2010.
2. Abeloff: Abeloff's clinical oncology, 4th ed. Churchill Livingstone, an imprint of Elsevier; 2008.
3. ACR-ASNR-ASSR-SIR-SNIS Practice Parameter for the Performance of Vertebral Augmentation amended 2014.
4. Bayley E, et al. Clinical outcomes of sacroplasty in sacral insufficiency fractures: a review of the literature. *Eur Spine J* (2009) 18:1266–1271.
5. Berenson J, Pflugmacher R, Jarzem P, Zonder J, Schechtman K, Tillman JB, et al.; Cancer Patient Fracture Evaluation (CAFE) Investigators. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. *Lancet Oncol*. 2011 Mar;12(3):225-35. Epub 2011 Feb 16.
6. BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis TEC Assessment Program.
7. Boonen S, Van Meirhaeghe J, Bastian L, Cummings SR, Ranstam J, Tillman JB, Eastell R, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. *J Bone Miner Res*. 2011 Jul;26(7):1627-37.
8. Bouza C, Lopez T, Magro A, Navalpotro L, Amate JM. Efficacy and safety of balloon kyphoplasty in the treatment of vertebral compression fractures: a systematic review. *Eur Spine J*. 2006 Jan 21:1-18.
9. Buchbinder R, Osborne RH, Ebeling PR, Wark JD, Mitchell P, Wriedt C, et al. randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med*. 2009 Aug 6;361(6):557-68.
10. Chou R., Qaseem, A., Snow, V., et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. Oct 2 2007;147(7):478-491.
11. Clark W, Bird P, Gonski T, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicenter, randomized, double-blind, placebo-controlled trial. *Lancet*. 2016;388: 1408-16.
12. Coumans JVCE, Reinhardt MK, Lieberman IH. Kyphoplasty for vertebral compression fractures: 1-year clinical outcomes from a prospective study. *J Neurosurg*. 2003 Jul;99(1 Suppl):44-50.
13. De Negri P, Tirri T, Paternoster G, Modano P. Treatment of painful osteoporotic or traumatic vertebral compression fractures by percutaneous vertebral augmentation procedures: a nonrandomized comparison between vertebroplasty and kyphoplasty. *Clin J Pain*. 2007 Jun;23(5):425-30.
14. Deramond H, Saliou G, Aveillan M, Lehmann P, Vallee JN. Respective contributions of vertebroplasty and kyphoplasty to the management of osteoporotic vertebral fractures. *Joint Bone Spine*. 2006 Dec;73(6):610-3. Epub 2006 Oct 11.
15. Eck JC, Nachtigall D, Humphreys SC, Hodges SD. Comparison of vertebroplasty and balloon kyphoplasty for treatment of vertebral compression fractures: a meta-analysis of the literature. *Spine J*. 2008 May-Jun;8(3):488-97.
16. ECRI Institute. Percutaneous kyphoplasty for the treatment of vertebral fractures. Plymouth Meeting (PA): ECRI Institute Health Technology Assessment Information Service. 2006 Mar 75 p. (Windows on Medical Technology™, no. 132).
17. ECRI Institute. Percutaneous vertebroplasty for the treatment of vertebral fractures. Plymouth Meeting (PA): ECRI Institute Health Technology Assessment Information Service; 2008 Dec.
18. Eichholz KM, O'Toole JE, Christie SD, Fessler RG. Vertebroplasty and kyphoplasty. *Neurosurg Clin N Am*. 2006 Oct;17(4):507-18.
19. Esses SI, McGuire R, Jenkins J, Finkelstein J, Woodard E, Watters WC 3rd, et al. AAOS Clinical Practice Guideline: The Treatment of Symptomatic Osteoporotic Spinal Compression Fractures. *J Am Acad Orthop Surg*. 2011 Mar;19(3):183-4.
20. Farrokhi MR, Alibai E, Maghami Z. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. *J Neurosurg Spine*. 2011 May;14(5):561-9. Epub 2011 Mar 4.

21. Feng L, Shen JM, Feng C, et al. Comparison of radiofrequency kyphoplasty (RFK) and balloon kyphoplasty (BKP) in the treatment of vertebral compression fractures: a meta-analysis. *Medicine*. 2017 Jun;96(25):e7150.
22. Frey ME, Depalma MJ, Cifu DX, Bhagia SM, Carne W, Daitch JS. Percutaneous sacroplasty for osteoporotic sacral insufficiency fractures: a prospective, multicenter, observational pilot study. *Spine J*. 2008 Mar-Apr;8(2):367-73. Epub 2007 Jul 20.
23. Frey ME, et al. Efficacy and safety of percutaneous sacroplasty for painful osteoporotic sacral insufficiency fractures. a prospective multi-center trial. *SPINE* 32(15):1635–1640.
24. Gaitanis IN, Hadjipavlou AG, Katonis PG, Tzermiadianos MN, Pasku DS, Patwardhan AG. Balloon kyphoplasty for the treatment of pathological vertebral compressive fractures. *Eur Spine J*. 2005 Apr;14(3):250-60. Epub 2004 Oct 8.
25. Garfin SR, Buckley RA, Ledlie J, Balloon Kyphoplasty Outcomes Group. Balloon kyphoplasty for symptomatic vertebral body compression fractures results in rapid, significant, and sustained improvements in back pain, function, and quality of life for elderly patients. *Spine*. 2006 Sep 1;31(19):2213-20.
26. Grohs JG, Matzner M, Trieb K, Krepler P. Minimal invasive stabilization of osteoporotic vertebral fractures: a prospective nonrandomized comparison of vertebroplasty and balloon kyphoplasty. *J Spinal Disord Tech*. 2005 Jun;18(3):238-42.
27. Hadjipavlou AG, Tzermiadianos MN, Katonis PG, Szpalski M. Percutaneous vertebroplasty and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures and osteolytic tumours. *J Bone Joint Surg Br*. 2005 Dec;87(12):1595-604.
28. Haig A. J., Colwell, M. *Back Pain* ACP Press; 2005.
29. Han S, Wan S, Ning L, Tong Y, Zhang J, Fan S. Percutaneous vertebroplasty versus balloon kyphoplasty for treatment of osteoporotic vertebral compression fracture: a meta-analysis of randomised and non-randomised controlled trials. *Int Orthop*. 2011 Sep;35(9):1349-58. Epub 2011 Jun 3.
30. Hulme PA, Krebs J, Ferguson SJ, Berlemann U. Vertebroplasty and kyphoplasty: a systematic review of clinical studies. *Spine*. 2006 Aug 1;31(17):1983-2001.
31. Institute for Clinical Systems Improvement (ICSI). *Health Care Guideline: Adult Acute and Subacute Low Back Pain* 15 ed. Bloomington (MN): Institute for Clinical Systems Improvement; January 2012. Accessed October 17, 2012.
32. Institute for Clinical Systems Improvement (ICSI). (2004, January). *Vertebroplasty and balloonassisted vertebroplasty for the treatment of osteoporotic compression fractures*. Technology Assessment Report #79. Retrieved 8/14/04 from
33. Jacobson RE, Palea O, Granville M. Progression of vertebral compression fractures after previous vertebral augmentation: technical reasons for recurrent fractures in a previously treated vertebra. *Cureus*. 2017 Oct 16;9(10):e1776. doi 10.7759/cureus.1776.
34. Kallmes DF, Comstock BA, Heagerty PJ, Turner JA, Wilson DJ, Diamond TH, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med*. 2009 Aug 6;361(6):569-79.
35. Kasperk C, Grafe IA, Schmitt S, Nöldge G, Weiss C, Da Fonseca K, et al. Three-year outcomes after kyphoplasty in patients with osteoporosis with painful vertebral fractures. *J Vasc Interv Radiol*. 2010 May;21(5):701-9. Epub 2010 Mar 20.
36. Kasperk C, Hillmeier J, Nöldge G, Grafe IA, DaFonseca K, Raupp D, et al. Treatment of painful vertebral fractures by kyphoplasty in patients with primary osteoporosis: a prospective nonrandomized controlled study. *J Bone Miner Res*. 2005 Apr;20(4):604-12. Epub 2004 Dec 6.
37. Kathuria S. Post-Vertebral Augmentation Spine Imaging. *Neuroimag Clin N Am* 24 (2104) 337-347.
38. Kim Y. J., Lee, J. W., Park, K. W., et al. Pulmonary cement embolism after percutaneous vertebroplasty in osteoporotic vertebral compression fractures: incidence, characteristics, and risk factors. *Radiology*. Apr 2009;251(1):250-259.
39. Klazen CA, Lohle PN, de Vries J, Jansen FH, Tielbeek AV, Blonk MC, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. *Lancet*. 2010 Sep 25;376(9746):1085-92. Epub 2010 Aug 9
40. Lavelle W, Carl A, Lavelle ED, Khaleel MA. Vertebroplasty and kyphoplasty. *Med Clin North Am*. 2007 Mar;91(2):299-314.

41. Ledlie JT, Renfro M. Balloon kyphoplasty: one-year outcomes in vertebral body height restoration, chronic pain, and activity levels. *J Neurosurg*. 2003 Jan;98(1 Suppl):36-42. age 17 of 18 Coverage Policy Number: 0040
42. Ledlie JT, Renfro MB. Kyphoplasty treatment of vertebral fractures: 2-year outcomes show sustained benefits. *Spine*. 2006 Jan 1;31(1):57-64.
43. Lee M. J., Dumonski, M., Cahill, P., et al. Percutaneous treatment of vertebral compression fractures: a meta-analysis of complications. *Spine (Phila Pa 1976)*. May 15 2009;34(11):1228-1232.
44. Lovi A., Teli, M., Ortolina, A., et al. Vertebroplasty and kyphoplasty: complementary techniques for the treatment of painful osteoporotic vertebral compression fractures. A prospective non-randomised study on 154 patients. *Eur Spine J*. Jun 2009;18 Suppl 1:95-101.
45. Mattie R, Laimi K, Yu S, Saltychev M. Comparing Percutaneous Vertebroplasty and Conservative Therapy for Treating Osteoporotic Compression Fractures in the Thoracic and Lumbar Spine. *JBJS* 2016; 98: 1041-51.
46. National Institute for Clinical Excellence (NICE). Balloon kyphoplasty for vertebral compression fractures. Interventional procedure guidance 166. London, UK: NICE; 2006 Apr. Revised 2008 Jan.
47. National Institute for Clinical Excellence (NICE). Percutaneous vertebroplasty. Interventional procedure guidance 12. London, UK: NICE; 2003 Sept. Revised 2008 Nov.
48. Otten LA, Bornemann R, Jansen TR, et al. Comparison of balloon kyphoplasty with the new KIVA® VCF system for the treatment of vertebral compression fractures. *Pain Physician*. 2013; 16:E505-E512.
49. Pateder DB, Khanna AJ, Lieberman IH. Vertebroplasty and kyphoplasty for the management of osteoporotic vertebral compression fractures. *Orthop Clin North Am*. 2007 Jul;38(3):409-18; abstract vii.
50. Rousing R, Andersen MO, Jespersen SM, et al. Percutaneous vertebroplasty compared to conservative treatment in patients with painful acute or subacute osteoporotic vertebral fractures. *Spine*. 2009; 34(13): 1349-54.
51. Rousing R, Hansen KL, Andersen MO, et al. Twelve-months follow-up in forty-nine patients with acute/semiacute osteoporotic vertebral fractures treated conservatively or with percutaneous vertebroplasty: a clinical randomized study. *Spine*. 2010; 35(5): 478-482.
52. Savage JW, Schroeder GD, Anderson PA. Review Article: Vertebroplasty and Kyphoplasty for the Treatment of Osteoporotic Vertebral Compression Fractures. *J Am Acad Orthop Surg* 2014; 22: 653-664.
53. Sorensen ST, Kirkegaard AO, Carreon L, et al. Vertebroplasty or kyphoplasty as palliative treatment for cancer-related vertebral compression fractures: a systematic review. *The Spine Journal*. 2019;19: 1067-75.
54. Spivak JM, Johnson MG. Percutaneous treatment of vertebral body pathology. *J Am Acad Orthop Surg*. 2005 Jan-Feb;13(1):6-17.
55. Staples MP, Kallmes DF, Comstock BA, Jarvik JG, Osborne RH, Heagerty PJ, Buchbinder R. Effectiveness of vertebroplasty using individual patient data from two randomised placebo controlled trials: meta-analysis. *BMJ*. 2011 Jul 12;343:d3952.
56. Taylor R. S., Fritzell, P., Taylor, R. J. Balloon kyphoplasty in the management of vertebral compression fractures: an updated systematic review and meta-analysis. *Eur Spine J*. Aug 2007;16(8):1085-1100.
57. Taylor RS, Fritzell P, Taylor RJ. Balloon kyphoplasty in the management of vertebral compression fractures: an updated systematic review and meta-analysis. *Eur Spine J*. 2007 Feb 3;
58. Taylor RS, Taylor RJ, Fritzell P. Balloon kyphoplasty and vertebroplasty for vertebral compression fractures: a comparative systematic review of efficacy and safety. *Spine*. 2006 Nov 1;31(23):2747-55.
59. Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology. *Vasc Interv Radiol*. 2009 Jul;20(7 Suppl):S326-31.
60. Trout AT, Kallmes DF, Kaufmann TJ. New fractures after vertebroplasty: adjacent fractures occur significantly sooner. *AJNR Am J Neuroradiol*. 2006 Jan;27(1):217-23.
61. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: the Kiva system as a vertebral augmentation treatment – a safety and effectiveness trial: a randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. *Spine*. 2015 Jun;40(12):865-75. doi: 10.1097/BRS.0000000000000906.



62. U.S. Department of Health and Human Services. FDA Public Health Notification\*: Complications Related to the Use of Bone Cement and Bone Void Fillers in Treating Compression Fractures of the Spine. October 31, 2002; Updated May 7, 2004.
63. Wardlaw D, Cummings SR, Van Meirhaeghe J, Bastian L, Tillman JB, Ranstam J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet*. 2009 Mar 21;373(9668):1016-24. Epub 2009 Feb 24.
64. Washington State Health Care Authority. Vertebroplasty, kyphoplasty and Sacroplasty Health Technology Assessment. Olympia WA: Health Technology Assessment Program, 2010 Nov.
65. Yang E, Xu J, Huang G, Xiao W, Liu X, Zeng B, Lian, X. Percutaneous Vertebroplasty versus Conservative Treatment in Aged Patients With Acute Osteoporotic Vertebral Compression Fractures. *SPINE* Apr 2016; 41(8) 653-660.

## **CMM-608: Lumbar Decompression**

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### **CMM-608.1: General Guidelines**

- The determination of medical necessity for the performance of lumbar decompression is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for lumbar decompression include **ANY** of the following:
  - ◆ Acute/unstable traumatic spinal fractures or dislocations with or without neural compression
  - ◆ Cauda equina syndrome (CES)
  - ◆ Epidural hematoma
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis)
  - ◆ Primary or metastatic neoplastic disease causing pathologic fracture, cord compression or instability
  - ◆ Severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neurocompressive pathology
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

### **CMM-608.2: Initial Primary Lumbar Decompression**

Initial primary lumbar decompression is considered medically necessary when ALL of the following are met:

- No previous surgeries at the level(s) involved
- All other sources of pain have been excluded
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Subjective symptoms including at least **TWO** of the following:
  - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
    - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
    - Severe, disabling, crippling, or incapacitating pain
  - ◆ Persistent radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative treatment as described below
  - ◆ Pain, cramping, weakness, or tingling in the lower back, buttock(s), and leg(s) brought about by walking or positions that cause thecal sac or nerve root compression (e.g. standing, extension)

- Performed for **EITHER** of the following:
  - ◆ Neurogenic claudication secondary to central/lateral recess/foraminal stenosis when **BOTH** of the following are met:
    - Subjective symptoms including **EITHER** of the following:
      - Symptoms worsen with standing and/or walking
      - Symptoms are alleviated with sitting and/or forward flexion
    - Objective physical examination findings concordant with recent (within 6 months) MRI/CT
  - ◆ Spondylolisthesis with neurogenic claudication symptoms or radicular pain from lateral recess or foraminal stenosis associated with listhesis demonstrated on plain x-rays and/or MRI/CT
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - ◆ Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - ◆ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - ◆ Epidural steroid injection(s)/selective nerve root block(s)
- Recent (within 6 months) MRI/CT identifies nerve root impingement and/or thecal sac impingement caused by stenosis/listhesis that is concordant with patient symptoms and/or physical examination findings

### **CMM-608.3: Repeat Lumbar Decompression at the Same Level**

Repeat lumbar decompression at the same level is considered medically necessary when ALL of the following is met:

- Recent (within 6 months) post-operative MRI /CT confirms radiographic evidence of neural structure compression (e.g. nerve root(s) compression)
- Greater than 12 weeks since last decompression surgery
- Initial relief of symptoms following previous decompression procedure at the same level(s) unless recent (within 6 months) post-operative imaging demonstrates persistent significant neurologic compression at the surgical level
- All other sources of pain have been excluded
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Subjective symptoms including at least **TWO** of the following:
  - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
    - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
    - Severe, disabling, crippling, or incapacitating pain
  - ◆ Persistent radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative treatment as described below

- ◆ Pain, cramping, weakness, or tingling in the lower back, buttock(s), and leg(s) brought about by walking or positions that cause thecal sac or nerve root compression (e.g. standing, extension)
- Performed for **EITHER** of the following:
  - ◆ Neurogenic claudication secondary to central/lateral recess/foraminal stenosis when **ALL** of the following are met:
    - Subjective symptoms including **EITHER** of the following:
      - Symptoms worsen with standing and/or walking
      - Symptoms are alleviated with sitting and/or forward flexion
    - Objective physical examination findings concordant with recent (within 6 months) post-operative MRI/CT
  - ◆ Spondylolisthesis with neurogenic claudication symptoms or radicular pain from lateral recess, or foraminal stenosis associated with listhesis demonstrated on plain x-rays and/or MRI/CT
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
  - ◆ Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
  - ◆ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
  - ◆ Epidural steroid injection(s)/selective nerve root block(s)

#### **CMM-608.4: Non-Indications**

- **ANY** of the following procedures are considered **experimental, investigational, or unproven**:
  - ◆ Percutaneous lumbar discectomy
  - ◆ Percutaneous laser discectomy
  - ◆ Laser-assisted disc decompression
  - ◆ Percutaneous laser disc decompression
  - ◆ Percutaneous nucleotomy
  - ◆ Minimally invasive lumbar decompression (MILD)
  - ◆ Minimally invasive thoracic discectomy for the treatment of axial spinal pain
  - ◆ Percutaneous endoscopic discectomy
- Interspinous/interlaminar process spacer devices (ISS) and interspinous/interlaminar stabilization/distraction devices, and interspinous process decompression (IPD) systems/devices (e.g. Coflex Interlaminar Technology Implant, Superior ISS Interspinous Spacer System, X-STOP Interspinous Process Decompression System, X-STOP PEEK Interspinous Process Decompression System) are considered **experimental, investigational and/or unproven** for **ALL** indications including, but not limited to:
  - ◆ Lumbar interspinous/interlaminar distraction without fusion for indirect spinal decompression
  - ◆ Lumbar interspinous fixation with fusion with or without decompression for stabilization
  - ◆ Lumbar spinal stabilization with an interspinous process device/interlaminar device without fusion in conjunction with decompression laminectomy

## CMM-608.5: Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definitions
<b>22867</b>	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
<b>+22868</b>	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
<b>22869</b>	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
<b>+22870</b>	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
<b>63005</b>	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g. spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
<b>63011</b>	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral
<b>63012</b>	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
<b>63017</b>	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g. spinal stenosis), more than 2 vertebral segments; lumbar
<b>63047</b>	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), [e.g. Spinal or lateral recess stenosis]), single vertebral segment; lumbar
<b>63048</b>	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g. spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
<b>0274T</b>	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g. fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
<b>0275T</b>	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g. fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

## CMM-608.6: References

1. Andreisek G, Hodler J, Steurer J. Uncertainties in the diagnosis of lumbar spinal stenosis. *Radiology* 2011;261(3):681-4.
2. Backstrom KM, Whitman JM, Flynn TW. Lumbar spinal stenosis-diagnosis and management of the aging spine. *Manual Therapy* 2011;16(4):308-17
3. Bae HW, Davis RJ, Laurusen C, et al. Three-year follow-up of the prospective, randomized, controlled trial of coflex interlaminar stabilization vs instrumented fusion in patients with lumbar stenosis. *NeuroSurgery* 2016;79(2): 169-81.
4. Bae HW, Laurusen C, Maislin G, et al. Therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. *International Journal of Spine Surgery* 2015;9.
5. Benyamin RM, Staats PS, MiDAS Encore. MILD® is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized controlled trial. *Pain Physician* May 2016;19(4):229-242.
6. Brox JI, Nygaard OP, Holm I, Keller A, Ingebrigtsen T, Reikeras O. Four-year follow-up of surgical versus non-surgical therapy for chronic low back pain. *Annals of the Rheumatic Diseases* 2010;69(9):1643-8
7. Choi D, et al. Review of metastatic spine tumour classification and indications for surgery: the consensus statement of the Global Spine Tumour Study Group. *European Spine Journal* 2010;19(2):215-22.
8. Chou R, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Annals of Internal Medicine* 2007;147(7):478-91
9. Chou R, Huffman LH. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Annals of Internal Medicine* 2007;147(7):505-14
10. Chou R, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine* 2009;34(10):1066-77.
11. Conn A, Buenaventura RM, Datta S, Abdi S, Diwan S. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009;12(1):109-35.
12. Curlee PM. Other disorders of the spine. In: Canale ST, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 11th ed. Philadelphia, PA: Mosby Elsevier; 2008:2273-352.
13. Darouiche RO. Spinal epidural abscess. *New England Journal of Medicine* 2006;355(19):2012-20.
14. Davis RJ, Errico TJ, Bae H, et al. Decompression and coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis. *SPINE* 2013;38(18): 1529-39.
15. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *Journal of the American Medical Association* 2010;303(13):1259-65.
16. Eliyas JK, Karahalios D. Surgery for degenerative lumbar spine disease. *Disease-a-Month* 2011;57(10):592-606
17. Errico TJ, Kamerlink JR, Quirno M, et al. Survivorship of coflex interlaminar-interspinous implant. *SAS Journal* 2009;3(2): 59-67.
18. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine*. 2018;43(15): 1089-94.
19. Fu KM, et al. Morbidity and mortality in the surgical treatment of 10,329 adults with degenerative lumbar stenosis. *Journal of Neurosurgery: Spine* 2010;12(5):443-6.
20. Ghany WA, Amer A, Saeed K, et al. Evaluation of interspinous spacer outcomes in degenerative lumbar canal stenosis: clinical study. *World Neurosurgery* 2016;95: 556-64.
21. Guyer R, Musacchio M, Cammisa FP, et al. ISASS recommendations/coverage criteria for decompression with interlaminar stabilization-coverage indications, limitations, and/or medical necessity. Published November 10, 2016.

22. Hsu KY, Zucherman JF, Hartjen CA, et al. Quality of life of lumbar stenosis-treated patients in whom the X STOP interspinous device was implanted. *J Neurosurg Spine* 2006;5: 500-7.
23. Kalichman L, Hunter DJ. Diagnosis and conservative management of degenerative lumbar spondylolisthesis. *European Spine Journal* 2008;17(3):327-35.
24. Kanayama M, Hashimoto T, Shigenobu K, Oha F, Togawa D. Effective prevention of surgical site infection using a Centers for Disease Control and Prevention guideline-based antimicrobial prophylaxis in lumbar spine surgery. *Journal of Neurosurgery: Spine* 2007;6(4):327-9.
25. Klein G, Mehlman CT, McCarty M. Nonoperative treatment of spondylolysis and grade I spondylolisthesis in children and young adults: a meta-analysis of observational studies. *Journal of Pediatric Orthopedics* 2009;29(2):146-56.
26. Kreiner DS, et al. Diagnosis and treatment of degenerative lumbar spinal stenosis. Evidence-based clinical guidelines for multidisciplinary spine care [Internet] North American Spine Society. 2011
27. Kreiner DS, MacVicar J, Duszynski B, et al. The MILD procedure: a systematic review of the current literature. *Pain Med* 2014 Feb;15(2):196-205.
28. Kumar N, Shah SM, Ng YH, et al. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. *Asian Spine Journal* 2014;8(2): 161-169.
29. Lee BS, Nault R, Grabowski M, et al. Utility of repeat magnetic resonance imaging in surgical patients with lumbar stenosis without disc herniation. *The Spine Journal*. 2019;19: 191-98.
30. Lewandrowski K. Successful outcome after outpatient transforaminal decompression for lumbar foraminal and lateral recess stenosis: the positive predictive value of diagnostic epidural steroid injection. *Clinical Neurology and Neurosurgery*. 2018;173: 38-45.
31. Lonne G, Johnsen LG, Rossvoll I, Andresen H, Storheim K, Zwart JA, Nygaard OP. Minimally invasive decompression versus X-Stop in lumbar spinal stenosis: a randomized controlled multicenter study. *Spine* 2015 Jan 15; 40(2): 77-85.
32. Lurie JD, Tosteson TD, Tosteson A, et al. Long-term outcomes of lumbar spinal stenosis: eight-year results of the spine patient outcomes research trial (SPORT). *Spine (Phila Pa 1976)* 2015;40(2): 63-76.
33. Moojen WA, Arts MP, Jacobs WCH, et al. Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomized controlled trial. *BMJ* 2013;347.
34. Musacchio M, Laurysen C, Davis RJ, et al. Evaluation of decompression and interlaminar stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. *International Journal of Spine Surgery* 2016;10(6).
35. Nandakumar A, Clark NA, Peehal JP, et al. The increase in dural sac area is maintained at 2 years after X-stop implantation for the treatment of spinal stenosis with no significant alteration in lumbar spine range of movement. *The Spine Journal* 2010;10: 762-8.
36. NASS Coverage Policy Recommendations, Endoscopic Discectomy, 2014.
37. NASS Coverage Policy Recommendations, Interspinous Devices without Fusion, 2014.
38. NASS Coverage Policy Recommendations, Interspinous Fixation with Fusion, 2014.
39. NASS Coverage Policy Recommendations, Laser Spine Surgery, 2014.
40. NASS Coverage Policy Recommendations, Lumbar Discectomy, 2014.
41. NASS Coverage Policy Recommendations, Lumbar Interspinous Device without Fusion.
42. NASS Coverage Policy Recommendations, Lumbar Interspinous Device without Fusion and with Decompression, 2018.
43. Ong KL, Auerbach JD, Lau E, et al. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis. *Neurosurg Focus* 2014;36(6).
44. Park S, Yoon SH, Hong TP, et al. Minimum 2-year follow-up result of degenerative spinal stenosis treated with interspinous U (Coflex™). *J Korean Neurosurg* 2009;46: 292-9.
45. Patel VV, Nunley PD, Whang PG, et al. Superior® interspinous spacer for treatment of moderate degenerative lumbar spinal stenosis: durable three-year results of a randomized controlled trial. *Journal of Pain Research* 2015;8: 657-662.
46. Patil CG, Sarmiento JM, Ugiliweneza B, et al. Interspinous device versus laminectomy for lumbar spinal stenosis: a comparative effectiveness study. *The Spine Journal* 2014;14: 1484-92.
47. Pearson A, Lurie J, Tosteson T, et al. Who should have surgery for spinal stenosis?: treatment effect predictors in SPORT. *Spine (Phil Pa 1976)* 2012;37(21): 1791-1802.



48. Pintauro M, Duffy AI, Vahedi P, et al. Interspinous implants: are the new implants better than the last generation? A review. *Curr Rev Musculoskelet Med* 2017;10: 189-98.
49. Porchet F, Vader JP, Larequi-Lauber T, et al. The assessment of appropriate indications for laminectomy. *J Bone Joint Surg [Br]*. 1999;81-B: 234-9.
50. Radcliff K, Vaccaro AR, Hilibrand A, et al. Lasers in spine surgery. *J Am Acad Orthop Surg*. 2019;00: 1-12. doi:10.5435/JAAOS-D-18-00001.
51. Rasouli MR, Rahimi-Movaghar V, Shokraneh F, Moradi-Lakeh M, Chou R. Minimally invasive discectomy versus microdiscectomy/open discectomy for symptomatic lumbar disc herniation. *Cochrane Database Syst Rev*. 2014 Sep 4; 9: CD010328.
52. Richter A, Halm HF, Hauck M, et al. Two-year follow-up after decompressive surgery with and without implantation of an interspinous device for lumbar spinal stenosis: a prospective controlled study. *J Spinal Disord Tech* 2014;27(6):336-41.
53. Richter A, Schutz C, Hauck M, et al. Does an interspinous device (Coflex™) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. *Eur Spine J* 2010;19: 283-9.
54. Roder C, Baumgartner B, Berlemann U, et al. Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study. *Eur Spine J* 2015;24: 2228-2235.
55. Sansur CA, et al. Morbidity and mortality in the surgical treatment of 10,242 adults with spondylolisthesis. *Journal of Neurosurgery: Spine* 2010;13(5):589-93
56. Schmidt s, Franke J, Rauschmann M, et al. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. *J Neurosurg Spine* 2017. Published online Jan 26, 2018.
57. Siddiqui M, Karadimas E, Nicol M, et al. Influence of X-Stop on neural foramina and spinal canal area in spinal stenosis. *SPINE* 2006;31(25): 2958-62.
58. Siddiqui M, Nicol M, Karadimas E, et al. The positional magnetic resonance imaging changes in the lumbar spine following insertion of a novel interspinous process distraction device. *Spine* 2005;30(23): 2677-82.
59. Staats PS, Chafin TB, Golovac S, et. al. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2 year results of MiDAS ENCORE. *Reg Anesth Pain Med* 2018 Oct;43(7):789-794.
60. Thome C, et al. Outcome after less-invasive decompression of lumbar spinal stenosis: a randomized comparison o. Tran de QH, Duong S, Finlayson RJ. Lumbar spinal stenosis: a brief review of the nonsurgical management. *Canadian Journal of Anaesthesia* 2010;57(7):694-703f unilateral laminotomy, bilateral laminotomy, and laminectomy. *Journal of Neurosurgery: Spine* 2005;3(2):129-41
61. Watters WC, et al. An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spondylolisthesis. *Spine Journal* 2009;9(7):609-14
62. Weinstein JN, et al. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. *Journal of Bone and Joint Surgery. American Volume* 2009;91(6):1295-304.
63. Weinstein JN, Tosteson TD, Lurie JD, Tosteson ANA, Blood E, Hanscom B, Herkowitz H, Cammisa F, Albert T, Boden S, Hilibrand A, Goldberg H, Berven S, An H for the SPORT tors. Surgical versus Nonsurgical Therapy for Lumbar Spinal Stenosis. *N Engl J Med* 2008; 358: 749-810.
64. WU A, Zhou Y, Li QL, et al. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: a systematic review and meta-analysis. *PLOS ONE* 2014;9(5).
65. Weinstein JN, et al. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the Spine Patient Outcomes Research Trial. *Spine* 2010;35(14):1329-38.
66. Yuan W, Su Q, Liu T, et al. Evaluation of coflex interspinous stabilization following decompression compared with decompression and posterior lumbar interbody fusion for the treatment of lumbar degenerative disease: a minimum 5-year follow-up study. *Journal of Clinical Neuroscience* 2017;35: 24-29.
67. Zhao X, Ma J, Ma X, et al. Interspinous process devices (IPD) alone versus decompression surgery for lumbar spinal stenosis (LSS): a systematic review and meta-analysis of randomized controlled trials. *International Journal of Surgery* 2017;39: 57-64.

<b>CMM-609: Lumbar Fusion (Arthrodesis)</b>	
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## **CMM-609.1: General Guidelines**

- The determination of medical necessity for the performance of lumbar fusion (arthrodesis) is always made on a case-by-case basis.
- Adult spinal deformity surgery does not require documentation of any of the following:
  - ◆ Spinal instability and/or spondylolisthesis
  - ◆ Failure of provider-directed non-surgical management
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Proof of smoking cessation
  - ◆ Absence of unmanaged significant behavioral health disorders
- Urgent/emergent conditions for thoracolumbar fusion (arthrodesis) include **ANY** of the following:
  - ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis) when instability is present or debridement and/or decompression is anticipated to result in instability
  - ◆ Primary or metastatic neoplastic disease causing pathologic fracture, cord compression, when instability is present or resection and/or decompression is anticipated to result in instability
  - ◆ Congenital, neuromuscular, or infantile/juvenile/adolescent idiopathic scoliosis
  - ◆ Traumatic spinal fractures or dislocations with or without neural compression when instability is present or decompression of the spinal canal is anticipated to result in instability
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

### **CMM-609.2: Lumbar Fusion (Arthrodesis)**

Lumbar fusion (arthrodesis) with decompression is considered medically necessary when ALL of the following are met:

- The patient is a candidate for lumbar decompression. Refer to **CMM-608: Lumbar Decompression**.
- Performed for actual or anticipated iatrogenic instability from decompression and when **EITHER** of the following are met:
  - ◆ Actual or anticipated instability identified intra-operatively created by disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet during spinal decompression
  - ◆ Confirmatory imaging including **ANY** of the following (not required when instability is created and/or identified intra-operatively):
    - Recent (within 6 months) imaging documenting postoperative instability created by the disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet
    - Removal of the pars interarticularis is performed that requires fusion to stabilize
    - Pars fracture
    - Previous spinal decompression that resulted in iatrogenic spondylolisthesis
- Absence of untreated, underlying psychological conditions/issues (e.g. depression, chronic pain syndrome, secondary gain, drug and alcohol abuse, etc.) as a contributor to chronic pain
- Documentation of nicotine-free status with **EITHER** of the following:
  - ◆ Patient is a never-smoker
  - ◆ Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL

Lumbar fusion (arthrodesis) without decompression is considered medically necessary when ALL of the following criteria are met:

- Significant level of pain on a daily basis defined as **EITHER** of the following:
  - ◆ Visual Analog Scale (VAS) /Numeric Rating Scale (NRS)  $\geq 7$  on a daily basis
  - ◆ Severe, disabling, crippling, or incapacitating pain
- Clinically significant functional impairment (e.g. inability to perform household chores, prolonged standing or essential job functions)
- Less than clinically meaningful improvement with **EITHER** of the following for at least 3 consecutive months unless contraindicated, except for discogenic lower back/degenerative disc disease (see specific criteria below):
  - ◆ Prescription strength analgesics, steroids, and/or NSAIDs
  - ◆ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician
- Absence of untreated, underlying psychological conditions/issues (e.g. depression, chronic pain syndrome, secondary gain, drug and alcohol abuse, etc.) as a contributor to chronic pain

- Documentation of nicotine-free status with **EITHER** of the following:
  - ◆ Patient is a never-smoker
  - ◆ Patient has refrained from smoking, use of tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- Performed for **ANY** of the following:
  - ◆ Degenerative spondylolisthesis without spondylolysis when confirmatory imaging results show **EITHER** of the following:
    - Dynamic segmental instability documented by flexion-extension plain X-rays OR comparison of a supine and upright image, with a difference in translational alignment between vertebrae greater than 3 mm between views
    - Grade II or higher spondylolisthesis (i.e. instability) defined as at least 3 mm of anterolisthesis of the upper vertebra in relation to the lower vertebra, either isthmic (i.e. secondary to a posterior arch stress fracture) or degenerative type
  - ◆ Spondylolisthesis with spondylolysis when confirmatory imaging results show **ANY** of the following:
    - Multi-level spondylolysis on recent (within 6 months) plain X-rays
    - Symptomatic Grade 1 or 2 spondylolisthesis (anterolisthesis) with recent (within 6 months) plain X-rays supporting progression of anterolisthesis
    - Symptomatic Grade 3 or higher spondylolisthesis (anterolisthesis) demonstrated on recent (within 6 months) plain x-rays with 50% or more anterior slippage and plain X-rays supporting regression of anterolisthesis
    - Progressive spinal pain without confirmatory imaging of progression of spondylolisthesis
  - ◆ Discogenic lower back/degenerative disc disease when **ALL** of the following are met:
    - Presence of chronic, unremitting, discogenic axial lower back pain and associated disability secondary to single-level degenerative lumbar disc disease (DDD) for at least one year
    - Structured physician-supervised, multi-modal, nonoperative management of medical care with licensed healthcare professionals which includes regularly scheduled appointments, follow-up evaluation, and less than clinically meaningful improvement with at least **TWO** of the following for at least 12 consecutive months unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician
      - Epidural steroid injection(s)/selective nerve root block(s)
      - Facet joint injection(s)/medial branch block(s)/radiofrequency ablation(s)
    - Moderate to severe single-level disc degeneration has been confirmed on recent (within 6 months) plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI)
  - ◆ Initial disc herniation when **BOTH** of the following are met:

- This patient is a candidate for initial primary lumbar discectomy. Refer to **CMM-606: Initial Primary/Repeat Lumbar Microdiscectomy and Excision of Extradural Lesion other than Neoplasm.**
- **ANY** of the following is present:
  - Primary extraforaminal disc herniation at L5-S1, in which a far lateral approach is not feasible because of the presence of the iliac wings
  - Primary foraminal disc herniation for which facet resection is necessary to retrieve the disc, which will result in iatrogenic instability
  - Primary disc herniation in the lumbar spine that is at the level of the spinal cord (i.e., low lying conus medullaris)
- ◆ Recurrent disc herniation when **BOTH** of the following are met:
  - The patient is a candidate for repeat lumbar discectomy. Refer to **CMM-606.3: Repeat Lumbar Microdiscectomy at the Same Level.**
  - Confirmatory plain X-rays including neural structure compression demonstrated by the most recent (within 6 months) imaging **AND** plain X-ray evidence of anterolisthesis resulting in **EITHER** of the following:
    - Segmental instability with 3 mm or more of anterior translation displacement of the vertebra on the adjacent vertebra below
    - Grade II or higher spondylolisthesis (i.e., instability)
- ◆ Second or greater recurrent disc herniation when the patient is a candidate for repeat lumbar discectomy. Refer to **CMM-606.3: Repeat Lumbar Microdiscectomy at the Same Level.**
- ◆ Isthmic spondylolisthesis when congenital or acquired pars defect is documented by recent (within 6 months) imaging studies

### **CMM-609.3: Adjacent Segment Disease**

Lumbar fusion (arthrodesis) for adjacent segment disease is considered medically necessary when ALL of the following are met:

- The patient meets criteria for lumbar fusion. Refer to: **CMM-609.2: Lumbar Fusion (Arthrodesis).**
- The prior lumbar fusion (arthrodesis) procedure at an adjacent level was performed at least 6 months prior.
- Evidence of anterolisthesis on plain X-rays resulting in **BOTH** of the following:
  - ◆ Segmental instability with 3 mm or more of anterior translation displacement of the vertebra on the adjacent vertebra below
  - ◆ Grade II or higher spondylolisthesis (i.e., instability)
- Neural structure compression demonstrated by recent (within 6 months) plain X-rays
- Significant initial relief of symptoms following prior spinal fusion(s)

### **CMM-609.4: Failed Lumbar Disc Arthroplasty Implant**

Lumbar discectomy and fusion following failed lumbar disc arthroplasty implant is considered medically necessary when EITHER of the following are met:

- Recent (within 6 months) post-operative plain X-rays show evidence of implant malposition or implant failure (e.g. subsidence, loosening, infection, dislocation/subluxation, vertebral body fracture, dislodgement)
- **ALL** of the following are met:
  - ◆ The patient meets criteria for lumbar fusion. Refer to: **CMM-609.2: Lumbar Fusion (Arthrodesis)**.
  - ◆ Recent (within 6 months) post-operative MRI /CT confirms evidence of neural structure compression (e.g. either retained disc material or a recurrent disc herniation)
  - ◆ Greater than 6 months since disc arthroplasty surgery

### **CMM-609.5: Repeat Lumbar Fusion (Arthrodesis) at the Same Level**

Repeat lumbar fusion (arthrodesis) at the same level is considered medically necessary when EITHER of the following are met:

- Recent (within 6 months) post-operative plain X-rays show evidence of implant malposition or implant failure (e.g. migration, pedicle screw breakage, pedicle screw loosening, dislodged hooks, rod breakage, rod bending, rod loosening, loss of curve correction, decompensation, etc.)
- **ALL** of the following are met:
  - ◆ The patient meets criteria for lumbar fusion. Refer to: **CMM-609.2: Lumbar Fusion (Arthrodesis)**.
  - ◆ Recent (within 6 months) post-operative confirmatory imaging including **EITHER** of the following:
    - MRI /CT
    - CT or plain x-rays documenting pseudarthrosis
  - ◆ Greater than 6 months since the last fusion (arthrodesis) surgery

### **CMM-609.6: Non-Indications**

Lumbar fusion (arthrodesis) is considered not medically necessary when the sole indication is ANY of the following:

- Disc herniation in the absence of **ANY** of the following:
  - ◆ Primary extraforaminal disc herniation at L5-S1, in which a far lateral approach is not feasible because of the presence of the iliac wings
  - ◆ Primary foraminal disc herniation for which facet resection is necessary to retrieve the disc, which will result in iatrogenic instability
  - ◆ Primary disc herniation in the lumbar spine that is at the level of the spinal cord (i.e., low lying conus medullaris)
- Multi-level degenerative disc disease without instability
- Neurocompressive pathology
- Facet joint disorders without instability
- Initial discectomy/laminectomy without instability
- An adjunct to primary decompression of central and/or lateral recess stenosis in the absence of instability, spondylolisthesis, or an actual or anticipated bony resection that will result in iatrogenic instability
- Spondylolysis without spondylolisthesis

ALL of the following devices/procedures are considered experimental, investigational, or unproven (not an all-inclusive list):

- Pre-sacral interbody fusion including AxiaLIF
- Minimally invasive surgical approaches using only indirect visualization (e.g. endoscopic fusion, percutaneous fusion (video imaging))
- Anterior interbody fusion or implantation of intervertebral body fusion devices using laparoscopic approach
- Device/implant not FDA approved
- Devices for disc annular repair
- Dynamic (intervertebral) stabilization (e.g. Dynesys, Stabilimax NZ)
- Interlaminar lumbar instrumented fusion (e.g. ILIF)
- Interspinous and interlaminar distraction devices
- Interspinous fixation/posterior non-pedicle supplemental fixation devices for spinal fusion (e.g. Affix, Aspen Spinous Process Fixation System, Coflex-F)
- Least invasive lumbar decompression interbody fusion (e.g. LINDIF)
- Isolated facet fusion, with or without instrumentation, including allograft bone graft substitutes used exclusively as stand-alone stabilization devices (e.g. TruFuse (any level), NuFix® (any level))
- Total facet arthroplasty



**CMM-609.7: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

<b>CPT®</b>	<b>Code Description/Definition</b>
<b>22533</b>	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
<b>+22534</b>	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
<b>22558</b>	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
<b>+22585</b>	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
<b>22586</b>	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
<b>22612</b>	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
<b>+22614</b>	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
<b>22630</b>	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
<b>+22632</b>	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)
<b>22633</b>	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
<b>+22634</b>	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression); each additional interspace and segment (List separately in addition to code for primary procedure)
<b>22800</b>	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
<b>22802</b>	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
<b>22804</b>	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
<b>22808</b>	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
<b>22810</b>	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
<b>22812</b>	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments

<b>+22840</b>	Posterior non-segmental instrumentation (e.g. Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
<b>+22841</b>	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
<b>+22842</b>	Posterior segmental instrumentation (e.g. pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
<b>+22843</b>	Posterior segmental instrumentation (e.g. pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
<b>+22844</b>	Posterior segmental instrumentation (e.g. pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
<b>+22845</b>	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
<b>+22846</b>	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
<b>+22847</b>	Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)
<b>+22848</b>	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
<b>22849</b>	Reinsertion of spinal fixation device
<b>+22853</b>	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
<b>+22854</b>	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
<b>+22859</b>	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
<b>0195T</b>	Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
<b>+0196T</b>	Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L4-L5 interspace (List separately in addition to code for primary procedure)
<b>0202T</b>	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
<b>0219T</b>	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical

<b>0220T</b>	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic
<b>0221T</b>	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar
<b>+0222T</b>	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)
This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.	

### **CMM-609.8: References**

1. Abdu RW, Abdu WA, Pearson AM, Zhao W, Lurie JD, Weinstein JN. Reoperation for Recurrent Intervertebral Disc Herniation in the Spine Patient Outcomes Research Trial. *Spine* July 2017; 42(14): 1106-1114.
2. Agency for Healthcare Research and Quality (AHRQ). Treatment of degenerative lumbar spinal stenosis: summary, Evidence report/technology assessment: number 32. AHRQ publication no. 01-E047. Archived. Rockville, MD: Agency for Healthcare Research and Quality; 2001 Mar.
3. American Academy of Orthopaedic Surgeons (AAOS). Position statement: The effects of tobacco exposure on the musculoskeletal system. 2011.
4. American Academy of Orthopedic Surgeons (AAOS). Surgery and smoking. July 2007.
5. American Association of Neurological Surgeons. *The Journal of Neurosurgical Spine* July 2014; 21: 48-53.
6. American College of Occupational and Environmental Medicine (ACOEM). ACOEM Practice Guidelines, 2nd edition. Ch12. Low back complaints. Copyright ©2008, 2004, 1997 by the American College of Occupational and Environmental Medicine.
7. American College of Occupational and Environmental Medicine (ACOEM). Low back disorders. Occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers. 2nd ed. 2007.
8. Anand N, Baron EM, Thaiyananthan G, Khalsa K, Goldstein TB. Minimally invasive multilevel percutaneous correction and fusion for adult lumbar degenerative scoliosis: a technique feasibility study. *J Spinal Disord Tech*. 2008 Oct;21(7):459-67.
9. Anand N, Rosemann R, Khalsa B, Baron EM. Mid-term to long-term clinical and functional outcomes of minimally invasive correction and fusion for adults with scoliosis. *Neurosurg Focus*. 2010 Mar;28(3):E6.
10. Anderson DG, Samartzis D, Shen FH, Tannoury C. Percutaneous instrumentation of the thoracic and lumbar spine. *Orthop Clin North Am*. 2007 Jul;38(3):401-8, vii.
11. Andersen T, Christensen FB, Langdahl BL, Ernst C, Fruensgaard S, Ostergaard J, Andersen JL, Rasmussen S, Niedermann B, Høy K, Helmig P, Holm R, Lindblad BE, Hansen ES, Egund N, Bünger C. Fusion mass bone quality after uninstrumented spinal fusion in older patients. *Eur Spine J*. 2010 Dec;19(12):2200-8.
12. Appaduray SP, Lo P. Effects of diabetes and smoking on lumbar spine surgery outcomes. *J Clin Neurosci* 2013; 20: 1713-7.
13. Applied Spine Technologies, Inc. Stabilimax NZ® Dynamic spine stabilization system. Study enrollment criteria.
14. Aryan HE, Newman CB, Gold JJ, Acosta FL Jr, Coover C, Ames CP. Percutaneous axial lumbar interbody fusion (AxialLIF) of the L5-S1 segment: initial clinical and radiographic experience. *Minim Invasive Neurosurg*. 2008 Aug;51(4):225-30.
15. Audat Z, Moutasem O, Yousef K, Mohammad B. Comparison of clinical and radiological results of posterolateral fusion, posterior lumbar interbody fusion and transforaminal lumbar interbody fusion techniques in the treatment of degenerative lumbar spine. *Singapore Med J*. 2012 Mar;53(3):183-7.

16. Bartynski WS, Lin L. Lumbar root compression in the lateral recess: MR imaging, conventional myelography, and CT myelography comparison with surgical confirmation. *AJNR AM J Neuroradiology* 2003; 24(3): 348-360.
17. Beastall J, Karadimas E, Siddiqui M, Nicol M, Hughes J, Smith F, Wardlaw D. The Dynesys lumbar spinal stabilization system: a preliminary report on positional magnetic resonance imaging findings. *Spine*. 2007 Mar 15;32(6):685-90.
18. Bothmann M, Kast E, Boldt GJ, Oberle J. Dynesys fixation for lumbar spine degeneration. *Neurosurg Rev*. 2008 Apr;31(2):189-96. Epub 2007 Sep 29.
19. Bohinski R, Jain V, Tobler W. Presacral retroperitoneal approach to axial lumbar interbody fusion—a new, minimally invasive technique at L5-S1: clinical outcomes, complications and rates in 50 patients at 1-year follow up. *SAS Journal*. 2010;(4):54-62.
20. Botolin S, Agudelo J, Dwyer A, Patel V, Burger E. High rectal injury during trans-1 axial lumbar interbody fusion L5-S1 fixation. *Spine*. (Phila Pa 1976). 2010 Feb 15;35(4):E144-8.
21. Brox JI, Nygaard ØP, Holm I, Keller A, Ingebrigtsen T, Reikerås O. Four-year follow-up of surgical versus non-surgical therapy for chronic low back pain. *Ann Rheum Dis*. 2010 Sep;69(9):1643-8. Epub 2009 Jul 26.
22. Brox JI, Reikerås O, Nygaard Ø, Sørensen R, Indahl A, Holm I, Keller A, Ingebrigtsen T, Grundnes O, Lange JE, Friis A. Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. *Pain*. 2006 May;122(1-2):145-55. Epub 2006 Mar 20.
23. Brox JI, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, et al. Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. *Spine*. 2003 Sep 1;28(17):1913-21.
24. Cakir B, Carazzo C, Schmidt R, Mattes T, Reichel H, Käfer W. Adjacent segment mobility after rigid and semirigid instrumentation of the lumbar spine. *Spine*. 2009 May 20;34(12):1287-91.
25. Canale: Arthrodesis. Lumbar spine. *Campbell's operative orthopaedics*. 10th ed. p. 1704-12. Mosby, Inc.; 2003.
26. Canale and Beaty: *Campbells Operative Orthopaedics*, 11th ed. Degenerative spondylolisthesis and scoliosis. Copyright ©2007 Mosby
27. Carragee EJ, Lincoln T, Parmar VS, Alamin T. A gold standard evaluation of the "discogenic pain" diagnosis as determined by provocative discography. *Spine*. 2006 Aug 15;31(18):2115-23.
28. Carreon LY, Glassman SD, Howard J. Fusion and nonsurgical treatment for symptomatic lumbar degenerative disease: a systematic review of Oswestry Disability Index and MOS Short Form-36 outcomes. *Spine J*. 2008 Sep-Oct;8(5):747-55.
29. Chaput C, Padon D, Rush J, Lenehan E, Rahm M. The significance of increased fluid signal on magnetic resonance imaging in lumbar facts in relationship to degenerative spondylolisthesis. *Spine* 2007; 32(17): 1883-7.
30. Choma TJ, Schuster JM, Norvell DC, Dettori JR, Chutkan NB. Fusion versus nonoperative management for chronic low back pain: do comorbid diseases or general health factors affect outcome? *Spine* (Phila Pa 1976). 2011 Oct 1;36(21 Suppl):S87-95.
31. Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, Carragee EJ, Grubbs M, Murphy DR, Resnick DK, Stanos SP, Shaffer WO, Wall EM; American Pain Society Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine* (Phila Pa 1976). 2009 May 1;34(10):1066-77.
32. Chung SK, Lee SH, Lim SR, Kim DY, Jang JS, Nam KS, Lee HY. Comparative study of laparoscopic L5-S1 fusion versus open mini-ALIF, with a minimum 2-year follow-up. *Eur Spine J*. 2003 Dec;12(6):613-7. Epub 2003 Oct 17.
33. [Clinicaltrials.gov, NCT01019057](https://clinicaltrials.gov/ct2/show/study/NCT01019057). An evaluation of interlaminar instrumented lumbar fusion.
34. Cowan JA Jr, Dimick JB, Wainess R, Upchurch GR Jr, Chandler WF, La Marca F. Changes in the utilization of spinal fusion in the United States. *Neurosurgery*. 2006 Jul;59(1):15-20; discussion 15-20.
35. Dakwar E, Cardona RF, Smith DA, Uribe JS. Early outcomes and safety of the minimally invasive, lateral retroperitoneal transpsoas approach for adult degenerative scoliosis. *Neurosurg Focus*. 2010 Mar;28(3):E8.
36. Devereaux MW. Low back pain. *Prim Care*. 2004 Mar;31(1):33-51.

37. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*. 2010 Apr 7;303(13):1259-65.
38. Durrani A, Mistur R, Shanti N: Presacral Approach for L5-S1 Fusion. *Techniques in Orthopaedics*. 2011 Sept; Volume 26, Number 3, pp. 166-172.
39. Eck JC, Hodges S, Humphreys SC. Minimally invasive lumbar spinal fusion. *J Am Acad Orthop Surg*. 2007 Jun;15(6):321-9.
40. Eck JC, Sharan A, Ghogawala Z, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: Lumbar fusion for intractable low-back pain without stenosis or spondylolisthesis. *J Neurosurg Spine*. 2014; 21:42-47.
41. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute. 2009 August 19. Dynamic pedicle-and screw-based stabilization systems for chronic back pain.
42. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute. 2010. iFuse Implant system for sacroiliac joint arthrodesis.
43. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute. 2009 October 14. Minimally Invasive Spinal Fusion Surgery Using eXtreme Lateral Interbody Fusion OR Axial Lumbar Interbody Fusion for Low-back Pain.
44. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute. 2006 August 3. Semi-rigid spinal stabilization systems for use in non-cervical spinal fusion surgery.
45. ECRI Institute. Spinal fusion and discography for chronic low back pain and uncomplicated lumbar degenerative disc disease (Washington HTA). Plymouth Meeting (PA): ECRI Institute Health Technology Assessment Information Service; 2007 October 19. (Evidence Report).
46. Fairbank J, Frost H, Wilson-MacDonald J, Yu LM, Barker K, Collins R; Spine Stabilisation Trial Group. Randomised controlled trial to compare surgical stabilization of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. *BMJ*. 2005 May 28;330(7502):1233.
47. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine*. 2018;43(15): 1089-94.
48. Forbin W, et al. Precision measurement of segmental motion from flexion-extension radiographs of the lumbar spine. *Clin Biomech* 1996 Dec; 11(8): 457-465
49. Fu TS, Lai PL, Tsai TT, Niu CC, Chen LH, Chen WJ. Long term results of disc excision for recurrent lumbar disc herniation with or without posterolateral fusion. *Spine* 30: 2830-2834.
50. Fujibayashi S, Neo M, Takemoto M, Ota M, Nakamura T. Paraspinal-approach transforaminal lumbar interbody fusion for the treatment of lumbar foraminal stenosis. *J Neurosurg Spine*. 2010 Oct;13(4):500-8.
51. Gelalis ID, Kang JD. Thoracic and lumbar fusions for degenerative disorders: rationale for selecting the appropriate fusion techniques. *Orthop Clin North Am*. 1998 Oct;29(4):829-42.
52. Gerszten PC, Tobler W, Raley TJ, Miller LE, Block JE, Nasca RJ: Axial Presacral Lumbar Interbody Fusion and Percutaneous Posterior Fixation for Stabilization of Lumbosacral Isthmic Spondylolisthesis. *Journal of Spinal Disorders & Techniques*. Epub ahead of print September 29, 2011.
53. Ghiselli G, Wang JC, Bhatia NN, Hsu WK, Dawson EG. Adjacent segment degeneration in the lumbar spine. *J Bone Joint Surg Am*. 2004 Jul;86-A(7):1497-503.
54. Ghogawala Z, Benzel EC, Amin-Hanjani S, Barker FG 2nd, Harrington JF, Magge SN, et al. Prospective outcomes evaluation after decompression with or without instrumented fusion for lumbar stenosis and degenerative Grade I spondylolisthesis. *J Neurosurg Spine*. 2004 Oct;1(3):267-72.
55. Gibson JNA, Waddell G. Surgery for degenerative lumbar spondylosis. *Cochrane Database Systematic Reviews* 1999, Issue 1. Updated 2005. In: *The Cochrane Library*, Copyright ©2007 The Cochrane Collaboration.
56. Glassman SD, Anagnost SC, Parker A, et al. The effect of cigarette smoking and smoking cessation on spinal fusion. *Spine (Phila Pa 1976)*. 2000;25(20): 2608-15.
57. Glassman SD, Carreon LY, Djurasovic M, Dimar JR, Johnson JR, Puno RM, Campbell MJ. Lumbar fusion outcomes stratified by specific diagnostic indication. *Spine J*. 2008 Sep 18.
58. Grob D, Benini A, Junge A, Mannion AM. Clinical experience with the dynesys semirigid fixation system for the lumbar spine. Surgical and patient-oriented outcome in 50 cases after an average of 2 years. *Spine*. 2005 Feb;30(3):324-31.

59. Gundanna M, Miller L, Block J: Complications with Axial Presacral Lumbar Interbody Fusion: A FiveYear Postmarket Surveillance Experience. *SAS Journal*. 2011; 5: 90-94.
60. Guyton JL, Perez EA. Fractures of Acetabulum and Pelvis Ch 53. In: Canale & Beaty: *Campbell's Operative Orthopaedics*, 11th ed. Copyright © 2007.
61. Hanley EN, David SM. Current concepts review—lumbar arthrodesis for the treatment of back pain. *J Bone Joint Surg Am*. 1999 May;81-A(5):716-30.
62. Hansen H, Manchikanti L, Simopoulos TT, Christo PJ, Gupta S, Smith HS, Hameed H, Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician*. 2012 May;15(3):E247-78
63. Harris EB, Massey P, Lawrence J, Rihn J, Vaccaro A, Anderson DG. Percutaneous techniques for minimally invasive posterior lumbar fusion. *Neurosurg Focus*. 2008;25(2):E12.
64. Heim SE, Altimari A. Laparoscopic approaches to fusion of the lumbosacral spine: latest techniques. *Orthop Clin North Am*. 2002 Apr;33(2):413-20.
65. Heindel P, Tuchman A, Hsieh PC, Pham MH, D'Oro A, Patel NN, Jakoi AM, Hah R, Liu JC, Buser Z, Wang JC. Reoperation Rates After Single-level Lumbar Discectomy. *SPINE* April 2017; 42(8); E496-E501.
66. Herkowitz HN. Spine update. Degenerative lumbar spondylolisthesis. *Spine* 1995; 20(9): 1084-90.
67. Hsu CJ, Chou WY, Chang WN, Wong CY. Clinical follow up after instrumentation-augmented lumbar spinal surgery in patients with unsatisfactory outcomes. *J Neurosurg Spine*. 2006 Oct;5(4):281-6.
68. Hu Y, Gu YJ, Xu RM, Zhou LJ, Ma WH. Short-term clinical observation of the Dynesys neutralization system for the treatment of degenerative disease of the lumbar vertebrae. *Orthop Surg*. 2011 Aug;3(3):167-75. doi: 10.1111/j.1757-7861.2011.00142.x.
69. Huarn KF, Chen TY. Clinical results of single central interbody fusion case and transpedicle screws fixation for recurrent herniated lumbar disc and low-grade spondylolisthesis. *Chang Gung Med J* 2003. 26: 170-177.
70. Ibrahim T, Tleyjeh IM, Gabbar O. Surgical versus non-surgical treatment of chronic low back pain: a meta-analysis of randomised trials. *Int Orthop*. 2008 Feb;32(1):107-13.
71. Inamasu J, Guiot BH. Laparoscopic anterior lumbar interbody fusion: a review of outcome studies. *Minim Invasive Neurosurg*. 2005 Dec;48(6):340-7.
72. Institute for Clinical Systems Improvement (ICSI). *Adult low back pain*. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Sep. 64 p. 15th Edition January 2012.
73. International Society for Advancement of Spine Surgery (ISASS). *Policy Statement on Lumbar Spinal Fusion Surgery*. July 15, 2011.
74. Jackson KL, Devine JG. The Effects of Smoking and Smoking Cessation on Spine Surgery: A Systemic Review of the Literature. *Global Spine J*. 2016 Nov; 6(7): 695-701.
75. Kalakoti P, Sciubba DM, Pugely AJ, et al. Impact of psychiatric comorbidities on short-term outcomes following intervention for lumbar degenerative disc disease. *Spine*. 2018;43(19):1363-1371. doi: 10.1097/BRS.0000000000002616.
76. Kelly MP, Mok JM, Berven S. Dynamic constructs for spinal fusion: an evidence-based review. *Orthop Clin North Am*. 2010 Apr;41(2):203-15.
77. Kleimeyer JP, Cheng I, Alamin TF, et al. Selective anterior lumbar interbody fusion for low back pain associated with degenerative disc disease versus nonsurgical management. *Spine*. 2018;43(19):1372-1380. doi: 10.1097/BRS.0000000000002630.
78. Kong CB, Jeon DW, Chang BS, Lee JH, Suk KS, Park JB. Outcome of spinal fusion for lumbar degenerative disease: a cross-sectional study in Korea. *Spine (Phila Pa 1976)*. 2010 Jul 1;35(15):1489-94.
79. Knight RQ, Schwaegler P, Hanscom D, Roh J. Direct lateral lumbar interbody fusion for degenerative conditions: early complication profile. *J Spinal Disord Tech*. 2009 Feb;22(1):34-7.
80. Kreiner DS, Shaffer WO, Baisden JL, Gilbert TJ, Summers JT, Toton JF, Hwang SW, Mendel RC, Reitman CA. NASS. An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis (update). *The Spine Journal*. 2013 Jul; 13(7): 734-43.
81. Kuhns BD, Kouk S, Buchanan C, Lubelski D, Alvin MD, Benzel ED, Mroz TE, Tossi J. Sensitivity of Magnetic Resonance Imaging in the Diagnosis of Mobile and Non-Mobile L4-5 Degenerative Spondylolisthesis. *The Spine Journal* 2014, doi: 10.1016/j.spinee.2014.08.006.

82. Kumar A, Beastall J, Hughes J, Karadimas EJ, Nicol M, Smith F, Wardlaw D. Disc changes in the bridged and adjacent segments after Dynesys dynamic stabilization system after two years. *Spine*. 2008 Dec 15;33(26):2909-14.
83. Kuri M, Nakagawa M, Tanaka H, et al. Determination of the duration of preoperative smoking cessation to improve wound healing after head and neck surgery. *Anesthesiology*. 2005;102(5):892-96.
84. Kwon B, Kim DH. Review Article: Lateral Lumbar Interbody Fusion: Indications, Outcomes and Complications. *J Am Acad Orthop Surgery*. 2016; 24: 96-105
85. Lindley EM, McCullough MA, Burger EL, Brown CW, Patel VV. Complications of axial lumbar interbody fusion. *J Neurosurg Spine*. 2011 Sep;15(3):273-9. Epub 2011 May 20.
86. Lindstrom D, Azodi OS, Wladis A, et al. Effects of a perioperative smoking cessation intervention on postoperative complications: a randomized trial. *Ann Surg* 2008; 248: 739-45.
87. Lubelski D, Williams SK, O'Rourke C, Obuchoowski NA, Wang JC, Steinmetz MP, Melillo AJ, Benzel EC, Modic MT, Quencer R, Mroz TE. Differences in the Surgical Treatment of Lower Back Pain Among Spine Surgeons in the United States. *Spine* 2016; 41(11): 978-986.
88. Lurie JD, Tosteson AN, Tosteson TD, et al. Reliability of Magnetic Resonance Imaging Readings for Lumbar Disc Herniation in Patients with Symptomatic Lumbar Spine Disc Herniations in the Spine Ourcomes Research Trial (SPORT) *Spine* 2008; 33:991-998
89. Lurie JD, Doman DM, Spratt KF, et al. Patients with Symptomatic Lumbar Spine Disc Herniations. *Spine* 2009; 34: 701-705.
90. Marnisch N, Brumann M, Hodler J, Held U, Brunner F, Steurer J. Radiologic Criteria for the Diagnosis of Spinal Stenosis. *Radiology*. 2012 July; 264 (1): 174-79
91. Marchi L, Oliveira L, Coutinho E, Pimenta L. Results and complications after 2-level axial lumbarinterbody fusion with a minimum 2-year follow-up. *J Neurosurg Spine*. 2012;17:187–192.
92. Marotta N, Cosar M, Pimenta L, Khoo LT. A novel minimally invasive presacral approach and instrumentation technique for anterior L5-S1 intervertebral discectomy and fusion: technical description and case presentations. *Neurosurg Focus*. 2006 Jan 15;20(1):E9.
93. Martin CT, Gao Y, Duchman KR, Pugely AJ. The Impact of Current Smoking and Smoking Cessation on Short-Term Morbidity Risk After Lumbar Spine Surgery. *Spine* 2016;41(7): 577-584.
94. Matz PG, Meagher RJ, Lamer T, Tontz WL Jr, Annaswamy TM, Cassidy RC, Cho CH, Dougherty P, Easa JE, Enix DE, Gunnoe BA, Jallo J, Julien TD, Maserati MB, Nucci RC, O'Toole JE, Rosolowski K, Sembrano JN, Villavicencio AT, Witt JP. Guideline summary review: An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spondylolisthesis. *Spine J*. 2016 Mar; 16(3): 439-48.
95. McAfee P, Khoo LT, Pimenta L, Capuccino A, Sengoz A, Coric D, Hes R, Conix B, Asgarzadie F, Hamzaoglu A, Mirofsky Y, Anekstein Y. Treatment of lumbar spinal stenosis with a total posterior arthroplasty prosthesis: implant description, surgical technique, and a prospective report on 29 patients. *Neurosurg Focus*. 2007 Jan 15;22(1):E13.
96. Mills E, Eyawo O, Lockhart I, et al. Smoking cessation reduces postoperative complications: a systematic review and meta-analysis. *Am J Med*. 2011;124(2): 144-54.
97. Mirza SK, Deyo RA. Systematic review of randomized trials comparing lumbar fusion surgery to nonoperative care for treatment of chronic back pain. *Spine (Phila Pa 1976)*. 2007 Apr 1;32(7):816-23.
98. Moojen WA, Arts MP, Bartels RH, Jacobs WC, Peul WC. Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: a systematic review and meta-analysis. *Eur Spine J*. 2011 Oct;20(10):1596-606.
99. Moller AM, Villebro N, Pedersen T, et al. Effect of preoperative smoking intervention on postoperative complications: a randomized clinical trial. *Lancet* 2002; 359: 114-7.
100. Myers K, Hajek P, Hinds C, et al. Stopping smoking shortly before surgery and postoperative complications: a systematic review and meta-analysis. *Arch Intern Med* 2011; 171: 983-9.
101. North American Spine Society. Clinical guidelines for multidisciplinary spine care. Diagnosis and treatment of degenerative lumbar spinal stenosis. Copyright ©North American Spine Society. Revised 2011.
102. North American Spine Society. Diagnosis and treatment of degenerative lumbar spondylolisthesis. 2008.

103. North American Spine Society. Public Education Series. Bone Graft Alternatives. ©2006 North American Spine Society. Accessed October 29, 2009.
104. North American Spine Society. Coverage Policy Recommendations. Lumbar Fusion 2014.
105. O'Donnell JA, Anderson JT, Haas AR, Percy R, Woods ST, Ahn UM, Ahn NU. Treatment of Recurrent Lumbar Disc Herniation With or Without Fusion in Workers' Compensation Subjects. *SPINE* 2017; 42(14): E864-E870.
106. Ozgur BM, Aryan HE, Pimenta L, Taylor WR. Extreme Lateral Interbody Fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion. *Spine J.* 2006 Jul-Aug;6(4):435-43.
107. Panagopoulos J, Hush J, Steffens D, et al. Do MRI Findings Change Over a Period of Up to 1 Year in Patients with Low Back Pain and/or Sciatica? *Spine* 2017; 42: 504-512.
108. Park P, Foley KT. Minimally invasive transforaminal lumbar interbody fusion with reduction of spondylolisthesis: technique and outcomes after a minimum of 2 years' follow-up. *Neurosurg Focus.* 2008;25(2):E16.
109. Park Y, Ha JW. Comparison of one-level posterior lumbar interbody fusion performed with a minimally invasive approach or a traditional open approach. *Spine.* 2007 Mar 1;32(5):537-43.
110. Patil SS, Lindley EM, Patel VV, Burger EL. Clinical and radiological outcomes of axial lumbar interbody fusion. *Orthopedics.* 2010 Dec 1;33(12):883.
111. Phillips FM, Tzermiadianos MN, Voronov LI, et al. Effect of the Total Facet Arthroplasty System after complete laminectomy-facetectomy on the biomechanics of implanted and adjacent segments. *Spine J.* 2009;9(1):96-102.
112. Raja M, Garg A, Yadav P, et al. Diagnostic Methods for Detection of Cotinine Level in Tobacco Users: A Review. *J Clin Diagn Res.* 2016 Mar; 10(3): ZE04–ZE06.
113. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 4: radiographic assessment of fusion. *J Neurosurg Spine.* 2005 Jun;2(6):653-7.
114. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 5: correlation between radiographic and functional outcome. *J Neurosurg Spine.* 2005 Jun;2(6):658-61.
115. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 6: magnetic resonance imaging and discography for patient selection for lumbar fusion. *J Neurosurg Spine.* 2005 Jun;2(6):662-9.
116. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: intractable low-back pain without stenosis or spondylolisthesis. *J Neurosurg Spine.* 2005 Jun;2(6):670-2.
117. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 8: lumbar fusion for disc herniation and radiculopathy. *J Neurosurg Spine.* 2005 Jun;2(6):673-8.
118. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: fusion in patients with stenosis and spondylolisthesis. *J Neurosurg Spine.* 2005 Jun;2(6):679-85.
119. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 10: fusion following decompression in patients with stenosis without spondylolisthesis. *J Neurosurg Spine.* 2005 Jun;2(6):686-91.
120. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 11: interbody techniques for lumbar fusion. *J Neurosurg Spine.* 2005 Jun;2(6):692-9.
121. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 12: pedicle screw fixation as an adjunct to posterolateral fusion for low-back pain. *J Neurosurg Spine.* 2005 Jun;2(6):700-6.
122. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 16: bone graft extenders and substitutes. *J Neurosurg Spine.* 2005 Jun;2(6):733-6.



123. Rodgers WB, Cox CS, Gerber EJ. Early complications of extreme lateral interbody fusion in the obese. *J Spinal Disord Tech.* 2010a Aug;23(6):393-7.
124. Rodgers WBV, Gerber EJ, Patterson JR. Fusion after minimally disruptive anterior lumbar interbody fusion: Analysis of extreme lateral interbody fusion by computed tomography. *SAS Journal* 4 2010b :63-66.
125. Schaeren S, Broger I, Jeanneret B. Minimum four-year follow-up of spinal stenosis with degenerative spondylolisthesis treated with decompression and dynamic stabilization. *Spine.* 2008 Aug 15;33(18):E636-42.
126. Schnake KJ, Schaeren S, Jeanneret B. Dynamic stabilization in addition to decompression for lumbar spinal stenosis with degenerative spondylolisthesis. *Spine.* 2006 Feb 15;31(4):442-9.
127. Schwarzenbach O, Berlemann U, Stoll TM, Dubois G. Posterior dynamic stabilization systems: DYNESYS. *Orthop Clin North Am.* 2005 Jul;36(3):363-72.
128. Sengupta D. Dynamic stabilization devices in the treatment of low back pain. *Orthop Clin N Am.* 2004Jan;35(10):43-56. Review.
129. Sengupta DK, Herkowitz HN. Lumbar spinal stenosis: treatment strategies and indications for surgery. *Orthop Clin North Am.* 2003 Apr;34(2):281-95.
130. Siecean A, Seicean S, Alan N, et al. Effect of smoking on the perioperative outcomes of patients who undergo elective spine surgery. *Spine* 2013; 38: 1294-302.
131. Society for Minimally Invasive Spine Surgery (SMISS). Position statement on presacral lumbar interbody fusion. February 29, 2012.
132. Sonntag VKH, Marciano FF. Is fusion indicated for lumbar spinal disorders? *Spine.* 1995 Dec;20(24 Supp):138S-142S.
133. Sorensen LT. Wound healing and infection in surgery: the pathophysiological impact of smoking, smoking cessation, and nicotine replacement therapy: a systemic review. *Ann Surg* 2012; 255: 1069-79.
134. Spinellil J, Rainville J. In: Frontera: Essentials of Physical Medicine and Rehabilitation, 2nd ed. CH 45. Lumbar spondylolysis and spondylolisthesis. Copyright ©2008 Saunders.
135. Tajima N, Chosa E, Watanabe S. Posterolateral lumbar fusion. *J Orthop Sci.* 2004 May;9(3):327-33.
136. Tang G, Rodts G, Haid RW Jr. Patient selection in lumbar arthrodesis for low back pain. In: Haid RW Jr., Resnick DK, editors. *Surgical management of low back pain.* Rolling Meadow, IL: American Association of Neurological Surgeons; 2001. Chapter 2.
137. Theadom A, Cropley M. Effects of preoperative smoking cessation on the incidence and risk of intraoperative and postoperative complications in adults smokers: a systematic review. *Tobacco control* 2006; 15: 352-8.
138. Tobler WD, Ferrara LA. The presacral retroperitoneal approach for axial lumbar interbody fusion: a prospective study of clinical outcomes, complications and fusion rates at a follow-up of two years in 26 patients. *J Bone Joint Surg Br.* 2011 Jul;93(7):955-60.
139. Tobler W, Gerszten P, Bradley W, Raley T, Nasca R, Block J: Minimally-invasive Axial Pre-sacral L5-S1 Interbody Fusion: Two Year Clinical and Radiographic Outcomes. *Spine.* 2011 Sept; 36(20): E1296-E1301.
140. Tormenti MJ, Maserati MB, Bonfield CM, Okonkwo DO, Kanter AS. Complications and radiographic correction in adult scoliosis following combined transpoas extreme lateral interbody fusion and posterior pedicle screw instrumentation. *Neurosurg Focus.* 2010 Mar;28(3):E7.
141. Torg JS. Spinal Injuries. Ch 16 In DeLee: DeLee and Drez's Orthopaedic Sports Medicine, 3rd ed. Copyright ©2009.
142. TruFuse Facet Fusion. minSURG Corporation. © minSURG™ Corporation, 2008.
143. U.S. Food and Drug Administration (FDA). Centerpulse Spine-Tech, Inc. Dynesys Spinal System. 510(k) summary. K031511. March 5, 2004.
144. U.S. Food and Drug Administration (FDA). Satellite Spinal System. 510(k) summary K060415. February 2006.
145. U.S. Food and Drug Administration (FDA). Trans1 AxiaLif™ System.510 (k) Summary K050965. 4/15/2005.
146. U.S. National Institutes of Health. Clinicaltrials.gov. Dynamic Stabilization for Lumbar Spinal Stenosis With Stabilimax NZ® Dynamic Spine Stabilization System. Updated Aug 11, 2010. Suspended.

147. Van Loon P, Kuhn S, Hofmann A, Hessmann MH, Rommens PM. Van Loon P, Kuhn S, Hofmann A, Hessmann MH, Rommens PM. *Injury*. 2011 Oct;42(10):1012-9.
148. Villavicencio AT, Burneikiene S, Roeca CM, Nelson EL, Mason A. Minimally invasive versus open transforaminal lumbar interbody fusion. *Surg Neurol Int*. 2010 May 31;1:12.
149. Vinas FC. Lumbar spine fractures and dislocations. *eMedicine* 2003 Jan 25. Updated Nov 2017.
150. Vokshoor A, Keenan MA. Spondylolisthesis, spondylolysis, and spondylosis. *eMedicine*. Jan 2009. Updated February 2017.
151. Washington State Department of Labor and Industries. Guidelines for lumbar fusion (Arthrodesis). Olympia, WA: Washington State Department of Labor and Industries; 2002 Aug. 5p.
152. Washington State Health Care Authority. Health technology Assessment. Spinal Fusion and Discography. For chronic low back pain and uncomplicated lumbar degenerative disc disease. October 2007.
153. Watters WC, Bono CM, Gilbert TJ, Krenier DS, Mazanex DJ, Shaffer WO, et al. An evidence-based clinical guidelines for the diagnosis and treatment of degenerative lumbar spondylolisthesis. *Spine Journal* 2009; 9(7): 609-14.
154. Weinstein JN, Lurie JD, Tosteson TD, Hanscom B, Tosteson AN, Blood EA, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med*. 2007 May 31;356(22):2257-70.
155. Welch WC, Cheng BC, Awad TE, Davis R, Maxwell JH, Delamarter R, Wingate JK, Sherman J, Macenski MM. Clinical outcomes of the Dynesys dynamic neutralization system: 1-year preliminary results. *Neurosurg Focus*. 2007 Dec 15;22(1):E8.
156. Williams KD, Park AL. Degenerative disc disease and internal disc derangement. In: Canale & Beaty: *Campbell's Operative Orthopaedics*, 11th ed. Copyright © 2007 Mosby Ch 39.
157. Wong J, Lam DP, Abrishami A, et al. Short-term preoperative smoking cessation and postoperative complications: a systematic review and meta-analysis. *Can J Anaesth*. 2012;59(3): 268-79.
158. Wu RH, Fraser JF, Härtl R. Minimal Access Versus Open Transforaminal Lumbar Interbody Fusion: Meta-Analysis of Fusion Rates. *Spine (Phila Pa 1976)*. 2010 Jun 24.
159. Yue JJ, Timm JP, Panjabi MM, Jaramillo-de la Torre J. Clinical application of the Panjabi neutral zone hypothesis: the Stabilimax NZ posterior lumbar dynamic stabilization system. *Neurosurg Focus*. 2007 Jan 15;22(1):E12.
160. Yuan PS, Day TF, Albert TJ, Morrison WB, Pimenta L, Cragg A, Weinstein M. Anatomy of the percutaneous presacral space for a novel fusion technique. *J Spinal Disord Tech*. 2006 Jun;19(4):237-41.
161. Zdeblick TA. Minimally invasive fusion techniques. Laparoscopic spinal fusion. *Orthop Clin North Am*. 1998 Oct;29(4):635-45.
162. Zhu Q, Larson CR, Sjøvold SG, Rosler DM, Keynan O, Wilson DR, Cripton PA, Oxland TR. Biomechanical evaluation of the Total Facet Arthroplasty System: 3-dimensional kinematics. *Spine (Phila Pa 1976)*. 2007 Jan 1;32(1):55-62.

**CMM-610: Lumbar Total Disc Arthroplasty**

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## **CMM-610.1: General Guidelines**

- The determination of medical necessity for the performance of lumbar total disc arthroplasty is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.

## **CMM-610.2: Initial Primary Lumbar Total Disc Arthroplasty**

Initial primary lumbar total disc arthroplasty is considered medically necessary when ALL of the following are met:

- An FDA approved implant is used in accordance with FDA requirements
- Presence of chronic, unremitting, discogenic axial lower back pain and associated disability secondary to single-level degenerative lumbar disc disease (DDD) for at least one year
- Age 18 to 60 years old
- Significant level of pain on a daily basis defined as **EITHER** of the following:
  - ◆ Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
  - ◆ Severe, disabling, crippling, or incapacitating pain
- Clinically significant functional impairment (e.g. inability to perform household chores, prolonged standing or essential job functions)
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Structured physician-supervised, multi-modal, nonoperative management of medical care with licensed healthcare professionals which includes **ALL** of the following:
  - ◆ Regularly scheduled appointments
  - ◆ Follow-up evaluation
  - ◆ Less than clinically meaningful improvement with **BOTH** of the following for at least 6 consecutive months unless contraindicated:
    - Prescription strength analgesics, steroids, and/or NSAIDs
    - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician
- Moderate to severe single-level disc degeneration at L4-L5 or L5-S1 has been confirmed on recent (within 6 months) plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI)
- Absence of significant facet arthropathy at the operative level

### **CMM-610.3: Non-Indications**

Lumbar artificial total disc arthroplasty is considered not medically necessary for ANY of the following:

- The revision of a failed lumbar artificial total disc arthroplasty
- The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid)
- Lumbar partial disc prosthetics
- Simultaneous multi-level implantation
- The implant will be inserted outside of the spinal motion segments approved by the FDA
- The patient has osteopenia or osteoporosis (T-score < -1.0)
- Above or below or in combination with a spinal fusion or other stabilizing type surgical procedure
- A lumbar disc prosthesis not approved by the FDA or for an FDA approved indication
- Degenerative disc disease above L4-L5
- Presence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Age less than 18 years or greater than 60
- As an adjunct to the treatment of primary central or far-lateral disc herniation
- There is evidence on imaging studies of **ANY** of the following:
  - ◆ Lytic or degenerative spondylolisthesis of Grade 2 or greater
  - ◆ Lumbar spinal stenosis
  - ◆ Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
  - ◆ Scoliosis
  - ◆ Spinal fracture
  - ◆ Infection
  - ◆ Multi-level degenerative disc disease (2 or more levels) on a preoperative MRI and plain X-rays
  - ◆ Significant facet arthropathy at the operative level
  - ◆ Presence of tumor or active infection at the site of implantation
  - ◆ Lumbar nerve root compression or bony spinal stenosis
- Allergy or sensitivity to implant materials
- Isolated radicular compression syndromes especially due to lumbar disc herniation
- Involved vertebral endplate is dimensionally smaller than the approximate dimensions of the implant in anterior/posterior width and lateral width
- Clinically compromised vertebral bodies at the affected level due to current or past trauma

## **CMM-610.4: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

<b>CPT®</b>	<b>Code Description/Definitions</b>
<b>22857</b>	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
<b>22862</b>	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
<b>22865</b>	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
<b>+0163T</b>	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
<b>+0164T</b>	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
<b>+0165T</b>	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules

## **CMM-610.5: References**

- Ahrens M, Tsantrizos A, Donkersloot P, Martens F, Lauweryns P, Le Huec JC, et al. Nucleus replacement with the DASCOR disc arthroplasty device: interim two-year efficacy and safety results from two prospective, non-randomized multicenter European studies. *Spine (Phila Pa 1976)*. 2009 Jun 1;34(13):1376-84.
- Balsano M, Zachos A, Ruggiu A, Barca F, Tranquilli-Leali P, Doria C. Nucleus disc arthroplasty with the NUBAC™ device: 2-year clinical experience. *Eur Spine J*. 2011 May;20 Suppl 1:S36-40. Epub 2011 Mar 18.
- Bertagnoli R, Karg A, Voigt S. Lumbar partial disc replacement. *Orthop Clin N Am*. 2005;36:341-7.
- Bertagnoli R, Yue JJ, Fenk-Mayer A, Eerulker J, Emerson JW. Treatment of symptomatic adjacent-segment degeneration after lumbar fusion with total disc arthroplasty by using the ProDisc prosthesis: a prospective study with 2-year minimum follow up. *J Neurosurg Spine*. 2006[a];4:91-7.
- Bertagnoli R, Yue JJ, Kershaw T, Shah RV, Pfeiffer F, Fenk-Mayer A, et al. Lumbar total disc arthroplasty utilizing the ProDisc prosthesis in smokers versus nonsmokers. *Spine*. 2006[b];31:992-7.
- Bertagnoli R, Yue JJ, Shah RV, Nanieva R, Pfeiffer F, Fenk-Mayer A, et al. The treatment of disabling single-level lumbar discogenic low back pain with total disc arthroplasty utilizing the ProDisc Prosthesis. *Spine*. 2005;30(19):2230-6.
- BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Artificial vertebral disc replacement. TEC Assessment Program June 2007. Vol. 22, No. 2. Accessed October 12, 2012.
- BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. TEC Assessment Program, November 2007 Vol. 22, No. 12. Republished August 2009, Vol. 24, No. 3.
- Blumenthal S, McAfee PC, Guyer RD, Hochschuler, Geisler RD, Holt RT. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the Charité™ artificial disc versus lumbar fusion. Part I: evaluation of clinical outcomes. *Spine*. 2005;30(14):1565-75.
- Blumenthal SL, Ohnmeiss DD, Guyer RD, Hochschuler SH. Prospective study evaluating total disc replacement: preliminary results. *J Spinal Disord Tech*. 2003 Oct;16(5):450-4.

11. Blumenthal SL, Ohnmeiss DD, Guyer R, Hochschuler S, McAfee P, Garcia R, Salib R, Yuan H, Lee C, Bertagnoli R, Bryan V, Winter R. Artificial intervertebral disks and beyond: a North American Spine Society Annual Meeting Symposium. *Spine Journal: Official Journal of the North American Spine Society*. Nov-Dec 2002;2(6):460-3.
12. Boden SD, Balderston RA, Heller J, Hanley EN Jr., Zigler JE. An AOA critical issue. *Disc Replacements: This Time Will We Really Cure Low-Back and Neck Pain?* *J Bone Joint Surg Am*. 2004 Feb;86-A(2):411-22.
13. Boswell MV, Shah RV, Everett CR, Sehgal N, Mckenzie-Brown AM, Abdi S, Bowman RC, Deer TR, Datta S, Colson JD, Spillane WF, Smith HS, Lucas LF, Burton AW, Chopra P, Staats PS, Wasserman RA, Manchikanti L. Interventional techniques in the management of chronic spinal pain: evidence-based practice guidelines. *Pain Phys* 2005;8(1):1-47. Updated 2005.
14. Bree Collaborative Spine/Low Back Pain Topic – Report and Recommendations. November, 2013.
15. Chung SS, Lee CS, Kang CS. Lumbar total disc replacement using ProDisc II: A prospective study with a 2-year minimum follow-up. *J Spinal Disord Tech*. 2006;19:411-5.
16. Cinotti G, Thierry D, Postacchini F. Results of disc prosthesis after a minimum follow-up period of 2 years. *Spine*. 1996;21(8):995-1000.
17. Cunningham BW, McAfee PC, Geisler FH, Holsapple G, Adams K, Blumenthal SL, et al. Distribution of in vivo and in vitro range of motion following 1-level arthroplasty with the CHARITE artificial disc compared with fusion. *J Neurosurg Spine*. 2008 Jan;8(1):7-12.
18. David T. Long-term results of one-level lumbar arthroplasty: minimum 10-year followup of the Charite artificial disc in 106 patients. *Spine*. 2007;32:661-6.
19. Davidson, M, Keating, JL. A Comparison of Five Low Back Disability Questionnaires: Reliability and Responsiveness: *Phys Ther*: 2002; 82: 8-24 Di Silvestre M, Bakaloudis G, Lolli F, Vommaro F, Parisini P. Two-level total lumbar disc replacement. *Eur Spine J*. 2009 Jun;18 Suppl 1:64-70. Epub 2009 Apr 28.
20. ECRI Institute. Artificial intervertebral disc replacement (AIDR) for lumbar degenerative disc disease (DDD). Emerging Technology Evidence Report. Plymouth Meeting (PA): ECRI Institute; 2009a October 14.
21. FDA Summary of Safety and Effectiveness Data Prodisc-L Total Disc Replacement.
22. Fekete TF, Porchet F. Overview of disc arthroplasty-past, present and future. *Acta Neurochir (Wien)*. 2010 Mar;152(3):393-404.
23. Fischer, CR, Ducoffe, AR, Errico, TJ. Review Article: Posterior Lumbar Fusion: Choice of Approach and Adjunct Techniques. *J Am Acad Orthop Surg* 2014; 22: 503-511 Geisler FH, Guyer RD, Blumenthal SL, McAfee PC, Cappuccino A, Bitan F, Regan JJ. Patient selection for lumbar arthroplasty and arthrodesis: the effect of revision surgery in a controlled, multicenter, randomized study. *J Neurosurg Spine*. 2008a Jan;8(1):13-6.
24. Freeman BJC, Davenport J. Total disc replacement in the lumbar spine: a systematic review of the literature. *Eur Spine J*. 2006;15 (Suppl. 3):S439-47.
25. Geisler FH, Guyer RD, Blumenthal SL, McAfee PC, Cappuccino A, Bitan F, Regan JJ. Effect of previous surgery on clinical outcome following 1-level lumbar arthroplasty. *J Neurosurg Spine*. 2008b Feb;8(2):108-14.
26. German JW, Foley KT. Disc arthroplasty in the management of the painful lumbar motion segment. *Spine*. 2005;30(16S):S60-7.
27. Griffith SL, Shelokov AP, Buttner-Janzen K, LeMaire, JP, Zeegers WS. A multicenter retrospective study of the clinical results of the LINK® SB Charité intervertebral prosthesis: the initial European experience. *Spine*. 1994;19:1842-9. Guyer RD, McAfee PC, Banco RJ, Bitan FD, Cappuccino A, Geisler FH, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: Five-year follow-up. *Spine J*. 2008a Sep 18.
28. Guyer RD, Geisler FH, Blumenthal SL, et al. Effect of age on clinical and radiographic outcomes and adverse events following 1 level lumbar arthroplasty after a minimum 2 year follow-up. *J Neurosurg Spine*. 2008b;8(2): 101-7.
29. Hannibal M, Thomas DJ, Low J, Hsu KY, Zucherman J. ProDisc-L total disc replacement: a comparison of 1-level versus 2-level arthroplasty patients with a minimum 2-year follow-up. *Spine*. 2007 Oct 1;32(21):2322-6.

30. Huang RC, Girardi FP, Lim MR, Cammisa FP. Advantages and disadvantages of nonfusion technology in spine surgery. *Orthop Clin N Am.* 2005;36:263-9.
31. Institutes for Clinical Systems Improvement (ICSI). Lumbar artificial intervertebral discs. Bloomington, MN: Institute for Clinical Systems Improvement (ICSI); 2005 Dec.
32. Jacobs WC, Van der Gaag NA, Kruyt MC, Tuschel A, de Kleuver M, Peul WC, Verbout AJ, Oner FC. Total Disc Replacement for Chronic Discogenic Low-Back Pain: A Cochrane Review. *Spine (Phila Pa 1976).* 2012 Sep 19.
33. Katsimihias M, Bailey CS, Issa K, Fleming J, Rosas-Arellano P, Bailey SI, Gurr KR. Prospective clinical and radiographic results of CHARITÉ III artificial total disc arthroplasty at 2- to 7-year follow-up: a Canadian experience. *Can J Surg.* 2010 Dec;53(6):408-4145.
34. Kostuik JP. Intervertebral disk replacement. Experimental study. *Clinical Orthopaedics & Related Research.* 1997 Apr;337:27-41.
35. Kuhns BD, Louk S, Buchanan C, Lubelski D, Alvin MD, Benzel EC, Mroz TE, Tozzi J. Sensitivity of Magnetic Resonance Imaging in the Diagnosis of Mobile and Non-Mobile L4-5 Degenerative Spondylolisthesis. *The Spine Journal.* 2014.
36. Kurtz SM, Pelozo J, Siskey R, Villarraga ML. Analysis of a retrieved polyethylene total disc replacement component. *Spine J.* 2005 May-Jun;5(3):344-50.
37. Kurtz SM, van Ooij A, Ross R, Malefit JdW, Pelozo J, Ciccarelli L, Villarraga ML. Polyethylene wear and rim fracture in total disc arthroplasty. *Spine J.* 2007;7:12-21.
38. Leahy M, Zigler JE, Ohnmeiss DD, Rashbaum RF, Sachs BL. Comparison of results of total disc replacement in postdiscectomy patients versus patients with no previous lumbar surgery. *Spine.* 2008 Jul 1;33(15):1690-3; discussion 1694-5.
39. Leary SP, Regan JJ, Lanman TH, Wagner WH. Revision and Explantation Strategies Involving the Lumbar Artificial Disc Replacement. *Spine.* 2007;32(9):1001-11
40. Le Huec [a] J-C, Basso Y, Aunoble S, Friesem T, Bruno MB. Influence of Facet and Posterior Muscle Degeneration on Clinical Results of Lumbar Total Disc Replacement: Two-Year Follow-Up. *J Spinal Disord Tech.* 2005 Jun;18(3):219-23.
41. Le Huec [b] JC, Basso Y, Mathews H, Mehdod A, Aunoble S, Friesem T, Zdeblick T. The effect of single-level, total disc arthroplasty on sagittal balance parameters: a prospective study. *Eur Spine J.* 2005;14:480-6.
42. Leivseth G, Braaten S, Frobin W, Brinckmann P. Mobility of lumbar segments instrumented with a ProDisc II Prosthesis: A two-year follow-up study. *Spine.* 2006;31(15):1726-33.
43. LeMaire JP, Carrier H, Sari Ali E-H, Skalli W, Lavaste F. Clinical and radiological outcomes with the Charité™ artificial disc: a 10-year minimum follow-up. *J Spinal Disord Tech.* 2005 Aug;18(4):353-9.
44. Lurie JD, Tosteson TD, Tosteson AN, Zhao W, Morgan TS, Abdu WA, Herkowitz H, Weinstein, JN. Surgical versus Nonoperative Treatment for Lumbar Disc Herniation. *Spine* 39 (1): 3-16.
45. Markwalder TM, Wenger M, Marbacher S. A 6.5-year follow-up of 14 patients who underwent ProDisc total disc arthroplasty for combined long-standing degenerative lumbar disc disease and recent disc herniation. *J Clin Neurosci.* 2011 Dec;18(12):1677-81.
46. Marshman LA, Friesem T, Rampersaud YR, Le Huec JC, Krishna M. Subsidence and malplacement with the Oblique Maverick Lumbar Disc Arthroplasty: technical note. *Spine J.* 2008 Jul-Aug;8(4):650-5. Epub 2007 May 22.
47. Martin CW and the Work Comp Board (WCB) Evidence Based Practice Group. Artificial cervical and lumbar disc implants: a review of the literature. Updated Apr 2005.
48. McAfee PC, Geisler FH, Saiedy SS, Moore SV, Regan JJ, Guyer RD, et al. Revisability of the CHARITÉ artificial disc replacement. *Spine.* 2006;31(11):1217-26.
49. McAfee PC, Cunningham B, Holsapple G, Adams K, Blumenthal S, Guyer RD. A prospective, randomized, multicenter Food and Drug device exemption study of lumbar total disc replacement with the Charité™ artificial disc versus lumbar fusion. Part II: Evaluation of radiographic outcomes and correlations of surgical technique accuracy with clinical outcomes. *Spine.* 2005;30(14):1576-83.
50. McAfee PC, Fedder IL, Saiedy S, Shucosky EM, Cunningham BW. SB Charité disc replacement: report of 60 prospective randomized cases in a U.S. center. *J Spinal Disord Tech.* 2003 Aug;16(4):424-33.
51. Mirza SK, Deyo RA. Systematic Review of Randomized Trials Comparing Lumbar Fusion Surgery to Nonoperative Care for Treatment of Chronic Back Pain. *Spine.* 2007;32(7):816-23.



52. National Institutes for Health and Clinical Excellence (NICE). Prosthetic intervertebral disc replacement in the cervical spine. Interventional Procedure Guidance 341. May 2010.
53. North American Spine Society (NASS). Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis. Updated 2006.
54. North American Spine Society (NASS). Coverage Policy Recommendations. Lumbar Artificial Disc Replacement. May 2014.
55. Ontario Health Technology Assessment Committee (OHTAC). OHTAC Recommendation: Updated Health Technology Policy Assessment (HPTA) on Artificial Disc Replacement for Lumbar and Cervical Degenerative Disc Disease. Updated Apr 2006. Ont Health Technol Assess Ser. 2006;6(10):1-98.
56. Panjabi M, Malcolmson G, Teng E, Tominaga Y, Henderson G, Serhan H. Hybrid Testing of Lumbar Discs Versus Fusions. *Spine*.2007;32(9):959-66.
57. Park CK, Ryu KS, Jee WH. Degenerative changes of discs and facet joints in lumbar total disc replacement using ProDisc II: minimum two-year follow-up. *Spine*. 2008 Jul 15;33(16):1755-61.
58. Park CK, Ryu KS, Lee KY, Lee HJ. Clinical Outcome of Lumbar Total Disc Replacement Using ProDisc-L® in Degenerative Disc Disease: Minimum 5-year Follow-up Results at a Single Institute. *Spine (Phila Pa 1976)*. 2011 Aug 18. Regan JJ. Clinical results of Charité lumbar total disc replacement. *Orthop Clin N Am*. 2005;36:323-40:1-10.
59. Park SJ, Lee CS, Chung SS, Lee KH, Kim WS, Lee JY. Long-Term Outcomes Following Lumbar Total Disc Replacement Using ProDisc-II: Average 10-Year Follow-Up at a Single Institution. *Spine* 2016. 41(11): 971-977.
60. Punt IM, Vissor VM, van Rhijn LW, et al. Complications and reoperations of the SB Charite lumbar disc prosthesis: experience in 75 patients. *Eur Spine J*. 2008;17(1): 36-43.
61. Ross R, Mirza AH, Norris HE, et al. Survival and clinical outcome of SB Charite III disc replacement for back pain. *J Bone Joint Surg BR*. 2007;89(6): 785-9.
62. SariAli E, LeMaire JP, Pascal-Mousselard H, et al. In vivo study of the kinematics in axial rotation of the lumbar spine after total intervertebral disc replacement: long-term results: a 10-22 years follow-up evaluation. *Eur Spine J*. 2006.
63. Scott-Young MN, Lee MJ, Nielsen DE, Magno CL, Kimlin KR, Mitchell EO. Clinical and Radiological Mid-Term Outcomes of Lumbar Single-Level Total Disc Replacement. *Spine (Phila Pa 1976)*. 2011 Sep 8. [Epub ahead of print].
64. Sharan AD, Goldstein JA. Cervical artificial disc replacement technologies. Updated Aug 2015.
65. Shim CS, Lee S-H, Shin H-- Versus ProDisc: A Comparative Study of a Minimum 3-Year Follow-up. *Spine*. 2007;32(9):1012-8.
66. Siepe CJ, Heider F, Haas E, Hitzl W, Szeimies U, Stäbler A, Weiler C, Nerlich AG, Mayer MH. Influence of lumbar intervertebral disc degeneration on the outcome of total lumbar disc replacement: a prospective clinical, histological, X-ray and MRI investigation. *Eur Spine J*. 2012 May 29.
67. Siepe CJ, Korge A, Grochulla F, Mehren C, Mayer HM. Analysis of post-operative pain patterns following total lumbar disc replacement: results from fluoroscopically guided spine infiltrations. *Eur Spine J*. 2008 Jan;17(1):44-56.
68. Siepe CJ, Mayer HM, Heinz-Leisenheimer M, Korge A. Total lumbar disc replacement: different results for different levels. *Spine*. 2007 Apr 1;32(7):782-90.
69. Siepe CJ, Mayer M, Wiechert K, Korge A. Clinical results of total lumbar disc replacement with ProDisc I: Three-year results for different indications. *Spine*.2006;31:1923-32.
70. Siepe CJ, Zelenkov P, Sauri-Barraza JC, Szeimies U, Grubinger T, Tepass A, Stäbler A, Mayer MH. The fate of facet joint and adjacent level disc degeneration following total lumbar disc replacement: a prospective clinical, x-ray, and magnetic resonance imaging investigation. *Spine (Phila Pa 1976)*. 2010 Oct 15;35(22):1991-2003.
71. Tropiano P, Huang RC, Giradi FP, et al. Lumbar total disc replacement: surgical technique. *J Bone Joint Surg AM*. 2006;88A (Supp 1, Part 1): 50-64.
72. Total disc replacement for chronic low back pain: background and a systemic review of the literature. The Cochrane Review. In: The Cochrane Library, Issue 12, 2005. Chichester, UK: John Wiley & Sons, Ltd.; 2005. Oxford: Update software. Uschold TD, Fusco D, Germain R, Tumialan LM, Chang SW. Cervical and Lumbar Spinal Arthroplasty: Clinical Review. *AJNR Am J Neuroradiol*. 2011 Oct 27.
73. U.S. Food and Drug Administration. Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. Nov 2002. Updated Nov 2002.

74. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). New Device Approval. ProDisc®-L Total Disc Replacement – P050010. Updated Aug 2006.
75. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). New Device Approval. Charite™ Artificial Disc- P040006. Issued October 26, 2004. Updated March 9, 2005.
76. van den Eerenbeemt KD, Ostelo RW, van Royen BJ, Peul WC, van Tulder MW. Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature. *AJNR Am J Neuroradiol*. 2011 Oct 27. Wang G. Health Technology Assessment: Artificial Disc Replacement. Washington State Department of Labor and Industries. Updated Nov 2004.
77. van Ooij A, Kurtz SM, Stessels F, et al. Polyethylene wear debris and long term clinical failure of the Charite disc prosthesis: a study of 4 patients. *Spine*. 2007;32(2):223-9.
78. Wagner WH, Regan JJ, Leary SP, et al. Access strategies for revision or explanation of the Char. *J Vasc Surg*. 2006;44:1266-72.
79. van Ooij A, Oner FC, Verbout AJ. Complications of artificial disc replacement: a report of 27 patients with the SB Charite disc. *J Spinal Disord Tech*. 2003;16(4): 369-83.
80. Weinstein JN, Lurie JD, Tosteson TD, Zhao W, Blood EA, Tosteson ANA, Birkmeyer N, Herkowitz H, Longley M, Lenke L, Emery S, Hu SS. Surgical Compared with Nonoperative Treatment for Lumbar Degenerative Spondylolisthesis. Four –Year Results in the Spine Patient Outcomes Research Trial (SPORT) Randomized and Observational Cohorts. *J Bone Joint Surg Am*. 2009; 91: 1295-1304. Yaszay B, Bendo JA, Goldstein JA, Quirno M, Spivak JM, Errico TJ. Effect of intervertebral disc height on postoperative motion and outcomes after ProDisc-L lumbar disc replacement. *Spine*. 2008 Mar 1;33(5):508-12; discussion 513
81. Zeller JL. Artificial spinal disk superior to fusion for treating degenerative disk disease. *JAMA*. 2006;296(22):2665-6.
82. Zigler JE, Delamarter RB. Five-year results of the prospective, randomized, multicenter, food and drug administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. *J Neurosurg Spine*. 2012;17: 493-501.
83. Zigler J, Delamater R, Spivak JM, et al. Results of the prospective randomized, multicenter food and drug administration investigational device exemption study of the ProDisc®-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. *Spine*. 2007;32(11): 1155-62.
84. Sigler JE, Glenn J, Delamarter RB. Five year adjacent level degenerative changes in patients with single level disease treated using lumbar total disc replacement with ProDisc®-L versus circumferential fusion. *Neurosurg Spine*. 2012.
85. Zindrick MR, Tzermiadianos MN, Voronov LI, Lorenz M, Hadjipavlou A. An evidence-based medicine approach in determining factors that may affect outcome in lumbar total disc replacement. *Spine*. 2008 May 15;33(11):1262-9.

## **CMM-611: Sacroiliac Joint Fusion or Stabilization**

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## **CMM-611.1: General Guidelines**

- The determination of medical necessity for the performance of sacroiliac joint fusion or stabilization is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.

## **CMM-611.2: Minimally Invasive Sacroiliac Joint Fusion or Stabilization**

Minimally invasive sacroiliac joint (SIJ) fusion using titanium triangular implants (SI BONE [iFUSE Implant™]) for the treatment of lumbopelvic pain originating from the SIJ is considered medically necessary when ALL of the following are met:

- Performed by an orthopedic surgeon or neurosurgeon with specific training and expertise in percutaneous sacroiliac joint fusion surgical techniques and regularly use image-guidance for placement of implants
- Presence of non-radiating lumbopelvic pain caudal to L5, buttock, hip, and/or groin pain without radiation into the leg(s) that impairs physical activities
- SIJ pain interfering with activities of daily living
- Patient localizes posterior pain to the posterior superior iliac spine (Fortin's point)
- Localized tenderness to palpation over the sacral sulcus and posterior SIJ
- Elicitation of typical pain on three (3) or more provocative physical examination maneuvers/tests that stress the SIJ:
  - ◆ Thigh thrust test
  - ◆ Compression test
  - ◆ Gaenslen's maneuver
  - ◆ Distraction test
  - ◆ FABER/Patrick's sign
  - ◆ Posterior provocation test
- Absence of localized tenderness to palpation of similar severity to palpation of the sacral sulcus and posterior SIJ over the greater trochanter, lumbar spine, and coccyx
- Diagnostic confirmation of the SIJ as a pain generator through  $\geq 75\%$  reduction in pain for the expected duration of effect of the anesthetic agent used upon two separate contrast-enhanced fluoroscopically or CT-guided intra-articular SIJ blocks using a local anesthetic performed
- SIJ pain without minimal clinically important difference (MCID) from a minimum of a consecutive six (6) months of conservative, non-surgical treatment including **ALL** of the following unless contraindicated:
  - ◆ Non-steroidal anti-inflammatory drugs (NSAIDs)
  - ◆ Prescription medication optimization
  - ◆ Activity modification
  - ◆ Physician supervised/prescribed active physical therapy (including home exercise program) targeting lumbopelvic (core) area

- ◆ Chiropractic care
- Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia)
- Documentation of nicotine-free status with **EITHER** of the following:
  - ◆ Patient is a never-smoker
  - ◆ Patient has refrained from smoking, use of smokeless tobacco, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- Absence of unmanaged significant behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse)
- Absence of alternative diagnoses that are a more likely cause of the patient's ongoing pain or disability
- Recent (within 6 months) diagnostic imaging studies that include **ALL** of the following:
  - ◆ Plain X-rays and/or cross sectional imaging (CT or MRI) that excludes the presence of destructive lesions (e.g. tumor, infection), acute fracture or inflammatory arthropathy that would not be properly addressed by SIJ fusion
  - ◆ Plain X-rays of the pelvis including the ipsilateral hip to evaluate potential concomitant hip pathology
  - ◆ Cross-sectional imaging (e.g. CT or MRI) of the lumbar spine to evaluate potential concomitant neural compression or other degenerative conditions

### **CMM-611.3: Open Sacroiliac Joint Fusion**

Open sacroiliac joint (SIJ) fusion is considered medically necessary when ALL of the following are met:

- Recent (within 6 months) plain X-rays and/or cross-sectional imaging (CT or MRI) demonstrate localized SIJ pathology
- Documentation of nicotine-free status with **EITHER** of the following:
  - ◆ Patient is a never-smoker
  - ◆ Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by blood cotinine lab results of  $\leq 10$  ng/mL
- **ANY** of the following:
  - ◆ Post-traumatic injury of the SIJ (e.g. following pelvic ring fracture)
  - ◆ As an adjunctive treatment for SIJ infection
  - ◆ Management of sacral tumor (e.g. partial sacrectomy)
  - ◆ When performed as part of a multisegmental long fusion constructs for the correction of spinal deformity (e.g. idiopathic scoliosis, neuromuscular scoliosis)
  - ◆ Failed prior percutaneous SIJ fusion

### **CMM-611.4: Non-Indications**

- Minimally invasive or percutaneous SIJ fusion or stabilization using titanium triangular implants is considered **experimental, investigational, or unproven**, including, but not limited to **ANY** of the following:
  - ◆ Any case that does not fulfill **ALL** of the above criteria
  - ◆ Less than six months of SIJ pain and/or functional impairment
  - ◆ Failure to pursue conservative treatment of the SIJ unless contraindications are clearly documented
  - ◆ Systemic arthropathy (e.g. ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis)
  - ◆ Generalized pain behavior (e.g. somatoform disorder) or generalized pain disorder (e.g. fibromyalgia)
  - ◆ Presence of infection, tumor, or fracture
  - ◆ Acute traumatic instability of the SIJ
  - ◆ Presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for the patient's pain
  - ◆ Any condition that would prevent insertion of the implants
  - ◆ Bilateral procedures on the same date of service
- The use of minimally invasive fusion products other than SI BONE (iFuse Implant™) System (e.g. Rialto SI Fusion System, SImmetry SI Joint Fusion System, Silex Sacroiliac Joint Fusion System, SiJoin Direct Posterior Fusion, Samba-Screw System, SI-LOK Sacroiliac Joint Fixation System) for minimally invasive SIJ fusion is considered **experimental, investigational or unproven**.
- Open sacroiliac joint (SIJ) fusion is considered **experimental, investigational, or unproven**, for **ANY** of the following indications:
  - ◆ Mechanical low back pain
  - ◆ Sacroiliac joint syndrome
  - ◆ Degenerative sacroiliac joint
  - ◆ Radicular pain syndromes

### **CMM-611.5: Procedure (CPT®) Codes**

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definitions
<b>27279</b>	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
<b>27280</b>	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules

## CMM-611.6: References

1. Al-Khayer A, Hegarty J, Hahn D, Grevitt MP. Percutaneous sacroiliac joint arthrodesis: a novel technique. *Journal of Spinal Disorders and Techniques* 2008; 21(5): 359-363.
2. Ackerman S, Cummings J, Polly D, Knight T, Schneider K, Holt T. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States Medicare population: potential economic implications of a new minimally-invasive technology. *Clin Outcomes Res.* 2013; 2013(5): 575-587.
3. Ashman B, Norvell D, Hermsmeyer J. Chronic sacroiliac joint pain: fusion versus denervation as treatment options. *Evid-Based Spine-Care J.* 2010; 1(03): 35-44.
4. Belanger TA, Dall BE. Sacroiliac arthrodesis using a posterior midline fascial splitting approach and pedicle screw instrumentation: a new technique. *J Spinal Disord.* 2001; 14(2): 118-124.
5. Bernard TN, Kirkaldy-Willis WH. Recognizing specific characteristics of nonspecific low back pain. *Clin Orthop.* 1987; (217): 266-80.
6. Blue Cross Blue Shield Association. *Diagnosis and Treatment of Sacroiliac Joint Pain.* January 2018.
7. Boradhurst NA, Bond MJ. Pain provocation tests for the assessment of sacroiliac joint dysfunction. *J Spinal Disord.* 1998; 11(4): 341-345.
8. Bornemann R, Roesler PP, Straus A, et al. 2-year clinical results of patients with sacroiliac joint syndrome treated by arthrodesis using a triangular implant system. *Technol Health Care Off J Eur Soc Eng Med.* November 2016.
9. Buchowski JM, Kebaish KM, Sinkov V, Cohen DB, Sieber AN, Kostuik JP. Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. *Spine Journal* 2005. 5(5): 520-528.
10. Capobianco R, Cher D. Safety and effectiveness of minimally invasive sacroiliac joint fusion in women with persistent post-partum posterior pelvic girdle pain: 12-month outcomes from a prospective, multi-center trial. *SpingerPlus.* 2015; 4(1): 570.
11. Cher DJ, Frasco MA, Arnold RJ, Polly DW. Cost-effectiveness of minimally invasive sacroiliac joint fusion. *Clin Outcomes Res CEOR* 2016; 8: 1-14.
12. Cher DJ, Polly D, Berven S. Sacroiliac joint pain: burden of disease. *Med Devices Evid Res.* 2014; 7: 73-81.
13. Cher DJ, Reckling WC. Quality of life in preoperative patients with sacroiliac dysfunction is at least as depressed as in other lumbar spinal conditions. *Med Devices Evid Res.* 2015; 8: 395-403.
14. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac fusion using the iFuse Implant System. *Med Devices Evid Res.* 2015; 8: 485-492.
15. Cohen SP, Strassels SA, Kurihara C, et al. Outcome Predictors for Sacroiliac Joint (Lateral Branch) Radiofrequency Denervation. *Reg Anesth Pain Med.* 2009; 34(3): 206-214.
16. Cohen SP, Hurley RW, Buckenmaier CC, Kurihara C, Morlando B, Dragovich A. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac pain. *Anesthesiology.* 2008; 109(2): 279-288.
17. Cummings J Jr, Capobianco RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Ann Surg Innov Res.* 2013; 7(1): 12.
18. Dengler J, Duhon B, Whang P, et al. Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint: A Pooled Analysis. *Spine.* March 2017.
19. Dengler J, Kools D, Pflugmacher R, et al. 1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain. *Pain Physician.* 2017; 20: 537-550.
20. Dengler J, Stureson B, Kools D, et al. Referred leg pain originating from the sacroiliac joint: 6-month outcomes from the prospective randomized controlled iMIA trial. *Acta Neurochir (Wien).* Nov 2016; 158(11): 2219-2224.
21. DePalma MJ, Ketchum JM, Saullo TR. Etiology of chronic low back pain in patients having undergone lumbar fusion. *Pain Medicine* 2011. 12(5): 732-739.
22. Duhon B, Bitan F, Lockstadt H, Kovalsky D, Cher D, Hillen T. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. *Int J Spine Surg.* 2016; 10: Article 13.

23. Duhon BS, Cher DJ, Wine KD, Kovalsky DA, Lockstadt H, on behalf of the SIFI Study Group. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. *Glob Spine J.* 2016; 6(3): 257-269.
24. Duhon BS, Cher D, Wine K, Lockstadt H, Kovalsky D, Soo C-L. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med Devices Evid Res.* 2013; 6: 219-229.
25. Endres S, Ludwig E. Outcome of distraction interference arthrodesis of the sacroiliac joint for sacroiliac arthritis. *Indian J Orthop.* 2013; 47(5): 437-442.
26. Eno JJ, Boone C, Bellino M, Bishop J. The Prevalence of Sacroiliac Joint Degeneration in Asymptomatic Adults. *J Bone Joint Surg AM.* 2015; 97(11): 932-936.
27. Fortin JD, Aprill CN, Ponthieux B, Pier J. Sacroiliac joint pain referral maps upon applying a new injection/arthrography technique. Part II: Clinical evaluation. *Spine* 1994; 19: 1483-9.
28. Fortin JD, Dwyer AP, West S, Pier J. Joint: pain referral maps upon applying a new injection/arthrography technique. Part I. Asymptomatic volunteers. *Spine.* 1994; 19: 1475-82.
29. Gaetani P, Miotti D, Risso A, et al. Percutaneous arthrodesis of sacroiliac joint: a pilot study. *J Neurosurg Sci.* 2013; 57(4): 297-301.
30. Graham Smith A, Capobianco R, Cher D, et al. Open versus minimally invasive sacroiliac fusion: a multi-center comparison of perioperative measures and clinical outcomes. *Ann Surg Innov Res.* 2013; 7(1): 14.
31. Heiney J, Capobianco R, Cher D. Systemic review of minimally invasive sacroiliac joint fusion using a lateral transarticular approach. *Int J Spine Surg.* 2015; 9: Article 40.
32. Kancherla VK, McGowan SM, Audley BN, Sokunbi G, Puccio ST. Patient Reported Outcomes from Sacroiliac Joint Fusion. *Asian Spine J.* 2017; 11(1): 120-126.
33. Katz V, Schofferman J, Reynolds J. The sacroiliac joint: a potential cause of pain after lumbar fusion to the sacrum. *Journal of Spinal Disorders and Techniques* 2003; 16(1): 96-99.
34. Khurana A, Guha AR, Mohanty K, Ahuja S. Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws: clinical and radiological outcome. *Journal of Bone and Joint Surgery British Volume* 2009; 91(5): 627-631.
35. Kim JT, Rudolf LM, Glaser JA. Outcome of percutaneous sacroiliac joint fixation with porous plasma-coated triangular titanium implants: an independent review. *Open Orthop J.* 2013; 7: 51-56.
36. Kube RA, Muir JM. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery. *Open Orthop J.* 2016; 10(1).
37. International Society for the Advancement of Spine Surgery (ISASS) Policy Statement – Minimally Invasive Sacroiliac Joint Fusion. July 2016.
38. Irwin RW, Watson T, Miick RP, Ambrosius WT. Age, Body Mass Index, and Gender Differences in Sacroiliac Joint Pathology. *Am J Phys Med Rehabil.* 2007; 86(1): 37-44.
39. Ledonio CGT, Polly DW, Swiontkowski MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? *Clin Orthop.* 2014; 472(6): 1831-1838.
40. Ledonio C, Polly D, Swiontkowski MF, Cummings J. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. *Med Devices Evid Res.* 2014; (7): 187-193.
41. Liliang PC, Lu K, Weng HC, Liang CL, Tsai YD, Chen HJ. The therapeutic efficacy of sacroiliac joint blocks with triamcinolone acetone in the treatment of sacroiliac joint dysfunction without spondyloarthropathy. *Spine* 2009; 34(9): 896-900.
42. Liliang PC, Lu K, Liliang CL, Tsai YD, Wank KW, Chen HJ. Sacroiliac joint pain after lumbar and lumbosacral fusion: findings using dual sacroiliac joint blocks. *Pain Medicine* 2011; 12(4): 565-570.
43. Lindsey DP, Kiapour A, Yerby SA, Goel VK. Sacroiliac Joint Fusion Minimally Affects Adjacent Lumbar Segment Motion: A Finite Element Study. *Int J Spine Surg.* 2015; 9: 64.
44. Lindsey D, Perez-Orribo L, Rodriguez-Martinez N, et al. Evaluation of a minimally invasive procedure for sacroiliac joint fusion – an in vitro biomechanical analysis of initial and cycled properties. *Med Devices Evid Res.* 2014; (7): 131-137.
45. Lingutla KK, Pollock R, Ahuja S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. *Eur Spine J.* March 2016: 1-8.
46. Local Coverage Determination (LCD): Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain (L36000)
47. Local Coverage Determination (LCD): Minimally-Invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint. (L36406)



48. Lorio M, Polly D, Ninkovic I, et al. Utilization of Minimally Invasive Surgical Approach for Sacroiliac Joint Fusion in Surgeon Population of ISASS and SMISS Membership. *The Open Orthopaedics Journal*. January 2014; 8(1): 1-6.
49. Lorio M, Rashbaum R. ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion. *Int J Spine Surg*. 2014; 8: Article 25.
50. Lorio MP. ISASS policy statement – minimally invasive sacroiliac joint fusion (July 2016). 2016.
51. Maingne JY, Aivaliklis A, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. *Spine*. 1996; 21(16): 1889-1892.
52. Mason, LW, Chopra I, Mohanty K. The percutaneous stabilization of the sacroiliac joint with hollow modular anchorage screws: a prospective outcome study. *European Spine Journal* 2013; 22(10); 2325-2331.
53. McGuire RA, Chen Z, Donahoe K. Dual fibular allograft technique for sacroiliac joint arthrodesis. *Evidence Based Spine Care Journal* 2012; 3(3): 21-8.
54. Miller, LE, Block JE. Minimally invasive arthrodesis for chronic sacroiliac joint dysfunction using the SImmetry SI Joint Fusion system. *Medical Devices* 2014; 7; 125-130.
55. Miller L, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI joint Fusion System: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac disruption. *Med Devices Evid Res*. 2013; 6: 77-84.
56. NASS Coverage Policy Recommendations. Percutaneous Sacroiliac Joint Fusion. 2015.
57. National Institute for Health and Care Excellence. Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain [IPG578]. 2017; <https://www.nice.org.uk/guidance/ipg578>.
58. Ohtori S, Sainoh T, Takaso M, et al. Clinical Incidence of Sacroiliac Joint Arthritis and Pain after Sacropelvic Fixation for Spinal Deformity. *Yonsei Med J*. 2012; 53(2): 416.
59. Ou-Yang DC, York PJ, Kleck CJ, Patel VV. Current Concepts Review: Diagnosis and Management of Sacroiliac Joint Dysfunction. *J Bone Joint Surg Am*. 2017; 99: 2027-36.
60. Patel N. Twelve-Month Follow-Up of a Randomized Trial Assessing Cooled Radiofrequency Denervation as a Treatment for Sacroiliac Region Pain. *Pain Pract Off J World Inst Pain*. January 2015.
61. Patel N, Gross A, Brown L, Gekht G. A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. *Pain Med Malden Mass*. 2012; 13(3): 383-398.
62. Polly D, Cher D, Whang PG, Frank C, Sembrano J. for the INSITE Study Group. Does Level of Response to SI Joint Block Predict Response to SI Joint Fusion? *Int J Spine Surg*. 2016; 10: Article 4.
63. Polly DW, Cher DJ, Wine KD, et al. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. *Neurosurgery*. 2015; 77(5): 674-691.
64. Polly DW, Swofford J, Whang PG et al. Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs Non-Surgical Management for Sacroiliac Joint Dysfunction. *Int J Spine Surg*. 2016; 10: Article 28.
65. Rappaport LH, Luna IY, Joshua G. Minimally Invasive Sacroiliac Joint Fusion Using a Novel Hydroxyapatite-Coated Screw: Preliminary 1-Year Clinical and Radiographic Results of a 2-Year Prospective Study. *World Neurosurg*. 2017; 101: 493-497.
66. Rashbaum RF, Ohnmeiss DD, Lindley EM, Kitchel SH, Patel VV. Sacroiliac Joint Pain and Its Treatment. *Clin Spine Surg*. 2016; 29(2): 42-48.
67. Rudolf L. MIS Fusion of the SI Joint: Does Prior Lumbar Spinal Fusion Affect Patient Outcomes? *Open Orthop J*. 2013; 7: 163-168.
68. Rudolf L. Sacroiliac joint arthrodesis – MIS technique with titanium implants: report of the first 50 patients and outcomes. *Open Orthop Journal* 2012; 6(1):495-502.
69. Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac fusion using triangular implants. *Open Orthop J*. 2014; 8: 375-383.
70. Sachs D. Minimally Invasive versus Open Sacroiliac Joint Fusion: A Comparison of Process Measures and Description of Technique. *International Society for the Advancement of Spine Surgery*. Vancouver, BC Canada; 2013: 187.
71. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv Orthop*. 2013.

72. Sachs D., Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. *Annals of Surgical Innovation and Research* 2012; 6(13); 1-4.
73. Sachs D, Capobianco R, Cher D, et al. One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. *Med Devices Evid Res.* 2014. 7: 299-304.
74. Sachs D, Kovalsky D, Redmond A, et al. Durable intermediate to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants. *Med Devices Evid Res.* 2016; 9: 213-222.
75. Schoell K, Buser Z, Jakoi A, et al. Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. *Spine J.* Nov 2016; 16(11): 1324-1332. PMID 27349627.
76. Schofferman J, Reynolds J, Herzog R, Covington E, Dreyfuss P, O'Neill C. Failed back surgery: etiology and diagnostic evaluation. *Spine Journal* 2003; 3(5): 400-403.
77. Schroader JE, Cunningham ME, Ross T, Boachie-Adjei O. Early Results of Sacro-Iliac Joint Fixation Following Long Fusion in the Sacrum in Adult Spine Deformity. *Hosp Spec Surg J.* 2013; 10(1): 30-35.
78. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. *Spine.* 1995; 20(1): 31-37.
79. Sembrano JN, Polly DW. How often is low back pain not coming from the back? *Spine.* 2009; 34(1): E27-E32.
80. Smith AG, Capobianco R, Cher D, et al. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison. *Annals of Surgical Innovation and Research* 2013; 7: 14.
81. Soriano-Baron H, Lindsey DP, Rodriguez-Martinez N, et al. The Effect of Implant Placement on Sacroiliac Joint Range of Motion: Posterior vs Trans-articular. *Spine.* 2015; 40(9): E525-E530.
82. Spain K, Holt T. Surgical revision after sacroiliac joint fixation or fusion. *Int J. Spine Surg.* Apr 2017; 11:5. PMID 28377863.
83. Spiker WR, Lawrence BD, Raich AI, Skelly AC, Brodke DS. Surgical versus injection treatment for injection-confirmed chronic sacroiliac pain. *Evid-Based Spine-Care J.* 2012; 3(4): 41-53.
84. Stuge B, Laerum E, Kirkesola G, Volestad N. The efficacy of a treatment program focusing on specific stabilizing exercises for pelvic girdle pain after pregnancy: a randomized controlled trial. *Spine.* 2004; 29(4): 351-359.
85. Stuesson B, Kools D, Pflugmacher R, Gasbarrini A, Prestamburgo D, Dengler J. Six-Month Outcomes from a Randomized Controlled Trial of Minimally Invasive SI Joint Fusion with Triangular Titanium Implants vs. Conservative Management. *Eur Spine J.* 2017; 26(3): 708-719.
86. Szadek KM, Hoogland PV, Zuurmond WW, de Lange JJ, Perez RS. Nociceptive nerve fibers in the sacroiliac joint in humans. *Reg Anesth Pain Med.* 2008; 33(1): 36-43.
87. Szadek KM, van der Wurff P, van Tulder MW, Zuurmond WW, Perez RSGM. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. *J Pain.* 2009; 10(4): 354-368.
88. Vanaclocha V, Herrera JM, Siz-Sapena N, Rivera-Paz M, Verdu-Lopez F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. *Neurosurgery.* April 2017.
89. Vanaclocha VV, Verdu-Lopez F, Sanchez-Pardo M, et al. Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients. *J Spine.* 2014; 3(5).
90. Waisbrod H, Krainick JU, Gerbershagen HU. Sacroiliac joint arthrodesis for chronic lower back pain. *Arch Orthop Trauma Surg Arch.* 1987; 106(4): 238-240.
91. Whang PG, Cher D, Polly D, et al. Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. *Int J Spine Surg.* 2015; 9: Article 6.
92. Wise CL, Dall BE. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. *Journal of Spinal Disorders and Techniques* 2008; 21(8): 579-584.
93. Yoshihara H. Sacroiliac joint pain after lumbar/lumbosacral fusion: current knowledge. *European Spine Journal* 2012; 21(9): 1788-1796.
94. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. *J Neurosurg Spine.* April 2015; 23(1): 59-66.

## **CMM-612: Grafts**

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## **CMM-612.1: General Guidelines**

- The determination of medical necessity for grafts (orthobiologics) is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- Definition/technique for bone marrow aspirate concentrate (see **CMM-612.3: Bone Marrow Aspirate Concentrate** for criteria):
  - ◆ A bone marrow aspirate concentrate (BMAC) is intended as a high concentration of viable connective tissue osteoprogenitor cells. The aspiration technique requires that no more than 2 mL of blood is aspirated from any given area in the iliac crest to avoid dilution with peripheral blood. The aspiration of 80 to 100 cc of marrow from the iliac crest is performed using a sequential technique (Muschler) through a small incision made over the iliac crest through different trajectories until the desired amount is obtained. A single aspiration instead of using a sequential technique produces the lowest yield of viable cells. The aspirate is then transferred to the concentrating device (centrifuge) that removes the red blood cell fractions and plasma. The BMAC can be admixed to the osteoconductive biocompatible substrates of choice e.g. collagen sponges, hydroxyapatite (HA) substrates and other porous ceramics as well as particulate demineralized bone matrix (DBM) to fabricate composite hybrid grafts.

## **CMM-612.2: Recombinant Human Bone Morphogenetic Protein (rhBMP-2) (InFuse®)**

The clinical criteria of this policy addresses the scope and clinical indications for Recombinant Human Bone Morphogenetic Protein – 2 (rhBMP-2) (InFuse®) in spinal fusion surgeries only and not for other indications for its use in the appendicular skeleton (e.g. tibial fracture non-union repair surgery). These criteria are developed to manage patients very unlikely to fuse without rhBMP. Patients very likely to fuse without rhBMP include most pediatric patients, healthy patients undergoing one level lumbar fusion procedures and undergoing routine anterior and posterior cervical fusions.

- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **medically necessary** for a stand alone anterior lumbar interbody fusion (ALIF) for all patients except males with a strong reproductive priority.
- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **medically necessary** for posterolateral lumbar fusion and posterior lumbar interbody fusion (PLIF and TLIF) when **ONE or MORE** of the following conditions at high risk for fusion failure is present:
  - ◆ Revision spinal fusion surgery for pseudarthrosis following one or more previous failed spinal fusion surgery(ies)
  - ◆ Spinal fusion surgery in a compromised graft bed (e.g. prior radiation therapy)
  - ◆ Thoracolumbar fusion for correction of spinal deformity performed at more than one level
  - ◆ Multilevel spinal fusion surgeries (> 3 spinal motion segments)

- ◆ Long posterior fusions to the sacrum in adults patients undergoing correction or stabilization of spinal deformity
- ◆ Single level anterior interbody lumbar or lumbosacral fusion (ALIF) using an FDA approved fusion device when there is Grade III or greater spondylolisthesis.
- ◆ Metabolic or other conditions when traditional, autogenous bone grafting has a high risk of failure (**ONE or MORE** of the following):
  - Current smoker
  - Insulin diabetic with poor glycemic control
  - Chronic renal disease
  - Alcohol Use Disorder (AUD)
  - Corticosteroid dependence
  - Pediatric patients with neuromuscular scoliosis or occipitocervical pathology
- ◆ Autogenous bone graft is either not available, is inadequate volume, or of poor quality to be useful (**ONE or MORE** of the following):
  - Rheumatoid arthritis
  - Osteoporosis
  - Trauma patients with concomitant pelvic injury
  - Patients at high risk for post-harvest iliac crest fracture
- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **not medically necessary** for **ANY** of the following:
  - ◆ Skeletally immature patients unless there is a high risk for fusion failure
  - ◆ Planned use of grafting in the vicinity of a resected or extant neoplasm
  - ◆ Known contraindications including pregnancy, hypersensitivity/allergy, infection, spinal malignancy
  - ◆ Routine anterior and/or posterior cervical fusion surgery other than in pediatric patients with a high risk of fusion failure
  - ◆ Routine pediatric spine fusion procedures including correction of adolescent idiopathic scoliosis
  - ◆ Single level anterior interbody lumbar or lumbo-sacral fusion (ALIF) using an FDA approved fusion device when there is Grade II or less spondylolisthesis

### **CMM-612.3: Bone Marrow Aspirate Concentrate (BMAC)**

- Bone marrow aspirate concentrate (BMAC) is considered **medically necessary** for hybrid or composite grafting (combined osteoinductive and osteoconductive) including autologous corticocancellous iliac crest bone graft (ICBG) for posterolateral lumbar spinal fusion surgery (spondylodesis) with or without spinal instrumentation.
- Bone marrow aspirate concentrate (BMAC) is considered **experimental, investigational, or unproven** for **ALL** of the following:
  - ◆ BMAC combined with allograft or synthetic scaffold as a substitute for autologous bone graft for spinal fusion surgery (spondylodesis) with or without spinal instrumentation
  - ◆ Application to cervical/thoracic spinal fusion surgery with or without instrumentation
  - ◆ Anterior spinal fusion surgery with or without instrumentation

- ◆ Application to spinal decompression without fusion
- ◆ Disc arthroplasty surgery
- ◆ Use of lumbar interspinous devices
- ◆ Obtaining BMAC without using the sequential technique as outlined
- ◆ Use of unfractionated BMAC
- ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis)
- ◆ Primary or metastatic neoplastic disease of the spine

#### **CMM-612.4: Bone Graft Substitutes**

ALL of the following bone graft substitutes for the enhancement of bone healing is considered experimental, investigational, or unproven:

- rhBMP-7 (i.e., OP-1™)
- INFUSE/MASTERGRAFT™ Posterolateral Revision Device
- Human amniotic membrane bone graft substitute
- Cell-based substitutes other than a bone marrow aspirate (e.g. mesenchymal stem cell therapy, OsteoCel®, ViviGen®, Trinity®) when used to enhance bone healing
- Human growth factors (e.g. fibroblast growth factor, insulin-like growth) when used to enhance bone healing
- Platelet rich plasma (e.g. autologous platelet derived growth factor) when used to enhance bone healing
- Allograft bone graft substitutes used exclusively as stand-alone stabilization devices for fusion (e.g. TruFuse® for isolated facet fusion, NuFix™ for isolated facet fusion, BacFast® HD for isolated facet fusion)
- Bone graft substitutes used to reduce donor site morbidity (e.g. iliac crest donor site reconstruction)
- Ceramic-based products (e.g. b-TCP)
- OptiMesh® deployable grafting system

## CMM-612.5: Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.	
CPT®	Code Description/Definition
<b>+20930</b>	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
<b>+20931</b>	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
<b>+20936</b>	Auto graft for spine surgery only (includes harvesting the graft); local (e.g. ribs, spinous process, or laminae fragments) obtained from same incision (List separately in addition to code for primary procedure)
<b>+20937</b>	Auto graft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
<b>+20938</b>	Auto graft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
<b>+20939</b>	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure).
This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.	

## CMM-612.6: References

1. Agarwal R, Williams K, Umscheid CA, Welch WC. Osteoinductive bone graft substitutes for lumbar fusion: a systematic review. *J Neurosurg Spine*. 2009 Dec;11(6):729-40.
2. Agency for Healthcare Research and Quality (AHRQ). Technology assessment: the role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. Updated 2005 Sep 21.
3. Agency for Healthcare Research and Quality (AHRQ). Bone Morphogenetic Protein: The State of Evidence for On-Label and Off-Label Use. August 6, 2010.
4. Ajiboye RM, Hamamoto JT, Eckardt MA, Wang JC. Clinical and radiographic outcomes of concentrated bone marrow aspirate with allograft and demineralized bone matrix for posterolateral and interbody lumbar fusion in elderly patients. *Eur Spine J*. 2015 Nov; 24(11): 2567-72.
5. American Academy of Orthopaedic Surgeons. Nonunions. Updated 2007 September.
6. American Academy of Orthopaedic Surgeons. Spinal fusion. Updated 2007 September.
7. American Academy of Orthopaedic Surgeons. Research. Statistics on Orthopedic Patients and Conditions. 2006.
8. Apatech, Inc. Actifuse.
9. Bansai S, Chauhan V, Sharma S, Maheshwari R, Juyal A, Raghuvanshi S. Evaluation of hydroxyapatite and beta-tricalcium phosphate mixed with bone marrow aspirate as a bone graft substitute for posterolateral spinal fusion. *Indian J Orthop*. 2009 Jul; 43(3): 234-9.
10. Bapat MR, Chaudhary K, Garg H, Laheri V. Reconstruction of large iliac crest defects after graft harvest using autogenous rib graft: a prospective controlled study. *Spine (Phila Pa 1976)*. 2008 Nov 1;33(23):2570-5.
11. Baskin DS, Ryan P, Sonntag V, Westmark R, Widmayer MA. A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein-2 with the CORNERSTONE-SR allograft ring and the ATLANTIS anterior cervical plate. *Spine*. 2003;28(12):1219-25.
12. Benglis D, Wang MY, Levi AD. A comprehensive review of the safety profile of bone morphogenetic protein in spine surgery. *Neurosurgery*. 2008 May;62(5 Suppl 2):ONS423-31; discussion ONS431.

13. Boakye M, Mummaneni PV, Garrett M, Rodts G, Haid R. Anterior cervical discectomy and fusion involving a polyetheretherketone spacer and bone morphogenetic protein. *J. Neurosurg: Spine*. 2005 May;2:521-5.
14. Boden SD, Kang J, Sandhu H, Heller JG. Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies. *Spine*. 2002;27(23):2662-73.
15. Bohner M. Design of ceramic-based cements and putties for bone graft substitution. *Eur Cell Mater*. 2010 Jul 1;20:1-12.
16. Burkus JK, Sandhu HS, Gornet MF, Longley MC. Use of rhBMP-2 in combination with structural cortical allografts: clinical and radiographic outcomes in anterior lumbar spinal surgery. *J Bone Joint Surg Am*. 2005 Jun;87-A(6):1205-12.
17. Camargo PM, Lekovic V, Weinlaender M, Vasilic N, Madzarevic M, Kenney EB. A reentry study on the use of bovine porous bone mineral, GTR, and platelet-rich plasma in the regenerative treatment of intrabony defects in humans. *Int J Periodontics Restorative Dent*. 2005 Feb;25(1):49-59.
18. Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J*. 2011 Jun;11(6):471-91.
19. Carragee EJ, Mitsunaga KA, Hurwitz EL, Scuderi GJ. Retrograde ejaculation after anterior lumbar interbody fusion using rhBMP-2: a cohort controlled study. *Spine J*. 2011 Jun;11(6):511-6.
20. Carreon LY, Glassman SD, Anekstein Y, Puno RM. Platelet gel (AGF) fails to increase fusion rates in instrumented posterolateral fusions. *Spine*. 2005 May 1;30(9):E243-6; discussion E247.
21. Carreon LY, Glassman SD, Brock DC, Dimar JR, Puno RM, Campbell MJ. Adverse events in patients re-exposed to bone morphogenetic protein for spine surgery. *Spine*. 2008 Feb 15;33(4):391-3.
22. Carlisle E, Fischgrund JS. Bone morphogenetic proteins for spinal fusion. *Spine*. 2005;5:240S-9S.
23. Chaua AMT, Mobbs RJ. Bone graft substitutes in anterior cervical discectomy and fusion. *Eur Spine J*. 2009 Apr;18(4):449-64.
24. Delawi D, Dhert WJ, Rillardon L, Gay E, Prestamburgo D, Garcia-Fernandez C. A prospective, randomized, controlled, multicenter study of osteogenic protein-1 in instrumented posterolateral fusions: report on safety and feasibility. *Spine (Phila Pa 1976)*. 2010 May 20;35(12):1185-91.
25. Dimar JR 2nd, Glassman SD, Burkus JK, Pryor PW, Hardacker JW, Carreon LY. Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. *J Bone Joint Surg Am*. 2009 Jun;91(6):1377-86.
26. Dawson E, Bae HW, Burkus JK, Stambough JL, Glassman SD. Recombinant human bone morphogenetic protein-2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial. *J Bone Joint Surg Am*. 2009 Jul;91(7):1604-13.
27. Dimar JR, Glassman SD, Burkus KJ, Carreon LY. Clinical outcomes and fusion success at 2 years of single-level instrumented posterolateral fusions with recombinant human bone morphogenetic protein-2/compression resistant matrix versus iliac crest bone graft. *Spine*. 2006 Oct 15;31(22):2534-9.
28. Dmitriev AE, Lehman RA Jr, Symes AJ. Bone morphogenetic protein-2 and spinal arthrodesis: the basic science perspective on protein interaction with the nervous system. *Spine J*. 2011 Jun;11(6):500-5.
29. Einhorn TA. Clinical applications of recombinant human BMPs: early experience and future development. *J Bone Joint Surg Am*. 2003;85-A(Suppl 3):82-8.
30. Epstein NE. Pros, cons, and costs of INFUSE in spinal surgery. *Surg Neurol Int*. 2011 Jan 24;2:10.
31. Feldman MD. Recombinant human bone morphogenetic protein-2 for spinal surgery and treatment of open tibial fractures. February 16, 2005.
32. Friedlaender GE, Perry CR, Cole JD, Cook SD, Cierny G, Muschler GF, et al. Osteogenic protein-1 (bone morphogenetic protein-7) in the treatment of tibial nonunions: a prospective, randomized clinical trial comparing rhOP-1 with fresh bone autograft. *J Bone Joint Surg Am*. 2001;83-A(Suppl 1 Pt 2):S151-8.
33. Garrison KR, Donell S, Ryder J, Shemilt I, Mugford M, Harvey I, Song F. Clinical effectiveness and cost-effectiveness of bone morphogenetic proteins in the non-healing of fractures and spinal fusion: a systematic review. *Health Technol Assess*. 2007 Aug;11(30):1-150, iii-iv.



34. Gautschi OP, Frey SP, Zellweger R. Bone morphogenetic proteins in clinical applications. *ANZ J Surg.* 2007 Aug;77(8):626-31.
35. Glassman SD, Dimar JR 3rd, Burkus K, Hardacker JW, Pryor PW, Boden SD, Carreon LY. The efficacy of rhBMP-2 for posterolateral lumbar fusion in smokers. *Spine.* 2007 Jul 1;32(15):1693-8.
36. Glassman SD, Dimar JR, Carreon LY, Campbell MJ, Puno RM, Johnson JR. Initial fusion rates with recombinant human bone morphogenetic protein-2/compression resistant matrix and a hydroxyapatite and tricalcium phosphate/collagen carrier in posterolateral spinal fusion. *Spine.* 2005;30(15):1694-8.
37. Granjeiro JM, Oliveira RC, Bustos-Valenzuela JC, Sogayar MC, Taga R. Bone morphogenetic proteins: from structure to clinical use. *Braz J Med Biol Res.* 2005 Oct;38(10):1463-73.
38. Hart R, Komzak M, Okai F, Nahlik D, Jajtner P, Puskeiler M. Allograft alone versus allograft with bone marrow concentrate for the healing of the instrumented posterolateral lumbar fusion. *Spine J.* 2014 Jul 1; 14(7): 1318-24.
39. Helgeson MD, Lehman RA Jr, Patzkowski JC, Dmitriev AE, Rosner MK, Mack AW. Adjacent vertebral body osteolysis with bone morphogenetic protein use in transforaminal lumbar interbody fusion. *Spine J.* 2011 Jun;11(6):507-10.
40. Helm GA, Gazit Z. Future uses of mesenchymal stem cells in spine surgery. *Neurosurg Focus.* 2005 Dec 15;19(6):E13.
41. Johnson RG. Bone marrow concentrate with allograft equivalent to autograft in lumbar fusions. *Spine* 2014 Apr 20; 39(9): 695-700.
42. Johnsson R, Stromqvist B, Aspenberg P. Randomized radiostereometric study comparing osteogenic protein-1 (BMP-7) and autograft bone in human noninstrumented posterolateral lumbar fusion: 2002 Volvo Award in clinical studies. *Spine.* 2002;27(23):2654-61.
43. Kanayama M, Hashimoto T, Shigenobu K, Yamane S, Bauer TW, Togawa D. A prospective randomized study of posterolateral lumbar fusion using osteogenic protein-1 (OP-1) versus local autograft with ceramic bone substitute: emphasis of surgical exploration and histologic assessment. *Spine.* 2006 May 1;31(10):1067-74.
44. Khan SN, Sandhu HS, Lane JM, Cammisa FP Jr, Girardi FP. Bone morphogenetic proteins: relevance in spine surgery. *Orthop Clin North Am.* 2002;33(2):447-63.
45. Khashan M, Inoue S, Berven SH. Cell based therapies as compared to autologous bone grafts for spinal arthrodesis. *Spine* 2013 Oct 1; 38 (21): 1885-91.
46. Leung VY, Chan D, Cheung KM. Regeneration of intervertebral disc by mesenchymal stem cells: potentials, limitations, and future direction. *Eur Spine J.* 2006 Aug;15 Suppl 3:S406-13. Epub 2006 Jul 15.
47. Luhmann SJ, Bridwell KH, Cheng I, Imamura T, Lenke LG, Schootman M. Use of bone morphogenetic protein-2 for adult spinal deformity. *Spine (Phila Pa 1976).* 2005 Sep 1;30(17 Suppl):S110-7.
48. McKay WF, Peckham SM, Badura JM. A comprehensive clinical review of recombinant human bone morphogenetic protein-2 (INFUSE((R)) Bone Graft). *Int Orthop.* 2007 Dec;31(6):729-734.
49. Mehta S, Watson JT. Platelet rich concentrate: basic science and current clinical applications. *J Orthop Trauma.* 2008 Jul;22(6):432-8.
50. Minamide A, Yoshida M, Kawakami M, Okada M, Enyo Y, Hashizume H, Boden SD. The effects of bone morphogenetic protein and basic fibroblast growth factor on cultured mesenchymal stem cells for spine fusion. *Spine.* 2007 May 1;32(10):1067-71.
51. Mulconrey DS, Bridwell KH, Flynn J, Cronen GA, Rose PS. Bone morphogenetic protein (RhBMP-2) as a substitute for iliac crest bone graft in multilevel adult spinal deformity surgery: minimum two-year evaluation of fusion. *Spine (Phila Pa 1976).* 2008 Sep 15;33(20):2153-9.
52. Mussano F, Ciccone G, Ceccarelli M, Baldi I, Bassi F. Bone morphogenetic proteins and bone defects: a systematic review. *Spine.* 2007 Apr 1;32(7):824-30.
53. Nandi SK, Roy S, Mukherjee P, Kundu B, De DK, Basu D. Orthopaedic applications of bone graft & graft substitutes: a review. *Indian J Med Res.* 2010 Jul;132:15-30.
54. NASS Coverage Policy Recommendations. Recombinant Human Bone Morphogenetic Protein (rhBMP-2). 2014.
55. Odri GA, Hami A, Pomero V, Seite M, Heymann D, Bertrand-Vasseur A, Skalli W, Delecrin J. Development of a per-operative procedure for concentrated bone marrow adjunction in postero-lateral fusion: radiological, biological and clinical assessment. *Eur Spine J.* 2012 Dec; 21(12): 2665-72.

56. Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat. Osteogenic protein-1 for long bone nonunion. Health Technology Assessment Scientific Literature Review. Toronto, ON: Ontario Ministry of Health and Long-Term Care; April 2005.
57. Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat. Bone morphogenetic proteins and spinal surgery for degenerative disc disease. Health Technology Scientific Literature Review. Toronto, ON: Ontario Ministry of Health and Long-Term Care; March 2004.
58. Papakostidis C, Kontakis G, Bhandari M, Giannoudis PV. Efficacy of autologous iliac crest bone graft and bone morphogenetic proteins for posterolateral fusion of lumbar spine: a meta-analysis of the results. *Spine*. 2008 Sep 1;33(19):E680-92.
59. Patterson TE, Boehm C, Nakamoto C, Rozic R, Walker E, Piuze N, Muschler GF. The Efficiency of Bone Marrow Aspiration for Harvest of Connective Tissue Progenitors from the Human Iliac Crest. *JBJS*. 2017 Oct;99(19): 1673-82.
60. Piuze NS, Hussain ZB, Chahla J, Cinque ME, Moatshe G, Mantripragada V, Muschler GF, LaPrade RF. Variability in the Preparation, Reporting, and Use of Bone Marrow Aspirate Concentrate in Musculoskeletal Disorders: A Systematic Review of the Clinical Orthopaedic Literature. *J Bone Joint Surg* 2018; 100: 517-25.
61. Pradhan BB, Bae HW, Patel VV, Delamarter RB. Graft resorption with the use of bone morphogenetic protein: lessons from anterior lumbar interbody fusion using femoral ring allografts and recombinant human bone morphogenetic protein-2. *Spine*. 2006 May 1;31(10):E277-84.
62. Resnick DK. Reconstruction of anterior iliac crest after bone graft harvest decreases pain: a randomized, controlled clinical trial. *Neurosurgery*. 2005 Sep;57(3):526-9; discussion 526-9.
63. Singh K, Smucker JD, Boden SD. Use of recombinant human bone morphogenetic protein-2 as an adjunct in posterolateral lumbar spine fusion: a prospective CT-scan analysis at one and two years. *J Spinal Disord Tech*. 2006 Aug;19(6):416-23.
64. Smucker JD, Rhee JM, Singh K, Yoon ST, Heller JG. Increased swelling complications associated with off-label usage of rhBMP-2 in the anterior cervical spine. *Spine*. 2006 Nov 15;31(24):2813-9.
65. U.S. Food and Drug Administration. INTER FIX Threaded Fusion Device: important medical information.
66. U.S. Food and Drug Administration. New device approval: INFUSE® bone graft-P000054. Updated May 17, 2004.
67. U.S. Food and Drug Administration. New device approval: InFUSE™ bone graft/LT-CAGE™ lumbar tapered fusion device-P000058. Updated 2002 Sep 6.
68. U.S. Food and Drug Administration. Supplement S002. July 2004. InFUSE™ bone graft/LT-CAGE™ lumbar tapered fusion device-P000058.
69. U.S. Food and Drug Administration. New humanitarian device approval: OP-1™ - H010002. Updated 2001 Nov 30.
70. U.S. Food and Drug Administration. New humanitarian device approval: OP-1 Putty- H020008. Updated 2004 Apr 27.
71. U.S. Food and Drug Administration. InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. Summary of Safety and Effectiveness Data. January 10, 2022.
72. U.S. Food and Drug Administration. Osteofil Allograft Paste. 510(k) summary K043420.
73. Vaccaro AR, Whang PG, Patel T, Phillips FM, Anderson DG, Albert TJ, Hilibrand AS, Brower RS, Kurd MF, Appannagari A, Patel M, Fischgrund JS. The safety and efficacy of OP-1 (rhBMP-7) as a replacement for iliac crest autograft for posterolateral lumbar arthrodesis: minimum 4-year follow-up of a pilot study. *Spine J*. 2008 May-Jun;8(3):457-65.
74. Washington State Health Care Authority. Health Technology Assessment. On- and off- label uses of rhBMP-2 or rhBMP-7 for spinal fusion. February 14, 2012.
75. Yamada T, Yoshii T, Sotome S, Uyasa M, Kato T, Arai Y, Kawabata S, Tomizawa S, Sakaki K, Hirai T, Shinomiya K, Okawa A. Hybrid grafting using bone marrow aspirate combined with porous B-tricalcium phosphate and trephine bone for lumbar postero lateral fusion: a prospective, comparative study versus local bone grafting. *Spine* 2012 Feb 1; 37(3): E174-9.
76. Yu NY, Schindeler A, Little DG, Ruys AJ. Biodegradable poly(alpha-hydroxy acid) polymer scaffolds for bone tissue engineering. *J Biomed Mater Res B Appl Biomater*. 2010 Apr;93(1):285-95.