blue of california

Medical Policy

Spinal Fusion	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Surgery
Original Policy Date: March 5, 2012	**Effective Date:** February 22, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

The purpose of this policy is to establish the criteria for when surgical spinal fusion (arthrodesis and arthroplasty) may be considered medically necessary.

Policy

Lumbar Fusion

The determination of medical necessity for the use of lumbar spinal fusion (arthrodesis) with or without instrumentation is always made on a case-by-case basis.

Lumbar fusion (arthrodesis) is considered **medically necessary** in patients who demonstrate unstable vertebral fractures, spinal dislocations or where surgery is being performed for tumor, spinal infection, or other disease processes that have led to or will lead to lumbar segmental instability as defined in the rationale section.

Lumbar fusion (arthrodesis) may be considered **medically necessary** in patients with severe chronic (at least one year in duration) low back pain with or without radiculopathy which is aggravated by activity and demonstrate:

- Isthmic spondylolisthesis; **or**
- Degenerative spondylolisthesis or degenerative scoliosis with evidence of spinal stenosis with associated neurological findings (radicular pain with or without neurogenic claudication); **or**
- A pseudoarthrosis (non-union) from a prior spinal fusion; **or**
- The clinical need for a third lumbar discectomy at the same level; **or**
- Spinal stenosis which requires decompressive surgery with concomitant lumbar segmental instability; **or**
- Scoliosis or kyphosis resulting in severe skeletal deformity which compromises the patient's visceral function, severely interferes with the patient's ability to carry out their activities of daily living, produces severe pain or documented progression.

Lumbar spinal fusion may be considered **not medically necessary** if the following criteria have not been met:

- Lumbar segmental instability has been documented at the level(s) being considered for fusion as defined above; **and**
- The patient has received an adequate diagnostic evaluation to rule out all other potential causes of pain; **and**
- The patient has undergone a magnetic resonance imaging (MRI) or a computed tomography (CT) scan with or without myelography within the past six months which demonstrates severe disc pathology; **and**
- The patient has participated in a minimum of three (3) months up to six (6) months of a supervised active rehabilitation exercise program with appropriate adjunctive care. When comparing the long-term outcomes of spinal fusion versus an aggressive rehabilitative exercise program combined with a cognitive behavioral approach, the scientific literature demonstrates comparable outcomes with respect to pain and function. Spinal fusion, however, carries increased risks of serious complications as compared to rehabilitative exercises.; **and**
- The patient does not have an active psychological diagnosis or disturbance or psychosocial issues that would substantially reduce the possibility of a successful outcome; **and**

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- The patient does not have clinically significant comorbid factors such as morbid obesity, smoking, diabetes, renal disease, osteoporosis, or other comorbid factors which could increase the likelihood of a negative outcome of the surgical procedure while dramatically increasing patient risk; **and**
- If the patient has undergone a discogram, it must be positive for concordant pain at the proposed level to be fused with at least one normal control level documented.

Lumbar spinal fusion may be considered **medically necessary** in a carefully selected group of patients with severe single level degenerative disc disease who fulfill the following criteria:

- The patient has received an adequate diagnostic evaluation to rule out all other potential causes of pain; **and**
- The patient has undergone a MRI or a CT scan with or without myelography within the past six months which demonstrates severe single level disc pathology; **and**
- The patient has undergone a discogram by an independent examiner and it must be positive for concordant pain at the proposed single level to be fused with at least one normal control level documented; **and**
- The patient has participated in a minimum of six months of an active supervised rehabilitative exercise program with appropriate adjunctive care. When comparing the long term outcomes of spinal fusion versus an aggressive rehabilitative exercise program combined with a cognitive behavioral approach, the scientific literature demonstrates comparable outcomes with respect to pain and function. Spinal fusion, however, carries increased risks of serious complications as compared to rehabilitative exercises.; **and**
- The patient does not have an active psychological diagnosis or disturbance or psychosocial issues that would substantially reduce the possibility of a successful outcome; **and**
- The patient does not have clinically significant comorbid factors such as morbid obesity, smoking, diabetes, renal disease, osteoporosis, or other comorbid factors which could increase the likelihood of a negative outcome of the surgical procedure while dramatically increasing patient risk.

Extreme Lateral Interbody Fusion (XLIF®)

Extreme lateral interbody fusion (XLIF®) may be considered **medically necessary** in patients who meet the lumbar spinal fusion criteria listed above and the following criteria:

- L1 to L4 pathology; **and**
- When used as an approach to perform an interbody fusion; **and**
- Lumbar deformities with less than 30 degrees rotation; **and**
- Degenerative spondylolisthesis less than or equal to grade 2; **and**
- Bilateral retroperitoneal scarring is not present; **and**
- There is no need for direct posterior decompression through the same approach.

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Axial Lumbar Interbody Fusion (AxiaLIF®)

Axial lumbar interbody fusion (AxiaLIF® AxiaLIF II ®) or Interlaminar Lumbar Instrumented Fusion (ILIF ™) is considered **investigational** based on the lack of published scientific literature.

Lumbar Artificial Disc Replacement

Based on the lack of long term efficacy and safety in comparison to standard spinal fusion techniques, lumbar artificial disc replacement (arthroplasty) is considered **investigational**.

Cervical Fusion

The determination of medical necessity for the use of cervical spinal fusion (arthrodesis) with or without instrumentation is always made on a case-by-case basis.

Cervical fusion (arthrodesis) is considered **medically necessary** in patients who demonstrate unstable vertebral fractures, spinal dislocations, segmental instability secondary to traumatic injury, or where surgery is being performed for tumor, infection, or other disease processes that have led to cervical segmental instability.

Cervical fusion (arthrodesis) may be considered **medically necessary** in patients with severe chronic neck pain with or without radiculopathy which is aggravated by activity and fulfill the following criteria:

- Is performed as part of a cervical decompressive procedure; **and**
- Patient has received an adequate diagnostic evaluation to rule out all other potential causes of pain; **and**
- Patient has undergone a MRI or CT scan with or without myelography within the past six months which indicates spinal stenosis (central and/or lateral recess) with clear evidence of a neural compressive lesion/nerve root compromise and/or spinal cord compression which correlates with the clinical examination findings; **and**
- Patient has participated in a reasonable trial of an active rehabilitative exercise program with appropriate adjunctive care; **and**
- Patient does not have clinically significant comorbid factors which could potentially increase the likelihood of a negative outcome of the surgical procedure while dramatically increasing patient risk; **and**
- Patient does not have an active psychological diagnosis or disturbance or psychosocial issues that would substantially reduce the possibility of a successful outcome.

Cervical fusion (arthrodesis) may be considered **medically necessary** in patients who demonstrate a pseudoarthrosis (non-union) from a prior fusion.

Cervical fusion (arthrodesis) using both an anterior and posterior approach (360^0 fusion) may be considered **medically necessary** in patients as an adjunct to an extensive anterior approach procedure or in certain cases of severe instability.

Cervical Artificial Disc Replacement

Based on the lack of long term efficacy and safety in comparison to standard spinal fusion techniques, cervical artificial disc replacement (arthroplasty) is considered **investigational**.

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Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review

• History and physical and/or consultation note including:
  o Activity limitations
  o Clinical findings
  o Comorbidities
  o Conservative treatments and duration
  o Duration of back pain
  o Psychosocial assessment
  o Reason for procedure
• Radiology report(s) (i.e., MRI, CT, discogram)
Post Service
• Procedure report(s)

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the appendix for this policy

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