

Note: The following appendices will not appear in the Code of Federal Regulations.

APPENDIX 1: FINALIZED MIPS QUALITY MEASURES

NOTE: Except as otherwise finalized in this final rule, previously finalized measures and specialty measure sets will continue to apply for the 2021 MIPS payment year and future years.

TABLE Group A: Finalized New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years

A.1. Continuity of Pharmacotherapy for Opioid Use Disorder

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	468
Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.
Measure Steward:	University of Southern California
Numerator:	Adults in the denominator who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than 7 days.
Denominator:	Adults aged 18 years and older who had a diagnosis of OUD.
Exclusions:	Pharmacotherapy for OUD initiated after June 30th of performance period.
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High Priority Measure:	Yes (Appropriate Use and Opioid-Related)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are adopting this measure because the opioid epidemic is immensely affecting the nation and it is imperative to measure opioid use. This clinical concept is currently not represented within MIPS. There are three existing opioid use related measures for MIPS but none cover the topic of pharmacotherapy. This measure captures patients diagnosed with opioid use disorder (OUD) who are receiving and adhering to the prescribed therapy. The performance data provided by the measure steward supports there is opportunity for improvement. Based on the measure steward research, only about a quarter to a third of individuals with commercial insurance or Medicaid coverage taking medication for OUD remained on the medication for at least 180 days without a gap of more than 7 days. The MAP acknowledged the public health importance of measures that address opioid use disorder and noted the gap in this area. However, the MAP recognized that the current measure is specified and tested at the health plan and state level and recommended the measure be refined and resubmitted prior to rulemaking because the measure has not been tested or endorsed at the clinician or clinician group level. While we agree that the measure should be tested at the clinician level, we believe there is an urgent need for measures that address the opioid epidemic affecting the nation. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients with opioid use disorder that achieve continuity of pharmacotherapy aggregated at the clinician level.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>
Comment:	One commenter supported adoption of new measure Q468: Continuity of Pharmacotherapy for Opioid Use Disorder, but has concerns about the potential for confounders in the measure data sources. The commenter urged CMS to consider, and account for the possibilities of confounders as the agency determines whether and how to adopt this measure.
Response:	We thank the commenter for their support. We will work with the measure steward to consider accounting for confounders when implementing this measure, but maintain the notion that the measure is appropriate for implementation. This measure also addresses an at-risk population not addressed within MIPS measures which outweighs the risk of potential variables.
FINAL ACTION:	We are finalizing the <i>Continuity of Pharmacotherapy for Opioid Use Disorder</i> measure as proposed for the 2019 Performance Period and future years.

A.2. Average Change in Functional Status Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	2643
Quality #:	469
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to 1 year (9 to 15 months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	<p>The average change (preoperative to 1 year post-operative) in functional status for all patients in the denominator.</p> <p>There is not a traditional numerator for this measure; the measure calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. For example: Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI 1 year post-op 26.4 points on a 100 point scale</p>
Denominator:	<p>Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively.</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>
Exclusions:	<p>The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)</p>
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre-to post-operative. Results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>
<p>Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. The commenter stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Another commenter is pleased this measure emphasizes the change in functional status.</p> <p>Response: We thank the commenters for their support.</p> <p>Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oswestry Disability Index (ODI) as the functional status assessment basis for this quality measure.</p> <p>Response: The measure steward has developed and tested this measure using the ODI tool to assess the change in functional status. We do not believe that the PROMIS scale will add value to this quality measure. Rather, we believe that the addition of the PROMIS scale introduces variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools.</p> <p>Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.</p> <p>Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF</p>	

Category	Description
	<p>endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. The Oswestry Disability Index is a standardized tool that will allow eligible clinicians to track the progress of their patient's functional improvement. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance.</p>
	<p>FINAL ACTION: We are finalizing the <i>Average Change in Functional Status Following Lumbar Spine Fusion Surgery</i> measure as proposed for the 2019 Performance Period and future years.</p>

A.3. Average Change in Functional Status Following Total Knee Replacement Surgery

Category	Description																				
NQF #:	2653																				
Quality #:	470																				
Description:	For patients age 18 and older undergoing total knee replacement surgery, the average change from pre-operative functional status to 1 year (9 to 15 months) post-operative functional status using the Oxford Knee Score (OKS) patient reported outcome tool.																				
Measure Steward:	Minnesota Community Measurement																				
Numerator:	<p>There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative OKS score.</p> <p>For example: The average change in knee function was an increase of 15.9 points 1 year post-operatively on a 48 point scale.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account patients who have an improvement and patients whose function decreases post-operatively. For example: Patient Pre-op OKS:I Postop OKS:I Change in OKS</p> <table border="0"> <tr> <td>Patient A: I 33 :I 45 :I 12</td> <td>Patient K: I 24 :I 43 :I 19</td> </tr> <tr> <td>Patient B: I 17 :I 39 :I 22</td> <td>Patient L: I 29 :I 34 :I 5</td> </tr> <tr> <td>Patient C: I 16 :I 31 :I 15</td> <td>Patient M: I 23 :I 39 :I 16</td> </tr> <tr> <td>Patient D: I 23 :I 40 :I 17</td> <td>Patient N: I 29 :I 45 :I 16</td> </tr> <tr> <td>Patient E: I 34 :I 42 :I 8</td> <td>Patient O: I 29 :I 45 :I 16</td> </tr> <tr> <td>Patient F: I 10 :I 42 :I 32</td> <td>Patient P: I 34 :I 41 :I 7</td> </tr> <tr> <td>Patient G: I 14 :I 44 :I 30</td> <td>Patient Q: I 11 :I 14 :I 3</td> </tr> <tr> <td>Patient H: I 32 :I 44 :I 12</td> <td>Patient R: I 13 :I 39 :I 26</td> </tr> <tr> <td>Patient I: I 19 :I 45 :I 26</td> <td>Patient S: I 18 :I 45 :I 27</td> </tr> <tr> <td>Patient J: I 26 :I 19 :I -7</td> <td></td> </tr> </table> <p>Average change in OKS 1 year post-op 15.9 points on a 48 point scale</p>	Patient A: I 33 :I 45 :I 12	Patient K: I 24 :I 43 :I 19	Patient B: I 17 :I 39 :I 22	Patient L: I 29 :I 34 :I 5	Patient C: I 16 :I 31 :I 15	Patient M: I 23 :I 39 :I 16	Patient D: I 23 :I 40 :I 17	Patient N: I 29 :I 45 :I 16	Patient E: I 34 :I 42 :I 8	Patient O: I 29 :I 45 :I 16	Patient F: I 10 :I 42 :I 32	Patient P: I 34 :I 41 :I 7	Patient G: I 14 :I 44 :I 30	Patient Q: I 11 :I 14 :I 3	Patient H: I 32 :I 44 :I 12	Patient R: I 13 :I 39 :I 26	Patient I: I 19 :I 45 :I 26	Patient S: I 18 :I 45 :I 27	Patient J: I 26 :I 19 :I -7	
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Patient H: I 32 :I 44 :I 12	Patient R: I 13 :I 39 :I 26																				
Patient I: I 19 :I 45 :I 26	Patient S: I 18 :I 45 :I 27																				
Patient J: I 26 :I 19 :I -7																					
Denominator:	<p>Eligible Population: Patients with total knee replacement procedures (Primary TKR Value Set, Revision TKR Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose functional status was measured by the Oxford Knee Score within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>																				
Exclusions:	None																				
Measure Type:	Patient Reported Outcome																				
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes																				
High Priority Measure:	Yes (Patient Reported Outcome)																				
Collection Type:	MIPS CQMs Specifications																				
Rationale:	<p>We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>																				
Comment:	<p>One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. They stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Several commenters are pleased this measure emphasizes the change in functional status and said that CMS should consider development of additional short and long-term outcomes measures for total joint procedures.</p> <p>Response: We thank the commenters for their support.</p> <p>Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oxford Knee Score (OKS) as the functional status assessment basis for this quality measure. A second commenter expressed concern that the OKS is a proprietary tool and that there are a number of validated tools available. Another commenter recommended the use of KOOS Jr and other potential measuring surveys to be available for use. The commenter also stated that KOOS Jr. and HOOS Jr. tools were selected as the preferred measurement instruments by the national orthopaedic specialty societies due to the ease of the tools.</p> <p>Response: We thank the commenters for their input. The measure steward has developed and tested this measure using the OKS tool to assess the change in functional status. We do not believe that the introduction of additional tools (PROMIS, KOOS Jr, HOOS Jr.) will add value to this quality measure. Rather, we believe that the addition tools introduce variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools. In addition, it would not be appropriate to include the</p>																				

Category	Description
	<p>HOOS Jr. survey since the patient population within this measure includes patients that have had a total knee replacement procedure. The HOOS Jr. is used to assess hip injuries and osteoarthritis.</p>
	<p>Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.</p>
	<p>Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance.</p>
	<p>FINAL ACTION: We are finalizing the <i>Average Change in Functional Status Following Total Knee Replacement Surgery</i> measure as proposed for the 2019 Performance Period and future years.</p>

A.4. Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	471
Description:	For patients age 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to 3 months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	<p>The average change (preoperative to 3 months post-operative) in functional status for all patients in the denominator.</p> <p>There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively.</p> <p>For example: Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36</p> <p style="text-align: center;">Average change in ODI 3 months post-op 26.4 points on a 100-point scale</p>
Denominator:	<p>Eligible Population: Patients with lumbar discectomy laminotomy procedure (Single Disc-Lami Value Set) for a diagnosis of disc herniation (Disc Herniation Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within 3 months preoperatively AND at 3 months (6 to 20 weeks) postoperatively.</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed.</p>
Exclusions:	The following exclusions must be applied to the eligible population: Patient had any additional spine procedures performed on the same date as the lumbar discectomy laminotomy.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. The results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>
Comment:	One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. They stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Another commenter is pleased this measure emphasizes the change in functional status.
Response:	We thank the commenters for their support.
Comment:	One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oswestry Disability Index (ODI) as the functional status assessment basis for this quality measure.
Response:	The measure steward has developed and tested this measure using the ODI tool to assess the change in functional status. We do not believe that the PROMIS scale will add value to this quality measure. Rather, we believe that the addition of the PROMIS scale introduces variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools.
Comment:	One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Category	Description
	<p data-bbox="100 220 1503 294">Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance.</p> <p data-bbox="100 317 1474 363">FINAL ACTION: We are finalizing the <i>Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery</i> measure as proposed for the 2019 Performance Period and future years.</p>

A.5. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	472
Description:	Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Female patients who received an order for at least one DXA scan in the measurement period.
Denominator:	Female patients ages 50 to 64 years with an encounter during the measurement period.
Exclusions:	<p>Exclude from the denominator patients with a combination of risk factors (as determined by age) or one of the independent risk factors:</p> <ul style="list-style-type: none"> • Ages: 50-54 (>=4 combo risk factors) or 1 independent risk factor • Ages: 55-59 (>=3 combo risk factors) or 1 independent risk factor • Ages: 60-64 (>=2 combo risk factors) or 1 independent risk factor <p>Combination risk factors (The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period):</p> <p>The following risk factors may occur any time in the patient's history but must be active during the measurement period:</p> <ul style="list-style-type: none"> • White (race) • BMI <= 20 kg/m2 (must be the first BMI of the measurement period) • Smoker (current during the measurement period) • Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) <p>The following risk factor may occur any time in the patient's history and must not start during the measurement period:</p> <ul style="list-style-type: none"> • Osteopenia <p>The following risk factors may occur at any time in the patient's history or during the measurement period:</p> <ul style="list-style-type: none"> • Rheumatoid arthritis • Hyperthyroidism • Malabsorption syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption • Chronic liver disease • Chronic malnutrition <p>The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period:</p> <ul style="list-style-type: none"> • Documentation of history of hip fracture in parent • Osteoporotic fracture • Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] <p>Independent risk factors (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period):</p> <p>The following risk factors may occur at any time in the patient's history and must not start during the measurement period:</p> <ul style="list-style-type: none"> • Osteoporosis <p>The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period:</p> <ul style="list-style-type: none"> • Gastric bypass • FRAX[R] 10-year probability of all major osteoporosis related fracture >= 9.3 percent • Aromatase inhibitors <p>The following risk factors may occur at any time in the patient's history or during the measurement period:</p> <ul style="list-style-type: none"> • Type I diabetes • End stage renal disease • Osteogenesis imperfecta • Ankylosing spondylitis • Psoriatic arthritis • Ehlers-Danlos syndrome • Cushing's syndrome • Hyperparathyroidism • Marfan syndrome • Lupus
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
High Priority measure:	Yes (Appropriate Use)
Collection Type:	eCQM Specifications

Category	Description
Rationale:	<p>We are adopting this measure because it will serve as a counterbalance to the existing measure of appropriate use (that is, Screening for Osteoporosis for Women Aged 65-85 Years of Age (Quality ID #039)). This measure addresses the inappropriate use of DXA scans for women age 50 – 64 years without risk factors for osteoporosis. The MAP recognized the need for early detection of osteoporosis but reiterated the importance of appropriate use of this screening technique and noted this measure could be complementary to the existing osteoporosis screening measure (Quality ID #039). The MAP recognized the potential need for a balancing measure to prevent the potential underuse of DXA scans. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>
<p>Comment: One commenter supported the addition of this measure.</p> <p>Response: We thank the commenter for their support.</p> <p>Comment: One commenter expressed that clinicians may not be aware of the distinction between screening DXA scans and those appropriately performed as medically necessary follow-up care in a diagnosed individual to ascertain response to pharmacological interventions. The commenter urged CMS to clarify this distinction within its final rule and consider augmenting the pharmacologic therapy quality measure with a subpart that captures appropriate DXA re-testing to ascertain response to treatment. A second commenter urged CMS to defer implementing any quality measures that might deter osteoporosis screening until most men and women who are at heightened risk of fragility fractures receive testing and pharmacotherapy within the standard of care.</p> <p>Response: Thank you for your comment and support of the DXA screening measure. We affirm that the intent of this measure is to encourage screening in the population at greatest risk for osteoporosis and assess progress toward appropriate screening. We appreciate your suggestion for an additional measure on appropriate screening as a follow-up to pharmacologic therapy in the treatment of osteoporosis and will give consideration to developing such a measure. This measure includes a number of applicable risk factors that would remove the at-risk patient from the denominator. The intended patient population is not considered high risk where a DXA scan is not appropriate. This measure does not deter appropriate osteoporotic screening for patients that meet the risks factors.</p> <p>FINAL ACTION: We are finalizing the <i>Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture</i> measure as proposed for the 2019 Performance Period and future years.</p>	

A.6. Average Change in Leg Pain Following Lumbar Spine Fusion Surgery

Category	Description										
NQF #:	Not Applicable (NA)										
Quality #:	473										
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to 1 year (9 to 15 months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.										
Measure Steward:	Minnesota Community Measurement										
Numerator:	<p>The average change (preoperative to 1 year post-operative) in leg pain for all patients in the denominator.</p> <p>There is not a traditional numerator for this measure; the measure is calculating the average change in leg pain score from pre-operative to post-operative leg pain score. The measure is NOT aiming for a numerator target value for a post-operative pain score.</p> <p>The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose pain increases post-operatively. For example: Patient I: Pre-op VAS I: Post-op VAS I:(Pre-op minus Post-op)</p> <table style="margin-left: 40px;"> <tr> <td>Patient A: I: 8.5 I: 3.5 I: 5.0</td> <td>Patient F I: 7.5 I: 1.5 I: 6.0</td> </tr> <tr> <td>Patient B: I: 9.0 I: 2.5 I: 6.5</td> <td>Patient G I: 9.0 I: 4.5 I: 4.5</td> </tr> <tr> <td>Patient C: I: 7.0 I: 0.5 I: 6.5</td> <td>Patient H I: 5.5 I: 7.5 I: -2.0</td> </tr> <tr> <td>Patient D: I: 6.5 I: 8.0 I: -1.5</td> <td>Patient I I: 9.0 I: 5.0 I: 4.0</td> </tr> <tr> <td>Patient E I: 8.5 I: 2.0 I: 6.5</td> <td>Patient J I: 7.0 I: 2.5 I: 4.5</td> </tr> </table> <p style="margin-left: 40px;">Average change in VAS points 4.0 Average change in leg pain 1 year post-op 4.0 points on a 10 point scale.</p>	Patient A: I: 8.5 I: 3.5 I: 5.0	Patient F I: 7.5 I: 1.5 I: 6.0	Patient B: I: 9.0 I: 2.5 I: 6.5	Patient G I: 9.0 I: 4.5 I: 4.5	Patient C: I: 7.0 I: 0.5 I: 6.5	Patient H I: 5.5 I: 7.5 I: -2.0	Patient D: I: 6.5 I: 8.0 I: -1.5	Patient I I: 9.0 I: 5.0 I: 4.0	Patient E I: 8.5 I: 2.0 I: 6.5	Patient J I: 7.0 I: 2.5 I: 4.5
Patient A: I: 8.5 I: 3.5 I: 5.0	Patient F I: 7.5 I: 1.5 I: 6.0										
Patient B: I: 9.0 I: 2.5 I: 6.5	Patient G I: 9.0 I: 4.5 I: 4.5										
Patient C: I: 7.0 I: 0.5 I: 6.5	Patient H I: 5.5 I: 7.5 I: -2.0										
Patient D: I: 6.5 I: 8.0 I: -1.5	Patient I I: 9.0 I: 5.0 I: 4.0										
Patient E I: 8.5 I: 2.0 I: 6.5	Patient J I: 7.0 I: 2.5 I: 4.5										
Denominator:	<p>Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period.</p> <p>Denominator: Patients within the eligible population whose leg pain was measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively.</p> <p>*The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed</p>										
Exclusions:	<p>The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)</p>										
Measure Type:	Patient Reported Outcome										
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes										
High priority measure:	Yes (Patient Reported Outcome)										
Collection Type:	MIPS CQMs Specifications										
Rationale:	<p>We are adopting this measure because it evaluates the management of pain from pre- to post-operative, which represents an important patient reported outcome. The results can be used by clinicians in evaluating whether the patient's pain has reduced post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>										
<p>Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. The commenter stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning).</p> <p>Response: We thank the commenter for their support.</p> <p>Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.</p> <p>Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance.</p> <p>FINAL ACTION: We are finalizing the <i>Average Change in Leg Pain Following Lumbar Spine Fusion Surgery</i> measure as proposed for the 2019 Performance Period and future years.</p>											

A.7. Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	Not Applicable (N/A)
Description:	The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.
Measure Steward:	Minnesota Community Measurement
Numerator:	Denominator patients with documentation that the patient was on daily aspirin or anti-platelet medication during the measurement period, unless allowed contraindications or exceptions are present.
Denominator:	18 years or older at the start of the measurement period AND less than 76 years at the end of the measurement period. AND Patient had a diagnosis of ischemic vascular disease (Ischemic Vascular Disease Value Set) with any contact during the current or prior measurement period OR had ischemic vascular disease (Ischemic Vascular Disease Value Set) present on an active problem list at any time during the measurement period. AND At least one established patient office visit (Established Pt Diabetes & Vasc Value Set) for any reason during the measurement period
Exclusions:	The following exclusions are allowed to be applied to the eligible population: <ul style="list-style-type: none"> • Patient was a permanent nursing home resident at any time during the measurement period. • Patient was in hospice or receiving palliative care at any time during the measurement period. • Patient died prior to the end of the measurement period. • Patient had only urgent care visits during the measurement period.
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High priority measure:	No
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Rationale:	We proposed this measure because the measure exclusions are more appropriate than those in the currently adopted Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204) measure. The measure accounts for history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or anti-platelets, or use of non-steroidal anti-inflammatory agents. The MAP acknowledged both that clinicians may still report Aspirin or Anti-platelet Medication measures separately from the composite to drive quality improvement. The MAP conditionally supported this measure with the condition that there are no competing measures in the program. We refer readers to Table C where we are removing Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204). Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972 .
<p>Comment: A commenter recommended utilizing the Core Quality Measure Collaborative (CQMC) to evaluate both the Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet measure and the measure CMS proposed to replace it with a new measure: Ischemic Vascular Disease: Use of Aspirin or Antiplatelet Medication, during their maintenance review of the ACO/PMH/PC Core Measure Set. This will allow payers, clinicians, and other stakeholders to weigh in on the measures' exclusion criteria and other characteristics. Another commenter encouraged CMS to continue alignment of the MIPS measure set with those recommended by the CQMC. Another commenter opposed the proposed adoption of this measure because they believe that it is already captured in the Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) measure and recommended not including such a measure in the program where it could displace reporting of the higher-value composite measure.</p> <p>Response: We appreciate the suggestion to allow stakeholders to weigh in on the exclusion criteria; however, we do not steward either of the measures and may not have the flexibility to revise the measures based on payers, clinicians or other stakeholders' feedback. Engaging the CQMC is beneficial to obtaining stakeholder feedback, but we encourage the commenter to provide this feedback to the CQMC. We are aware that this new measure is captured in the composite measure Q441 and that the composite measure is more robust. Although we believe Q441 may be burdensome to some eligible clinicians, we also believe it is a more meaningful measure than this new IVD measure. Therefore, to be consistent with our policy to remove measures that are duplicative to other measures and to ensure measures are more meaningful, we have decided to not finalize inclusion of this new IVD measure.</p> <p>FINAL ACTION: We are not finalizing the <i>Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication</i> measure as proposed for the 2019 Performance Period.</p>	

A.8. Zoster (Shingles) Vaccination

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	474
Description:	The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.
Measure Steward:	PPRNet
Numerator:	Patients with a shingles vaccine ever recorded.
Denominator:	Patients 50 years of age and older.
Exclusions:	None
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	MIPS CQMs Specifications
Rationale:	<p>We are adopting this measure because there are no measures currently in MIPS that address shingles vaccination for patients 50 years and older as recommended by the CDC. The MAP concluded that this measure would address the important topic of adult immunization. It discussed the new guidelines under development for the Zoster vaccination that could impact the amount of doses, the age of administration, and the specific vaccine that is used, but also noted that guidelines are constantly evolving and measures should be routinely updated based on changing guidelines. The MAP conditionally supported this measure pending NQF endorsement, and specifically requested evaluating the measure to ensure it has appropriate exclusions and reflects the most current CDC guidelines given the concerns about the cost of the vaccine and potential concerns about administering to immunocompromised patients. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>
Comment:	One commenter did not support the proposed adoption of this measure because it needs to be updated to reflect the most recent clinical guidelines.
Response:	The measure steward has aligned this measure with the most current clinical guidelines and it will be implemented as such. As indicated in our rationale, the measure will address the impacts to the amount of doses, the age of administration and the specific vaccine utilized. This measure addresses an important gap in adult immunization.
Comment:	Several commenters noted that the proposed rule rationale of “60 years and older” should be “50 years and older.”
Response:	We thank the commenters for their concerns regarding the age criteria with the rationale. The correct age was included in the description and denominator within the proposed rule, but did not align with the rationale. We agree with the denominator including patients over the age of 50 years and aligned the rationale with the measure’s age criteria.
Comment:	One commenter supported the proposed new measure for Zoster (Shingles) Vaccination. The commenter also supported broader adoption of a herpes zoster measure across specialty sets to reduce the number of missed immunization opportunities for this debilitating condition. The commenter supported the alignment of reporting mechanisms and believed doing so will strengthen and enhance the development and implementation of adult immunization quality measures.
Response:	We thank the commenter for their support of the new measure, Zoster (Shingles) Vaccination.
FINAL ACTION:	We are finalizing the <i>Zoster (Shingles) Vaccination</i> measure as proposed for the 2019 Performance Period and future years. The rationale is updated to state “patients 50 years and older” which aligns with the description and denominator age criteria.

A.9. HIV Screening

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	475
Description:	Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).
Measure Steward:	Centers for Disease Control and Prevention
Numerator:	Patients with documentation of the occurrence of an HIV test between their 15th and 66th birthdays and before the end of the measurement period.
Denominator:	Patients 15 to 65 years of age who had an outpatient visit during the measurement period.
Exclusions:	Patients diagnosed with HIV prior to the start of the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	eCQM Specifications
Rationale:	<p>We are adopting this measure because HIV screening is a national and global priority. While there are three currently adopted HIV measures in MIPS, they do not include screening the general population. The MAP acknowledged the importance of HIV screening from a population health perspective, but also questioned whether encouraging HIV screening through the MIPS program is the most effective strategy for improving this population health goal. It also expressed concern about how this measure under consideration identified individuals who may have a HIV screening in the community. Additionally, several MAP members expressed concern regarding the specifications requiring one time lifetime screening. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome.</p> <p>Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.</p>
Comment:	One commenter did not support the proposed adoption of this measure because they stated that there is no demonstrated performance gap (measure testing results showed very high performance overall) and the measure still needs to be tested at the clinician-level.
Response:	<p>We believe it is important to implement an HIV screening measure as it addresses an important national and global priority. This measure has been developed as an eCQM Specification and should have little burden in the submission of this measure. The version of this measure proposed has been tested at the clinician-level. The measure steward developed and tested a previous version of this measure at the community center-level. The NQF Health and Well-Being 2015-2017 Committee reviewed this facility-level version of the measure and voted to pass the measure on evidence and performance gap, but decided the measure did not meet the scientific acceptability criteria. The NQF standing committee noted that when this previous version of the measure was tested at the facility-level a performance gap was demonstrated, performance at four community health centers ranged from 20.6 to 31.1 percent and performance at a fifth community health center serving a high-risk population was 65.3 percent (NQF, Health and Well-Being 2015-2017: Technical Report, April 17, 2017, http://www.qualityforum.org/Projects/h/Health_and_Well_Being_2015-2017/Final_Report.aspx). Since then, the measure steward modified the measure and tested it at the clinician-level. As we indicated in our proposal, the MAP reviewed this clinician-level version of the measure in 2018 and conditionally supported it pending NQF review and endorsement. The steward plans to seek NQF endorsement on this clinician-level measure. We believe implementing this measure at the clinician-level will raise awareness and improve patient care leading to improvement in population health.</p>
FINAL ACTION:	We are finalizing the <i>HIV Screening</i> measure as proposed for the 2019 Performance Period and future years.

A.10. Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Category	Description
NQF #:	0101
Quality #:	Not Applicable (N/A)
Description:	<p>This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:</p> <p>Screening for Future Fall Risk: Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months.</p> <p>Falls Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.</p> <p>Plan of Care for Falls: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.</p>
Measure Steward:	National Committee for Quality Assurance
Numerator:	<p>This measure has three rates. The numerators for the three rates are as follows:</p> <p>A) Screening for Future Fall Risk: Patients who were screened for future fall* risk** at last once within 12 months. B) Falls Risk Assessment: Patients who had a risk assessment*** for falls completed within 12 months. C) Plan of Care for Falls: Patients with a plan of care**** for falls documented within 12 months.</p> <p>*A fall is defined as a sudden, unintentional change in position causing an individual to land at a lower level, on an object, the floor, or the ground, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force.</p> <p>**Risk of future falls is defined as having had had 2 or more falls in the past year or any fall with injury in the past year.</p> <p>***Risk assessment is comprised of balance/gait assessment AND one or more of the following assessments: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months.</p> <p>****Plan of care must include consideration of vitamin D supplementation AND balance, strength and gait training.</p>
Denominator:	<p>A) Screening for Future Fall Risk: All patients aged 65 years and older seen by an eligible provider in the past year.</p> <p>B & C) Falls Risk Assessment & Plan of Care for Falls: All patients aged 65 years and older seen by an eligible provider in the past year with a history of falls (history of falls is defined as 2 or more falls in the past year or any fall with injury in the past year).</p>
Exclusions:	Patients who have documentation of medical reason(s) for not screening for future fall risk, undergoing a risk-assessment or having a plan of care (for example, patient is not ambulatory) are excluded from this measure.
Measure Type:	Process
Measure Domain:	Patient Safety
High Priority Measure:	Yes
Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Rationale:	We are adopting this measure because it is a combined version of three of the currently adopted measures 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk. The new combined Falls measure (based on specifications in NQF 0101) is more robust and will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care which creates a more comprehensive screening measure. As noted in Table C, we are proposing to remove 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk because they will be subsumed by this new measure. While we note that has not been put forth through the MAP for consideration in MIPS, the three individual measures have been NQF endorsed as one measure.
Comment:	We received a number of comments opposing the new composite measure. Comments included a need for more clinical review, that vendors need time to develop and certify the respective replacement measures, and that CMS does not describe a benchmark for the composite measure. Several commenters were in support of the new composite measure stating that that it is a more robust and more comprehensive screening measure.
Response:	We thank all of the commenters for expressing the opposition of combining three measures to create a composite measure. We agree with the feedback provided and will postpone the implementation of the Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls measure until the measure can be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population.
FINAL ACTION:	We are not finalizing the <i>Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls</i> measure for the 2019 Performance Period.