Quality ID #473: Leg Pain After Lumbar Fusion
– National Quality Strategy Domain: Person and Caregiver-Centered Experience and Outcomes
– Meaningful Measure Area: Functional Outcomes

2022 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Patient-Reported Outcome-Based Performance Measure – High Priority

DESCRIPTION:
For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively.
* hereafter referred to as VAS Pain

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 VAS Pain score that is less than or equal to 3.0 OR an improvement of 5.0 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 leg pain 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

Definition:
Denominator Identification Period - The twelve month period in which eligible patients have a procedure. This allows for enough time for a follow-up assessment to occur during the performance period. The "denominator identification period" includes dates of procedure 10/1/2020 to 9/30/2021.

Denominator Criteria (Eligible Cases):
Patients aged ≥ 18 years by October 1 of the Denominator Identification Period
AND
Patient procedure during performance period (CPT): 22533, 22558, 22586, 22612, 22630, 22633
WITHOUT
Telehealth Modifier: GQ, GT, 95, POS 02

AND NOT

DENOMINATOR EXCLUSIONS:

Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic, or congenital lumbar scoliosis: M1051

- 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 (M1051)** 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 (M1051)** 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 (M1051)** 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 (M1051)** 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 leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at one year (9 to 15 months) postoperatively

Definitions:

Measure Assessment Period (Performance Period) - The period of time following the procedure date that is in which a postoperative VAS pain scale score is obtained.

Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure.

Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained via a telephone screening or prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If

more than one postoperative VAS was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.
Visual Analog Scale (VAS) - A "visual analog scale" is a continuous line indicating the continuum between two states of being. A copy of the tool can be obtained below and at the following link Visual Analog Scale Tool.
Leg Pain Target #1 - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their leg pain as less than or equal to 3.0.
Leg Pain Target #2 - A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively one year (9 to 15 months) after the procedure AND the change improvement is greater than or equal to 5.0 points.

***NUMERATOR NOTE**: It is recommended that both a preoperative and postoperative be administered to the patient increasing chances 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 M1052 or* **G2147** *is submitted.*

- *VAS Pain Scale is not administered postoperatively at one year (9 to 15 months)*
- *Leg pain is measured using a different patient reported functional pain tool or via telephone screening*
- *Postoperative VAS Pain scale is administered less than 9 months or greater than 15 months (1 year window)*
- *Postoperative VAS value is greater than 3.0 and no valid preoperative VAS Pain scale to measure change*
- *Postoperative VAS value is greater than 3.0 and preoperative VAS Pain scale (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: Leg pain as measured by the Visual Analog Scale (VAS) at one year (9 to 15 months) postoperatively was less than or equal to 3.0 **OR** Leg pain measured by the Visual Analog Scale (VAS) within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points or greater **(G2146)**

OR

Performance Not Met: Leg pain was not measured by the Visual Analog Scale (VAS) at one year (9 to 15 months) postoperatively **(M1052)**

OR

Performance Not Met: Leg pain measured by the Visual Analog Scale (VAS) at one year (9 to 15 months) postoperatively was greater than 3.0 **AND** Leg pain measured by the Visual Analog Scale (VAS) within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 points **(G2147)**

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 wk) 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 score based on 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0.

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 VAS	Post-op VAS	Post-op ≤ 3.0?	If No, (Pre-op minus Post-op)	If No, Met Improvement Target of ≥ 5.0?	Met Numerator Target?
Patient A	8.5	3.5	No	5.0	Yes	Yes
Patient B	9.0	2.5	Yes	na	na	Yes
Patient C	7.0	0.5	Yes	na	na	Yes
Patient D	6.5	8.0	No	-1.5	No	No
Patient E	8.5	2.0	Yes	na	na	Yes
Patient F	7.5	1.5	Yes	na	na	Yes
Patient G	9.0	4.5	No	4.5	No	No
Patient H	5.5	7.5	No	-2.0	No	No
Patient I	9.0	5.0	No	4.0	No	No
Patient J	7.0	2.5	Yes	na	na	Yes
Rate						**60%**

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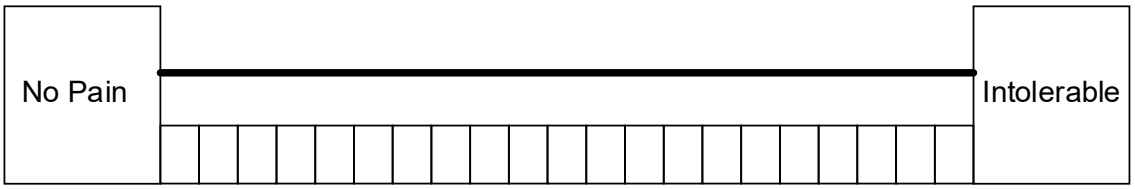
MEASURE TOOL:

Visual Analog Scale (VAS) - A visual analog scale is a continuous line indicating the continuum between two states of being.

Leg Pain:

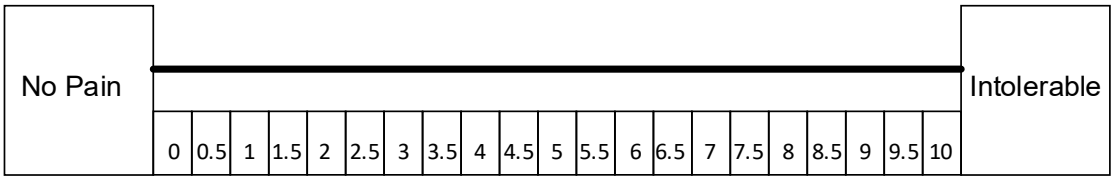
How severe is your **leg pain** today?

Please place an "X" in a box below the line to indicate how bad you feel your leg pain is today. Please select ("X") only ONE box.



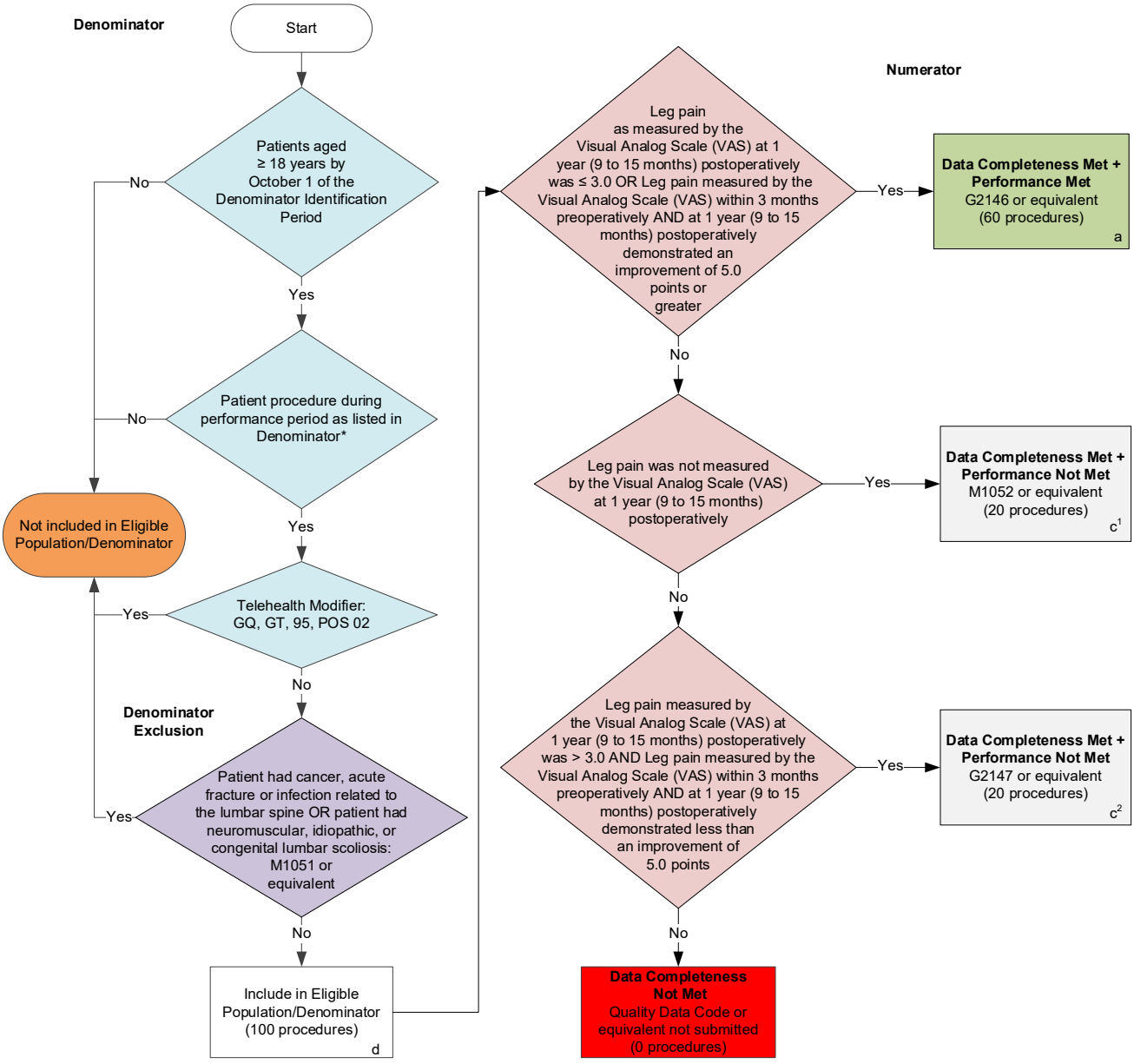
The tool must contain the end points of "No Pain" and "Intolerable". The tool must not display the actual numbers to the patient. It is not acceptable to substitute a numeric rating scale (e.g.; to ask the patient on a scale of one to 10 what number would you use to rate your pain).

Below is the key for MIPS eligible clinicians to utilize in order to convert patient's "X" to a number for measuring change. Do not use this scale for patient completion. The corresponding numeric value is used for measurement of improvement. The numeric equivalent has 21 possible points from 0 to ten with 0.5 intervals (e.g.; 0, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0).



2022 Clinical Quality Measure Flow for Quality ID #473: Leg Pain 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=60 procedures) + Performance Not Met (c^1+c^2=40 procedures) = 100 procedures = **100.00%**

Eligible Population/Denominator (d=100 procedures) = 100 procedures

Performance Rate=

Performance Met (a=60 procedures) = 60 procedures = **60.00%**

Data Completeness Numerator (100 procedures) = 100 procedures

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

NOTE: Submission Frequency: Procedure

2022 Clinical Quality Measure Flow Narrative for Quality ID #473: Leg Pain 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 aged greater than or equal to 18 years by October 1 of the Denominator Identification Period*:
    a. If *Patients aged 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 aged 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 *Telehealth Modifier*.
4. Check *Telehealth Modifier:*
    a. If *Telehealth Modifier* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Telehealth Modifier* equals No, proceed to check *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuoromuscular, idiopathic or congenital lumbar scoliosis*.
5. Check *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuoromuscular, idiopathic or congenital lumbar scoliosis*:
    a. If *Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuoromuscular, 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 neuoromuscular, idiopathic or congenital lumbar scoliosis* equals No, include in *Eligible Population/Denominator.*
6. Denominator Population:
    a. Denominator Population is all Eligible Procedures in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 100 procedures in the Sample Calculation.
7. Start Numerator
8. Check *Leg pain as measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points*

or greater:

a. If *Leg pain as measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 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 and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 60 procedures in the Sample Calculation.

b. If *Leg pain as measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was less than or equal to 3.0 OR Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 year (9 to 15 months) postoperatively demonstrated an improvement of 5.0 points or greater* equals No, proceed to check *Leg pain was not measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively*.

8. Check *Leg pain was not measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively*:

a. If *Leg pain was not measured by the Visual Analog Scale (VAS) 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 20 procedures in the Sample Calculation.

b. If *Leg pain was not measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively* equals No, proceed to check *Leg pain measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was greater than 3.0 AND Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 points*.

9. Check *Leg pain measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was greater than 3.0 AND Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 points*:

a. If *Leg pain measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was greater than 3.0 AND Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 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 20 procedures in the Sample Calculation.

b. If *Leg pain measured by the Visual Analog Scale (VAS) at 1 year (9 to 15 months) postoperatively was greater than 3.0 AND Leg pain measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 Year (9 to 15 months) postoperatively demonstrated less than an improvement of 5.0 points* equals No, proceed to check *Data Completeness Not Met*.

10. Check *Data Completeness Not Met*:

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

Sample Calculations

Data Completeness equals Performance Met (a equals 60 procedures) plus Performance Not Met (c^1 plus c^2 equals 40 procedures) divided by Eligible Population / Denominator (d equals 100 procedures. All equals 100 procedures divided by 100 procedures. All equals 100.00 percent.

Performance Rate equals Performance Met (a equals 60 procedures) divided by Data Completeness Numerator (100 procedures). All equals 60 procedures divided by 100 procedures. All equals 60.00 percent.

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

NOTE: Submission Frequency: Procedure

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.