

MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

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SUBJECT: Lumbar Spinal Fusion
INDEX TITLE: Medical Management
ORIGINAL DATE: January 2013

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	<input type="checkbox"/> Fully Insured	<input type="checkbox"/> Individual Product	<input type="checkbox"/> Marketplace (Exchange)	<input checked="" type="checkbox"/> All
GOVERNMENT PROGRAMS	<input type="checkbox"/> MA HMO	<input type="checkbox"/> MA PPO	<input type="checkbox"/> MA C-SNP	<input type="checkbox"/> MA D-SNP	<input checked="" type="checkbox"/> MA All	
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health to cover Lumbar Spinal Fusion when it is medically necessary (refer to CRM.015.MH Medical Necessity policy) and covered under the member's specific benefit plan.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health Medical Director (Medical Director).

II. DEFINITIONS

Cauda Equina Syndrome (CES) occurs when the nerve roots of the cauda equina are compressed and disrupt motor and sensory function to the lower extremities and bladder. Patients with this syndrome are often admitted to the hospital as a medical emergency. CES can lead to incontinence and even permanent paralysis. The collection of nerves at the end of the spinal cord is known as the cauda equina, due to its resemblance to a horse's tail.

Flatback Syndrome is the loss of lumbar lordosis of the spine after one has scoliosis surgery. The normal lumbar curvature becomes flat, or you may even get a reverse curvature (called lumbar kyphosis). The condition is characterized by the inability to stand up straight, and typically patients will have back pain in their upper or lower spine. It can occur in patients of any age, but it is more likely to be found in older adults who have had scoliosis surgery.



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Laminectomy is a surgical procedure where an opening is made in the lamina (the roof of the vertebrae) to relieve pressure on the nerve roots of the spine

Spondylolisthesis is a slipping or displacement of one vertebrae over another. There are different degrees or grades of the displacement. Grading of spondylolisthesis is defined as the following:

- Grade I- 1 percent to 25 percent slip
- Grade II- 26 percent to 50 percent slip
- Grade III- 51 percent to 75 percent slip
- Grade IV- 76 percent to 100 percent slip

III. PURPOSE

The purpose of this policy is to provide the medical necessity indications for the lumbar spinal fusion procedure.

IV. SCOPE

This policy applies to various MedStar Health Departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / Background

An estimated 75 to 85 percent of all Americans will experience some form of back pain during their lifetime. Although low back pain can be quite debilitating and painful, in about 90 percent of all cases, pain improves without surgery. Conservative treatment options include physical therapy, back exercises, weight reduction, steroid injections (epidural steroids), nonsteroidal anti-inflammatory medications, rehabilitation and limited activity. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues should also be addressed when present. All of these treatment options are aimed at relieving the inflammation in the back and irritation of nerve roots. For the few patients in which conservative treatment for low back pain does not provide relief, or for certain specific conditions shown to not benefit from conservative treatment, surgery may be needed. For urgent/emergent conditions including, but not limited to: acute spinal fracture and/or major trauma, acute neural compression with motor deficit, spinal infection or abscess, metastatic cancer or neoplasm, or cauda equina syndrome, a trial of conservative management is not required.



Spinal fusion is a surgical procedure used to correct problems with the small bones of the spine (vertebrae). It is essentially a “welding” process which results in the involved vertebrae healing into a single, solid bone. It is indicated for congenital or acquired spinal instability, for correction of a deformity, or due to trauma. This surgical procedure may relieve or reduce symptoms related to conditions such as spinal stenosis, fracture, tumor, infection, scoliosis, and/or spondylolisthesis.

There are various approaches for the procedure including anterior, posterior, or lateral. The procedure may be combined with a laminectomy (decompression) procedure to relieve pressure on spinal nerves.

B. Specific Indications

Spinal Lumbar Fusion is considered medically necessary for spinal instability associated with the following emergent/urgent conditions (Conservative treatment is not required):

- Spinal fracture and/or major trauma confirmed by imaging studies; OR
- Spinal infection or abscess confirmed by imaging studies; OR
- Spinal tumor or epidural compression due to neoplasm confirmed by imaging studies; OR
- Cauda Equina syndrome; OR
- Related complication of severe weakness (1-2 out of 5 strength) on physical exam

Spinal Lumbar Fusion is considered medically necessary for the following conditions when the listed criteria are met:

- Spinal stenosis when all of the following are met:
 - Imaging findings consistent with symptoms, signs and diagnosis
 - All other causes of pain have been ruled out
 - Symptoms of unremitting pain with predominant radicular or neurogenic components that affect Activities of Daily Living (ADLs) which have not improved following a trial of conservative treatment as appropriate (defined later in this policy)

OR

- Spondylolisthesis when ALL of the following are met:
 - Imaging findings consistent with symptoms, signs and diagnosis
 - All other causes of pain have been ruled out
 - Symptoms of unremitting pain with predominant radicular or neurogenic components that affect Activities of Daily Living (ADLs) and have not improved following a trial of conservative treatment as appropriate (defined later in this policy)



Note: Grade III or IV Spondylolisthesis (>50%) slippage DOES NOT require a trial of conservative treatment (as defined later in this section).

OR

- Scoliosis (without stenosis) when at least one of the following criteria are met:
 - Medical history and physical findings of progressive deformity of over 10° in the past twelve (12) months OR
 - Deformity of >45° OR
 - Deformity of >35° with failure of non-operative pain management (>1 month of therapy) and/or functional impairment

OR

- Fusion following prior spinal surgery when at least one (1) of the following criteria are met (as indicated by the Public Policy statement of the International Society for the Advancement of Spine Surgery):
 - Recurrent disc herniation (after at least three (3) months from previous surgery)
 1. The patient has previously been operated at the same level for disk herniation, which resulted in meaningful symptom relief for at least 3 months; AND
 2. Recurrent disk herniation is seen on imaging at the same level that was previously operated; AND
 3. The patient has new pain or neurological symptoms consistent with the level of recurrence; AND
 4. The patient either has acute neurological symptoms (e.g. new onset of bowel and/or bladder incontinence, paralysis, or symptoms of CES) that cannot wait longer for surgical treatment or has been unresponsive to three (3) months of conservative medical management (including at least pain medication and exercise).

OR

- Adjacent segment degeneration with spinal stenosis or disc herniation (after at least six (6) months from previous surgery)
 - a. The patient has previously undergone fusion (for any diagnosis), which at some point resulted in substantial clinical improvement for a period of at least 6 months; AND
 - b. Imaging shows clear signs of disk degeneration, instability, and/or stenosis, at a level immediately adjacent to the fusion, which either were not present at the time of the original operation or have worsened from their initial state an amount that is clinically substantial; AND
 - c. The patient presents with clinically meaningful pain or neurological symptoms, which have been unresponsive to a minimum of three (3) consecutive months of structured conservative medical management



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(including at least pain medication, activity modification, and daily exercise).

OR

- Failure of previous fusion (nonunion) with continued motion or loosening of hardware

Considerations for Lumbar Fusion Surgery:

1. For those conditions which require a trial of conservative treatment, failure of conservative treatment is defined as failure of all 4 of the following, unless contraindicated:

- Eight (8) weeks or more of chiropractic/ physical therapy or osteopathic manipulative therapy
- Use, if not contraindicated, of prescription strength analgesics and/or anti-inflammatory medications for at least six (6) weeks
- Epidural steroids, if medically indicated and with member consent
- Bracing (especially in scoliosis and adjacent segment instability), if medically indicated

2. Members with a current history of smoking must participate in at least one (1) counseling session or smoking cessation program. According to the American Academy of Orthopaedic Surgeons (AAOS), smoking affects the tissues that make up the musculoskeletal system, increasing the risk of injury and disease. Smokers also have a higher rate of complications after surgery than nonsmokers — such as poor wound healing and infection — and outcomes are less satisfactory. This is related to the decrease in blood supply to the tissues.

3. Surgery on three or more levels of the spine is covered only for the following conditions: spondylolisthesis, scoliosis, kyphosis, or flatback syndromes.

C. Limitations

Lumbar spinal fusion surgery is **not covered** for any of the following:

- Surgery for nerve root compression or spinal stenosis without documented instability or spondylolisthesis
- Members requiring non-emergent/non-urgent surgery with current smoking history without documentation of at least one (1) counseling session or participation in a smoking cessation program.
- Spinal degeneration without instability
- Use of devices that are not approved by the Food and Drug Administration (FDA) or have been recalled by the FDA

- Members with psychological factors correlated with poor outcomes which include: history of drug or alcohol abuse, high degrees of somatization on clinical or psychological evaluation, presence of a personality disorder or major psychiatric illness, and/or current evidence of a factitious disorder should be evaluated and complete at least one (1) counseling session prior to surgery

D. Information Required for Review

In order to determine medical necessity for covered spinal surgical procedures, adequate information must be furnished by the treating physician. Required documentation includes the following:

- Office notes from referring physician and/or neurosurgical/orthopedic evaluation documenting extent of and response to conservative management including effect on ADLs.
- Chiropractor/physical therapy/Osteopath reports if these services were provided
- Radiology/imaging reports
- Specific procedure to be performed including spinal levels
- Documentation of participation in MedStar Health Plan Low Back Program if indicated
- Documentation of completion of one (1) counseling session or smoking cessation program for members who have a current history of smoking, if applicable.
- Documentation of completion of evaluation and one (1) counseling session for members with psychological factors correlated with poor outcomes as outlined in the limitations section

E. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable CPT and HCPCS Coding:

- 22533 Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
- 22558 Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar



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- 22612 Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
- 22630 Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
- 22633 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
- 22800 Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
- 22802 Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
- 22804 Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
- 22808 Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
- 22810 Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
- 22812 Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
- 22818 Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
- 22819 Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments

F. Review Process

1. The Medical Management staff assigned to review obtains the clinical information according to CRM.001.MH - Prior Authorization/Pre-Service Review policy, to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate according to CRM.005.MH - Medical Director Referral, CRM .015.MH - Medical Necessity and CRM.032.MH Benefit Exception policy.
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan (CRM.004.MH – Timeliness of Utilization Management Decisions – Medical Assistance; CRM.007.MH – Timeliness of Utilization



Management Decisions – Commercial, and CHIP: CRM.022.MH – Timeliness of Utilization Management Decisions – Medicare).

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy HS-LE0009 Records Retention, Management and Retirement, and as indicated in the Insurance Services Division Policy and Procedure CORP.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. References

Medical Literature/Clinical Information:

1. UPMC Health Plan. Low Back Pain Program – Primary Care Physician Guide. Last updated: 06/19/2012.
2. UPMC Health Plan. Low Back Pain Program and Surgical Prior Authorization Process for Lumbar Laminectomy and Spinal Fusion – Specialist Physician Guide. Last updated: 06/19/2012
3. International Society for the Advancement of Spine Surgery (ISASS). Policy Statement on Lumbar Spinal Fusion Surgery. July 15, 2011. http://www.isass.org/public_policy/2011-07-15_policy_statement_lumbar_surgery.html
4. American Association of Neurological Surgeons (AANS). Lumbar Spinal Stenosis. December 2011. <http://www.aans.org/en/Patient%20Information/Conditions%20and%20Treatments/Lumbar%20Spinal%20Stenosis.aspx>
5. American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo: Spinal Fusion, Last reviewed: June 2010. <http://orthoinfo.aaos.org/topic.cfm?topic=a00348>
6. American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo: Posterolateral Lumbar Fusion. Last reviewed: June 2010. <http://orthoinfo.aaos.org/topic.cfm?topic=A00594>
7. American Academy of Orthopaedic Surgeons (AAOS). Position Statement No. 1153: The Effects of Tobacco Exposure on the Musculoskeletal System. Revised June 2008. <http://www.aaos.org/about/papers/position/1153.asp>



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8. Washington State Health Care Authority. Health Technology Assessment (Presented by ECRI Institute). Lumbar Fusion and Discography

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