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Developed By: Medical Criteria Committee	

Approved: **Robert Neal Mills, MD** **Date:** 07/28/11

Description:
Low back pain is the most frequent cause of disability among individuals under the age of 45 and affects most people at some point in their lives. Conservative management is the first line of treatment for back pain and typically consists of rest, exercise, physical therapy, pain medication, local injections and lumbar bracing. Typically conservative therapy is not recommended in the presence of progressive neurological deficits, when a spinal fracture or dislocation is unstable or for progressive spinal deformity. When conservative management is not successful, surgery may be warranted.

Lumbar fusion was initially used as a treatment for infectious conditions of the spine as well as progressive spinal deformities and traumatic injuries. Other conditions that lumbar fusion has been used to treat are instability as a result of surgical removal of osseous and/or ligamentous structures in the surgical approach for various pathologies, spondylolisthesis, progressive scoliosis, pseudoarthrosis, degenerative disc disease and facet arthropathy.

In performing a lumbar fusion there are different surgical approaches and a variety of implant instrumentation. Bone graft is used to accomplish arthrodesis between lamina, transverse processes, and the vertebral bodies. The grafts can be taken from the patient (autograft), from a donor (allograft) or derived sources (i.e. bone morphogenic proteins or other substances which are used to augment the graft material and have osteo-inductive and/or osteo-conductive properties). Laminar hooks, pedicle screws, interbody devices and other instrumentation are used as an adjunct to fusion to stabilize the spine during the healing of the fusion and to align the spine in a corrected position in the sagittal and frontal planes.

Surgical approaches for lumbar fusion include the following:

From the front and side: Anterior lumbar interbody fusion (ALIF) and eXtreme lateral lumbar interbody fusion (XLIF).

From the back: Posterior lumbar interbody fusion (PLIF), posterior lumbar laminar and inter-transverse process fusion (PLF) or transforaminal lumbar interbody fusion (TLIF).

From the front and back: Combined anterior/posterior lumbar fusion utilizing two approaches.

Minimally invasive: Some surgeons use endoscope to perform minimally invasive decompressive laminotomies, discectomies and lumbar fusion.

Some newer technologies are being introduced which avoid fusion and preserve spinal motion. Such procedures include artificial disc replacement (e.g. Charite and ProDisc), interspinous process decompression systems (e.g. X-STOP) and dynamic stabilization (e.g. Dynesys Spinal System).

Criteria:
ODS will cover lumbar fusion for the following indications:

I. ODS will cover lumbar fusion for the following conditions when there is associated spinal instability:
   A. Acute spinal fracture or progressive neurological impairment with instability
   B. Neural compression after spinal fracture
   C. Epidural compression or vertebral destruction from a tumor

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D. Spinal tuberculosis, debridement of the spine for infection, or acute or chronic infection which results in spinal instability
E. Pseudoarthrosis (e.g. nonunion of prior fusion)
F. Spinal deformity (e.g. congenital, idiopathic, paralytic or disease associated scoliosis and/or kyphosis)
G. Instability secondary to intraoperative excessive facet removal, associated radical discectomy, removal of pars interarticularis or pars fracture
H. Spondylolisthesis which is symptomatic and interferes with the desired activities of daily living, quality of life, and/or is associated with a manifest or progressive neurologic defect.
I. Spinal deformity such as progressive degenerative scoliosis or idiopathic scoliosis over 40 degrees.

II. **For members who have not had prior lumbar surgery** and have chronic low back pain, associated neurological findings and documented radiological (x-ray, CT, and/or MRI) findings, ODS will cover lumbar fusions when **all** of the following criteria are met:
A. The member has tried at least 3 months of conservative therapy including rest, pain medications, physical therapy, and local injections; **and**
B. The surgeon requesting the lumbar fusion has evaluated the patient on at least two occasions prior to requesting the fusion; **and**

**Note: if the patient has a progressive neurological deficit, both criteria above can be waived.

C. Mechanical (non-radicular) low back pain with instability as demonstrated on flexion/extension and/or side bending x-rays; **or**
D. Spondylolisthesis which is symptomatic and interferes with the desired activities of daily living, quality of life, and/or is associated with a manifest or progressive neurological deficit. This would include congenital, isthmic, degenerative, traumatic, and neoplastic spondylolisthesis; **or**
E. The member has chronic, severe and significantly disabling low back pain from degenerative disc disease which has failed 6 months of conservative treatment and has documented radiological (e.g. x-ray, CT, and/or MRI) evidence of disease.

III. **For members who have had prior laminectomy, discectomy, or other decompressive procedure at the same level**, ODS will cover lumbar when the following criteria is met:
A. 3 months of conservative therapy has failed to relieve symptoms; **and**
B. Mechanical (non-radicular) low back pain with instability (as defined above in II C); **or**
C. Mechanical (non-radicular) low back pain with spondylolisthesis, sagittal, coronal, and/or rotational deformity, or other condition leading to a progressive, measurable deformity; **or**
D. Objective signs/symptoms compatible with neurogenic claudication or lumbar radiculopathy that is supported by MRI or CT and neurological exam; **or**
E. Evidence of a post-laminectomy structural deficiency.

IV. **For members who have had prior fusion at the same level**, ODS will cover lumbar fusion when **one** of the following criteria are met:
A. Pseudoarthosis with or without hardware failure; **or**
B. Neurogenic symptoms or lumbar radiculopathy supported by MRI, CT or myelography and a detailed clinical neurological examination.

V. **For member who have had prior fusion at an adjacent level(s)**, ODS will cover lumbar fusion if conservative therapy has failed to relieve symptoms and findings require additional levels to be included in the fusion mass. The member must meet the same criteria as described in II above for patients with no prior history of spinal surgery.

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Limitations:

- For artificial disc replacement requests please see ODS medical necessity criteria for Intervertebral Disc Prosthesis.
- For requests for X-STOP, please see ODS medical necessity criteria for Interspinous Process Decompression System (e.g. X-STOP).

Not Covered:

ODS considers the following experimental and investigational because there is insufficient evidence in peer reviewed medical literature to establish their effectiveness:

- Dynamic spine stabilization device systems (e.g. Dynesys)

Information to be Submitted with Pre-Authorization Request:

- Chart notes from the treating physician including subjective and objective symptoms and findings.
- Radiographic study reports
- Conservative treatment attempts
- Prior history of spine surgery or other treatment

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- Peer review by a board certified orthopedic surgeon and professor of orthopedics.
- Physician Advisors