

Introduction

There is broad agreement that lumbar fusion surgery is appropriate to mitigate the immediate threat of spinal instability from major trauma, tumor, infection, or congenital anomalies.

In many other circumstances, however, there is less accord concerning the benefit of lumbar fusion. Search and appraisal of scientific, economic and policy literature indicates that lumbar fusion surgery is associated with a substantial complication rate (Brox, *Spine*, 2003), is costly to patients and purchasers (CMS database, 2014), and for many, is of uncertain benefit compared with non-surgical care (Brox, *Spine*, 2003). Despite these concerns, the number of patients undergoing lumbar fusion is increasing rapidly and disproportionately to other spine surgeries. The regional rate for lumbar fusion among CMS patients varies by a factor of 20 (Weinstein, *Spine*, 2006) with a nearly three-fold difference in charges billed to CMS nationwide (CMS database, 2014) for this surgery. Standards for appropriateness, fitness for surgery, best surgical practice, and methods to ensure return to function are rudimentary, fragmented, and inconsistent. When clinical standards for reimbursement for lumbar fusion are relaxed, rates of fusion, complications, and reoperation rates all increase as does inpatient cost (Martin, *Spine*, 2013).

We acknowledge serious deficiencies in the medical literature addressing relative risks and benefits of lumbar fusion and that population-based research may have limitations in individual cases. We support the perspective that provider judgment has an important role in ensuring best care.

Given these constraints and uncertainties we nevertheless believe that much can be accomplished in improving outcomes for patients, performance for providers and affordability. To this end we have created the following community standards for safety and appropriateness to be used as minimum requirements for production, purchasing, and payment of health care for spinal fusion.

Inclusion Criteria

- Patients with more than 12 weeks of back or lower extremity pain of confirmed spinal origin with neurologic symptoms or signs.

Exclusion Criteria

- Back pain associated with degenerative joint disease in the absence of structural instability.
- Patients under 18 years of age.
- Use of lumbar fusion in the care of patients with spinal trauma, tumor, infection, inflammatory conditions, and scoliosis.

Even in the presence of spinal instability, a structured, conservative, non-surgical approach is preferred for patients without neurologic symptoms or signs. Failure of other therapies is likewise not a clear indication for lumbar fusion. Decompression surgery alone should be considered before lumbar fusion when the former is appropriate. We acknowledge that lumbar fusion may be considered in rare and specific situations as detailed in the bundle document.

To improve safety for patients, performance for providers and affordability for purchasers, we are proposing the following four-cycle model as a guide to providers, purchasers, and payers. This model requires documentation of disability despite explicit non-surgical care, meeting fitness requirements for patients prior to surgery, adherence of standards for best practice surgery, and implementation of a structured plan to rapidly return patients to function. The workgroup recommends that payors and purchasers fund elements of this lumbar fusion bundle.

References

In developing this bundled payment model, we have drawn from existing standards, data and reimbursement policies noted below. Citations related to clinical standards set forth in the bundle are noted in the associated evidence table, available here: www.breecollaborative.org/wp-content/uploads/Lumbar-Fusion-Evidence-Table-Final.pdf

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I. Disability Despite Non-Surgical Therapy

Note: A trial of non-surgical care is not indicated if symptoms, signs and imaging findings reveal objective (i.e., physical exam, imaging), severe, rapidly progressive condition.

A) Specification of the patient's degree of functional impairment

1. Clinically:
 - a. Due to back or radicular pain and/or
 - b. Neurologic symptoms or signs
2. With at least one of the following patient reported outcome measures:
 - a. PROMIS 10PF and PROMIS 10PI, the preferred measures
 - b. Oswestry Disability Index
 - c. Roland-Morris Disability Scale
 - d. EuroQual-5 Dimensions (EQ-5D)
 - e. Short Form 36 (SF-36)
 - f. A similarly peer-reviewed and validated patient-reported outcome
 - g. Therapeutic Associates Outcome Score

B) Documentation of imaging findings confirming lumbar instability that correlate with the patient's symptoms and signs

1. At least 4mm of a/p translation at L1-5 levels or 5mm of translation at L5-S1 when supine lateral (or cross table lateral) or standing extension lateral lumbar x-rays are compared to standing flexion views OR 11 degrees or greater end plate angular change at a single level, compared to an adjacent level.
2. Neural foraminal stenosis as the result of loss of foraminal height, associated with nerve root compression and concordant radiculopathy.
3. Previous decompressive surgery requiring significant facetectomies for foraminal decompression that are expected to create instability in the spinal segment.

C) Document at least three months of structured non-surgical therapy delivered by a collaborative team.

The care team should include a physiatrist, a spine surgeon, the primary care provider, physical therapist, care partner, **clinical psychologist or pain specialist**, and others as needed. A consultation with a physiatrist must be obtained to validate that optimal non-surgical care has occurred and that surgery is indicated. The primary care provider is accountable for leading the team to ensure delivery of comprehensive non-surgical care that includes the following non-surgical measures and medications unless neurologic signs or imaging findings are severe or rapidly progressive. Other appropriate and evidence-based medications, as indicated.

1. Trial of the following non-surgical measures:
 - a. Patient education.
 - b. Risk stratification with the STarT Back tool or similar to inform treatment plan

- c. Active physical therapy aimed specifically at patients with lumbar segmental instability, with a program of spinal stabilization and hip mobilization.
 - d. Behavioral therapies aimed at improving self-efficacy with an emphasis on effectively addressing important psychosocial elements such as fear avoidance, catastrophizing, and low expectations of recovery. Examples of behavioral therapies might include various methods of cognitive behavioral therapy, such as activity coaching (e.g., a progressive goal attainment program).
 - e. Identification and management of associated anxiety and depression.
2. Time-limited trial of non-steroidal anti-inflammatory drugs or skeletal muscle relaxants if not contraindicated:
 3. Spinal manipulation or other evidence-based non-surgical therapies may be used at the discretion of the collaborative care team.
 4. Use of opioids is discouraged.
 5. **If injection therapy is used as an adjunct to non-surgical care it should comply with the determination of the Health Technology Assessment Program or other evidence based guidelines.**

D) Documentation of severe disability unresponsive to non-surgical therapy

1. Formal consultation with collaborative team led by board certified physiatrist to confirm appropriateness, adequacy, completeness, and active participation in non-surgical therapy and need for lumbar fusion. Need for lumbar fusion should be based on persistent disability and absence of psychosocial barriers. A decision for lumbar fusion requires a meeting of all members of the team and a documented recommendation for fusion by the physiatrist.
2. **Measure severe disability unresponsive to nonsurgical care according to patient reported outcome indicator used at baseline (e.g., PROMIS-10, TAOs)**
3. Confirm that the degree and location of pain and/or physical impairment matches the anatomic location of imaging abnormalities.
4. Departures from these standards should be reviewed by the collaborative care team.

- E) Patient must participate in shared decision-making validated decision aid such as those approved by Washington State, if available. This requirement is in addition to informed consent

II. Fitness for Surgery

A) Document requirements related to patient safety

Patient should meet the following minimum requirements prior to surgery **and assist patients in meeting these requirements:**

1. Body Mass Index less than 40.
2. Hemoglobin A1c less than 8% in patients with diabetes.
3. Adequate nutritional status to ensure healing.
4. Sufficient liver function to ensure healing **particularly for high risk patients.**
5. Pre-operative plan for management of opioid dependency, if patient has taken opioids **for more than three months as per Bree Collaborative Supplement to AMDG Guidelines.**
6. Avoidance of nicotine with confirmation of at least one negative urine screen for a minimum of four weeks pre-operatively with six to eight weeks preferred.
7. Screen for alcohol abuse; manage if screen is positive.
8. Absence of an active, life-limiting condition that would likely cause death before recovery from surgery.
9. Absence of severe disability from an unrelated condition that would severely limit the benefits of surgery such as severe osteoporosis.
10. Absence of dementia that would interfere with recovery – performing surgery for a patient with such dementia requires preauthorization, informed consent of a person with Durable Power of Attorney for Health Care, and a contract with the patient’s care provider.
11. Screen for untreated depression or psychiatric disorder; manage if screen is positive.
12. Complete a pre-operative plan for post-operative return to function.
13. Screen for osteoporosis in high-risk individuals; manage if screen is positive.

B) Document patient engagement

2. Patient must designate a personal Care Partner.¹ Patient and Care Partner must actively participate in the following:
 - a. Surgical consultation.
 - b. Pre-operative evaluation.
 - c. Pre-surgical class and/or required surgical and anesthesia educational programs.
 - d. In-hospital care.
 - e. Post-operative care teaching.
 - f. Patient’s home care and exercise program.
3. Patient must participate in end of life planning, including completion of an advance directive and designation of durable power of attorney for health care.
4. Patient agrees to participate in a registry with two years follow-up data collection.

¹ A care partner is someone who joins the patient as a supportive lay partner who attends pre- and post-operative informational sessions with providers and provides general assistance to the patient until the patient is able to return to independent function. Instruction to the care partner should include the elements of discharge planning. The care partner must be intellectually, emotionally, and physically qualified to assume this role.

C) Document optimal preparation for surgery

1. Perform pre-operative history, physical, and screening lab tests based on review of systems:
 - a. Evaluate for cardiac and pulmonary fitness.
 - b. Obtain basic lab profile, plasma glucose, prothrombin time, complete blood count, urinalysis with culture, if indicated.
 - c. Culture nasal passages to identify staphylococcal carrier state.
 - d. Ensure A1c less than 8% in patients with diabetes.
 - e. Perform relevant imaging if not performed within previous six months.
 - f. Screen for predictors of delirium.
2. Obtain relevant consultations:
 - a. Evaluate for good dental hygiene with dental consultation as necessary.
 - b. Refer to Anesthesia for pre-operative assessment including identification and management of such conditions such as sleep apnea and pulmonary hypertension.
 - c. Consult Physical Therapy to instruct in improving return to function.
 - d. Request additional consults as necessary.
3. Collect patient-reported measures to confirm lack of significant response to non-surgical treatments using:
 - a. General health questionnaire: PROMIS-10[®].
 - b. Standardized disability survey: ODI.

III. Spinal Fusion Procedure

A) General standards for a surgical team performing surgery

1. The spine surgeon should perform a minimum of twenty lumbar fusion surgeries in the previous twelve months. Neurosurgeons must be board certified or board eligible. Orthopedic surgeons must have successfully completed a spine fellowship.
2. Members of the surgical team must have documented credentials, training, and experience. The roster of the surgical team should be consistent.
3. Surgical team may include two attending surgeons to reduce anesthesia time and blood loss particularly in complex cases.
4. Elective spine surgery must be scheduled to begin before 5:00 pm.
5. Surgery must be performed in an inpatient facility.
6. Facilities in which surgery is performed should have policies that align with the American College of Surgeons Statement on Health Care Industry Representatives in the Operating Room.

B) Elements of optimal surgical process

1. Optimize pain management and anesthesia:
 - a. Use multimodal pain management format to minimize sedation and encourage early ambulation.
 - b. Minimize use of opioids.
2. Avoid infection:
 - a. Administer appropriate perioperative course of antibiotics according to guidelines set forth in the Surgical Care Improvement Project (SCIP).
 - b. Restrict use of urinary catheter to less than 48 hours per SCIP guidelines.
 - c. Use chlorhexidine skin prep by patient prior to surgery if no contraindication.
3. Avoid bleeding and low blood pressure:
 - a. Administer standardized protocols using appropriate medications to limit blood loss.
 - b. Use standardized IV fluid protocols including those implemented by RNs post-operatively with appropriate supervision and monitoring.
4. Avoid deep venous thrombosis and embolism according to guidelines set forth in the SCIP.
5. Avoid hyperglycemia: use standardized protocol to maintain optimal glucose control.
6. Bone morphogenic protein: If bone morphogenic protein is used it must be in accord with Washington Health Technology Program policy:
http://www.hca.wa.gov/hta/Documents/findings_decision_bmp.pdf

C) Participation in registries

1. Hospitals should participate in the Spine SCOAP registry with results available to purchasers.
2. Providers must maintain a registry of patients undergoing lumbar fusion and collect prospective patient reported outcome measures as specified elsewhere in this document.

IV. Post-Operative Care and Return to Function

A) Standard process for post-operative care

1. Utilize a standardized and rapid recovery track to mobilize patients following surgery:
 - a. Provide accelerated physical therapy and mobilization if regional pain control is acceptable.
 - b. Provide a patient-oriented visual cue to record progress on functional milestones required for discharge.
 - c. Instruct patients in home exercise, use of walking aids, and precautions.
 - d. Instruct Care Partner to assist with home exercise regimen.
2. Patients that meet CMS standards for placement in a skilled nursing facility must have their post-operative nursing and rehabilitative needs addressed.
3. Hospitalists or appropriate medical consultants will be available for consultation to assist with complex or unstable medical problems in the post-operative period.

B) Use standardized hospital discharge process aligned with Washington State Hospital Association (WSHA) toolkit

1. Arrange follow up with care team according to WSHA toolkit and Bree Collaborative Potentially Avoidable Hospital Readmissions Report and Recommendations.
2. Evaluate social and resource barriers based on WSHA toolkit.
3. Reconcile medications.
4. Provide patient and family/caregiver education with plan of care:
 - a. Signs or symptoms that warrant follow up with provider.
 - b. Guidelines for emergency care and alternatives to emergency care.
 - c. Contact information for the spine surgeon and primary care provider.
5. Ensure post-discharge phone call to patient by care team to check progress, with timing of call aligned with Bree Collaborative Potentially Avoidable Hospital Readmissions Report and Recommendations.
6. Send post-discharge summary to primary care provider or after care provider within three business days of discharge.

C) Arrange home health services

1. Provide the patient and Care Partner with information about medically recommended home exercises.
2. Arrange additional home health services as necessary.

D) Schedule follow up appointments

1. Schedule return visits as appropriate.
2. Measure patient-reported functional outcomes with standard instrument.
3. If opioid use exceeds six weeks, develop a formal plan for opioid management.
4. **Continued smoking cessation**

Quality Standards

The provider group performing surgery must maintain or participate in a registry of all patients having first-time, single level lumbar fusion excluding patients with surgery for fracture, infection, cancer, or inflammatory conditions. This registry will be updated quarterly and be available for reporting to current or prospective purchasers and their health plan. It will be made available to quality organizations such as the Washington Health Alliance and the Foundation for Health Care Quality.

During the first year of the bundled contract, providers will be expected to install methods to measure appropriateness, evidence-based surgery, return to function, and the patient care experience according to the standards noted below. Reporting of results will be expected to begin the second year of the contract. The only exception to this reporting requirement is that the measures of patient safety and affordability noted in section 5 below will begin the first year of the contract.

See **Appendix 1** for more detailed information on quality standard numerators and denominators.

1. Standards for appropriateness

These standards are intended to document patient engagement in medical decision-making and measurement of disability prior to surgery. Report:

- a. Proportion of patients with lumbar fusion (as defined above) receiving formal shared decision-making decision aids pre-operatively.
- b. Proportion of patients with lumbar fusion with documented patient-reported measures of disability and quality of life function prior to surgery using the ODI and PROMIS-10 Global Health tools.
- c. Results of measures from 1b, specifically including ODI score and questions on the PROMIS-10 Global Health survey regarding everyday physical activities (Question 7) and pain (Question 10).

2. Standards for evidence-based surgery

These standards are intended to document adherence to evidence-based best practices related to the peri-operative process. Report the proportion of lumbar fusion patients that have received all of the following in the peri-operative period:

- a. Measures to manage pain using multimodal anesthesia.
- b. Measures to reduce risk of venous thromboembolism and pulmonary embolism.
- c. Measures to reduce blood loss.
- d. Measures to reduce infection such as administration of prophylactic antibiotics.
- e. Measures to maintain optimal blood sugar control.

3. Standards for ensuring rapid and durable return to function

These standards are intended to measure patient recovery. Report:

- a. Proportion of patients with lumbar fusion for which there are documented patient-reported measures of disability and quality of life six months and two years following surgery – the same measures should be used as in standard 1b.
- b. Results of measures from 2b, specifically including responses to the questions identified in standard 1c.

4. Standards for the patient care experience

These standards are intended to measure patient-centered care. Report:

- a. Proportion of patients with lumbar fusion surveyed using HCAHPS.
- b. Results of measures from 4a, specifically including responses to Q6 and Q22-Q25 in HCAHPS survey.

5. Standards for patient safety and affordability

These standards are intended to measure success in avoiding complications and reducing readmissions. Report:

- a. 30-day all-cause readmission rate for patients with lumbar fusion.
- b. Readmission rate for patients following lumbar fusion surgery with any of the nine complications included under the terms of the warranty.

Appendix 1: Detailed Quality Standards

For all of the following, lumbar fusion patients refers to first-time, single-level lumbar fusion, excluding patients with fusion for trauma, cancer, or inflammatory arthritis. Please note that three of the quality measures refer to specific results or scores and therefore have no numerator or denominator.

	Numerator	Denominator
1: Standards for appropriateness		
a	Number of patients with lumbar fusion receiving formal shared decision-making decision aids pre-operatively.	Total number of patients with lumbar fusion.
b	Number of patients with lumbar fusion with documented patient-reported measures of disability and quality of life function prior to surgery using the ODI and PROMIS-10 Global Health tools.	Total number of patients with lumbar fusion.
c	Results of measures from 1b, specifically including score for the Oswestry Disability Index and questions regarding everyday physical activities (Question 7) and pain (Question 10) on the PROMIS-10 Global Health survey.	
2: Standards for evidence-based surgery		
a	Number of patients with lumbar fusion receiving measures to manage pain using multimodal anesthesia in the peri-operative period.	Total number of patients with lumbar fusion.
b	Number of patients with lumbar fusion receiving measures to reduce risk of venous thromboembolism and pulmonary embolism in the peri-operative period.	Total number of patients with lumbar fusion.
c	Number of patients with lumbar fusion receiving measures to reduce blood loss in the peri-operative period.	Total number of patients with lumbar fusion.
d	Number of patients with lumbar fusion receiving measures to reduce infection such as administration of prophylactic antibiotics in the peri-operative period.	Total number of patients with lumbar fusion.
e	Number of patients with lumbar fusion receiving measures to maintain optimal blood sugar control in the peri-operative period.	Total number of patients with lumbar fusion.
3: Standards for ensuring rapid and durable return to function		
a	Number of patients with lumbar fusion for which there are documented patient-reported measures of disability and quality of life six months following surgery (the same measures should be used as in standard 1b).	Total number of patients with lumbar fusion.
b	Number of patients with lumbar fusion for which there are documented patient-reported measures of disability and quality of life two years following surgery (the same measures should be used as in standard 1b).	Total number of patients with lumbar fusion.
c	Results of measures from 2b, specifically the score from the Oswestry Disability Index and questions regarding everyday physical activities (Question 7) and pain (Question 10) on the PROMIS-10 Global Health survey).	

4: Standards for the patient care experience		
a	Number of patients with lumbar fusion surveyed using HCAHPS.	Total number of patients with lumbar fusion.
b	Results of measures from 4a, specifically responses to Q6 and Q22-Q25 if HCAHPS is used.	
5: Standards for patient safety and affordability		
a	Number of patients with lumbar fusion readmitted to the hospital within 30 days of discharge, all causes.	Total number of patients with lumbar fusion.
b	Number of patients with lumbar fusion readmitted to the hospital within 30 days of discharge for any of the nine complications and intervals included under the terms of the warranty.	Total number of patients with lumbar fusion.

Elective Lumbar Fusion Warranty

In developing this warranty for lumbar fusion the Accountable Payment Model (APM) subgroup of the Dr. Robert Bree Collaborative relied most heavily on a similar initiative creating a warranty for total knee replacement (TKR) and total hip replacement (THR). It is our opinion that lumbar fusion and total joint replacement shared sufficient similarities with respect to readmission to the hospital for avoidable complications that the model was transferrable to single level lumbar fusion surgery.

The warranty for TKR and THR was based on a study of complications of these surgeries commissioned by the Centers for Medicare and Medicaid Services (CMS) and subsequently adopted by the High Value Healthcare Collaborative (HVHC), a group of 18 major medical systems from across the country founded by the Dartmouth Institute. To see this report, please visit: http://www.breecollaborative.org/wp-content/uploads/bree_warranty_tkr_thr.pdf

The primary intent of the warranty is to set a high priority on patient safety. It is also intended to balance financial gain for providers and institutions performing lumbar fusion surgery with financial accountability for complications attributable to these procedures. In this warranty the intent is to distribute financial risk across professional and facility components in proportion to the revenue generated by the procedure.

Definitions related to a warranty for Lumbar Fusion

- Diagnostic code for osteoarthritis of the spine - excludes trauma, cancer, inflammatory conditions, and congenital scoliosis.
- Procedural codes for single level lumbar fusion.
- Age limits.
- Definition of complications excluded from additional reimbursement.
- Definition of warranty period.

Diagnostic codes

Diagnostic codes for posterior lumbar fusion with instrumentation 1 level include:

- 722.10 = Herniated disk
- 724.02 = Stenosis without neurogenic claudication
- 724.03 = Stenosis with neurogenic claudication
- 738.4 = Spondylolisthesis
- 722.52 = Degenerative disk disease
- 996.4 = Pseudoarthrosis

Procedure Codes

Procedure codes for posterior lumbar fusion with instrumentation 1 level include:

- 22633 = Includes both posterolateral and posterior interbody arthrodesis (fusion)
- 63047-59 = DLL or
 - 63012 = Gill Procedure for spondylolisthesis or
 - 63042 = Redo laminectomy
- 22853, 22854, 22859 = Application of cages
- 22840 = Posterior non-segmental instrumentation
- 20930 = Cadaver bone chips
- 20936 = Autograft (same incision)
- 38220 = Bone marrow aspiration/draft

Age limits

>=18 years old (no upper limit)

Complications

Definition of complications included in warranty:

- As specified by CMS TEP report (*Available in the total knee replacement and total hip replacement warranty*).
- Aligned with ICD-9 codes adopted by HVHC for lumbar fusion.

Complications for warranty are intended to meet the following criteria:

- Represent significant complications attributable to the lumbar fusion procedure.
- Are identifiable in administrative claims data.
- Are fair to hospitals and physicians.

1. Death as a result of any of the other complications included in the warranty.
2. Surgical complications:
 - a. Mechanical complications.
 - b. Periprosthetic joint complications:
 - Incision and drainage.
 - Revision.
 - Removal.
 - c. Wound infection:
 - Incision and drainage.
 - Revision.
 - Removal.
 - d. Surgical site bleeding requiring readmission for incision and drainage.
 - e. Pulmonary embolism.
3. Medical complications:
 - a. Acute myocardial infarction.
 - b. Pneumonia.
 - c. Sepsis/septicemia.

Warranty period and other terms

1. Warranty period is complication-specific:

7 days	30 days	90 days
<ul style="list-style-type: none"> • Acute myocardial infarction • Pneumonia • Sepsis/septicemia 	<ul style="list-style-type: none"> • Death • Pulmonary embolism • Surgical site bleeding • Wound infection 	<ul style="list-style-type: none"> • Infection involving implant • Mechanical complications

2. The warranty is valid only at the hospital performing the surgery. Therefore, patients experiencing complications are strongly encouraged to seek treatment at that hospital.