TO: Consensus Standards Approval Committee (CSAC)

FR: Angela Franklin, Kathryn Streeter and Ann Phillips

RE: Musculoskeletal Project Member Voting Results

DA: October 6, 2014

The CSAC will review recommendations from the *Musculoskeletal* project at its October 14th conference call.

This memo includes a summary of the project, recommended measures, and responses to the public and member comments received.

Member voting on the recommended measures ended on September 16, 2014.

Accompanying this memo are the following documents:

1. **NQF-Endorsed Measures for Musculoskeletal Conditions Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table**. This table lists 98 comments received and the NQF/Standing Committee responses.

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC may consider approval of 7 candidate consensus standards.

Musculoskeletal Measures Recommended for Endorsement:

- 0054 Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis
- 2523 Rheumatoid Arthritis: Assessment of Disease Activity
- 2524 Rheumatoid Arthritis: Functional Status Assessment

Musculoskeletal Measures Recommended for eMeasure Trial Approval:

- 2522 Rheumatoid Arthritis: Tuberculosis Screening
- 2525 Rheumatoid Arthritis: Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy
- 2550 Gout: ULT Therapy
- 2549 Gout: Serum Urate Target

Musculoskeletal Measures Not Recommended:

- 0052 Use of Imaging Studies for Low Back Pain
- 0514 MRI Lumbar Spine for Low Back Pain
- 0662 Median Time to Pain Management for Long Bone Fracture

Musculoskeletal Measures Not Recommended for eMeasure Trial Approval:

- 2521 Gout: Serum Urate Monitoring
- 2526 Gout: Anti-inflammatory Prophylaxis with ULT Therapy

BACKGROUND

This project focuses on the consensus-based endorsement, maintenance and harmonization of individual and composite musculoskeletal measures of process, outcomes and structure. The musculoskeletal topic area includes low back pain, osteoarthritis and rheumatoid arthritis, and pain management.

Musculoskeletal disorders (MSDs) are injuries or disorders, including inflammatory and degenerative disorders affecting the muscles, nerves, tendons, joints, cartilage and supporting blood vessels, and disorders of the nerves, tendons, muscles and supporting structures of the upper and lower limbs, neck, and lower back that are caused, precipitated or exacerbated by sudden exertion or prolonged exposure to physical factors such as repetition, force, vibration, or awkward posture. MSDs are a leading cause of disability in the United States, with increasing prevalence and cost associated with musculoskeletal diseases in an aging population. In addition to the morbidity associated with musculoskeletal disorders, there has been a significant increase in the total costs associated with treatment of musculoskeletal disorders. Low back pain is among the most common reasons for visits to physicians and a major reason for work-related disability. Because of the burden of these disorders, there is a critical need for nationally recognized musculoskeletal care measures.

DRAFT REPORT

The Musculoskeletal Draft Report presents the results of the evaluation of 12 measures considered under the CDP. Three measures are recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement and three measures were not recommended. Four measures received eMeasure trial approval, which is intended for eMeasures that are ready for implementation but cannot yet be adequately tested to meet NQF endorsement criteria, and two measures did not receive trial measure approval. The measures were evaluated against the 2013 version of the measure evaluation criteria.

	MAINTENANCE	NEW	TOTAL
Measures considered	4	8	12
Withdrawn from consideration	14	0	14
Recommended	1	2	3
Recommended for eMeasure Trial Approval	0	4	4
Not recommended	3	0	3
Not Recommended for eMeasure Trial Approval	0	2	2
Reasons not Recommended	Importance- 1 Scientific Acceptability- 2 Overall- NA Competing Measure- NA	Importance- 2 Scientific Acceptability- NA Overall- NA Competing Measure- NA	

COMMENTS AND THEIR DISPOSITION

NQF received 98 comments from 28 organizations (including seven member organizations) and individuals pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Musculoskeletal project page under the Public and Member Comment section.

Comment Themes and Committee Responses

Comments about the evidence to support Importance to Measure and Report, measure feasibility, and measure specifications including exclusions, were forwarded to the developers, who were invited to respond.

At its review of all comments, the Standing Committee had the benefit of developer responses. Committee members focused their discussion on measures with the most significant issues.

Measure Specific Comments

0662 Median Time to Pain Management for Long Bone Fracture

Comments included:

- One commenter, the American College of Emergency Physicians (ACEP) submitted a letter requesting reconsideration of this measure for endorsement. The letter included comments that:
    - the evidence and performance gap for the measure were previously established, including by an NQF Committee in 2011
    - there is inadequate pain management among patients with long bone fracture (LBF) presenting to the ED, and that certain populations may not be receiving appropriate pain management in the ED, and
    - the measure is in use in the Hospital Outpatient Quality Reporting (HOQR) program and has been approved by the NQF Measures Application Partnership for use in the PQRS program and was approved in 2014 for use in the American Board of Emergency Medicine Maintenance of Certification Part IV activities.

Developer response: The developer submitted a letter requesting reconsideration of this measure for endorsement. The developer expressed concern that this measure, which is focused on timely pain management for ED patients with long bone fractures, was considered in the Musculoskeletal portfolio. The developer notes that the measure "focuses on the coordination and timely delivery of care to ED patients" and should have been evaluated within the Care Coordination portfolio with other ED timeliness measures. The developer also noted that:

- the Committee cited a lack of evidence linking the process of care to defined patient outcomes, and responds that numerous studies demonstrated that pain is often inadequately managed in the ED
- the Committee highlighted a lack of exclusion tin the measure for patients for whom pain medication is contraindicated, and responds that these patients would not be included in the measure, and the measure was developed as part of a group of measures targeting efficiency of care in the ED and time to long bone fracture pain management was identified as measurement area for which a denominator population could be clearly defined with few unintended

consequences, and the denominator population would consist of patients for whom pain management is almost always warranted.

Committee response: The Committee agreed the measure addresses efficiency, and recognized that care in the ED should be timely and efficient and noted that the evidence presented indicates that disparities in adequate pain management exist based on age and race. However, members were concerned that the measuring median time to pain administration is an indirect way to measure the adequacy of pain management in the ED, and were concerned about unintended consequences for complex patients. Members also observed that there is a spectrum of patients with fractures included in the measure, and that the metric may be more or less meaningful depending on the type of fracture presented. The Committee again raised concerns that there is little evidence linking the measurement of the median time to pain management for long bone fractures to improved clinical outcomes, questioned whether there could be a more direct way of measuring adequacy of pain management, and questioned how success on the measure would be defined. As a result, the Committee declined to reconsider the measure.

NQF response: Throughout the various iterations of the NQF measure evaluation criteria, it is true that the basic criteria and concepts have remained largely unchanged. However, the measure evaluation guidance—which focuses on the specificity and rigor with which the criteria are applied—has become more comprehensive and more specific over time.

Assignment of measures is based on the focus of the measure and the relevant Committee expertise required in reviewing measures. While there were concerns expressed regarding assignment of this measure to this portfolio, the measure evaluation guidance is also intended to promote consistency in evaluation across measures against the NQF criteria, regardless of the project.

0514 MRI Lumbar Spine for Low Back Pain

Comments included:

- Three comments were submitted for this measure. Two comments were in support of the Committee's recommendation not to recommend the measure for continued endorsement.
- One commenter requested that the Committee reconsider the measure for endorsement, and the developer has requested reconsideration of the measure.

Developer response: The developer noted that the measure exclusions have been modified to address concerns raised during the pre-meeting work group call. However, there are still additional concerns noted about the specifications during the in-person meeting that are currently being addressed and are not yet ready to be reviewed at this time.

Committee response: Committee members were concerned that the next opportunity to review the revised measure could be as long as three years, however members agreed not to make any changes to their decision to not recommend the measure for continued endorsement at this time.

NQF MEMBER VOTING RESULTS

All of the recommended measures were approved with 67 percent approval or higher. Representatives of six (6) member organizations voted; no votes were received from the Consumer, Health Professional, Provider Organization, Public/Community Health Agencies or Quality Measurement, Research and Improvement Councils.

Voting Comments

Measure #2524 Rheumatoid Arthritis: Functional Status Assessment

- America's Health Insurance Plans: While we recognize that the completion of a functional assessment is the first step, we are concerned that this measure may not lead to improvement in functional status as an outcome. We recommend moving toward measures that assess improvements in functional status.

REMOVE ENDORSEMENT OF MEASURES

Fourteen (14) measures previously endorsed by NQF have not been re-submitted, withdrawn from maintenance of endorsement, or not recommended for continued endorsement:

Measure	Description	Reason for removal of endorsement
0305: Back Pain: Surgical Timing	Percentage of patients at least 18 years of age and younger than 80 with a back pain episode of 28 days or more without documentation of red flags who had surgery within the first six weeks of back pain onset (overuse measure, lower performance is better).	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0306: Back Pain: Patient Reassessment	Percentage of patients at least 18 years of age and younger than 80 with back pain with documentation that the physician conducted reassessment of both of the following within four to six weeks of their initial back pain visit or of a surgical procedure date: 1) Pain AND 2) Functional status	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0309: Back Pain: Appropriate Use of Epidural Steroid Injections	Percentage of patients at least 18 years of age and younger than 80 with back pain who have received an epidural steroid injection in the absence of radicular pain AND those patients with radicular pain who received an epidural steroid injection without image guidance (i.e. overuse measure, lower performance is better).	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0310: Back Pain: Shared Decision Making	Percentage of patients at least 18 years of age and younger than 80 with back pain with whom a physician or other clinician	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.

Measure	Description	Reason for removal of endorsement
	reviewed the range of treatment options, including alternatives to surgery prior to surgery. To demonstrate shared decision making, there must be documentation in the patient record of a discussion between the physician and the patient that includes all of the following. 1) Treatment choices, including alternatives to surgery; 2) Risks and benefits; 3) Evidence of effectiveness	
0312: Back Pain: Repeat Imaging Studies	Percentage of patients at least 18 years of age and younger than 80 with a back pain episode of 28 days or more who received inappropriate repeat imaging studies in the absence of red flags or progressive symptoms (overuse measure, lower performance is better).	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0313 : Back Pain: Advice Against Bed Rest	Percentage of patients at least 18 years of age and younger than 80 with a back pain episode of 28 days or more with medical record documentation that a physician advised them against bed rest lasting four days or longer.	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0314: Back Pain: Advice for Normal Activities	Percentage of patients at least 18 years of age and younger than 80 with a back pain episode of 28 days or more with medical record documentation that a physician advised them to maintain or resume normal activities.	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0315: Back Pain: Appropriate Imaging for Acute Back Pain	Percentage of patients at least 18 years of age and younger than 80 with a diagnosis of back pain for whom the physician ordered imaging studies during the six weeks after pain onset, in the absence of "red flags" (overuse measure, lower performance is better).	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.

Measure	Description	Reason for removal of endorsement
0316: Back Pain: Mental Health Assessment	The percentage of patients at least 18 years of age and younger than 80 with a diagnosis of back pain for whom documentation of a mental health assessment is present in the medical record prior to intervention or when pain lasts more than 6 weeks.	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0317: Back Pain: Recommendation for Exercise	Percentage of patients at least 18 years of age and younger than 80 with back pain lasting more than 12 weeks, with documentation of physician advice for supervised exercise.	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0319: Back Pain: Physical Exam	Percentage of patients at least 18 years of age and younger than 80 with a back pain episode of 28 days or more with documentation of a physical examination on the date of the initial visit with the physician.	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0322: Back Pain: Initial Visit	Percentage of patients at least 18 years of age and younger than 80 with a diagnosis of back pain who have medical record documentation of all of the following on the date of the initial visit to the physician: 1. Pain assessment 2. Functional status 3. Patient history, including notation of presence or absence of "red flags" 4. Assessment of prior treatment and response, and 5. Employment status	This measure was included in NCQA's Back Pain Recognition Program that was retired in August 2012.
0050: Osteoarthritis: Function and Pain Assessment	Type of score: Proportion Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis with assessment for function and pain	The developer was unable to complete necessary testing.
0051: Osteoarthritis (OA): Assessment for use of anti-inflammatory or analgesic	Type of score: Proportion Percentage of patient visits for patients aged 21 years and older	The developer was unable to complete necessary testing.

Measure	Description	Reason for removal of endorsement
over-the-counter (OTC) medications	with a diagnosis of OA with an assessment for use of anti-inflammatory or analgesic OTC medications	

APPENDIX

Measure Evaluation Summary Tables

LEGEND: H=High; M=Moderate; L=Low; I=Insufficient; IE=Insufficient with Exception; NA=Not Applicable; Y=Yes; N=No

Measures Recommended

0054 Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis

Submission | Specifications

Description: The percentage of patients 18 years and older by the end of the measurement period, diagnosed with rheumatoid arthritis and who had at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD).

Numerator Statement: Patients diagnosed with rheumatoid arthritis who were dispensed at least one ambulatory prescription for a disease- modifying anti-rheumatic drug (DMARD) during the measurement year.

Denominator Statement: All patients, ages 18 years and older by December 31 of the measurement year, who had two of the following with different dates of service on or between January 1 and November 30 of the measurement year:

- Outpatient visit, with any diagnosis of rheumatoid arthritis
- Nonacute inpatient discharge, with any diagnosis of rheumatoid arthritis

Visit type need not be the same for the two visits.

Exclusions: Exclude patients who have a diagnosis of HIV. Look for evidence of HIV diagnosis as far back as possible in the patient's history through the end of the measurement year.

Exclude patients who have a diagnosis of pregnancy any time during the measurement year.

Adjustment/Stratification:

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [5/8/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-13**; **M-8**; **L-1**; **I-0; IE-0**; 1b. Performance Gap: **H-6**; **M-13**; **L-3**; **I-0;** 1c. Impact: **H-16**; **M-3**; **L-2**; **I-1**

Rationale:

- The developer presented clinical practice guidelines from the National Institute for Clinical Excellence (NICE) and the American College of Rheumatology (ACR) and a systematic review of empirical evidence to support the need for disease-modifying anti-rheumatic drugs (DMARDs) in patients with rheumatoid arthritis (RA) and linking treatment to better outcomes, such as slowing the progression of RA and preventing further damage to joints. The Committee agreed strong evidence is presented to support the measure is sufficient.

0054 Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis

- Committee members questioned whether there is a continued opportunity for improvement on the measure, with 90 percent of commercial plans meeting the measure, although performance was lower for Medicaid and Medicare plans. The developer noted that although the average performance rate is high across commercial health plans, there is still considerable variation among the different types of health plans, including variation by region. Given this consideration, the Committee agreed that there is room for improvement.

- The Committee agreed the measure will have a high impact, as RA is considered one of the leading causes of the morbidity, mortality in the country. Rheumatoid arthritis has also been established as a top 20 impact condition by the Centers for Medicare and Medicaid Services.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-11**; **M-11**; **L-0**; **I-0** 2b. Validity: **H-0**; **M-16**; **L-4**; **I-2**
<u>Rationale</u>:

- The Committee agreed that the reliability testing provided, with scores showing agreement ranging from 0.87-0.93, indicates the measure is highly reliable and the scores can distinguish differences in performance among the health plans.

- Committee members were concerned about factors that might influence getting a prescription or not, such as a variance in copay fees from plan to plan, or lack of rheumatologists in various regions. The Committee asked for clarification regarding whether plans, or whether providers should be accountable in the measure. The developer acknowledged that this is a broader issue not necessarily specific to this measure, and clarified that ultimately the plan is held accountable for this measure.

- Committee members also raised concerns regarding whether inactive RA should be captured in the measure, as prescribing DMARDs for this population would not be appropriate. The developer explained that this element would be difficult to capture via claims for this claims based measure.

- The Committee agreed that for data element validity, there was good agreement on denominator identification, as administrative data and medical record data agreed for over 73 percent of patients. There was some discussion about the variation, that some prescriptions were missed, perhaps due to the issues mentioned above such as high copays. The developer explained that while some patients might be missed, the assumption is the distribution of these types patients would be equal across the plans and not skew results.

3. Feasibility: H-13; M-8; L-0; I-0
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)
<u>Rationale</u>:

- Overall, the Committee agreed the measure if feasible to implement. The data elements are being already captured and generated in the EHR during the provision of care.

0054 Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis

4. Use and Usability: H-12; M-19; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- The Committee agreed the measure meets the use and usability criterion, noting that the measure is already widely used by a number of plans and rating systems for healthcare quality.

5. Related and Competing Measures

- This measure is related to: NQF #2525: Rheumatoid Arthritis: Disease Modifying Anti-Rheumatic Drug Therapy for RA. Description: Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis who are newly prescribed disease modifying anti-rheumatic drug (DMARD) therapy within 12 months. The two measures have a similar focus but address different levels of accountability and collect data from different data sources. The developers, NCQA and ACR have held an initial meeting to review the commonalities and differences in measure logic and value sets between the two measures. The stewards will continue this harmonization effort.

Standing Committee Recommendation for Endorsement: **Y-21**; **N-1**

6. Public and Member Comment

- Four comments were submitted for this measure. Although one commenter noted that there is likely a minimal gap in care for this measure, all four comments were supportive of the Committee's decision to recommend the measure for continued endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2523 Rheumatoid Arthritis: Assessment of Disease Activity

Submission | Specifications

Description: Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis and >=50% of total number of outpatient RA encounters in the measurement year with assessment of disease activity using a standardized measure.

Numerator Statement: # of patients with >=50% of total number of outpatient RA encounters in the measurement year with assessment of disease activity using a standardized measure.

Denominator Statement: Patients 18 years and older with a diagnosis of rheumatoid arthritis seen for two or more face-to-face encounters for RA with the same clinician during the measurement period.

Exclusions: N/A

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: American College of Rheumatology

STANDING COMMITTEE MEETING [5/7/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

2523 Rheumatoid Arthritis: Assessment of Disease Activity

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)
1a. Evidence: **H-2**; **M-13**; **L-0**; **I-0; IE-6**; 1b. Performance Gap: **H-9**; **M-11**; **L-1**; **I-0;** 1c. Impact: **H-10**; **M-10**; **L-1**; **I-0**
Rationale:

- The developer presented American College of Rheumatology clinical guidelines that recommend routine disease activity measurement to target low disease activity. These tools were developed to aid in measuring responses in clinical trials, and are based on expert opinion with Category C evidence. The Committee noted that there are not data from randomized controlled trials related to measuring disease activity to improve outcomes, and the Committee agreed that using validated assessments to set treatment goals and target therapy can result in improved patient outcomes, including better functional and radiographic outcomes.

- Performance gap data from 3 testing sites showed that 35-61 percent of patients met the criteria of an assessment in at least 50 percent of patient encounters with a mean rate of 50 percent. The Committee agreed this demonstrated there was room for improvement.

- The Committee agreed that this measure addresses a national health priority and will have a high impact, as rheumatoid arthritis has been established as a top 20 impact condition by the Centers for Medicare and Medicaid Services.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-1**; **M-20**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-19**; **L-0**; **I-1**
Rationale:

- The Committee agreed moderate reliability testing is presented, as testing was performed at the data element level, rather than the performance score.

- The Committee agreed the validity of the measure is moderate, as face validity testing is presented.

3. Feasibility: H-1; M-18; L-2; I-0
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)
Rationale:

- The Developer provided a sufficient eMeasure feasibility assessment for this eMeasure.

- The Committee agreed the measure is moderately feasible, as some Committee members noted that the feasibility might be dependent on kind of the current workflow of implementers of the measure, and there could be potential technical challenges with adding the data element fields required for the measure.

4. Use and Usability: H-3; M-17; L-1; I-0
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
Rationale:

2523 Rheumatoid Arthritis: Assessment of Disease Activity

- This measure has been reviewed and recommended by MAP for use in 2015 CMS programs. The developer indicated that the measure is expected to be included in stage three of the CMS Meaningful Use program. As a result, the Committee agreed the measure meets the criterion.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-1**

6. Public and Member Comment

Comments included:

- Ten comments were submitted for this measure. Although nine commenters were supportive of the Committee's decision to recommend the measure, several expressed feasibility concerns. One commenter noted that technical challenges may exist relative to collecting data for this measure from an EHR due to variations in physician office workflow and adding the necessary data element fields into the EHR. Commenters agreed that the measure is conceptually important, but were concerned about the reliability of data extractions on the assessments from EHRs.

Developer response:

- "As supported by growing evidence and established practice guidelines, we believe that the assessment of disease activity is a foundational concept in quality measurement and improvement. A tight control treatment strategy aiming for remission in early rheumatoid arthritis is more effective than usual care treatment in daily clinical practice. We initially also had concerns that collecting data for this measure could present implementations challenges. However, our measures testing sites have evidenced that it is feasible to support successful workflow and data extraction from an EHR to reliably collect and report data on this measure. We tested this measure in multiple sites with multiple different EHR systems and were able to successfully and reliably test this measure. In addition, the ACR also has experience with collecting this data through our RISE registry, which pulls data directly from practice's EHR systems to calculate performance. We have been able to successfully implement this measure in our RISE registry practices. Furthermore, this is a critically important clinical concept for rheumatologists and lays the foundation for future outcomes measures in the field."
- "To address the commenter's second concern, the measure does in fact list specific tools for measuring disease activity, which can be found in the measure specification guide, including:
  - Simplified Disease Activity Index (SDAI)
  - Clinical Disease Activity Index (CDAI)
  - Patient Activity Score (PAS)
  - Patient Activity Score II (PASII)
  - Routine Assessment of Patient Index Data (RAPID3)
  - Modified disease activity scores with twenty-eight-joint counts (DAS 28 CRP/DAS 28 ESR)

  The ACR recently undertook an extensive multi-year project, involving systematic literature reviews, expert consensus ratings, and national surveys to reach consensus on which RA disease activity measures are valid, reliable, and responsive, and feasible to implement in routine clinical practice."
- "The ACR-endorsed 6 RA disease activity measurement tools, which include overlapping core elements. All include a patient-reported component (PRO). No measure is currently a gold standard; there is good scientific evidence supporting each endorsed measure. Therefore, clinicians can select from a range of valid options appropriate to their practice settings and available resources. This novel approach to measurement has been extensively validated in RA over a period of several decades."

Committee response:

- The Committee accepted the developer's response and made no changes to their decision to recommend the measure for endorsement.

2523 Rheumatoid Arthritis: Assessment of Disease Activity
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2524 Rheumatoid Arthritis: Functional Status Assessment
Submission | Specifications
Description: Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis for whom a functional status assessment was performed at least once during the measurement period. **Numerator Statement**: Number of patients with functional status assessment documented once during the measurement period. Functional status can be assessed using one of a number of valid and reliable instruments available from the medical literature. **Denominator Statement**: Patients age 18 and older with a diagnosis of rheumatoid arthritis seen for two or more face-to-face encounters for RA with the same clinician during the measurement period. **Exclusions**: N/A **Adjustment/Stratification**: **Level of Analysis:** Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data : Electronic Health Record **Measure Steward**: AMERICAN COLLEGE OF RHEUMATOLOGY
STANDING COMMITTEE MEETING [5/7/2014] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap, 1c. High Impact) 1a. Evidence: **H-0**; **M-3**; **L-0**; **I-0; IE-19**; 1b. Performance Gap: **H-12**; **M-9**; **L-0**; **I-1;** 1c. Impact: **H-16**; **M-6**; **L-0**; **I-0** Rationale: • The Committee acknowledged that functional status as an outcome is important, as it is a predictor of future disability and mortality, and provides feedback to both the patient and the provider. The Committee noted that although there direct evidence was not provided about the relationship to health outcomes, there is indirect evidence for the relationship. The Committee agreed the developer provided sufficient evidence to meet the criterion. • The developers presented results from three test sites that showed a 44 to 87 percent variation in performance on the measure. The Committee agreed that this data sufficiently demonstrates a performance gap. • The Committee agreed this measure addresses a national health priority and the measure will have a high impact, as rheumatoid arthritis has been established as a top 20 impact condition by the Centers for Medicare and Medicaid Services.

2524 Rheumatoid Arthritis: Functional Status Assessment

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-3**; **M-19**; **L-0**; **I-0** 2b. Validity: **H-5**; **M-15**; **L-1**; **I-1**
<u>Rationale</u>:

- The Committee noted that testing was performed at the data element level, not the performance score, and as a result agreed the measure demonstrates moderate reliability.
- The Committee agreed the validity of the measure is moderate, noting face validity testing is presented for the measure.

3. Feasibility: H-2; M-13; L-5; I-2
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The developers provided a feasibility assessment of the critical data elements and all of these elements scored high (2 out of 3 or 3 out of 3) based on a survey of four EHR vendors. The surveyed EHR vendors also assessed the feasibility of the measure logic and determined that the submitted measure is feasible. Some Committee members raised concern over potential technical and workflow changes for providers, as 2 of 3 sites suggested that technical implementation would take several weeks and workflow implementation training would take several months. The developer responded that if this measure is recommended for NQF endorsement and becomes a part of CMS programs, there will be a strong incentive for EHR vendors to reduce the burden associated with implementation of the measure.

4. Use and Usability: H-6; M-12; L-3; I-1
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
<u>Rationale</u>:

- Committee noted that the developer anticipates this e-measure will be incorporated into the ACR registry and is a refinement of the current PQRS functional status rheumatoid arthritis measure.
- Some Committee members expressed concern that this measure would set the bar of performance too low and result in providers opting to select the “other” option rather than one the four recommended and validated functional assessment tools. The developer noted that all four recommended tools are nonproprietary and are available online, and that providers are strongly encouraged to use them rather than the “other” option.
- The Committee agreed the measure meets the use and usability criterion.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-3**

Comments included:

- Nine comments were received for this measure. Commenters were generally supportive of the measure,

2524 Rheumatoid Arthritis: Functional Status Assessment
however there were several concerns noted. • One commenter noted that feasibility may be challenging for implementation for family physicians, due to the fact that different functional status assessments are available for use. • One commenter expressed concern over the accuracy of functional assessments and their use in a quality measure. Another commenter agreed that while assessing pain and functional status with a validated tool is important, concerned was expressed that this measure may not lead to improvement in functional status as an outcome. Developer response: • "We appreciate this feedback, but maintain that functional status assessment is foundational to patient care and has been noted to be a primary concern for patients. There is strong agreement among national and international guidelines that measuring functional status is important to judge response to therapy and also to assess prognosis. We agree with the commenter that functional status does not always reflect RA disease activity; Disease activity and functional status are related, but distinct and not perfectly correlated concepts. Therefore, this measures provides an essential complement to the disease activity measure (2523: rheumatoid arthritis: assessment of disease activity) in order to capture the full spectrum of the patient's experience and provide the clinician with complete information to make evidence-based clinical care decisions." Committee response: • The Committee requested that the developer explicitly state that the measure only applies to rheumatologists and the developer agreed to make that clear in the specifications. The Committee accepted the developer's response and made no changes to their decision to recommend the measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Recommended for eMeasure Trial Approval

2522 Rheumatoid Arthritis: Tuberculosis Screening
Submission | Specifications
Description: Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis who have documentation of a tuberculosis (TB) screening performed within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD). **Numerator Statement**: Any record of TB testing documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic DMARD prescription. **Denominator Statement**: Patients 18 years and older with a diagnosis of rheumatoid arthritis who are seen for at least one face-to-face encounter for RA who are newly started on biologic therapy during the measurement period. **Exclusions**: N/A **Adjustment/Stratification**: **Level of Analysis:** Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data : Electronic Health Record **Measure Steward**: American College of Rheumtology

2522 Rheumatoid Arthritis: Tuberculosis Screening

STANDING COMMITTEE MEETING [5/7/2014)

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-2**; **M-7**; **L-0**; **I-0; IE-13**; 1b. Performance Gap: **H-8**; **M-14**; **L-0**; **I-0;** 1c. Impact: **H-15**; **M-7**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee noted that direct evidence was not provided linking the process of tuberculosis screening on patients who start a first course of biologic disease-modifying anti-rheumatic drugs (DMARDs) to improved outcome, but there is evidence showing that this population has an increased risk of tuberculosis. The Committee also noted that this is a key patient safety measure and a randomized control study would be unethical. The Committee unanimously passed the measure on the evidence criterion.

- The developer presented performance gap data using ACR's Rheumatology Clinical Registry that demonstrated there was a performance rate of 73.6 percent and 92.9 percent in 2011 and 2012, respectively. The Committee agreed that the data sufficiently demonstrated a performance gap.

- The Committee agreed this measure addresses a national health priority and the measure will have a high impact, as rheumatoid arthritis has been established as a top 20 impact condition by the Centers for Medicare and Medicaid Services.

2. Scientific Acceptability of Measure Properties: <u>As this e-measure is a candidate for the trial implementation pathway, testing for the measure will be submitted at a later time.</u>

Trial Measure Specifications: H-3; M-17; L-1; I-1

The measure may be considered for endorsement after sufficient data to assess reliability and validity testing have been submitted to NQF, within three years of trial approval.

<u>Rationale:</u>

- Committee members raised concern regarding multiple methods of testing and the accuracy for tuberculosis screening; specifically how providers are interpreting the results. The Committee agreed that was a broader issue not specific to this measure. Overall however, the Committee found the trial measure specifications to be consistent with the evidence.

3. Feasibility: H-5; M-15; L-0; I-2

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The developer provided an eMeasure feasibility assessment of the critical data elements and all of these elements scored high (2 out of 3 or 3 out of 3) based on a survey of four EHR vendors. The Committee agreed the measure is moderately feasible.

- Some Committee members raised concerns over tuberculosis testing accuracy. False positive test results could lead to tuberculosis treatment with potential harmful side effects. Although this could be unintended consequence, the Committee noted this is more of an issue problem with tuberculosis testing

2522 Rheumatoid Arthritis: Tuberculosis Screening
in general and not specific to this measure.
4. Use and Usability: H-4; M-16; L-2; I-0 *(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)* Rationale: • This developer noted that this measure has been reviewed by the Measures Application Partnership for use in 2015 CMS programs. The Committee agreed that the measure meets the usability and use criterion.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Trial Measure Approval : **Y-21**; **N-1**
Comments included: • Eleven comments were submitted for this measure, all in support of the Committee's decision to recommend the measure for trial measure approval.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2525 Rheumatoid Arthritis: Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy
Submission | Specifications
Description: Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis who are newly prescribed disease modifying anti-rheumatic drug (DMARD) therapy within 12 months. **Numerator Statement**: Patient received a DMARD **Denominator Statement**: Patient age 18 years and older with a diagnosis of rheumatoid arthritis seen for two or more face-to-face encounters for RA with the same clinician during the measurement period **Exclusions**: Patients with a diagnosis of HIV; patients who are pregnant; or patients with inactive Rheumatoid Arthritis. **Adjustment/Stratification**: **Level of Analysis:** Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data : Electronic Health Record **Measure Steward**: AMERICAN COLLEGE OF RHEUMATOLOGY
STANDING COMMITTEE MEETING [5/08/2014] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap, 1c. High Impact) 1a. Evidence: **H-9**; **M-10**; **L-0**; **I-2; IE-0**; 1b. Performance Gap: **H-4**; **M-16**; **L-2**; **I-0;** 1c. Impact: **H-12**; **M-10**; **L-0**; **I-0** Rationale: • The developer provided an overview of the measure and clarified that the description should read "percentage of patients greater than 18 years with a diagnosis of rheumatoid arthritis who are prescribed,

administered, or ordered a DMARD in a measurement year" as opposed to "newly prescribed DMARD therapy".

- The Committee noted that the evidence presented was primarily based on clinical guidelines with level C evidence. Members agreed that DMARD treatment is critical and noted that it would be very difficult to try to conduct a randomized controlled trial on this aspect of care. The Committee agreed that the evidence presented was sufficient to meet the evidence criterion.

- The developer also noted observational data that support DMARDs usage leading to decreased health care costs. Although this may not be the case with biologics due to cost, the developer noted, DMARDs have been shown to be cost effective and improve outcomes in both observational and randomized control trials.

- The Committee noted the high performance rate on the measure for participants in the ACR clinical registry and questioned the opportunity for improvement on the measure. The developer noted that a limited group of rheumatologists report through the registry, and the performance by registry participants might not be reflective of broader performance, which is likely lower. The Committee agreed that the data was sufficient enough to demonstrate a performance gap.

- The Committee agreed this measure addresses a national health priority and the measure will have a high impact, as rheumatoid arthritis has been established as a top 20 impact condition by the Centers for Medicare and Medicaid Services.

2. Scientific Acceptability of Measure Properties: <u>As this e-measure is a candidate for the trial implementation pathway, testing for the measure will be submitted at a later time.</u>

Trial Measure Specifications: H-3; M-17; L-0; I-2

The measure may be considered for endorsement after sufficient data to assess reliability and validity testing have been submitted to NQF, within three years of trial approval.

<u>Rationale:</u>

- The developer has completed testing at two sites and will submit additional data at a later time. Overall, the Committee agreed the specifications were clearly specified.

3. Feasibility: H-6; M-15; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The developer provided an eMeasure feasibility assessment of the critical data elements and all of these elements scored high (2 out of 3 or 3 out of 3) based on a survey of four EHR vendors The Committee agreed that the eMeasure is moderately feasible, noting that the required data elements are routinely generated and readily available.

4. Use and Usability: H-4; M-17; L-0; I-1

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

2525 Rheumatoid Arthritis: Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy

Rationale:

- The Committee noted that the measure is in use in the ACR registry and will be important to begin to address gaps in care. The Committee agreed that the measure meets the use and usability criterion.

5. Related and Competing Measures

- This measure is related to: NQF #0054: Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis. Description: The percentage of patients 18 years and older by the end of the measurement period, diagnosed with rheumatoid arthritis and who had at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD). The two measures have a similar focus but address different levels of accountability and collect data from different data sources. The developers, NCQA and ACR have held an initial meeting to review the commonalities and differences in measure logic and value sets between the two measures. The stewards will continue this harmonization effort

Standing Committee Recommendation for Trial Measure Approval: **Y-21**; **N-1**

6. Public and Member Comment

Comments included:

- Six comments were submitted for this measure. Five comments were in support of the Committee's decision to recommend the measure for trial measure approval.
- One commenter suggested that the measure only include patients who accept therapy and that the provider should not fail the measure when he/she has documented the recommendations for a DMARD and patient elects to forego it. The commenter also noted concerns about exclusions, specifically patients with comorbidities that DMARDs are contraindicated or deemed excessively risky.

Developer response:

- "We appreciate this comment and have discussed the topic throughout our measure development and also with NQF staff. The NQF discourages using patient preference as an exclusion or exception to measures. "Merely indicating that a patient declined a service or intervention does not indicate the quality of the exchange that occurred between the healthcare provider and patient. Exclusions for patient preference (refusal) could be related to quality problems" from NQF Measure Evaluation Criteria. National Quality Forum. "CSAC Guidance on Quality Performance Measure Construction." May 2011.We do not anticipate a 100% performance rate with this measure and plan to work with entities implementing this measure to clarify appropriate performance targets."

Committee response:

- The Committee discussed the whether or not adding the patient preference exclusion would be appropriate, and ultimately agreed that patients who refuse therapy should still be included. The Committee accepted the developer's response and made no changes to their decision to recommend the measure for Trial Measure Approval.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2549 Gout: Serum Urate Target

Submission | Specifications

Description: Percentage of patients aged 18 and older with a diagnosis of gout treated with urate-lowering therapy (ULT) for at least 12 months, whose most recent serum urate result is less than 6.8 mg/dL.

Numerator Statement: Patients whose most recent serum urate level is less than 6.8 mg/dL

Denominator Statement: Adult patients aged 18 and older with a diagnosis of gout treated with urate lowering

therapy (ULT) for at least 12 months
Exclusions: Patients with a history of solid organ transplant
Adjustment/Stratification:
Level of Analysis: Clinician : Individual
Setting of Care: Ambulatory Care : Clinician Office/Clinic
Type of Measure: Process
Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMERICAN COLLEGE OF RHEUMATOLOGY

STANDING COMMITTEE MEETING [5/7/2014]
1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>
(1a. Evidence, 1b. Performance Gap, 1c. High Impact)
1a. Evidence: **H-0**; **M-9**; **L-4**; **I-4; IE-4**; 1b. Performance Gap: **H-1**; **M-11**; **L-3**; **I-6;** 1c. Impact: **H-1**; **M-9**; **L-5**; **I-6**
<u>Rationale</u>:

- The developer presented evidence that included the 2012 American College of Rheumatology Guidelines for Management of Gout: Systematic Nonpharmacologic and Pharmacologic Therapeutic Approaches to Hyperuricemia. The evidence was based on a systematic review of the literature on pharmacologic and non-pharmacologic urate lowering therapies, which focused on published meta-analyses and randomized clinical trials. The Committee agreed that the evidence supported a relationship between uric acid levels and gout, but no direct evidence was presented to support a target serum urate level of 6.8 mg/dl versus other targets. The developer responded that while there is no direct evidence to support the target serum urate level of 6.8 mg/dl, evidence does indicate that lowering serum urate levels leads to improved outcomes in the form of decreased gouty attacks in individuals with a diagnosis of gout. The developer also noted that the literature indicates that 6.8 mg/dl is the solubility level for serum urate. The Committee noted that clear empirical evidence is needed for set serum urate targets and these targets should be specified in the measure.

- The Committee noted that evidence indicates serum urate levels are not consistently monitored in all patients diagnosed with chronic gout and receiving urate lowering therapy. However, the Committee questioned the need for regular monitoring of serum urate levels for all patients who are on urate lowering therapy and are stable over time, versus individuals in the acute phase of disease management. The Committee also questioned if a patient centered approach might be preferred based on the observation of symptoms indicating gouty attacks, or tophaceous gout and erosions, rather than targeting treatment towards a particular serum urate level. The developer responded that safety monitoring recommendations in patients with a diagnosis of gout include tests for liver function, renal function and a complete blood count. Serum urate levels could easily be included in those monitoring tests. Serum urate levels, the presence of tophus, tophus progression and the recurrence of attacks are all well correlated in patients receiving urate lowering therapy in chronic gout management.

2. Scientific Acceptability of Measure Properties: <u>As this e-measure is a candidate for the trial implementation pathway, testing for the measure will be submitted at a later time.</u>

2549 Gout: Serum Urate Target

Trial Measure Specifications: H-1; M-11; L-5; I-4 The measure may be considered for endorsement after sufficient data to assess reliability and validity testing have been submitted to NQF, within three years of trial approval.
Rationale:

- The Committee questioned whether having a snapshot of serum urate levels is a reliable method of monitoring a patient. The Committee also noted that clarification is needed regarding the clinical methods by gout is diagnosed, and a definition of what constitutes a gouty attack should be included in the measure specifications. The developer response was that a patient placed on urate-lowering therapy is sufficient indication that the physician has diagnosed gout.

- The Committee questioned if the measure numerator could be specified more accurately. The numerator in the measure specifications consists of all patients whose most recent serum urate level is less than 6.8 mg/dl. The Committee noted that the measure might be more meaningful if patients with a serum urate level of less than 6.8 mg/dl, on uric acid lowering therapy and experiencing no gouty attacks, tophi or erosions were excluded from the numerator.

3. Feasibility: H-5; M-11; L-2; I-3
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)
Rationale:

- The developer provided an eMeasure feasibility assessment of the critical data elements and all of these elements scored high (2 out of 3 or 3 out of 3) based on a survey of four EHR vendors. The Committee agreed that the submitted eMeasure specification follows industry standards to represent the measure electronically which should enable automated data extraction and measure score calculation. The Committee agreed that the measure is moderately feasible.

4. Use and Usability: H-1; M-11; L-4; I-5
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
Rationale:

- The Committee noted that unnecessary testing and/or treatment could have unintended consequences including increased cost of care. The developer responded that if the patient was already undergoing urate lowering therapy, benefit could be found in adjusting the dosage and that the cost burden of additional testing was not prohibitive. The Committee agreed that the measure meets the use and usability criterion.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Trial Measure Approval: **Y-13**; **N-4 (8/21/14)**:
Y-11

6. Public and Member Comment
Comments included:

- Eight comments were submitted for the measure. Seven of these comments were in support of the measure and one was not in support of the measure.

2549 Gout: Serum Urate Target
• One commenter again expressed concern over urate levels being a reliable method of monitoring a patient with gout, stating that the evidence does not strongly suggest that serum urate levels correlate with the disease state. The commenter also questioned whether the 6.8 mg/dL level most is appropriate, noting that the other measures use 6.0 mg/dL. Developer response: • "We would like to restate the evidence demonstrating strong association between serum urate levels and patient outcomes (gout attacks and tophi resolution). The ACR recognizes a huge variation in understanding the mechanisms of gout, best practices and available evidence between rheumatologists and other specialties. This discrepancy and gap of understanding confirms the importance of this measure, as our evidence shows a strong correlation between urate levels and patient outcomes. We further document that there are large gaps in quality looking at current practices. • "We realize that the guidelines recommend 6.0 mg/dl, however, quality measures make allowances for less stringent standards to allow for patients at the margins. The concentration for urate crystal solubility is 6.8 mg/dl. This higher level (than guidelines recommend) avoids penalizing physicians with patients who are improving, but with scores slightly above 6.0 mg/dl. We recognize that this level is a process indicator, rather than an outcome, so we allowed flexibility." Committee response: During evaluation of the measure at the in-person meeting, the Committee did not reach consensus on a recommendation for trial measure approval. After additional discussion the Committee re-voted on the measure during the Post-Comment Call, and recommended the measure for Trial Measure Approval. As suggested by the Committee, the developer agreed to change the measure specifications to include an exclusion for existing patients with documentation that no gout flares have occurred within the last year.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2550 Gout: ULT Therapy
Submission | Specifications
Description: Percentage of patients aged 18 and older with a diagnosis of gout and either tophus/tophi or at least two gout flares (attacks) in the past year who have a serum urate level > 6.0 mg/dL, who are prescribed urate lowering therapy (ULT) **Numerator Statement**: Patients who are prescribed urate lowering therapy (ULT) **Denominator Statement**: Adult patients aged 18 and older with a diagnosis of gout and a serum urate level > 6.0 mg/dL who have at least one of the following: presence of tophus/tophi or two or more gout flares (attacks) in the past year **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry **Measure Steward**: AMERICAN COLLEGE OF RHEUMATOLOGY
STANDING COMMITTEE MEETING [5/7/2014]

2550 Gout: ULT Therapy

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>
(1a. Evidence, 1b. Performance Gap, 1c. High Impact)
1a. Evidence: **H-0**; **M-14**; **L-2**; **I-1; IE-4**; 1b. Performance Gap: **H-4**; **M-15**; **L-0**; **I-2;** 1c. Impact: **H-1**; **M-14**; **L-2**; **I-4**
<u>Rationale</u>:

- Committee members noted that the initial evidence presented did not directly support the use of uric acid lowering therapies in patients with more severe gout. In response to workgroup calls, the developer presented additional evidence, including two randomized controlled trials demonstrating that Febuxostat lowered serum uric acid and reduce the frequency of gout attacks. Articles were also presented that describe the effects of allopurinol on lowering both uric acid and frequency of attack and tophus reduction.

- One Committee member noted that the studies presented focused on patients with high uric acid levels, and that evidence was not presented focusing on patients with minor or less severe attacks of gout. The developer clarified that this measure captures patients who have more severe disease by including those who have had at least two or more gout flares in the past year in the denominator. The Committee questioned whether a patient who has just one attack per year would need to be included in this measure.

- The majority of the Committee agreed that although a summary of the systematic review wasn't presented, the measure is based on evidence-based clinical guidelines, leading to a moderate rating of the evidence.

- The Committee found the data submitted sufficiently demonstrated that there was opportunity for improvement.

- The Committee agreed that this measure addressed a high-priority (high-impact) aspect of healthcare, as gout flares in this high risk population represent a significant cause of morbidity and cost.

2. Scientific Acceptability of Measure Properties: <u>As this e-measure is a candidate for the trial implementation pathway, testing for the measure will be submitted at a later time.</u>

The measure may be considered for endorsement after sufficient data to assess reliability and validity testing have been submitted to NQF, within three years of trial approval.
<u>Rationale</u>:

- The Committee agreed that the specifications are precise. There was a suggestion that the denominator specification be reviewed; the developer indicated that they would perform further analyses using data obtained through testing. Recommendations from the Committee included analyzing patients with recurring attacks separately; considering the contraindications in terms of exclusions; considering whether non-drug therapy trial could be incorporated – at least in the patients without tophaceous gout and erosions, and reviewing the 6 mg/dl threshold.

- Committee members raised concern about the reliability of the diagnosis particularly in primary care settings that could result in potential overtreatment. There was also concern about increase in gout flares

when initiating urate lowering therapy without receiving other education or prophylactic pieces, as exclusive focus on medication management could potentially result in less patient education that is an important part of gout care.

3. Feasibility: H-0; M-14; L-5; I-2

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The developer provided an eMeasure feasibility assessment of the critical data elements and all of these elements scored high (2 out of 3 or 3 out of 3) based on a survey of four EHR vendors. The Committee agreed that the submitted eMeasure specification follows industry standards to represent the measure electronically which should enable automated data extraction and measure score calculation. The Committee agreed that the measure is moderately feasible.

4. Use and Usability: H-1; M-12; L-4; I-4

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale:

- The developer stated that the specifications for this measure will be finalized and full field testing will be completed in the next 12 months, at which time the ACR will seek full NQF endorsement. In addition, the ACR will implement these measures into its EHR-enabled registry this year, at which time they will be part of the registry´s plan for public reporting. The Committee agreed that the measure met the use and usability criterion.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-14**; **N-7** - **The Committee recommended this measure for trial measure approval.**

6. Public and Member Comment

Comments included:

- Six comments were submitted for this measure. Five of the comments were in support of the Committee's recommendation to recommend the measure for trial measure approval. One commenter expressed concern that "this type of measure may over-emphasize pharmacologic management when dietary or education may be more effective at certain levels of serum urate".

Developer response:

- "In addition to the 2012 ACR Gout Guidelines, the threshold of 2 or more attacks per year was previously endorsed in the 2006 EULAR gout guidelines and 2007 British Society for Rheumatologists gout guidelines. These recommendations have been consistent across 3 separate agencies for the last decade, and we feel the threshold of 2 attacks per year should be retained. Severe/recalcitrant and polyarticular patients are unlikely to have fewer than 2 attacks per year and therefore would already be included in the denominator population. Nephrolithiasis in a gout patient is an ACR gout guideline indication; however, this is relatively small group of patients and ascertaining whether a stone is urate based is likely difficult to abstract from the chart."

Committee response:

- The Committee accepted the developer's response and made no changes to their decision to recommend

2550 Gout: ULT Therapy
the measures for Trial Measure Approval.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Not Recommended

0052 Use of Imaging Studies for Low Back Pain
Submission | Specifications
Description: The percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of diagnosis. **Numerator Statement**: Patients who received an imaging study with a diagnosis of low back pain on the Episode Date (i.e. the earliest date of service for an outpatient or ED encounter during the Intake Period (January 1-December 3 of the measurement year) with a principal diagnosis of low back pain) or in the 28 days following the Episode Date. The measure is reported as an inverted rate (i.e. 1 – numerator/denominator). A higher score indicates appropriate treatment of low back pain (i.e. the proportion for whom imaging studies did not occur). **Denominator Statement**: All patients 18 years as of January 1 of the measurement year to 50 years as of December 31 of the measurement year with a claim/encounter for an outpatient or emergency department visit code with a principal diagnosis of low back pain during the Intake Period (January 1-December 3 of the measurement year). **Exclusions**: No Exclusions **Adjustment/Stratification**: **Level of Analysis:** Health Plan, Integrated Delivery System **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Ambulatory Care : Urgent Care **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Imaging/Diagnostic Study **Measure Steward**: National Committee for Quality Assurance
STANDING COMMITTEE MEETING [05/8/2014] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap, 1c. High Impact) 1a. Evidence: **H-5**; **M-15**; **L-1**; **I-0; IE-1**; 1b. Performance Gap: **H-10**; **M-12**; **L-0**; **I-0;** 1c. Impact: **H-19**; **M-3**; **L-0**; **I-0** <u>Rationale</u>: • Evidence provided by the developer included the Clinical Practice Guideline for the treatment of Adult Acute and Subacute Low Back Pain from the Institute for Clinical Systems Improvement (ICSI), updated November 2012. The ICSI guideline, states "Clinicians should not recommend imaging (including computed tomography [CT], magnetic resonance imaging [MRI] and x-ray) for patients with non-specific low back pain." The Committee questioned the value of the ICSI guideline, noting that only six small randomized controlled trials (RCTs) were used to develop the guideline, and if the limited study populations were representative of all patients especially considering the exclusion of other guidelines and numerous systematic reviews on this topic. The Committee agreed that the evidence presented was

sufficient for meeting the evidence criterion.

- Data presented by the developer indicated significant variation in the rate of appropriate imaging for patients with low back pain across health plans. In 2012, there was a 15.5-point difference between plans in the 10th percentile and plans in the 90th percentile for commercial plans and 13.9 points for Medicaid plans. While the Committee agreed that this variation indicates a gap in quality care, the lack of change in performance since the measure was initially endorsed in 2009, indicates that practice variation has not changed.

- The Committee noted that total spending is quite high for the diagnosis and treatment of low back pain. A member of the Committee cited Martin's 2008 study, "Expenditures and Health Status among adults with spine problems," published in The Journal of the American Medical Association to provide some context. The Martin study estimates spending on low back pain between twenty to thirty billion dollars a year, with total spending on care for all spinal disorders estimated between sixty and one hundred billion dollars a year. The Committee agreed that the measure is high impact, as overutilization of imaging services is a significant factor in spending on services for low back pain.

2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific Acceptability criteria and failed at validity</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-8**; **M-14**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-7**; **L-4**; **I-4**

<u>Rationale</u>:

- The Committee questioned the practitioner's ability to accurately determine whether a patient has a negative diagnosis for low back pain in the 6 months prior, as specified in the denominator statement. The developer clarified the measure was a claims based measure.

- The developer presented the results of the measure score reliability testing, noting that the measure had a high reliability score in a comparison of signal to noise in commercial health plans and Medicaid plans. Beta-binomial analysis indicates that commercial HMO and PPO plans have an average reported reliability score of .99, and Medicaid plans have an average reliability score of .94. The Committee was satisfied with the measure specifications and the developer's interpretation of the measure score reliability testing.

- The Committee noted that scientific acceptability of the measure is highly dependent on validity. The Committee questioned why certain "red flag" conditions are not excluded from the measure. These "red flag" conditions include unexplained weight loss, insidious onset; unexplained fever; history of urinary or other infection; immunosuppression; diabetes mellitus; prolonged use of corticosteroids; osteoporosis; prior lumbar spine surgery. Some Committee members found the lack of exclusion of these conditions a significant threat to validity. Subsequently, the Committee agreed the measure did not meet the validity criterion.

- A member of the Committee noted that the American College of Radiology (2011) guideline includes appropriate criteria for the imaging of low back pain and encouraged the developer to strengthen the

0052 Use of Imaging Studies for Low Back Pain
measure by incorporating this guideline.
4. Feasibility: H-NA; M-X-NA L-NA; I-NA *(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)*
3. Use and Usability: H-NA; M-NA; L-NA; I-NA *(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)*
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-NA**; **N-NA**
6. Public and Member Comment Comments included: • Four comments were submitted for this measure; three were in support of the Committee's decision to not recommend the measure for continued endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-NA; N-NA; A-NA
8. Board of Directors Vote: Y-NA; N-NA
9. Appeals

0514 MRI Lumbar Spine for Low Back Pain
Submission | Specifications
Description: This measure calculates the percentage of MRI of the lumbar spine studies with a diagnosis of low back pain on the imaging claim, and for which the patient did not have prior claims-based evidence of antecedent conservative therapy. Antecedent conservative therapy may include (see subsequent details for codes): 1)Claim(s) for physical therapy in the 60 days preceding the lumbar spine MRI; 2)Claim(s) for chiropractic evaluation and manipulative treatment in the 60 days preceding the lumbar spine MRI; and, 3)Claim(s) for evaluation and management in the period >28 days and <60 days preceding the lumbar spine MRI. **Numerator Statement**: Of MRI of the lumbar spine studies (with a diagnosis of low back pain) in the denominator, number of studies without evidence of claims-based, prior antecedent conservative therapy. The numerator measurement of prior conservative therapy is based on the claim date of the MRI of the lumbar spine from the denominator, with the prior conservative therapy within the defined time periods relative to each MRI lumbar spine claim (i.e., a patient can be included in the numerator count more than once, if the patient had more than one MRI lumbar spine procedure in the measurement period, and the MRI lumbar spine procedure occurred on different days). **Denominator Statement**: MRI of the lumbar spine studies with a diagnosis of low back pain on the imaging claim. The diagnosis of low back pain must be on the MRI lumbar spine claim (i.e., the lumbar spine MRI must be billed with a low back pain diagnosis in one of the diagnosis fields on the claim). MRI lumbar spine studies without a diagnosis of low back pain on the claim are not included in the denominator count. If a patient had more than one MRI lumbar spine study for a diagnosis of low back pain on the same day, only one study would be counted; but, if a patient had multiple MRI lumbar spine studies with a diagnosis of low back pain on the claim during the

measurement period, each study would be counted (i.e., a patient can be included in the denominator count more than once).

Exclusions: Indications excluded from the measure's denominator include any patients with the following procedures or diagnosis codes:

- Patients with lumbar spine surgery in the 90 days prior to MRI;
- Cancer;
- Trauma;
- Intravenous drug abuse;
- Neurologic impairment;
- Human immunodeficiency virus (HIV);
- Unspecified immune deficiencies; and,
- Intraspinal abscess.

Additional details about those procedures and diagnoses excluded from the measure's denominator, including look-back periods (where applicable) and code lists, can be found in the "Denominator Exclusion Details" section.

Adjustment/Stratification:

Level of Analysis: Facility, Population : National, Population : State

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility

Type of Measure: Efficiency

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [5/14/2014]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-2**; **M-12**; **L-4**; **I-1; IE-2**; 1b. Performance Gap: **H-7**; **M-13**; **L-0**; **I-2;** 1c. Impact: **H-19**; **M-3**; **L-0**; **I-0**

<u>Rationale</u>:

- Evidence provided by the developer included a 2007 American College of Radiology (ACR) Appropriateness Criteria® low back pain (LBP) which recommends that uncomplicated acute LBP is a benign, self-limited condition that warrants no imaging studies. The 2007 ACR Appropriateness Criteria® is included in the total measure evidence, and is based on a systematic review of forty-eight studies. Forty of the studies were rated category three and four, with four being the lowest quality. None the studies were rated as category one. In addition to the 2007 ACR Appropriateness Criteria, the total measure evidence includes fourteen additional guidelines. The Committee also noted only minimal evidence was included for Medicare beneficiaries, who are included in the population defined by the measure.
- The Committee noted a performance gap between 14 percent and 16 percent when comparing facility scores at the 10^{th} and 90^{th} percentiles, indicating a continued opportunity for improvement and that the measure showed minimal improvement between 2007 and 2011. The developer explained that measure data was collected from paid claims and subject to a two- year delay, resulting in 2011 data reflecting 2009 performance. The developer also suggested that future improvement would be seen as a result of the 2010 initiation of public reporting, allowing all facilities to compare performance. The Committee also questioned the variance in performance between facilities in utilization of imaging services. The developer responded that facility size, type, caseload and access to the latest

information on care guidelines could account for performance differences between facilities. The Committee agreed that the data sufficiently demonstrated a gap in care.

- The Committee agreed that this measure addresses a high-priority (high-impact) aspect of healthcare, as MRI lumbar spine studies without antecedent conservative therapy can contribute to poor patient outcomes and a higher cost of care.

2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific Acceptability criteria and failed at validity.</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1**; **M-19**; **L-1**; **I-1** 2b. Validity: **H-0**; **M-4**; **L-15**; **I-3**

<u>Rationale</u>:

- noted the calculation of measure performance was based on exclusion of claims in the measure numerator for antecedent conservative therapy taking place in the period ranging from 28 days prior to 60 days prior to an MRI study. The Committee questioned if claims for evaluation and management (E/M) were reliable to establish that antecedent conservative therapy had taken place. The Committee also noted that delays in the scheduling of an MRI study might affect the measure calculation.

  The developer responded that with the restriction to the use of claims data in the measure, E/M codes were the only suitable proxy to determine if conservative therapy had taken place.

- The developer provided an overview of the measure score reliability testing, explaining that while the 53.1 percent median value for the signal to noise analysis was slightly lower than the target value, the measure is used to establish a median benchmark value of facility performance rather than categorize performance.

- The Committee questioned the exclusions including a history of prior back surgery and previous trauma. The Committee noted that history of surgery should be an absolute exclusion, rather than a 90-day exclusion, as post-op back surgery patients cannot be categorized as uncomplicated back pain patients.

- The Committee questioned the potential effect on measure validity by the inclusion of different sources and types of claims data from a variety of facilities. The developer responded that the inclusion of these additional data would allow for better future benchmarking in all facilities, that facilities would be able to compare performance.

- The Committee also questioned the interpretation of guidelines used in establishing exclusions for patients over 70 years of age, finding that in some cases, the guidelines cited are in direct conflict with the measure exclusions. Conflicts noted included suspected lumbar disc herniation, sciatica, acute radicular pain, spinal cord infarction or degenerative conditions. The developer responded that there are plans to update the measure by including codes for these conditions in the measure exclusions.

3. Feasibility: H-NA; M-NA; L-NA; I-NA

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

0514 MRI Lumbar Spine for Low Back Pain
4. Use and Usability: H-NA; M-NA; L-NA; I-NA *(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)*
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-NA**; **N-NA**
6. Public and Member Comment Comments included: • Three comments were submitted for this measure. Two comments were in support of the Committee's recommendation not to recommend the measure for continued endorsement. • One commenter requested that the Committee reconsider the measure for endorsement, and the developer has requested reconsideration of the measure. Developer included: • The developer noted that the measure exclusions have been modified to address concerns raised during the pre-meeting work group call. However, there are still additional concerns noted about the specifications during the in-person meeting that are currently being addressed and are not yet ready to be reviewed at this time. Committee response: • Committee members were concerned that the next opportunity to review the revised measure could be as long as three years, however members agreed not to make any changes to their decision to not recommend the measure for continued endorsement at this time.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-NA; N-NA; A-NA
8. Board of Directors Vote: Y-NA; N-NA
9. Appeals

0662 Median Time to Pain Management for Long Bone Fracture
Submission | Specifications

0662 Median Time to Pain Management for Long Bone Fracture

Description: Median time from emergency department arrival to time of initial oral, intranasal or parenteral pain medication administration for emergency department patients with a principal diagnosis of long bone fracture (LBF).

Numerator Statement: Time (in minutes) from emergency department arrival to time of initial oral, intranasal or parenteral pain medication administration for emergency department patients with a diagnosis of a (long bone) fracture.

Denominator Statement: N/A Measure is a continuous variable.

Exclusions: N/A Measure is a continuous variable. See numerator details.

Adjustment/Stratification:

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Efficiency

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [5/8/2014]

1. Importance to Measure and Report: <u>The measure did not meet the Importance criteria and failed at evidence</u>

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-0**; **M-3**; **L-7**; **I-9; IE-2**; 1b. Performance Gap: **H-NA**; **M-NA**; **L-NA**; **I-NA;** 1c. Impact: **H-NA**; **M-NA**; **L-NA**; **I-NA**

<u>Rationale</u>:

- Evidence provided by the developer included studies that evaluated pain management practices for long bone fractures in the hospital emergency room. The Committee questioned if the evidence provided by the developer directly supported the measure focus, which is to improve the median time of pain medication administration from emergency department arrival for emergency department patients with a principal diagnosis of long bone fracture. Committee members noted that the studies presented didn't sufficiently link the process of measuring and reporting the time gap between arrival and administration of pain medication for long bone fractures to improved clinical outcomes. Committee members agreed that less time to administration is likely better, but the evidence was also lacking to support a particular timeframe for treating pain in long bone fractures. Members acknowledged that there are no clinical guidelines that support or give a particular timeframe for treatment. Subsequently, the Committee agreed that the evidence presented was insufficient for meeting the evidence criterion.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-NA**; **M-NA**; **L-NA**; **I-NA** 2b. Validity: **H-NA**; **M-NA**; **L-NA**; **I-NA**

4. Feasibility: H-NA; M-NA; L-NA; I-NA

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

0662 Median Time to Pain Management for Long Bone Fracture
3. Use and Usability: H-NA; M-NA; L-NA; I-NA *(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)*
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-NA**; **N-NA**

6. Public and Member Comment

Comment:

- One commenter, the American College of Emergency Physicians (ACEP) submitted a letter requesting reconsideration of this measure for endorsement. The letter included comments that:
    - the evidence and performance gap for the measure were previously established, including by an NQF Committee in 2011
    - there is inadequate pain management among patients with long bone fracture (LBF) presenting to the ED, and that certain populations may not be receiving appropriate pain management in the ED, and
    - the measure is in use in the Hospital Outpatient Quality Reporting (HOQR) program and has been approved by the NQF Measures Application Partnership for use in the PQRS program and was approved in 2014 for use in the American Board of Emergency Medicine Maintenance of Certification Part IV activities.

The letter is available at this link.

Developer response: The developer submitted a letter requesting reconsideration of this measure for endorsement. The developer expressed concern that this measure, which is focused on timely pain management for ED patients with long bone fractures, was considered in the Musculoskeletal portfolio. The developer notes that the measure "focuses on the coordination and timely delivery of care to ED patients" and should have been evaluated within the Care Coordination portfolio with other ED timeliness measures. The developer also noted that:

- the Committee cited a lack of evidence linking the process of care to defined patient outcomes, and responds that numerous studies demonstrated that pain is often inadequately managed in the ED
- the Committee highlighted a lack of exclusion tin the measure for patients for whom pain medication is contraindicated, and responds that these patients would not be included in the measure, and
- the measure was developed as part of a group of measures targeting efficiency of care in the ED and time to long bone fracture pain management was identified as measurement area for which a denominator population could be clearly defined with few unintended consequences, and the denominator population would consist of patients for whom pain management is almost always warranted.

The letter is available at this link.

Committee response: The Committee agreed the measure addresses efficiency, and recognized that care in the ED should be timely and efficient and noted that the evidence presented indicates that disparities in adequate pain management exist based on age and race. However, members were concerned that the measuring median time to pain administration is an indirect way to measure the adequacy of pain management in the ED, and were concerned about unintended consequences for complex patients. Members also observed that there is a spectrum of patients with fractures included in the measure, and that the metric may be more or less meaningful depending on the type of fracture presented. The Committee again raised concerns that there is little evidence linking the measurement of the median time to pain management for long bone fractures to improved clinical outcomes, questioned whether there could be a more direct way of measuring adequacy of pain management, and questioned how success on the measure would be defined. As a result, the Committee declined to reconsider the measure.

NQF response: Throughout the various iterations of the NQF measure evaluation criteria, it is true that the basic criteria and concepts have remained largely unchanged. However, the measure evaluation guidance—which focuses on the specificity and rigor with which the criteria are applied—has become more comprehensive and more specific over time.

Assignment of measures is based on the focus of the measure and the relevant Committee expertise required in reviewing measures. While there were concerns expressed regarding assignment of this measure to this portfolio, the measure evaluation guidance is also intended to promote consistency in evaluation across measures against the NQF criteria, regardless of the project.

0662 Median Time to Pain Management for Long Bone Fracture
7. Consensus Standards Approval Committee (CSAC) Vote: Y-NA; N-NA; A-NA
8. Board of Directors Vote: Y-NA; N-NA
9. Appeals

Measures Not Recommended for eMeasure Trial Approval

2521 Gout: Serum Urate Monitoring
Submission | Specifications
Description: Percentage of patients aged 18 and older with a diagnosis of gout who were either started on urate lowering therapy (ULT) or whose dose of ULT was changed in the year prior to the measurement period, and who had their serum urate level measured within 6 months **Numerator Statement**: Patients whose serum urate level was measured within six months after initiating ULT or after changing the dose of ULT **Denominator Statement**: Adult patients aged 18 and older with a diagnosis of gout who were either started on urate lowering therapy (ULT) or whose dose of ULT was changed in the year prior to the measurement period **Exclusions**: None **Adjustment/Stratification**: **Level of Analysis:** Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry **Measure Steward**: AMERICAN COLLEGE OF RHEUMATOLOGY
STANDING COMMITTEE MEETING [5/7/2014] The measure did not pass Importance to Measure and Report criteria and failed at High Priority. **1. Importance to Measure and Report:** (1a. Evidence, 1b. Performance Gap, 1c. High Impact) 1a. Evidence: **H-0**; **M-5**; **L-5**; **I-5; IE-6**; 1b. Performance Gap: **H-2**; **M-11**; **L-2**; **I-6;** 1c. Impact: **H-0**; **M-8**; **L-6**; **I-7** Rationale: • Evidence presented by the developer included the 2012 American College of Rheumatology Guidelines for Management of Gout: Systematic Nonpharmacologic and Pharmacologic Therapeutic Approaches to Hyperuricemia. The evidence was based on a systematic review of the literature on pharmacologic and non-pharmacologic urate lowering therapies, which focused on published meta-analyses and randomized clinical trials. Adherence to urate lowering therapy has been identified as a major gap in quality of care. Problems with adherence prevent achievement of other critical goals of management specifically achieving treatment target of serum urate < 6 mg/dl in patients with indications for urate lowering therapy. The Guidelines recommend frequent monitoring of serum urate during ULT titration (every 2-5 weeks) and once target is achieved every 6 months. • The Committee noted that there were no trials cited in the evidence that establish a linkage between monitoring serum urate levels, treating to uric acid level targets and improved patient outcomes. The developer acknowledged that while there were no trials linking the monitoring serum urate levels to

treatment, observational data of international studies indicated that patients that are not monitored experience more gouty attacks than those that are monitored. Although consensus was not reached when rating the evidence criterion, the Committee proceeded to review the performance gap data.

- The Committee found the data submitted demonstrated that there was opportunity for improvement.
- The Committee did not agree that this measure addresses a high-priority (high-impact) aspect of healthcare and the measure did not pass the impact criterion.

2. Scientific Acceptability of Measure Properties:
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-NA**; **M-NA**; **L-NA**; **I-NA** 2b. Validity: **H-NA**; **M-NA**; **L-NA**; **I-NA**

4. Feasibility: H-NA; M-NA; L-NA; I-NA
(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

3. Use and Usability: H-NA; M-NA; L-NA; I-NA
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

5. Related and Competing Measures
- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-NA**; **N-NA**

6. Public and Member Comment
Comments included:
- Twelve comments were submitted for this measure. Two commenters agreed with the Committee's decision not to recommend the measure for Trial Measure Approval.
- Commenters against the Committee's decision argued that "there is good evidence that achieving a serum urate level <6 mg/dl is associated with a marked reduction in gout flares and disappearance of tophi. Commenters noted that "serum urate monitoring will detect intentional and unintentional medication non-adherence by patients, giving clinicians the opportunity to reinforce education about gout treatment, and will give clinicians important goals for treatment that will improve outcomes for people with gout". Other comments included "the vast majority of gout patients started on ULT do not have a repeat serum urate assessed and without titrating ULT to the dose necessary to achieve the therapeutic target, patients will be left suboptimally treated, with ongoing complications from gout".

Committee response:
- The Committee discussed the Comments received and again noted that there were no trials cited in the evidence that establish a linkage between monitoring serum urate levels, treating to uric acid level targets and improved patient outcomes. The Committee agreed not to make any changes to their decision to not recommend the measure for Trial Measure Approval.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-NA; N-NA; A-NA

8. Board of Directors Vote: Y-NA; N-NA

9. Appeals

2526 Gout: Anti-inflammatory Prophylaxis with ULT Therapy

Submission | Specifications

Description: Percentage of patients aged 18 and older with a diagnosis of gout initiated on urate- lowering therapy (ULT), who are receiving concomitant anti-inflammatory prophylaxis (defined as low dose colchicine, non-steroid anti-inflammatory drug (NSAID) or glucocorticoid)

Numerator Statement: Patients prescribed anti-inflammatory prophylaxis (including low-dose colchicine, non-steroidal anti-inflammatory (NSAID) or glucocorticoid)

Denominator Statement: Patients aged 18 and older with an established gout diagnosis initiating urate lowering (ULT) therapy

Exclusions: None

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMERICAN COLLEGE OF RHEUMATOLOGY

STANDING COMMITTEE MEETING [5/7/2014]

1. Importance to Measure and Report: The measure did not pass Importance to Measure and Report criteria and failed at High Priority.

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **H-1**; **M-3**; **L-8**; **I-2; IE-7**; 1b. Performance Gap: **H-1**; **M-8**; **L-9**; **I-3;** 1c. Impact: **H-2**; **M-5**; **L-12**; **I-2**

Rationale:

- The Committee discussed how the evidence presented was based on a small study and was not directly related to the measure as specified, as most of the data was on colchicine and there was less data presented to support NSAIDS and/or corticosteroids. The Committee noted that starting urate lowering therapy can lead to an increased rate of acute gout flares for several months, and anti-inflammatory prophylaxis leads to a reduction of flares. Although consensus was not reached, the measure moved forward, as 52 percent of the Committee rated the evidence as high, moderate, or insufficient evidence with exception.

- The developers presented a VA study demonstrating a performance gap of 10 percent. Although consensus not reached, the measure moved forward as 43 percent of the Committee rated performance gap as high or moderate.

- Committee members questioned the costliness of gout flares versus prophylaxis for a broader group of patients. There was also concern expressed regarding the cost of colchicine prophylaxis. The majority of the Committee gave the impact criterion a low rating and the measure did not pass Importance to Measure and Report.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **NA** 2b. Validity: **NA**

Rationale

2526 Gout: Anti-inflammatory Prophylaxis with ULT Therapy

4. Feasibility: NA

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale

3. Use and Usability: NA

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Rationale

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **NA**

6. Public and Member Comment

Comments included:

- Eleven comments were submitted for this measure. Two commenters agreed with the Committee's decision not to recommend the measure for Trial Measure Approval.
- One commenter noted that "there are a large number of anti inflammatories that would serve to prophylaxis against gout attack while starting or increasing urate lowering therapy. There are a number of different glucocorticoid preparations, large number of NSAIDS not to mention colchicine. Would need to be very broad in the number medications acceptable to meet the measure."
- One commenter stated that "this is an appropriate measure since flare risk is higher when initiating ULT; provision of anti-inflammatory prophylaxis will reduce that risk (i.e., prevent flares), thereby improving patient adherence to ULT. Duration of prophylaxis upon initiation of ULT is dependent upon disease activity (flares, tophi), but should be for at least 6 months in the uncomplicated case with appropriate disease control."
- One commenter stated that "this is a reasonable quality measure but need to include some sense of a timeframe around initiation of ULT - it says this is for patients "initiated on ULT" but after a period of time (e.g. 6 months), the patient may no longer need prophylaxis, so it might be good to qualify this as pertaining to patients "during the first 3-6 months of ULT" or something to that effect."

Developer response:

- "We appreciate the feedback and agree that there needs to be a variety of medications that meet the measure. As a result, we have provided an expansive list of medications in the measure specifications. We chose not to dictate the durations of prophylaxis as, although there are data supporting the use of prophylaxis when initiating urate lowering therapy, there are fewer data guiding the specific duration of the prophylaxis. Therefore, we propose this measure as an important first step in increasing evidence-based practice through the use of prophylaxis and will refine the measure as evidence becomes available to define best practice regarding the duration of prophylaxis.
- "We appreciate your feedback and have timing specifications for the initiation of ULT. After initiating urate lowering therapy, there is an increased rate of acute gout flares for several months. From recent randomized control trials, where prophylaxis was continued for only 8 weeks, 40% of patients flared upon cessation of prophylaxis, whereas if prophylaxis was continued for 6 months, only 5% of patients flared. In a small randomized control trial using colchicine vs. placebo, patients assigned to colchicine had fewer flares at 0-3 and 3-6 months (0.57 and 0 flares) vs. patients assigned to placebo (1.91, 1.05 flares), both differences statistically different."

Committee response:

- The Committee discussed the Comments received and agreed not to make any changes to their decision to not recommend the measure for Trial Measure Approval.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-NA; N-NA; A-NA

8. Board of Directors Vote: Y-NA; N-NA

2526 Gout: Anti-inflammatory Prophylaxis with ULT Therapy
9. Appeals