



Working together to improve health care quality, outcomes, and affordability in Washington State.

Lumbar Fusion Bundle and Warranty

2018

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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. When we reviewed this topic in 2014, we also found a disproportionate rise in lumbar fusion compared to other spine surgeries, high variation in quality and billed charges, and evidence that for many patients considered candidates for lumbar fusion, there was no clear benefit of surgery compared to non-surgical care.

To reduce needless variation in quality, members of the Collaborative --- providers, patients, employers, health plans, and quality organizations --- created a bundle of evidence-based care that included explicit, evidence-based standards for appropriateness, fitness for surgery, safe surgery, and return to function. See **Appendix A** for a list of Bree Collaborative Members and **Appendix B** for the workgroup charter and roster. These standards were supported by a robust evidence table. We added market relevant quality indicators selected by employers that include measures of shared decision-making, the patient care experience, and return to function. We also included a warranty against avoidable hospital readmissions. The bundle was completed late in 2014, endorsed by the State of Washington as a voluntary standard for quality, and was published in the public domain.

Over the last four years, academic publications related to application of the bundle have demonstrated: 1) over 50% of patients referred for lumbar fusion do not meet fundamental standards for appropriateness or fitness for surgery, 2) a growing national and international support among spine surgeons for the application of such standards, and 3) when the bundle is used as a basis for value-based purchasing, with direct contracting between provider and employer, quality, and affordability improve and satisfaction is high among patients, providers, and the employer.

We are encouraged by these early successes. We are also mindful of evolving medical literature, opportunities for refinement, and opportunity for extending the application of the standards. We have therefore reviewed the 2014 version of the bundle, quality indicators, warranty, and evidence table in detail to produce this current version.

We have intended that this bundle be used for patients with more than 12 weeks of back or lower extremity pain of confirmed spinal origin with neurologic symptoms or signs. The surgical elements of the bundle are not intended for the care of patients with back pain associated with degenerative joint disease in the absence of structural instability. We have not designed the bundle for patients under 18 years of age or those with spinal trauma, osteoporotic fracture, tumor, infection, inflammatory conditions, and scoliosis. The principles of this bundle and warranty may be broadly applicable to other spine surgeries.

We recommend that 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.

Citations related to these introductory comments and 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-Draft-2018.xlsx

See **Appendix C** for further detail about contracting for both providers and employers.

I. Disability Despite Non-Surgical Therapy

Note: A trial of non-surgical care is not indicated if symptoms, signs and imaging findings show an 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 PROMIS-10 and Oswestry Disability Index (ODI) with additional optional measures including the following patient reported outcome measures:
 - a. Roland-Morris Disability Scale
 - b. EuroQual-5 Dimensions (EQ-5D)
 - c. Short Form 36 (SF-36)
 - d. A similarly peer-reviewed and validated patient-reported outcome
 - e. 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. Proposed 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. A designated clinician (preferably a physiatrist) 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.

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 include cognitive behavioral therapy, and activity coaching m).
 - e. Identification and management of associated anxiety and depression.

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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 a designated physician (preferably a physiatrist) to confirm appropriateness, adequacy, completeness, and active participation in non-surgical therapy and need for lumbar fusion. The need for lumbar fusion should be based on persistent disability and mitigation of psychosocial barriers that would interfere with recovery. A decision for lumbar fusion requires a meeting of all members of the team and a recommendation for fusion documented by the designated physician or physiatrist.
 2. Documentation of severe disability unresponsive to non-surgical care according to patient reported outcome indicator used at baseline.
 3. Confirmation 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 with a validated decision aid such as those approved by Washington State, if these are available. This requirement is in addition to informed consent.

II. Fitness for Surgery

A) Document requirements related to patient safety

1. The patient should meet the following minimum requirements prior to surgery with the assistance of the care team as necessary. Exceptions should be discussed in the multidisciplinary conference:
 - a. Body Mass Index less than 40.
 - b. Avoidance of nicotine with confirmation of at least one negative urine screen for at least four weeks pre-operatively.
 - c. Participate in pre-operative plan for management of opioid dependency if patient has taken opioids for more than three preceding months following Bree Collaborative Supplement to AMDG Guidelines.
 - d. Hemoglobin A1c less than 8% in patients with diabetes.
 - e. Negative screen for alcohol abuse with appropriate management of screen is positive.
 - f. Negative screen for untreated depression, psychiatric disorder with appropriate management if screen is positive.
 - g. Adequate bone density in high-risk individuals.
 - h. Absence of anemia that would complicate recovery from surgery.
 - i. Absence of dementia that would interfere with recovery – performing surgery for a patient with such dementia requires informed consent of a person with durable power of attorney for health care, and a contract with the patient’s care partner.
 - j. Adequate nutritional status to ensure healing.
 - k. Sufficient liver function to ensure healing particularly for high-risk patients.
 - l. Absence of severe disability from an unrelated condition that would severely limit the benefits of surgery.
2. The care team must complete a pre-operative plan for post-operative return to function.
3. The care team must assess home environment for safety and adequate support.

B) Document patient engagement

1. The 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.
2. The patient must participate in end of life planning, including completion of an advance directive and designation of durable power of attorney for health care.
3. The patient must agree to participate in a registry such as Spine COAP and understand that they may be contacted at two years post-surgery for 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. The care team must:

1. Perform pre-operative history and physical examination with additional testing as needed. Recommended guidelines include the:
 - a. [2016 guideline from the National Institute for Health and Care Excellence](#) (NICE)
 - b. [2014 ACC/AHA Guideline on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Non-cardiac Surgery](#)
2. Treat nasal passages for possible staphylococcal carrier state or culture nasal passages and treat if positive.
3. Ensure A1c less than 8% within last three months in patients with diabetes.
4. Screen for predictors of delirium.
5. Perform relevant imaging as necessary if symptoms have changed.
6. Obtain relevant consultations:
 - a. Dental consultation if patient has poor dental hygiene.
 - b. Anesthesia consultation per [American Society of Anesthesiology Guidelines](#)
 - c. Physical therapy to instruct in improving return to function.
 - d. Other consultations as necessary.

III. Spinal Fusion Procedure

A) General standards for a surgical team performing surgery

1. The minimum number of lumbar fusions is 30 per primary or first assist surgeon and 60 per facility in the previous twelve months.
2. Neurosurgeons must be board certified or board eligible and credentialed to perform spine surgery by their institution.
3. Orthopedic surgeons must have completed a spine fellowship and be credentialed to perform spine surgery by their institution.
4. Members of the surgical team must have documented credentials, training, and experience. The roster of the surgical team should be consistent.
5. Surgical team may include two attending surgeons to reduce anesthesia time and blood loss particularly in complex cases.
6. Elective spine surgery must be scheduled to begin before 5:00 pm.
7. Surgery must be performed in a facility with sufficient staffing and access to resources to address potential complications.
8. 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.
9. Providers should follow guidelines for concurrent and overlapping surgeries as set forth by the American College of Surgeons.

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 according to both the [2015 Agency Medical Directors Guideline](#) and the [2018 Bree Collaborative Post-Op Supplement](#).
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 the minimum necessary hours.
 - c. Use chlorhexidine skin prep by patient prior to surgery if no contraindication.
3. Avoid bleeding and low blood pressure:
 - a. Employ measures to reduce blood loss and need for transfusion.
 - 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 morphogenetic protein: If bone morphogenetic protein is used it must be in accord with Washington Health Technology Program policy:
[Bone Morphogenetic Protein for use in Lumbar Fusion](#)

C) Participation in registries

1. Facilities must participate in a registry such as Spine COAP with results available to purchasers.
2. Providers must participate in a registry of patients undergoing lumbar fusion and collect patient reported outcome measures as part of an internal quality improvement program.

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 must be available for consultation to assist with complex or unstable medical problems in the post-operative period.

B) Use standardized facility 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. Assess home environment for safety and adequate support (e.g. architectural barriers, availability of assistive devices, availability of care companion)
4. Reconcile medications.
5. 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.
6. 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](#).
7. Send post-discharge summary to primary care provider or after care provider within three business days of discharge.
8. Pain management to align with [2015 Agency Medical Directors Guideline](#) and the [2018 Bree Collaborative Post-Op Supplement](#)

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 instruments at three months and if possible at 12 months as specified above using the same tools used for initial assessment.
3. Continue nicotine avoidance measures for at least three months following surgery.

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 spinal trauma, osteoporotic fracture, tumor, infection, inflammatory conditions, and scoliosis. The registry must be updated quarterly and should 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 D** 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 6) and pain (Question 7).

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 and need for transfusion.
- 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 three months, twelve months, and twenty four months if possible 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 or OAS CAHPS.
- b. Results of measures from 4a, specifically including responses to Q6 and Q22-Q25 in HCAHPS survey or corresponding OAS CAHPS measures.

5. Standards for patient safety and affordability

These standards are intended to measure success in avoiding complications and reducing admissions following surgery. The facility performing the surgery must have an agreement with a hospital to manage complications following surgery. The facility will provide information and instructions to the patient to seek treatment at that designated hospital. Report:

- a. 30-day all-cause admission rate for patients following a lumbar fusion bundle.
- b. Admission rate for patients following lumbar fusion bundle with any of the eight complications included under the terms of the warranty.

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 admission to the hospital for avoidable complications that the model was transferrable to 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). 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.

See **Appendix E** for detailed code sets.

Age limits

>=18 years old (no upper limit)

Complications

Definition of complications included in warranty:

- Based on categories of avoidable complications set forth in the CMS TEP report (*Available in the total knee replacement and total hip replacement warranty*) and
- As further defined with respect to surgical site infection by the Centers for Disease Control (CDC) in 2018 https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf
- Presence of any complication code in a primary or secondary diagnosis field

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 facilities and physicians.
1. Surgical complications:
 - a. Mechanical complications.
 - b. Superficial incisional SSI (per above CDC definition).
 - c. Deep incisional SSI (per above CDC definition) that may involve implant.
 - d. Surgical site bleeding requiring readmission for incision and drainage.
 2. Medical complications:
 - a. Acute myocardial infarction.

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- b. Pneumonia.
- c. Sepsis/septicemia.
- d. Pulmonary embolism

Warranty period and other terms

1. Warranty period begins at day of discharge from facility and 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">• Pulmonary embolism• Surgical site bleeding• Superficial incisional surgical site infection	<ul style="list-style-type: none">• Deep incisional surgical site infection that may involve implant• Mechanical complications

2. The facility performing the surgery must have an agreement with a hospital to manage complications following surgery. The facility will provide information and instructions to the patient to seek treatment at that designated hospital.

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Appendix A: Bree Collaborative Members

Member	Title	Organization
Susie Dade, MS	Deputy Director	Washington Health Alliance
Peter Dunbar, MB, ChB, MBA	CEO	Foundation for Health Care Quality
John Espinola, MD, MPH	Executive Vice President, Health Care Services	Premera Blue Cross
Gary Franklin, MD, MPH	Medical Director	Washington State Department of Labor and Industries
Stuart Freed, MD	Chief Medical Officer	Confluence Health
Richard Goss, MD	Medical Director	Harborview Medical Center – University of Washington
Christopher Kodama, MD	President, MultiCare Connected Care	MultiCare Health System
Wm. Richard Ludwig, MD	Chief Medical Officer, Accountable Care Organization	Providence Health and Services
Greg Marchand	Director, Benefits & Policy and Strategy	The Boeing Company
Robert Mecklenburg, MD	Medical Director, Center for Health Care Solutions	Virginia Mason Medical Center
Kimberly Moore, MD	Associate Chief Medical Officer	Franciscan Health System
Carl Olden, MD	Family Physician	Pacific Crest Family Medicine, Yakima
Drew Oliveira, MD	Executive Medical Director	Regence BlueShield
Mary Kay O’Neill, MD, MBA	Partner	Mercer
John Robinson, MD, SM	Chief Medical Officer	First Choice Health
Terry Rogers, MD (Vice Chair)	Retired	
Jeanne Rupert, DO, PhD	Provider	One Medical
Kerry Schaefer, MS	Strategic Planner for Employee Health	King County
Lani Spencer, RN, MHA	Vice President, Health Care Management Services	Amerigroup
Hugh Straley, MD (Chair)	Retired	Medical Director, Group Health Cooperative; President, Group Health Physicians
Angela Sparks, MD	Medical Director Clinical Knowledge Development & Support	Kaiser Permanente
Shawn West, MD	Family Physician	
Judy Zerzan, MD, MPH	Chief Medical Officer	Washington State Health Care Authority

Appendix B: Accountable Payment Models: Lumbar Fusion Workgroup Charter and Roster

Problem Statement

Health care in the United States is typically fee-for-service, rewarding providers for volume instead of quality. This misalignment between health care reimbursement and quality does not provide incentive for appropriateness, best outcomes, and affordability.

Aim

To recommend reimbursement models including warranties and bundled payments that align with patient safety, appropriateness, evidence-based quality, timeliness, outcomes and the patient care experience.

Purpose

To identify conditions of high variability in clinical practice and cost to purchasers, to define evidence-based standards of practice for these conditions and to develop quality measures that align with best practice. The intent of developing such standards and quality measures is to provide a basis for production, payment, and purchasing of health care that should be used by providers, health plans and purchasers as a basis for market-based health care reform.

Methods used by the Accountable Payment Models Workgroup (APM) should themselves be standardized, permitting applicability to a variety of medical conditions.

Duties and Functions

The APM workgroup shall:

- Select a series of medical conditions in which variation in practice and price to purchasers is not associated with commensurate quality of outcomes.
- Review existing standards related to each condition, particularly those developed by the Centers for Medicare and Medicaid Services.
- Ensure that appropriate content experts and opinion leaders are recruited to participate in the work associated with each medical condition the APM workgroup selects.
- Consult members of the Washington State Hospital Association, The Washington State Medical Association and other stakeholder organizations and subject matter experts on feedback on content of payment models the APM develops.
- Define scope of work for each medical condition.
- Identify common medical interventions for each condition to create a standardized patient care pathway.
- Use standardized evidence search and appraisal methods to create an evidence table that can be used to assess the value of each intervention.
- Eliminate interventions from the pathway that are not value-added to create a future-state patient care pathway.
- Develop quality metrics that can be used to assess performance as providers to support payment and purchasing of health care.
- Solicit feedback from stakeholders to improve the patient care pathway, evidence table and quality metrics.
- Present the final draft to the Bree Collaborative for approval.

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Structure

The APM will consist of individuals appointed by the Bree Collaborative Steering Committee. Individuals must have in-depth knowledge and expertise in at least one of the following: payment reform, the health care delivery system, benefit design, and/or quality improvement. There must be at least one representative from each stakeholder group: employer, health plan, hospital, provider (including a specialist), and quality improvement organization.

The chair of the APM workgroup will be appointed by the chair of the Collaborative with advice from the Collaborative steering committee.

The Collaborative project director will staff and provide management and support services for the APM. The CEO of the Foundation for Health Care Quality will also provide staff support and technical assistance.

Less than the full APM may convene to: gather and discuss information; conduct research; analyze relevant issues and facts or draft recommendations for the deliberation of the full APM. A quorum shall be a simple majority and shall be required to accept and approve recommendations to the PAR workgroup and the Collaborative.

Meetings

The APM will hold meetings at least once a month and more frequently if necessary.

The APM chair will conduct meetings. The Collaborative project director will arrange for the recording of each meeting, and will distribute meeting agendas and other materials prior to each meeting.

Name	Title	Organization
Robert Mecklenburg, MD (Co-Chair)	Medical Director, Center for Health Care Solutions	Virginia Mason Medical Center
Kerry Schaefer, MS (Co-Chair)	Strategic Planner for Employee Health	King County
Lydia Bartholomew, MD	Senior Medical Director, Pacific Northwest	Aetna
Arman Dagal, MD	Medical Director	Spine COAP
Sharon Eloranta, MD	Division Director, Clinical Excellence and Quality	CHI Franciscan Health
Farrokh Farrokhi, MD	Neurosurgeon	Virginia Mason Medical Center
Gary Franklin MD, MPH	Medical Director	Washington State Department of Labor and Industries
Andrew Friedman, MD	Physical Medicine and Rehabilitation	Virginia Mason Medical Center
Michael Hatzakis, MD	Physiatrist	Overlake Medical Center
Sara Groves-Rupp	Asst Administrator, Performance Improvement	University of Washington Medicine
Marcia Peterson	Manager of Benefits Strategy and Design	Washington State Health Care Authority
Linda Radach	Patient Advocate	
Jason Thompson, MD	Spine Surgeon	Proliance Surgeons
Mia Wise, DO	Medical Director, Provider & Customer Engagement	Premera Blue Cross

Appendix C: Guide to Direct Contracting

For the provider

1. Providers should align with employers in choosing a clinical “candidate product”
 - a. Opportunity to improve value for employer
 - b. High utilization in employed population
 - c. Easily defined boundaries
 - d. Predictable clinical course
 - e. Availability of credible, publicly accessible evidence to define quality

2. Assess organizational effort to operationalize “candidate product” in terms of
 - a. Commitment of clinicians and operational leaders to re-engineer processes, re-allocate resources and lead change, including identification of an accountable physician champion accountability
 - b. Standardization of care with a systems-based model
 - c. Commitment of stakeholders to the end-to-end patient pathway, including outpatient and inpatient providers, operating room, revenue cycle, patient relations, and subcontractors. Success relies less on a clinically integrated medical center than clinically and strategically aligned stakeholders, communication, a leader, and a project plan
 - d. Capacity to maintain access while increasing volume
 - e. Commitment to transition care back to patient’s local community and home provider
 - f. Review design with self-funded employer

3. Assess business case for the “candidate product”
 - a. Calculate margin on the “candidate product” in current fee-for-service format understanding the explicit clinical content of the bundle
 - b. Estimate incremental volume attracted by bundle
 - i. Current volume coming to the provider through the self-funded group
 - ii. Total utilization of the self-funded group
 - iii. Number of likely providers of the bundle that will compete for patients
 - iv. Willingness of employer to create benefit design to steer employees to high-value provider
 - c. Estimate startup cost of implementing bundle
 - i. Information technology to measure and report outcomes to employer, including additional investments to the EMR, patient portals/patient interfaces, and billing systems
 - ii. Additional personnel including clinical, operational, analytical, financial staff to manage bundle
 - iii. Commitment of clinical and operational leaders to meet with purchaser at regular intervals
 - d. Assess ability to take risk associated with variability in care under a fixed payment model and potential warranty/accountability events
 - e. Using incremental volume and estimated incremental margin, determine break-even price point of bundle.
 - f. Understand current cost of the employer in terms of removing variability of cost

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- g. Create an outlier rate and default rate to cover provider cost but not to enhance margin, reflecting a commitment to the employer to provide needed while avoiding unnecessary and inappropriate care
 - h. Estimate potential loss/opportunity cost not implementing bundle/direct contracting assuming employer/self-funder group will find a willing provider
4. Encourage and respond to quality-driven Request for Proposals from employers

For the employer

1. Assemble a work group that includes members with experience in provider strategies, benefit design, and contracts management
2. Choose a priority clinical condition or procedure with the following attributes
 - a. Prevalent condition among employees
 - b. High variation in direct cost, work loss, outcomes, patient experience, utilization or access
 - c. Easily definable boundaries that could align with bundled services
 - d. Define market-relevant quality and outcome measures
 - e. Determine if there is a product in the market that has evidence based quality standards that align with your outcome measures. If not release an RFI to gain knowledge of existing standards in the market and consider releasing an RFP for a partner provider to co-develop product using evidence standards and quality
3. Assess financial opportunity: current direct and indirect cost of the clinical condition minus the cost of the program administration and benefit redesign
4. Release a Request for Proposals for program administrator if unable to provide this internally that includes
 - a. Claim adjudication
 - b. Determining member eligibility
 - c. Customer service including employee member education and referral
 - d. Determining member benefit, including travel, food, care companion, co-pay/deductible,
 - e. Travel arrangements and logistics
 - f. Assessment of the patient care experience
 - g. Management of ERISA plan
 - h. Ability to coordinate with vendors to maximize employer benefit
 - i. Ability to collect and report on cost and patient experience
5. Develop benefit option that creates incentive for patient to choose high-value provider
 - a. Engage in change management with employees, unions and other stakeholders to encourage choice of providers based on quality
 - b. Develop a method of measuring outcome of employees choosing new model vs. control group of employees choosing usual care; choose quality indicators that are market relevant such as appropriateness and return to function
5. Release a Request for Proposals to provider groups
 - a. Based on the new model co-designed with providers
 - b. Arrange site visits and select one or more providers for direct contracting.
6. Negotiate contracts with both providers and administrators that are based on the quality standards of the new product
7. Meet regularly with providers and with administrators to ensure adherence to contract and to refine and improve delivery of the new product to employees

Appendix D: 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 6) and pain (Question 7) 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 6) and pain (Question 7) on the PROMIS-10 Global Health survey).	

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4: Standards for the patient care experience		
a	Number of patients with lumbar fusion surveyed using HCAHPS or OAS CAHPS	Total number of patients with lumbar fusion.
b	Results of measures from 4a, specifically responses to Q6 and Q22-Q25 if HCAHPS is used or corresponding OAS CAHPS measure.	
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.

Appendix E: Diagnostic, Procedural, and Complication Codes

Diagnostic codes

ICD 10 codes: excludes spinal deformity (scoliosis, kyphosis), infection, malignancy, trauma,

Spondylolisthesis

- M43.10, M43.15, M43.16, M43.17 - thoracolumbar, lumbar, and lumbosacral region

Spinal stenosis

- M48.05, M48.06, M48.07 - thoracolumbar, lumbar and lumbosacral region

Spinal instabilities

- M53.2X5, M53.2X6, M53.2X7 - thoracolumbar, lumbar, and lumbosacral region

Procedural Codes: Arthrodesis

Lateral Extracavitary Approach Technique

- 22533 - Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
- + 22534 - Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression; thoracic or lumbar, each additional vertebral segment

Anterior Interbody Technique

- 22558 - Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
- + 22585 - 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)

Posterior, Posterolateral Technique

- 22612 - Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)
- + 22614 - each additional vertebral segment (List separately in addition to code for primary procedure)

Posterior Interbody Technique:

- 22630 - Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
- + 22632 - 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)

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Combined Posterior or Posterolateral with Posterior Interbody Technique

- 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; lumbar
- + 22634 - each additional interspace and segment (List separately in addition to code for primary procedure)

Notes:

1. ICD10 codes: excludes spinal deformity (scoliosis, kyphosis), infection, malignancy, trauma, inflammatory conditions, degenerative disc disease, disc herniation, prior surgeries and congenital anomalies.
2. CPT codes may include:
 - a. Insertion of biomechanical device (e.g. cage, mesh)
 - i. 22853, + 22854: 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. Laminotomy
 - i. 63030, + 63035: Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, lumbar
 - c. Grafts for spine surgery
 - i. + 20930, + 20931: Allograft, morselized, or placement of osseopromotive material or structural (List separately in addition to code for primary surgery)

Complication Codes

See www.breecollaborative.org/wp-content/uploads/TJR-Codes-17-1031.xlsx for ICD-9/ICD-10 crosswalk of avoidable complications and codes for acute myocardial infarction, pneumonia, sepsis/septicemia, and pulmonary embolism. Codes specific to lumbar fusion are listed below:

1. **Surgical site bleeding**
 - a. **Intraoperative and post-procedural complications of skin and subcutaneous tissue L76**
 - i. Post-procedural hemorrhage of skin and subcutaneous tissue following other procedure L76.22
 - ii. Post-procedural hematoma and seroma of skin and subcutaneous tissue following other procedure L76.32
2. **Wound infection and other complications**
 - a. **Complications of procedures, not elsewhere classified: T81**

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- i. Post-procedural shock T81.1
- ii. Disruption of wound, not elsewhere specified T81.3
- iii. Infection following a procedure T81.4
- iv. Complications of foreign body accidentally left in body following procedure T81.5
- v. Acute reaction to foreign substance accidentally left during a procedure T81.6
- vi. Vascular complications following a procedure, not elsewhere classified T81.7
- vii. Other complications of procedures, not elsewhere classified T81.8

3. Mechanical complications

a. Mechanical complications of internal fixation device of other bones T84.21

- i. Breakdown (mechanical) of internal fixation of vertebrae T84.216
- ii. Displacement of internal fixation device of vertebrae T84.226
- iii. Other mechanical complication of internal fixation device of vertebrae T84.296

b. Mechanical complications of other bone device, implants and grafts T84.3

- i. Breakdown of other bone device, implants and grafts T84.31
- ii. Displacement of other bone device, implants and grafts T84.32
- iii. Other mechanical complication of other bone device, implants and grafts T84.39

4. Complications of other internal prosthetic devices, implants and grafts T85

- a. Unspecified complication of internal prosthetic device, implant or graft T85.9

5. Complications of other transplanted organs and tissues T86.8

- a. Complications of bone graft T86.83