Quality ID #469: Functional Status After Lumbar Fusion
– National Quality Strategy Domain: Person and Caregiver-Centered Experience and Outcomes
– Meaningful Measure Area: Functional Outcomes

2021 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Patient Reported Outcome-High Priority

DESCRIPTION:
For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively
* hereafter referred to as ODI

INSTRUCTIONS:
This measure is to be submitted **each time** a patient undergoes a lumbar fusion during the denominator identification period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

NOTE: *This measure is a target-based measure with two ways to meet the numerator; either a postoperative ODI score that is less than or equal to 22 OR a change of 30 points or greater from the preoperative to postoperative score. It is expressed as a proportion or rate. Patients having received a lumbar fusion procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures for performance calculation.*

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians, groups, or third party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

DENOMINATOR:
Patients 18 years of age or older as of October 1 of the denominator identification period who had a lumbar fusion procedure performed during the denominator identification period

Definitions:
Denominator Identification Period - The twelve month period in which eligible patients have a denominator eligible procedure. This allows for enough time for a follow-up assessment to occur during the twelve month performance period. The denominator identification period includes dates of procedure 10/1/2019 to 9/30/2020.

Denominator Criteria (Eligible Cases):
Patients age ≥ 18 years by October 1 of the Denominator Identification Period
AND

Patient procedure during performance period (CPT): 22533, 22558, 22586, 22612, 22630, 22633

AND NOT

DENOMINATOR EXCLUSION:

Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis: M1041

- Patients with a diagnosis of lumbar spine region cancer at the time of the procedure – The following codes would be sufficient to define the Denominator Exclusion (M1041) of lumbar spine region cancer: C41.2, C41.4, C79.51, C79.52, D16.6, D16.8, D48.0, D49.2

- Patients with a diagnosis of acute lumbar spine region fracture at the time of the procedure – The following codes would be sufficient to define the Denominator Exclusion (M1041) of lumbar spine region fracture: M48.44XA, M48.45XA, M48.46XA, M48.47XA, M48.48XA, M48.54XA, M48.55XA, M48.56XA, M48.57XA, M48.58XA, S22.060A, S22.060B, S22.061A, S22.061B, S22.062A, S22.062B, S22.068A, S22.068B, S22.069A, S22.069B, S22.070A, S22.070B, S22.071A, S22.071B, S22.072A, S22.072B, S22.078A, S22.078B, S22.079A, S22.079B, S22.080A, S22.080B, S22.081A, S22.081B, S22.082A, S22.082B, S22.088A, S22.088B, S22.089A, S22.089B, S24.103A, S24.104A, S24.113A, S24.114A, S24.133A, S24.134A, S24.143A, S24.144A, S24.153A, S24.154A, S32.000A, S32.000B, S32.001A, S32.001B, S32.002A, S32.002B, S32.008A, S32.008B, S32.009A, S32.009B, S32.010A, S32.010B, S32.011A, S32.011B, S32.012A, S32.012B, S32.018A, S32.018B, S32.019A, S32.019B, S32.020A, S32.020B, S32.021A, S32.021B, S32.022A, S32.022B, S32.028A, S32.028B, S32.029A, S32.029B, S32.030A, S32.030B, S32.031A, S32.031B, S32.032A, S32.032B, S32.038A, S32.038B, S32.039A, S32.039B, S32.040A, S32.040B, S32.041A, S32.041B, S32.042A, S32.042B, S32.048A, S32.048B, S32.049A, S32.049B, S32.050A, S32.050B, S32.051A, S32.051B, S32.052A, S32.052B, S32.058A, S32.058B, S32.059A, S32.059B, S32.10XA, S32.10XB, S32.110A, S32.110B, S32.111A, S32.111B, S32.112A, S32.112B, S32.119A, S32.119B, S32.120A, S32.120B, S32.121A, S32.121B, S32.122A, S32.122B, S32.129A, S32.129B, S32.130A, S32.130B, S32.131A, S32.131B, S32.132A, S32.132B, S32.139A, S32.139B, S32.14XA, S32.14XB, S32.15XA, S32.15XB, S32.16XA, S32.16XB, S32.17XA, S32.17XB, S32.19XA, S32.19XB, S32.2XXA, S32.2XXB, S32.9XXA, S32.9XXB, S34.101A, S34.102A, S34.103A, S34.104A, S34.105A, S34.109A, S34.111A, S34.112A, S34.113A, S34.114A, S34.115A, S34.119A, S34.121A, S34.122A, S34.123A, S34.124A, S34.125A, S34.129A, S34.131A, S34.132A, S34.139A, S34.3XXA

- Patients with a diagnosis of lumbar spine region infection at the time of the procedure – The following codes would be sufficient to define the Denominator Exclusion (M1041) of lumbar spine region infection:
- M46.25, M46.26, M46.27, M46.28, M46.35, M46.36, M46.37, M46.38, M46.45, M46.46, M46.47, M46.48, M46.55, M46.56, M46.57, M46.58

- Patients with a diagnosis of lumbar neuromuscular, idiopathic, or congenital scoliosis – The following codes would be sufficient to define the Denominator Exclusion (M1041) of neuromuscular, idiopathic, or congenital scoliosis: M41.05, M41.06, M41.07, M41.08, M41.45, M41.46, M41.47, M41.115, M41.116, M41.117, M41.125, M41.126, M41.127, M41.25, M41.26, M41.27, Q67.5, Q76.3

NUMERATOR:

All eligible patients whose functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI Version 2.1a) patient reported outcome tool at one year (9 to 15 months) postoperatively

Definitions:

Measure Assessment Period (Performance Period) - The period of time following the procedure date that a postoperative Oswestry Disability Index (ODI version 2.1a) functional status score can be obtained.

Preoperative Assessment Oswestry Disability Index (ODI version 2.1a)- A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation.

Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A postoperative ODI functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to nine months and after fifteen months postoperatively will not be used for measure calculation.

Oswestry Disability Index (ODI version 2.1a) Patient Reported Outcome Tool - An ODI patient reported outcome tool (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools. A copy of the tool can be obtained below or at the following link: https://eprovide.mapi-trust.org/instruments/oswestry-disability-index

Functional Status Target #1 - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status as less than or equal to 22.

Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 30 points

NUMERATOR NOTE*: It is recommended that both a preoperative and postoperative tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 is submitted.*

- *ODI is not administered postoperatively at one year (9 to 15 months)*
- *Functional status is measured using a different patient reported functional status tool or ODI version*
- *Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window)*
- *Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change*
- *Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure.)*

Numerator Options:

Performance Met: Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was less than or equal to 22 **OR** Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated a change of 30 points or greater **(G2142)**

OR

Performance Not Met: Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively **(M1043)**

OR

Performance Not Met: Functional status measured by the Oswestry Disability

Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was greater than 22 **AND** Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated a change of less than 30 points **(G2143)**

RATIONALE:

Mechanical low back functional status (LBP) remains the second most common symptom-related reason for seeing a physician in the United States. Of the US population, 85% will experience an episode of mechanical LBP at some point in their lifetime. For individuals younger than 45 years, LBP represents the most common cause of disability and is generally associated with a work-related injury. It is the third most common reason for disability for individuals older than 45 years. The prevalence of serious mechanical LBP (persisting > 2 week) is 14%, while the prevalence of true sciatica is approximately 2%.

Overall, spine surgery rates have declined slightly from 2002-2007, but the rate of complex fusion procedures increased 15-fold, from 1.3 to 19.9 per 100,000 Medicare beneficiaries. Complications increased with increasing surgical invasiveness, from 2.3% among patients having decompression alone to 5.6% among those having complex fusions. After adjustment for age, comorbidity, previous spine surgery, and other features, the odds ratio (OR) of life-threatening complications for complex fusion compared with decompression alone was 2.95 (95% confidence interval [CI], 2.50-3.49). A similar pattern was observed for rehospitalization within 30 days, which occurred for 7.8% of patients undergoing decompression and 13.0% having a complex fusion (adjusted OR, 1.94; 95% CI, 1.74-2.17). Adjusted mean hospital charges for complex fusion procedures were US $80,888 compared with US $23,724 for decompression alone (Deyo, R. JAMA 2010). The MNCM Spine Surgery Measure development workgroup developed patient reported outcome measures for two populations of patients undergoing different lumbar spine procedures, a more complex procedure (lumbar fusion) and a second procedure that represented the most common procedure CPT code 63030 for the most common diagnosis of disc herniation.

Lumbar spine surgery, an effective procedure for many spine conditions, may be controversial and less successful for some patients, particularly those with degenerative disc disease. Utilization data indicate up to a fifteen fold increase in the number of complex fusion procedures performed for Medicare beneficiaries (Trends, major medical complications and charges associated with surgery for lumbar spinal stenosis in adults Deyo, RA JAMA April 2010). News articles convey the experiences of some patients who have an increase in intensity of pain and loss of function after surgery. (Back surgery may backfire on patients in pain- NBC News Oct 2010, Doctors getting rich with fusion surgery debunked by studies- BusinessWeek Jan 2011, Pushing back on back surgery- StarTribune Aug 2009)

This PRO measure was developed with a focus on functional status from a patient's perspective to address and understand current gaps in care for patients undergoing lumbar fusion surgery. In 2018, the development workgroup reconvened and redesigned the measure construct to a target-based measure.

Rationale for measure construct and calculation change:

Target was derived from a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16(10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22.

CLINICAL RECOMMENDATION STATEMENTS:

Journal of Neurosurgery guidelines indicate that there is no evidence that conflicts with the previous recommendations published in the original version of the guideline. This recommendation is for the use of a reliable, valid and responsive outcomes instrument to assess functional outcome in lumbar spinal fusion patients. It is recommended that when assessing functional outcome in patients treated for low-back pain due to degenerative disease, a reliable, valid, and responsive outcomes instrument, such as the disease-specific Oswestry Disability Index (ODI), be used (Level II evidence).

MEASURE CALCULATION EXAMPLE:

Patient	Pre-op ODI	Post-op ODI	Post-op ≤ 22?	If No, (Pre-op minus Post-op)	If No, Met Change Target of ≥ 30?	Met Numerator Target?
Patient A	47	18	Yes	na	na	Yes
Patient B	45	52	No	-7	No	No
Patient C	56	12	Yes	na	na	Yes
Patient D	62	25	No	37	Yes	Yes
Patient E	42	57	No	-15	No	No
Patient F	51	10	Yes	na	na	Yes
Patient G	62	25	No	37	Yes	Yes
Patient H	43	20	Yes	na	na	Yes
Patient I	74	35	No	39	Yes	Yes
Patient J	59	23	No	36	Yes	Yes
Rate						**80%**

MEASURE TOOL:

ODI version 2.1a

This questionnaire is designed to give us information as to how your back (or leg) trouble affects your ability to manage in everyday life. Please answer every section. Mark one box only in each section that most closely describes you today.

Section 1 - Pain intensity

- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.

Section 2 - Personal care (washing, dressing, etc.)

- I can look after myself normally without causing additional pain.
- I can look after myself normally but it is very painful.
- It is painful to look after myself and I am slow and careful.

- I need some help but manage most of my personal care.
- I need help every day in most aspects of my personal care.
- I do not get dressed, I wash with difficulty and stay in bed.

Section 3 - Lifting

- I can lift heavy weights without additional pain.
- I can lift heavy weights but it gives me additional pain.
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- I can only lift very light weights.
- I cannot lift or carry anything at all.

Section 4 - Walking

- Pain does not prevent me from walking any distance.
- Pain prevents me from walking more than one mile.
- Pain prevents me from walking more than a quarter of a mile.
- Pain prevents me from walking more than 100 yards.
- I can only walk using a cane or crutches.
- I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- I can sit in any chair as long as I like.
- I can sit in my favorite chair as long as I like.
- Pain prevents me from sitting for more than 1 hour.
- Pain prevents me from sitting for more than half an hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.

Section 6 - Standing

- I can stand as long as I want without additional pain.
- I can stand as long as I want but it gives me additional pain.
- Pain prevents me from standing for more than 1 hour.
- Pain prevents me from standing for more than half an hour.
- Pain prevents me from standing for more than 10 minutes.
- Pain prevents me from standing at all.

Section 7 - Sleeping

- My sleep is never interrupted by pain.
- My sleep is occasionally interrupted by pain.
- Because of pain I have less than 6 hours sleep.
- Because of pain I have less than 4 hours sleep.
- Because of pain I have less than 2 hours sleep.
- Pain prevents me from sleeping at all.

Section 8 - Sex life (if applicable)

- My sex life is normal and causes no additional pain.
- My sex life is normal but causes some additional pain.
- My sex life is nearly normal but is very painful.
- My sex life is severely restricted by pain.
- My sex life is nearly nonexistent because of pain.
- Pain prevents me from having any sex life at all.

Section 9 - Social life

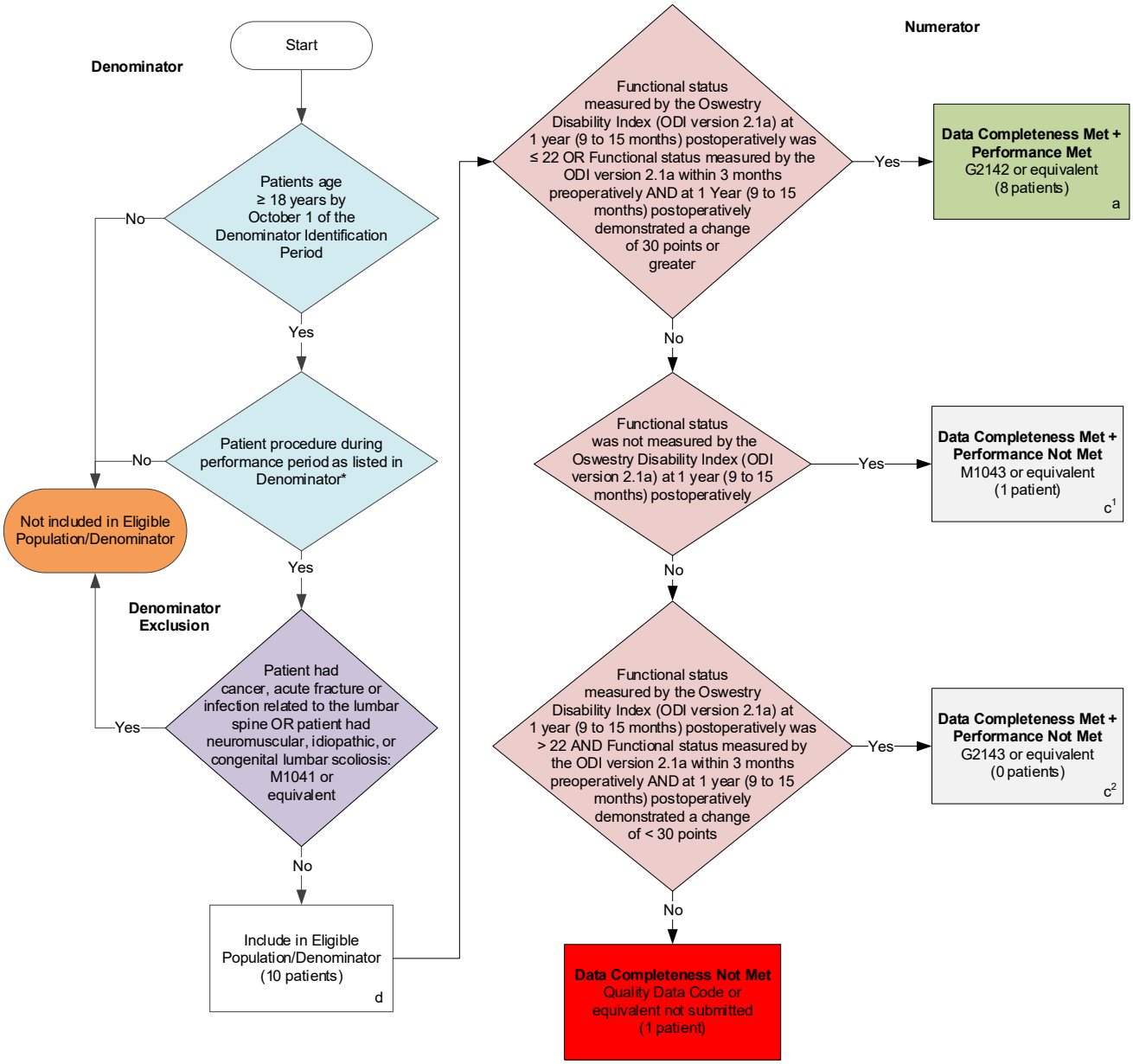
- My social life is normal and causes me no additional pain.
- My social life is normal but increases the degree of pain.
- Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- Pain has restricted my social life and I do not go out as often.
- Pain has restricted my social life to home.
- I have no social life because of pain.

Section 10 - Traveling

- I can travel anywhere without pain.
- I can travel anywhere but it gives me additional pain.
- Pain is bad but I am able to manage trips over two hours.
- Pain restricts me to trips of less than one hour.
- Pain restricts me to short necessary trips of under 30 minutes.
- Pain prevents me from traveling except to receive treatment

2021 Clinical Quality Measure Flow for Quality ID #469: Functional Status After Lumbar Fusion

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure.*



SAMPLE CALCULATIONS

Data Completeness=
Performance Met (a=8 patients) + Performance Not Met (c^1+ c^2=1 patient) = 9 patients = **90.00%**
Eligible Population / Denominator (d=10 patients) = 10 patients

Performance Rate=
Performance Met (a=8 patients) = 8 patients = **88.89%**
Data Completeness Numerator (9 patients) = 9 patients

*See the posted measure specification for specific coding and instructions to submit this measure.
NOTE: Submission Frequency: Patient

2021 Clinical Quality Measure Flow Narrative for Quality ID #469: Functional Status After Lumbar Fusion

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure.*

1. Start with Denominator
2. Check *Patients age greater than or equal to 18 years by October 1 of the Denominator Identification Period*:
    a. If *Patients age greater than or equal to 18 years by October 1 of the Denominator Identification Period* equals No, do not include in Eligible Population/Denominator. Stop processing.
    b. If *Patients age greater than or equal to 18 years by October 1 of the Denominator Identification Period* equals Yes, proceed to check *Patient procedure during performance period as listed in Denominator**.
3. Check *Patient procedure during performance period as listed in Denominator**:
    a. If *Patient procedure during performance period as listed in Denominator** equals No, do not include in Eligible Population/Denominator. Stop processing.
    b. If *Patient procedure during performance period as listed in Denominator** equals Yes, proceed to check *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis*.
4. Check *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis*:
    a. If *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis* equals Yes, do not include in Eligible Population/Denominator. Stop processing.
    b. If *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis* equals No, include in Eligible Population/Denominator.
5. Denominator Population:
    a. Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 10 patients in the Sample Calculation.
6. Start Numerator
7. Check *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated a change of 30 points or greater*:
    a. If *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated a change of 30 points or greater* equals Yes, include in *Data Completeness Met and Performance Met*
        - *Data Completeness Met and Performance Met* letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter a equals 8 patients in the Sample Calculation.

b. If *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated a change of 30 points or greater* equals No, proceed to check *Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively*.

8. Check *Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively*:

   a. If *Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively* equals Yes, include in *Data Completeness Met and Performance Not Met*.

      - *Data Completeness Met and Performance Not Met* letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c^1 equals 1 patient.

   b. If *Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively* equals No, proceed to check *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated a change of less than 30 points*.

9. Check *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated a change of less than 30 points*:

   a. If *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated a change of less than 30 points* equals Yes, include in *Data Completeness Met and Performance Not Met*

      - *Data Completeness Met and Performance Not Met* letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c^2 equals 0 patients.

   b. If *Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at 1 year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated a change of less than 30 points* equals No, proceed to check *Data Completeness Not Met*.

10. Check *Data Completeness Not Met*

    a. If *Data Completeness Not Met*, the Quality Data Code or equivalent was not submitted.

Sample Calculations

Data Completeness equals Performance Met (a equals 8 patients) plus Performance Not Met (c^1 plus c^2 equals 1 patient) divided by Eligible Population / Denominator (d equals 10 patients). All equals 9 patients divided by 10 patients. All equals 90 percent.

Performance Rate equals Performance Met (a equals 8 patients) divided by Data Completeness Numerator (9 patients).

All equals 8 patients divided by 9 patients. All equals 88.89 percent.

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient

The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.