NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Click to go to the link. ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 2525

Corresponding Measures:

De.2. Measure Title: Rheumatoid Arthritis: Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy

Co.1.1. Measure Steward: AMERICAN COLLEGE OF RHEUMATOLOGY

De.3. Brief Description of Measure: 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.

1b.1. Developer Rationale: The American College of Rheumatology (ACR) guidelines recommend the use of disease-modifying antirheumatic drugs (DMARDs) in every patient with active RA at the earliest stage of disease, ideally within 3 months of disease onset. These guidelines are based on results from numerous clinical trials demonstrating that DMARDs slow the progression of RA by decreasing inflammation and reducing articular erosions. In addition, both clinical trials and observational studies demonstrate that DMARDs improve functional status and health-related quality of life. Both underuse and disparities in DMARD use have been well-documented in numerous studies.

Sources:

Singh JA, Furst DE, Bharat A, Curtis JR. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.

Schmajuk G, Trivedi AN, Solomon DH, Yelin E, Trupin L, Chakravarty EF, Yazdany J. Receipt of disease-modifying antirheumatic drugs among patients with rheumatoid arthritis in Medicare managed care plans. JAMA. 2011 Feb 2;305(5):480-6.

Schmajuk G, Solomon DH, Yazdany J. Patterns of disease-modifying antirheumatic drug use in rheumatoid arthritis patients after 2002: a systematic review. Arthritis Care Res (Hoboken). 2013 Dec;65(12):1927-35.

S.4. Numerator Statement: Patient received a DMARD

S.6. 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

S.8. Denominator Exclusions: Patients with a diagnosis of HIV; patients who are pregnant; or patients with inactive Rheumatoid Arthritis.

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records, Registry Data

S.20. Level of Analysis: Clinician : Group/Practice, Clinician : Individual

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Evidence Summary

- Brief background: this measure considers RA patients 18 years+ who are newly prescribed DMARD therapy within 12 months.
- Developer provides a logic model depicting the relationship between DMARD prescription, DMARD use, decreased disease activity and erosions, and improved patient RA outcomes.
- Disease modifying anti-rheumatic drugs (DMARDs) improve the disease course of rheumatoid arthritis (RA) through attenuation of progression of bony erosions, reduction of inflammation and long-term structural damage.
- The utilization of DMARDs also improves functional status in individuals with RA.
- Evidence supports using a "treat to target" approach, where DMARDs are escalated, added and/or replaced to achieve the target of disease remission or low disease activity.
- RA affects approximately 1.3 million Americans (disproportionally women) and is incurable; goal of treatment is to slow progression.
- The guidelines recommend beginning treatment within three months of disease onset.

Questions for the Committee:

- What is the relationship of this measure to patient outcomes?
- How strong is the evidence for this relationship?
- Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Process measure based on SR and grading of body of evidence (box 3) Y -> Specifics on QQC not provided (box 4) -> Guideline: GRADE – strong (box 6) -> Moderate

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- Note: developer did not perform separate analysis according to their specifications, which are for both individual and group/practice level clinicians.
- Most recent performance data from 2017 data indicates high levels of performance, with the mean 90.47%, SD 9.62%, and interquartile range 6.42%.
- Minimum performance is 28.17 and max is 100. Deciles range from 84.63% (first decile) to 100% (tenth decile).

Disparities

- Disparities data is not routinely or uniformly collected in the RISE registry; ACR is exploring options to obtain this data to better monitor disparities.
- However, optimal clinical performance should be 100% regardless of social risk.
- Literature states there are disparities in DMARD use by race/ethnicity, socioeconomic status, age and geographic location have been reported in several well-conducted studies, some applying a similar performance measure.
    - According to Schmajuk, et al., blacks (-4 absolute percentage points; 95% CI, -6 to -2 points; P < .001), those with low socioeconomic status (-4 points; 95% CI, -6 to 2 points; P < .001), older individuals (-30 points; 95% confidence interval [CI], -29 to -32 points; P < .001) and those residing in certain geographic regions (in the Middle Atlantic region (-7 points; 95% CI, -13 to -2 points; P < .001) and South Atlantic regions (-11 points; 95% CI, -20 to -3 points; P < .001) as compared with the Pacific region) were significantly less likely to receive a DMARD for RA.
    - Solomon, et al. noted, "DMARD use declined significantly at older ages (compared with <75 years: ages 75 to 84, OR 0.58, 95% CI 0.37, 0.92, and age 85 and over, OR 0.09, 95% CI 0.02, 0.31)."
    - Suarez-Almazor, et al. studied disparities in the median time from onset of disease to initiation of DMARD therapy. They found a significant difference in timing between White patients, 1 year, and non-White patients, 7 years (p < 0.0001).

Questions for the Committee:

- At a mean of 90%, is there still a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

RATIONALE:

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission?

- This is a process measure for use of DMARD in individuals with Rheumatoid Arthritis. Evidence is present that early use of DMARDs reduces disease progression and improves disease course for patients.
- Evidence shows a high correlation with following the process and improved care, however, no evidence seems available to contradict the basis for this measure.
- Measure is use of DMARD in patients with RA (excluding inactive disease, HIV or pregnant). Current evidence does support more aggressive treatment in early RA results in better outcomes.
- agree Moderate evidence supporting this measure; one possible issue is guidelines recommend starting DMARD within 3 months of disease onset, yet look back is 12months
- Evidence applies directly to the outcome being measured.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Performance data included was from a disease registry hosted by the ACR - populated from abstracts of the electronic medical records of rheumatology providers, rheumatology groups and health system data. The performance gap within this specialty group was ~10%. Additionally, data was presented (not from the ACR Registry) that showed variation in regions of the US, between African Americans and others, in lower socioeconomic status and in the elderly.
- The performance gap is enough to warrant the measure, however, I'm more concerned about the disparities regarding race, age and geographic location.
- There are known disparities in DMARD use in certain subpopulations. Also published data suggests less agressive DMARD use in elderly patients (this may be related to patient preference or other unidentified risks eg. cancer risk). May be wise to put an upper age limit on the reported measure.
- while performance is high (>90%), there are sufficient disparities (race, age, geography) to meet the performance gap requirement
- 1b - yes. There appears to be at least 90% complaince with this measure however, the optimal perofrmance rate is set at 100%. Given racial an ethnic disparities in access to and use of DMARDs this measure needs to be evaluated more critically.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications **and** Testing

2b. Validity: Testing; Exclusions**;** Risk-Adjustment**;** Meaningful Differences**;** Comparability Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? ☐ **Yes** ☒ **No**

Evaluators: NQF Staff

Evaluation of Reliability and Validity:

- Note that the measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications. Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis. In this case, separate analyses for clinician: individual and clinician: group/practice.
- Measure score reliability assessed using signal-to-noise, with a mean reliability score 0.90, ranging from 0.03-1.00; the first quartile was 0.95.
- For validity, the developer assessed critical data element validity using data abstracted from randomly sampled patient records, which were used to calculate parallel forms reliability for the measure; and inter-rater agreement using a kappa coefficient, to assess whether EHR specifications and data exported electronically from the EHR were valid when compared to a front-end chart abstraction of the entire EHR by trained reviewer. Face validity testing was also conducted.

Questions for the Committee regarding reliability:

- Should the measure require a minimum case volume to ensure it is reliable? Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?

Committee should discuss the implications of the reliability testing and the need to perform analyses according to specifications.***Questions for the Committee regarding validity:***

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The staff is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☐ **Moderate** ☐ **Low** ☒ **Insufficient**

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Rationale

- **The measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications.**
- **Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis.**
- **In this case, separate analyses for clinician: individual and clinician: group/practice. The measure has therefore been scored as insufficient.**

Evaluation A: Scientific Acceptability

Measure Number: 2525

Measure Title: Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☐ **Claims** ☐ **Electronic Health Data** ☒ **Electronic Health Records** ☐ **Management Data**

☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☒ **Registry Data**

☐ **Enrollment Data** ☐ **Other**

Level of Analysis:

☒ **Clinician: Group/Practice** ☒ **Clinician: Individual** ☐ **Facility** ☐ **Health Plan**

☐ **Population: Community, County or City** ☐ **Population: Regional and State**

☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☒ **New** ☐ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**
   - Should the developer set a minimum case volume to ensure reliability?

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical <u>VALIDITY</u> testing** of <u>patient-level data</u> conducted?

   ☐ **Yes** ☐ **No**

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2
   - The measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications.
   - Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis.
   - In this case, separate analyses for clinician: individual and clinician: group/practice. The measure has therefore been scored as insufficient.
   - Measure score reliability was assessed using a signal to noise analysis.
   - Data for reliability testing was collected from outpatient rheumatology clinics that participate in the ACR's Rheumatology Informatics System for Effectiveness (RISE) registry.

- Practices included in the signal-to-noise analysis were limited to those that were evaluated on measure performance from January 2017 through December 2017, which totaled 107. Of these 107, 27 (25%) practices were individual providers, while the other 80 (75%) were group practices or health systems. Across all sites, 94,872 patients met the inclusion criteria.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

   - Mean reliability score 0.90, ranging from 0.03-1.00. The first quartile was 0.95 and the third 0.99. Developer states that a few extreme outliers with poor reliability can likely be attributed to low case volume.
   - The results demonstrate strong reliability.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☐ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☒ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    - The measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications.
    - Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis.
    - In this case, separate analyses for clinician: individual and clinician: group/practice. The measure has therefore been scored as insufficient.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

    Submission document: Testing attachment, section 2b2.

- Exclusions are based on the scientific literature and include active pregnancy (DMARDs are either teratogenic or inadequately studied; active HIV (safety of DMARDs inadequately studied); inactive RA (based on clinical guidelines).
- Developer states exclusions are relatively uncommon based on available literature.

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Testing attachment, section 2b4.

    - Developer states that performances ranged from 88-90% in sites that have established workflow to collect data on DMARD therapy. Data from the literature suggest that there is significant variation on DMARD use within the U.S. health care system.
    - Developer states that "the results demonstrate that variation in the use of DMARDs has decreased over time, supporting the impact of this measure. A more than 10 percentage point interquartile range supports persistent performance variation and a continued need for improvement in performance overall; the modest drop in average success from prior assessments (mean performance 92.5% in 2012 to 90.5% in 2017) likely reflects both changing demographics and a shift from non-EHR-based measure versions used in the past. Given that the measure exclusions account for the situations where use of DMARDs would be clinically inappropriate, optimal clinical performance for this measure should be 100%, as this measure reflects the ACR guidelines for care of RA patients."

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

    Submission document: Testing attachment, section 2b5.

    N/A

15. **Please describe any concerns you have regarding missing data.**

    Submission document: Testing attachment, section 2b6.

    - Developer states there is no missing data in the registry. Developer states that if a data element is missing, indicates the provider did not perform expected action, not that the data itself is missing. During the implementation process, providers work with the registry's technical experts to review the data elements necessary for measure performance calculations and direct the technical team on how to find those data elements in the practice's EHR system. The technical team is them able to extract the necessary data from both structured and unstructured fields. This ensures that accurate measure performance can be calculated no matter how the information is documented (in free text or as a scanned pdf).
    - There are no procedures for handling missing data.

16. **Risk Adjustment**

    16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

    16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

    ☐ Yes ☐ No ☒ Not applicable

    16c. **Social risk adjustment:**

    16c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

    16c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

    16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

    16d. **Risk adjustment summary:**

    16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion?
☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
☐ Yes ☐ No

16d.5.Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e**. Assess the risk-adjustment approach**

VALIDITY: TESTING

17. **Validity testing level: ☒ Measure score ☒ Data element ☒ Both**
18. **Method of establishing validity of the measure score:**

☒ **Face validity**

☐ **Empirical validity testing of the measure score**

☐ **N/A (score-level testing not conducted)**

19. **Assess the method(s) for establishing validity**

Submission document: Testing attachment, section 2b2.2

- Developer assessed critical data element validity using data abstracted from randomly sampled patient records, which were used to calculate parallel forms reliability for the measure.
- Developer assessed inter-rater agreement using a kappa coefficient, to assess whether EHR specifications and data exported electronically from the EHR were valid when compared to a front-end chart abstraction of the entire EHR by trained reviewers.
- Additional validation performed during RISE registry onboarding/yearly audit process.
    - Developer notes this is functionally a registry measure, that cannot be reproduced, but can be assessed through iterative work between practices, registry tech vendor, and data analytic centers.
    - RISE dashboard allows providers to evaluate against registry average.
- Yearly audits conducted to verify accuracy of the patient data extracted from the EHR systems of a random sample of participating practices
- Face validity testing during measure development process.

20. **Assess the results(s) for establishing validity**

Submission document: Testing attachment, section 2b2.3

- Original Kappa scores (from testing eMeasure): Kappa *Overall*, Range, % Agreement: **0.67** (0.44 to 0.89), 95.1%, which is considered substantial reliability.
    - Kappa, Range, % Agreement Denominator: **1.00**, (1.0, 1.0), 100%
    - Kappa, Range, % Agreement Numerator: **0.67**, (.44, .89), 95.1%
    - Kappa, Range, % Agreement Exceptions: **1.00** (1.0 to 1.0), 100% (100% agreement that there are no exceptions)
- 2018 registry manual audit of 2017 data found 97.99% success rate (correct responses).
- Median face validity score was 9 using RAND/UCLA rating scale; median feasibility score was 8. Of 14 raters, 13 had a validity score greater than or equal to 7. Public comments and input from committees and the Board of ACR was also collected.

21. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

Submission document: Testing attachment, section 2b1.

☒ **Yes**

☐ **No**

☐ **Not applicable** (score-level testing was not performed)

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?** *NOTE that data element validation from the literature is acceptable.*

    Submission document*: Testing attachment, section 2b1.*

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (data element testing was not performed)

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

ADDITIONAL RECOMMENDATIONS

25. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- The developer has pooled data at multiple levels (provider, group/practice) for reliability testing. By nature of their registry, participants in the registry include solo rheumatologists, individual rheumatologists in a group practice, challenging the testing of each level of analysis. Although this measure has not been tested to specification of the measure, this measure can capture data consistently.
- There are concerns about the reliability and may be insufficient in that the methodology doesn't meet NQF guidelines.
- Pts over 18 seen for 2 visits (SHOULD SAY WITH ACTIVE DISEASE) who received DMARD. Does not take into account non compliance. How is "received DMARD" measured - is this measure based on prescription being written. Multiple factors do play into patient ability to obtain medication. There should be an upper age limit placed on the measure.
- pooling of data (individual and group) does not allow for meeting specification requirements

- Exclusions needs to be more inclusive to allow for patient specific reasons for the lack of use of DMARDs however small the population

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- This testing is done in a registry that includes multiple EMRs, with an interactive process of review and implementation with the participating providers, and groups. This level of engagement is not likely outside this registry setting.
- It may need a different level of testing to meet the specifications.
- Will be very difficult to collect data.
- see 2a1
- No

2b1. Validity -Testing: Do you have any concerns with the testing results?

- Face validity has been accomplished. Data abstracted from EMR and compared to registry data was performed. Kappa coefficients were in the substantial range.
- The validity testing seems to be adequate.
- No
- none
- No

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- No significant threats to validity. There is a greater than 10% variation in performance, and there was a decrease in performance from 2017 and 2018 data (most likely due to data collection adjustments)
- There appear to be significant differences that are not included in the measure that calls into question the validity of the measure. Such things as the disparities and also the rationale for using 12 months for the use of DMARDs rather than a tighter measure such as 6 months. The timeframe seems important give the recommendation is within 3 months of the RA diagnosis.
- Underestimates patient compliance issues. Patient access to care issues. For example pt may present for 2 appts -- fails to get the intial work up completed after 1st appt so at 2nd appt is sent off to do labs and Xrays as requested previously but would then look like they did not meet the measure when in fact the work up was not complete by visit 2 so DMARD could not be safely started because they did not have labs. Also this will underestimate pts who get started post visit - ie. they didnt do labs, you had a phone call to initiate therapy the next week.
- no missing data, no threats to validity
- 2b4 - this measure has the capabiltiy to measure differences in prescriptions of DMARDs across enthin populations, insurances, geographic locations and socioeconomc status. 2b5 - results are comparable. 2b6 - yes, if data is missing in the population that presents with deparate use of DMARDs

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure?2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- Exclusions are appropriate, and most likely minimal. No risk adjustment. Current measure and the RISE registry do not capture social risk factor variables. Developer states that 100% of individuals with active RA should have DMARD intervention, yet there are no mechanisms to understand barriers that individuals not on DMARD therapy may be struggling with.

- Would seem to be more beneficial if collection more about race or income to see if these factors explain the differences.
- Should set upper rage limit. Self pay patients often take time to complete all the baseline testing and have limited access to DMARD. Social determinants of health impact pt follow up and compliance with testing.
- no exclusions, no risk adjustment
- 2b2 - yes but more exclusions may need to be added. 2b3 - as mentioned before, data on vulnerable populations must be collected for accurante measurement of this score.

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Data elements generated during routine care; all data elements in defined fields in electronic sources
- This measure was approved for trial use as an eCQM. However, the developer reported that current HQMF specifications were insufficient to capture all the data elements required for measurement.
- The developer also noted that ACR has practices participating in the ACR´s RISE registry using more than 30 different electronic health record vendors. Based on member input, ACR made a conscious decision to avoid forcing individual practitioners to change their workflow and documentation to satisfy requirements for HQMF specifications.
- ACR also noted that the majority of RISE participants are solo or small practices and unaffiliated with an academic or other institution, and few have IT services sufficient to support modifications to their electronic health records to meet eCQM standards.
- For these reasons, ACR decided to change this from an eMeasure to a standard quality measure. This submission is a registry measure using EHR data.
- The developer states they "will continue to monitor developments in coding and HQMF specifications to determine if the updates would provide the necessary flexibility to make this measure an eCQM."
- No fees or licensing required

Questions for the Committee:

- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- All data should be available within the EHR. However, over 10% of diagnoses on a patient's active problem list are in error or not present. This could cause inclusion of individuals into the measure who actually do not have RA, or individuals with RA may not be included. Additionally, in the past data provided by payers has been based on claims (a claim for a prescription) where the registry used for this measures is based on presence of a medication on the medication list.
- By using the RISE registry, the measurement data collection strategy seems feasible. However, perhaps some easy index such as zip code could be added to add more social stratification to the data.

- Rx data ok to use but would try to also capture prescriptions written outside of a clinic visit (e.g. started over the phone once labs result).
- agree with moderate rating
- There are various factors that may influence the use of (or lack of use) of DMARDs in patients with active RA that go beyond pregnancy or HIV. These factors are not being accounted for in the current measure and I think it is unreasonable to expect 100% complaince with this measure for those reasons. Disparities within ethnic populations also needs to be assessed within the RISE registry data.

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☐ **Yes** ☒ **No**

Current use in an accountability program? ☐ **Yes** ☒ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☒ **Yes** ☐ **No**

Accountability program details

- Current: RISE Registry – internal QI and external benchmarking
- Formerly in PQRS; developer is in discussion with CMS to revise measure for use in MIPS, but no current timeline or plan provided.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- Providers have access to results via registry (updated monthly), can contact ACR or registry vendor staff with issues and questions

Additional Feedback:

N/A

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- Developer notes improvement over time due to evidence that early, aggressive use of DMARDs improves outcomes; new DMARDs available; and increased direct to consumer marketing.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- Developer notes that participating providers have offered positive feedback, noting the measure has helped them better understand provider variation within practices as well as identification of higher-risk patients such as those with frequent disease flares.

Potential harms

- None found

Additional Feedback:

N/A

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided?4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- The registry used does provide ability for providers to identify patients with a measure gap. There is described a process for technical assistance from the RISE registry team for providers and groups - providing feedback.
- The lack of transparency to the public is a diffiency in the measure. It should be corrected as soon as possible.
- ACR is giving feedback to users of RISE. Many providers (most providers) do not participate in RISE. Rituximab is a safer agent in regards TB reactivation -- many providers do not routinely screen prior to rituximab.

- agree with Pass, in discussion to include with MIPS, and was formerly part of PQRS
- 4a1: not publicly reported. Available to RISE registry participants. 4a2 - Yes

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations?4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- A version of this measure has been in use by health plans and PQRS in the past. Payers have provided feedback to providers and systems on performance (albeit delayed in time due to the nature of delay in claims) with ability to improve care. Performance could be enhanced if a focus for this measure is with primary care and rheumatology to improve identification of those with RA not on DMARD. Little in the way of harms noted.
- There will need to be work on the improvement over time. However, there do not seem to be harms or unintended consequences to the measure.
- No major harms but may result in over prescribing.
- agree with moderate rating; early use of DMARDs improves outcomes according to literature therefore would expect this measure would improve outcomes
- 4b1 - idenitifying gaps to prescribing DMARDs i.e. patient preference, access to care/meds, insurance restrictions etc. 4b2 - No harm anticipated

Criterion 5: Related and Competing Measures

Related or competing measures

- Related to 0054: Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis (ART) (NCQA)
- The measures are related, not competing, because 0054 is specified for health plan/integrated delivery system level of analysis, and this measure (2525) is specified at the clinician level.

Harmonization

- The measures are not fully harmonized.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- N/A
- The NCQA measure seems very close and should be harmonized with.
- Other measures under review 0054
- related, but not competing 0054: NCQA measure DMARD for RA (ART) which is measured at health plan level;
- Yes: NQF - Rheumatoid Arthritis DMARD Therapy.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/12/2019
No NQF Members have submitted support/non-support choices as of this date.
Public Comment

**The value set for Rheumatoid Arthritis DMARD Therapy (2.16.840.1.113883.3.1564.2722) includes Brand Name Drugs. The Joint Commission recommends removing Brand Name TTYs, and use Semantic Clinical Drugs (SCDs). According to the CMS Measures Blueprint (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf), "...authoring guidance has encouraged developers NOT to included branded term types because changes in branded identifiers for any single "general drug" (such as Semantic Clinical Drug [SCD]) occur throughout the year and, even with the inclusion of value set addendum releases, there can be value sets that are out of synch with some implementer system content. Given that RxNorm application content (and all drug information vendor products) can be used to map from the more stable general identifier to a branded identifier, and from other code systems such as National Drug Code (NDC) or proprietary code systems, the branded RxNorm TTYs were often not included under the assumption that if an implementer had a different identifier, they could map from the more stable general identifier to a branded identifier, and from other code systems such as National Drug Code (NDC) or proprietary code systems, the branded RxNorm TTYs were often not included under the assumption that if an implementer had a different identifier, they could map to the included SCD RXCUI or GPCK RXCUI or any other TTY and ID according to the intention."

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

DMARD_Evidence_Form_Final.docx,DMARD_evidence_form_2019_FINAL.docx

1a.1 <u>For Maintenance of Endorsement:</u> Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 2525

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

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission: 4/1/2019

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

☐Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: <u>Disease modifying anti-rheumatic drug (DMARD) prescription for patients with rheumatoid arthritis</u>

☐ Appropriate use measure:

☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

This measure is used to assess the percentage of patients with rheumatoid arthritis dispensed at least one ambulatory prescription for a disease modifying anti-rheumatic drug (DMARD).

DMARD prescription → DMARD use → decreased disease activity and erosions → decreased disability, decreased pain, improved functional status, improved health-related quality of life

Disease modifying anti-rheumatic drugs (DMARDs) improve the disease course of rheumatoid arthritis (RA) through attenuation of progression of bony erosions, reduction of inflammation and long-term structural damage. The utilization of DMARDs also improves functional status in individuals with RA. Evidence supports using a "treat to target" approach, where DMARDs are escalated, added and/or replaced to achieve the target of disease remission or low disease activity. This approach has been shown to improve clinical and radiographic outcomes (*Schipper LG et al. A tight control treatment strategy aiming for remission in early rheumatoid arthritis is more effective than usual care treatment in daily clinical practice: a study of two cohorts in the Dutch Rheumatoid Arthritis Monitoring registry. Ann Rheum Dis. 2012 Jun;71(6):845-50; Smolen JS et al. Treating rheumatoid arthritis to target: recommendations of an international task force. Ann Rheum Dis. 2010 Apr;69(4):631-7; Grigor C et al. Effect of a treatment strategy of tight control for rheumatoid arthritis (the TICORA study): a single-blind randomized controlled trial. Lancet 2004;364:263–9.).*

RA is a chronic autoimmune disorder often characterized by progressive joint destruction and multisystem involvement. It affects approximately 1.3 million Americans and affects women disproportionately (*Helmick CG et al., Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Am J Public Health. 2012 Mar;102(3):426-33*). There is no cure; consequently, the goal of treatment is to slow the progression of the disease and thereby delay or prevent joint destruction, relieve pain, and maintain functional capacity.

Evidence-based guidelines, summarized below, support early initiation of DMARD therapy in patients diagnosed with RA. All patients with RA are candidates for DMARD therapy, and the majority of newly diagnosed individuals should be started on DMARD therapy within three months of diagnosis.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(S) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

<table>
<tr><td>Source of Systematic Review:
Title
Author
Date
Citation, including page number
URL</td><td>2015 American College of Rheumatology
Guideline for the Treatment of Rheumatoid Arthritis
Singh J et al.
2016 Dec
Arthritis Rheumatol.;68(1):1-26
https://onlinelibrary.wiley.com/doi/epdf/10.1002/art.39480</td></tr>
<tr><td>Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.</td><td>Figure 1. Recommendations for patients with symptomatic early RA.
<table>
<tr><th>Recommendations for patients with symptomatic Early RA</th><th>Level of Evidence (evidence reviewed)</th></tr>
<tr><td>1. *Regardless of desease activity level, use a treat-to-target strategy rather than a non-targeted approach (PICO A.1).</td><td>Low (17)</td></tr>
<tr><td>2. *If the desease activity is low, in patients who have never taken a DMARD:
• Use DMARD monotherapy (MTX preferred) over double therapy (PICO A.2).
• Use DMARD monotherabpy (MTX preferred) over triple therapy (PICO A.3).</td><td>Low (18-21)
Low (22-25)</td></tr>
<tr><td>3. ‡If the disease activity is moderate or high, in patients who have never taken a DMARD:
• Use DMARD monotherapy over double therapy (PICO A.4).
• Use DMARD monotherapy over triple therapy (PICO A.5).</td><td>Moderate (18, 20, 21)
High (22-25)</td></tr>
<tr><td>4. *If disease activity remains moderate or high despite DMARD monotherapy (with or without glucocorticoids), use combination DMARDs or a TNFi or a non-TNF biologic (all choices with or without MTX, in no particular order of preference), rather than continuing DMARD monotherapy alone (PICO A.7).</td><td>Low (26-28)</td></tr>
<tr><td>5. ‡If disease activity remains moderate or high despite DMARDs:
• Use a TNFi monotherapy over tofacitinib monotherapy (PICO A.8).
• Use a TNFi + MTX over tofacitinib + MTX (PICO A.9).</td><td>Low (29)
Low (30)</td></tr>
<tr><td>6. ‡If disease activity remains moderate or high despite DMARD (PICO A.6) or biologic therapies (PICO A.12), add low-dose glucocorticoids.</td><td>Moderate (31-37)
Low (31-37)</td></tr>
<tr><td>7. ‡If disease flares, add short-term glucocorticoids at the lowest possible dose and for the shortest possible duration (PICO A.10, A.11).</td><td>Very low (38-43)</td></tr>
</table>
Green and bolded [with asterisk *] = strong recommendation
Yellow and italicized [with double dagger ‡] = conditional recommendation</td></tr>
</table>

Figure 2. Recommendations for patients with established RA.

Recommendations for patients with Established RA[1]	Level of Evidence (evidence reviewed)
1. *Regardless of disease activity level, use a treat-to-target strategy rather than a non-targeted approach (PICO B.1).	**Moderate (44-46)**
2. ***If the disease activity is low, in patients who have never taken a DMARD, use DMARD monotherapy (MTX preferred) over a TNFi (PICO B.2).**	**Low (47,48)**
3. ‡If the disease activity is moderate or high in patients who have never taken a DMARD: • *Use DMARD monotherapy (MTX preferred) over tofacitinib (PICO B.3).* • *Use DMARD monotherapy (MTX preferred) over combination DMARD therapy (PICO B.4).*	*High (49)* *Moderate (18, 20-25)*
4. ***If disease activity remains moderate or high despite DMARD monotherapy, use combination traditional DMARDs or add a TNFi or a non-TNF biologic or tofacitinib (all choices with or without MTX, in no particular order of preference), rather than continuing DMARD monotherapy alone (PICO B.5).**	**Moderate to Very Low (23, 26, 29, 30, 47,48, 50-59)**
5. ***If disease activity remains moderate or high despite TNFi therapy in patients who are currently not on DMARDs, add one or two DMARDs to TNFi therapy rather than continuing TNFi therapy alone (PICO B.6).**	**High (60-65)**
6. ‡If disease activity remains moderate or high despite use of a single TNFi: • *Use a non-TNF biologic, with or without MTX, over another TNFi with or without MTX (PICO B.12 and B.14).* • *Use a non-TNF biologic, with or without MTX, over tofacitinib with or without MTX (PICO B.13 and B.15).*	*Low to Very low (66-72)* *Very low[4]*
7. ‡If disease activity remains moderate or high despite use of a single non-TNF biologic, use another non-TNF biologic, with or without MTX, over tofacitinib, with or without MTX (PICO B.16 and B.17).	*Very low[4]*
8. ‡If disease activity remains moderate or high despite use of multiple (2+) sequential TNFi therapies, first use a non-TNF biologic, with or without MTX, over another TNFi or tofacitinib (with or without MTX) (PICO B.8, B.9, B.10, B.11).	*Very low (73-75)*
9. ‡If the disease activity still remains moderate or high despite the use of multiple TNFi therapies, use tofacitinib, with or without MTX, over another TNFi, with or without MTX, if use of a non-TNF biologic is not an option (PICO B.23 and B.24).	*Low (29, 30)*
10. ‡If disease activity remains moderate or high despite use of at least one TNFi and at least one non-TNF-biologic: • *First use another non-TNF biologic, with or without MTX, over tofacitinib (PICO B.21 and B.22).* • *If disease activity remains moderate or high, use tofacitinib, with or without MTX, over another TNFi (PICO B.19 and B.20).*	*Very low (29, 30)* *Very low (29)*
11. ‡If disease activity remains moderate or high despite use of DMARD, TNFi, or nonTNF biologic therapy, add short-term, low does glucocorticoid therapy (PICO B.26 and B.27).	*High to Moderate (33, 41, 76, 77)*
12. ‡If disease flares in patients on DMARD, TNFi, or non-TNF biologic therapy, add short-term glucocorticoids at the lowest possible dose and the shortest possible duration (PICO B.28 and B.29).	*Very low (40-43)*
13. ‡If the patient is in remission: • *Taper DMARD therapy (PICO B.31)[2].* • *Taper TNFi, non-TNF biologic, or tofacitinib (PICO B.33, B.35, B.37) (please also see #15)*	*Low[3] (78)* *Moderate to Very low[3] (79, 80)*
14. *If disease activity is low: • **Continue DMARD therapy (PICO B.30).** • **Continue TNFi, non-TNF biologic or tofacitinib rather than discontinuing respective mediation (PICO B.32, B.34 and B.36).**	**Moderate (78)** **High to Very low (79, 80)**
15. ***If the patient's disease is in remission, do not discontinue all RA therapies (PICO B.38).**	**Very low[4]**

Green and bolded [with asterisk *] = strong recommendation

Yellow and italicized [with double dagger ‡] = conditional recommendation

Summary of 2015 American College of Rheumatology recommendations for the treatment of Early and Established rheumatoid arthritis (RA). Green and bolded [with asterisk] = strong recommendation. A strong recommendation means that the panel was confident that the desirable effects of following the recommendation outweigh the undesirable effects (or vice versa), so the course of action would apply to most patients, and only a small proportion would not want to follow the recommendation. Yellow and italicized [with double dagger] = conditional recommendation: The desirable effects of following the recommendation probably outweigh the undesirable effects, so the course of action would apply to the majority of the patients, but some may not want to follow the recommendation. Because of this, conditional recommendations are preference sensitive and always warrant a shared decision-making approach. A treatment recommendation favoring one medication over another means that the preferred medication would be the recommended first option and the nonpreferred medication may be the second option. Favoring one medication over the other does not imply that the nonfavored medication is contraindicated for use; it is still an option. Therapies are listed alphabetically; azathioprine, gold, and cyclosporine were considered but not included. Disease-modifying antirheumatic drugs (DMARDs) include hydroxychloroquine, leflunomide, methotrexate (MTX), and sulfasalazine. PICO = population, intervention, comparator, and outcomes; TNFi = tumor necrosis factor inhibitor.

Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	See above for grade; below for grade explanation

<table>
<tr>
<td>Provide all other grades and definitions from the evidence grading system</td>
<td>
Figure 3. Implications of strong and conditional GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodology recommendations.
<table>
<tr><td></td><td>Strong recommendation</td><td>Conditional recommendation</td></tr>
<tr><td>Patients</td><td>Most people in your situation would want the recommended course of action and only a small proportion would not</td><td>The majority of people in your situation would want the recommended course of action, but many would not*</td></tr>
<tr><td>Clinicians</td><td>Most patients should receive the recommended course of action</td><td>Be prepared to help patients to make a decision that is consistent with their own values</td></tr>
<tr><td>Policy makers</td><td>The recommendation can be adapted as a policy in most situations</td><td>There is a need for substantial debate and involvement of stakeholders</td></tr>
</table>
∗ = majority means >50% of the people.

The GRADE method distinguishes 4 levels of quality of evidence based on the degree of confidence that the pooled effect estimate lies close to the true effect. Thus, the quality of evidence for each outcome could be rated as high, moderate, low, or very low. The overall evidence quality grade was the lowest quality rating among the individual outcomes deemed critical for the comparison between interventions. In the absence of any data, the level of evidence was rated as very low, because it was based on clinical experience only.

We developed this guideline following the recently revised ACR guideline development process (http://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines). This process includes the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology (available at www.gradeworkinggroup.org)

Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924–6.

Andrews J, Guyatt G, Oxman AD, Alderson P, Dahm P, Falck-Ytter Y, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. J Clin Epidemiol 2013;66:719–25.
Andrews JC, Schunemann HJ, Oxman AD, Pottie K, Meerpohl JJ, Coello PA, et al. GRADE guidelines: 15. Going from evidence to recommendation: determinants of a recommendation's direction and strength. J Clin Epidemiol 2013;66:726–35.
</td>
</tr>
<tr>
<td>Grade assigned to the recommendation with definition of the grade</td>
<td>See above</td>
</tr>
</table>

Provide all other grades and definitions from the recommendation grading system	See above
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	See above
Estimates of benefit and consistency across studies	N/A
What harms were identified?	N/A
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	N/A

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The American College of Rheumatology (ACR) guidelines recommend the use of disease-modifying antirheumatic drugs (DMARDs) in every patient with active RA at the earliest stage of disease, ideally within 3 months of disease onset. These guidelines are based on results from numerous clinical trials demonstrating that DMARDs slow the progression of RA by decreasing inflammation and reducing articular erosions. In

addition, both clinical trials and observational studies demonstrate that DMARDs improve functional status and health-related quality of life. Both underuse and disparities in DMARD use have been well-documented in numerous studies.

Sources:

Singh JA, Furst DE, Bharat A, Curtis JR. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.

Schmajuk G, Trivedi AN, Solomon DH, Yelin E, Trupin L, Chakravarty EF, Yazdany J. Receipt of disease-modifying antirheumatic drugs among patients with rheumatoid arthritis in Medicare managed care plans. JAMA. 2011 Feb 2;305(5):480-6.

Schmajuk G, Solomon DH, Yazdany J. Patterns of disease-modifying antirheumatic drug use in rheumatoid arthritis patients after 2002: a systematic review. Arthritis Care Res (Hoboken). 2013 Dec;65(12):1927-35.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Data source: Performance among providers and practices participating in the Rheumatology Informatics System for Effectiveness (RISE) registry during the measurement periods

Average performance over time

Dates: July 1, 2014 through June 30, 2016

Practices: 44

Providers: 223

2014 Q3: 90.87%

2014 Q4: 90.75%

2015 Q1: 93.38%

2015 Q2: 91.61%

2015 Q3: 91.51%

2015 Q4: 91.52%

2016 Q1: 91.5%

2016 Q2: 91.6%

Most recent performance

Dates: January 1, 2017 through December 31, 2017

Practices: 107

Setting: 73% group, 25% solo practitioner, 2% health system

Patients: 94,872

Mean: 90.47%

Standard Deviation: 9.62%

Min: 28.17%

Max: 100.00%

Interquartile Range: 6.42%

Deciles

10%: 84.63%

20%: 88.03%

30%: 89.38%

40%: 90.96%

50%: 93.03%

60%: 94.14%

70%: 95.12%

80%: 95.94%

90%: 97.23%

100%: 100.00%

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

N/A

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Relevant disparities data are not routinely and uniformly collected on all patients within the RISE registry.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

This measure is not risk-adjusted and the RISE registry has limited data on social risk factors. Furthermore, optimal clinical performance for this measure should be 100%, regardless of social risk, as this measure reflects the minimum performance standard. Nevertheless, as part of RISE's ongoing efforts to expand and improve, the American College of Rheumatology is exploring ways to obtain better social risk data to appropriately monitor performance disparities going forward. However, we know from literature that disparities in DMARD use by race/ethnicity, socioeconomic status, age and geographic location have been reported in several well-conducted studies, some applying a similar performance measure.

The largest study examined nationwide performance data on the HEDIS DMARD quality measure in over 90,000 individuals with RA enrolled in Medicare managed care plans. According to Schmajuk, et al., blacks (-4 absolute percentage points; 95% CI, -6 to -2 points; P < .001), those with low socioeconomic status (-4 points; 95% CI, -6 to 2 points; P < .001), older individuals (-30 points; 95% confidence interval [CI], -29 to -32 points; P < .001) and those residing in certain geographic regions (in the Middle Atlantic region (-7 points; 95% CI, -13 to -2 points; P < .001) and South Atlantic regions (-11 points; 95% CI, -20 to -3 points; P < .001) as compared with the Pacific region) were significantly less likely to receive a DMARD for RA.

Several additional studies using the Medicare Current Beneficiaries Survey, nationwide data from the Medicare fee-for-service population, and clinic-based populations have also found significant disparities in DMARD use. Solomon, et al. noted, "DMARD use declined significantly at older ages (compared with <75 years: ages 75 to 84, OR 0.58, 95% CI 0.37, 0.92, and age 85 and over, OR 0.09, 95% CI 0.02, 0.31)."

Suarez-Almazor, et al. studied disparities in the median time from onset of disease to initiation of DMARD therapy. They found a significant difference in timing between White patients, 1 year, and non-White patients, 7 years ($p < 0.0001$).

Even when looking at patients with expanded drug coverage under Part D, Yazdany et al. discovered disparities in DMARD use. "Beneficiaries with low incomes were more likely to receive glucocorticoids alone (12.3%; 95% confidence interval [95% CI] 10.9-13.8% versus 9.4%; 95% CI 8.6-10.1%), as were those living in certain US regions." They found it was more common for patients to only be on glucocorticoid without a DMARD in the Mid-Atlantic region (14.4%; 95% CI 12.3–16.5%) compared to the Pacific region (8.5%; 95% CI 6.7–10.2%).

Sources:

Schmajuk G, Trivedi AN, Solomon DH, Yelin E, Trupin L, Chakravarty EF, Yazdany J. Receipt of disease-modifying antirheumatic drugs among patients with rheumatoid arthritis in Medicare managed care plans. JAMA. 2011 Feb 2;305(5):480-6.

Solomon DH, Yelin E, Katz JN, Lu B, Shaykevich T, Ayanian JZ. Treatment of rheumatoid arthritis in the Medicare Current Beneficiary Survey. Arthritis Res Ther. 2013 Mar 18;15(2):R43.

Suarez-Almazor ME, Berrios-Rivera JP, Cox V, Janssen NM, Marcus DM, Sessoms S. Initiation of disease-modifying antirheumatic drug therapy in minority and disadvantaged patients with rheumatoid arthritis. J Rheumatol. 2007 Dec;34(12):2400-7.

Yazdany J, Tonner C, Schmajuk G et al. Receipt of Glucocorticoid Monotherapy Among Medicare Beneficiaries with Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2014 Oct; 66(10): 1447–1455.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Musculoskeletal : Rheumatoid Arthritis

De.6. Non-Condition Specific*(check all the areas that apply):*

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

https://www.rheumatology.org/Portals/0/Files/DMARD-Measure.pdf

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** DMARD_Value_Sets_Updated_2018-03-30.xls

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

Current HQMF specifications were insufficient to capture all the data elements required for measurement. Also, we have practices participating in the ACR´s RISE registry using more than 30 different electronic health record vendors. Based on member input, ACR made a conscious decision to provide the most flexible route to electronic health record data-based measurement and avoid forcing individual practitioners to change their workflow and documentation to satisfy requirements for HQMF specifications. Finally, as the majority of RISE participants are solo or small practices and unaffiliated with an academic or other institution, few have IT services sufficient to support modifications to their electronic health records to meet eCQM standards. For these reasons, we decided to change this from an eMeasure to a standard quality measure.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Patient received a DMARD

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

DMARD therapy includes:

abatacept

adalimumab

Adalimumab-adbm

Adalimumab-atto

anakinra

certolizumab

etanercept

Etanercept-szzs

golimumab

infliximab

Infliximab-abda

Infliximab-dyyb

Infliximab-qbtx

Sarilumab

rituximab

tocilizumab

Tofacitinib

Non-Biologic Agents-

auranofin

azathioprine

gold

hydroxychloroquine

leflunomide

methotrexate

minocycline

penicillamine

sulfasalazine

Anti-inflammatory medications, including glucocorticoids do not meet the measure.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

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

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Patients 18 years and older with a diagnosis of Rheumatoid Arthritis seen for two or more encounters for Rheumatoid Arthritis during the measurement period.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Patients with a diagnosis of HIV; patients who are pregnant; or patients with inactive Rheumatoid Arthritis.

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

Patients who have a diagnosis of HIV, who are pregnant, or have inactive rheumatoid arthritis can be identified using the ICD-9, ICD-10, and/or SNOMED diagnosis codes included in S2b.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

CASES MEETING TARGET PROCESS/TARGET POPULATION

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

A random sample is obtained by assigning each patient a sequential number and then using a random number generator to select patients.

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Electronic Health Records, Registry Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Data source 1: electronic health records

Instrument: RA Measure Testing Data Collection Form

Data source 2: Rheumatology Informatics System for Effectiveness (RISE) Registry

Data collection: passive abstraction from EHR

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available in attached appendix at A.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Clinician : Group/Practice, Clinician : Individual

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Outpatient Services

If other:

S.22. <u>COMPOSITE Performance Measure</u> - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

N/A

2. Validity – See attached Measure Testing Submission Form

DMARD_Measure_Testing_Form_Final.docx,DMARD_measure_testing_form_January_2019_FINAL_Updated_4.3.2019-636912729262571589.docx

2.1 <u>For maintenance of endorsement</u>

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 <u>For maintenance of endorsement</u>

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 <u>For maintenance of endorsement</u>

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 2525
Measure Title: Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy
Date of Submission: 1/7/2019

Type of Measure:

☐ Outcome (*including PRO-PM*)	☐ Composite – ***STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

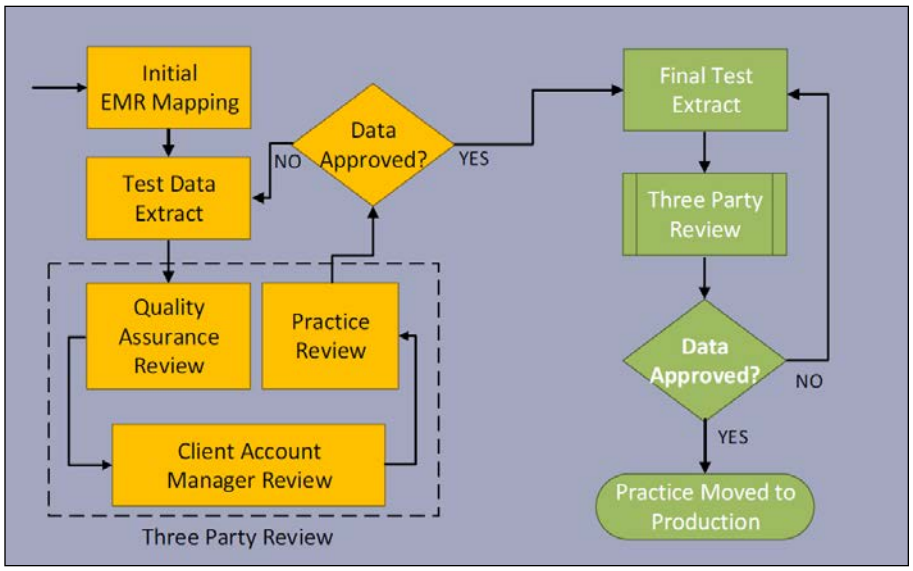
Measure Specified to Use Data From: (*must be consistent with data sources entered in S.17*)	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☒ registry	☒ registry
☒ abstracted from electronic health record	☒ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other:	☐ other:

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

Registry data used for the most recent testing of this measure was collected through the ACR's Rheumatology Informatics System for Effectiveness (RISE) registry. RISE is a Qualified Clinical Data Registry (QCDR) that has been in operation since 2014. It was developed to serve as a tool for improving quality of care in rheumatology practices and a mechanism for providers to complete various federal reporting requirements for Medicare reimbursements. As of September 30, 2018, 218 practices across the United States with a total of nearly 1.5 million patients were fully connected to the RISE registry.

RISE uses proprietary computer programming to extract patient data from the EHR systems of participating providers. The data is then aggregated and used to calculate performance on a number of quality measures, including this measure. Practices that participate in RISE must complete an extensive data validation process, as seen in Figure 1, in order to be considered fully connected. During this process, practices work closely with RISE registry technical experts to gather the necessary information on the practice and identify where and how patient information, such as outcome measures, medications, laboratory results, diagnoses, etc., is stored in the provider's EHR. After the initial mapping to the various EHR fields is complete, the RISE team works with the practice to systematically extract and review test data via the RISE dashboard. The extracted data is used to calculate performance on each quality measure in RISE. The practice and registry technical experts then review the measure performance by drilling down into the patients included in and excluded from each step of the measure and the specific patient data used in the measure calculations. This allows the practices to confirm that each part of the measure calculation (denominator, numerator, exclusions and exceptions) does not include false negatives or positives and uses only accurate information. If any inaccuracies are discovered, the data extraction and mapping are refined and the review process begins again. This continues until the practice and the RISE team can validate that all the measure scores and patient data used to calculate the performance are accurate.

Figure 1. Custom mapping and data validation for RISE registry participants



Once practices are fully connected, they continue to monitor their data accuracy through the analytic dashboard. Additionally, a limited data set extracted from the registry data is shared with a third-party center for wider analytic purposes. This data analytic center is a highly regarded academic center experienced in working with EHR data. The center performs a variety of additional accuracy and validation checks on the limited data set.

For each measure incorporated into the RISE registry, the various data elements identified in the value set (including ICD-10, LOINC and CPT codes) and measure specifications are used to build a comprehensive data dictionary in order to identify the various data elements across the different EHRs at each practice. The data dictionary is then used as the basis for the XML programming code that runs against the registry data to calculate measure performance. The flowchart of the programming for the Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy measure can be seen in Figures 2a and 2b.

Figure 2a. Flowchart of calculation for the Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy measure

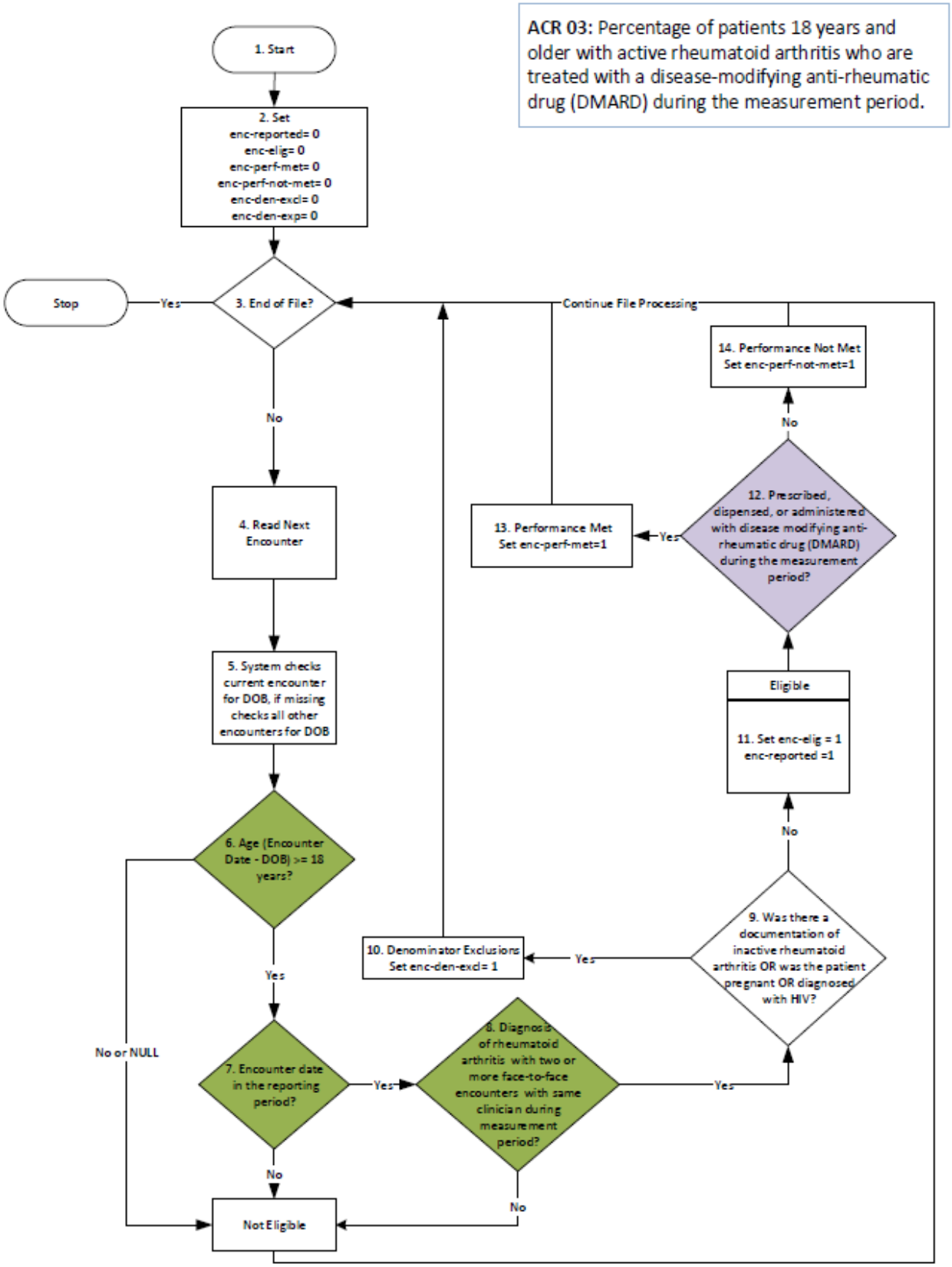


Figure 2b. Supplement to flowchart of calculation for the Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy measure

Data Dictionary References

Denominator

Element ID	Element Name
1510	Encounter Date
2050	Date of Birth
4115	Encounter ACR 01, 02, 03, 04, 06, 07, 08
3220	Diagnosis of Active Rheumatoid Arthritis (RA)
3222	Date of diagnosis of Rheumatoid Arthritis (RA)

Numerator

Element ID	Element Name
3226	Non-Biologic disease-modifying antirheumatic drugs (DMARDs)
3765	Date of prescription of Non-Biologic disease-modifying antirheumatic drug (DMARDs)
3225	Biologic disease-modifying antirheumatic drugs (DMARDs)
3760	Date of prescription of Biologic disease-modifying antirheumatic drugs (DMARDs)

Denominator exclusion

Element ID	Element Name
4125	Documentation of inactive rheumatoid arthritis (RA)
4130	Date of documentation of inactive rheumatoid arthritis (RA)
3230	Diagnosis of HIV
4205	Date of diagnosis of HIV
3235	Patient currently pregnant
4170	Date of pregnancy

Aggregation of Encounters for a Given Patient

Denominator = pt-elig = max(enc-elig)
Numerator = pt-perf-met = max(enc-perf-met)
pt-perf-not-met = max(enc-perf-not-met) and not max(enc-perf-met)
Denominator Exclusion = pt-perf-excl = max(enc-den-excl) and not max(enc-perf-not-met) and not max(enc-perf-met)
Denominator Exception = pt-perf-exp = max(enc-den-exp) and not max(enc-perf-not-met) and not max(enc-perf-met)
pt-reported = max(enc-reported)

Aggregation of Patients for a Given Provider

eligible-instances = sum(pt-elig)
performance-met-instances = sum(pt-perf-met)
performance-not-met-instances = sum(pt-perf-not-met)
performance-exclusion-instances = sum(pt-perf-excl)
performance-exception-instances = sum(pt-perf-exp)
reported-instances = sum(pt-reported)
reporting-rate = reported-instances / eligible-instances
performance-rate = performance-met-instances / (performance-met-instances + performance-not-met instances)

1.3. What are the dates of the data used in testing? 1/2013 to 12/2013

1/2017 to 12/2017

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	**Measure Tested at Level of:**
☒ individual clinician	☒ individual clinician
☒ group/practice	☒ group/practice
☐ hospital/facility/agency	☐ hospital/facility/agency
☐ health plan	☐ health plan
☐ other:	☐ other:

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

We recruited two testing sites that were geographically dispersed, included racial/ethnically diverse patient populations, and that used different electronic health record (EHR) systems for collection of RA disease activity measures. We have summarized the geographic location and characteristics of the sites in Table 1 below.

Table 1. Geographic location, site characteristics and data sources used for rheumatoid arthritis DMARD quality measure.

Geographic Location	Site Characteristics	Data Source
Northeast United States	Large health system serving a largely *rural* population of over 2.6 million over 44 counties. The rheumatology clinics have over 24,000 patient visits per year. Within this system, rheumatology clinical encounters were analyzed.	*Epic-based electronic health record.* Structured fields within the electronic record were queried.
Southeastern United States	Large community health system that serves both a *rural and urban* population in a statewide geographic region. The rheumatology clinics register over 20,000 visits annually.	*Cerner-based electronic health record*. Structured fields within the electronic record were queried

For the signal-to-noise testing, we used data collected from outpatient rheumatology clinics that participate in the ACR's Rheumatology Informatics System for Effectiveness (RISE) registry. In the first quarter of 2017, 109 practices were fully connected to the RISE registry. The participating practices covered all regions of the country and represented a variety of practice settings: 28 solo practices, 77 group practices, two health systems, and two unknown settings. The practices used nearly 30 different EHR systems, including NextGen, eClinicalWorks, and Amazing Charts.

For testing purposes, the practices included in the signal-to-noise analysis were limited to those that were evaluated on measure performance from January 2017 through December 2017, which totaled 107. Of these 107, 27 (25%) practices were individual providers, while the other 80 (75%) were group practices or health systems. Given the high percentage of individual providers also classified as individual practices, the analysis covers both individual- and practice-level results.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

Data were analyzed at the individual patient level. All patients receiving care in rheumatology clinics in the Northeastern and Southeastern health systems were eligible for the denominator population if they met inclusion criteria, including ≥2 encounters for RA, being over age 18 years, and meeting these criteria over the measurement period of January 2013-December 2013.

For the front-end chart abstraction, a *simple random sample* was constructed each site. The number of patients in the testing projects are included in Table 2 below.

Table 2. Patient characteristics of individuals with rheumatoid arthritis, by site, for DMARD quality measure testing studies.

Site	Total E-measure Patient Population (N)	Random Sample for Front-end EHR review (N)	Sex (% female)
Northeastern site	1542	81	74%
Southeastern site		81	

For the signal-to-noise testing, patients were included in the analysis if they were seen at one of the practices that met the practice inclusion criteria for Item 1.5 and if they met the patient inclusion criteria for the measure, including ≥2 encounters for RA, being over age 18 years, and meeting these criteria over the measurement period of January 2017 through December 2017. Across all sites, 94,872 patients met the inclusion criteria.

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

For validity testing studies that involved a front-end electronic health record chart abstraction, a simple random sample of the eligible denominator population from the automated report generated by the e-measure was created for the sites (see Table 2 for details). The characteristics of the random sample were similar to the denominator population.

For reliability testing, as noted above, we used physicians/practices reporting in 2017.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

We do not routinely and uniformly collect social risk factors on all patients for this measure. Furthermore, we do not anticipate that measure reliability and validity would be impacted by social risk factors because the measure is a process measure, and therefore not risk-adjusted, and completion of the process at the core of this measure is important for all patients, regardless of patients' social status. Finally, the measure has been tested and implemented with positive results without requiring social risk information, so we do not believe the analysis of social risk factors is required.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Please see section "2b2. VALIDITY TESTING" for critical data element testing results.

For signal-to-noise testing, data elements for this quality measure were extracted for the RISE registry from EHRs using computer programming, and therefore by virtue of automation, this process is repeatable (reliable); this was further verified during data element validation (described below). Data from the RISE registry included the number of patients and number passing the measure for each practice. With this, we can calculate pass rate and sample size for each practice, and we can compare variability in measure performance between practices. Because reliability depends on pass rate and sample size, it varies between practices.

Psychometricians use a rule of thumb of 90 percent for drawing conclusions about individuals. (*Hays RD, Revicki D. Reliability and validity (including responsiveness). In: Fayers P, Hays R, eds. Assessing Quality of Life In Clinical Trials. New York: Oxford University Press; 2005.; Adams, John L., The Reliability of Provider Profiling: A Tutorial. Santa Monica, CA: RAND Corporation, 2009. https://www.rand.org/pubs/technical_reports/TR653.html.*) For binary measures, a tutorial by the RAND Corporation recommends fitting practices to a beta-binomial model. This can be done with the SAS Betabin macro (*Ian Wakeling - Qi Statistics. MACRO BETABIN Version 2.2 March 2005, www.qistatistics.co.uk*). This provides parameters a and b.

For the beta-binomial model, practice-to-practice variation = σ^2 = ab / ((a+b+1)*(a+b)^2).

Practice specific/measurement error for a binomial distribution = p*(1-p)/n; or when p = 1 or p = 0, substitute 3/n for p, by the rule of three.

Reliability = σ^2 / (σ^2 + p(1-p)/n), which represents the fraction of variance observed between practices not explained by practice specific variance.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e*.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Please see section "2b2. VALIDITY TESTING" for critical data element testing results.

For the signal-to-noise testing, each practice has a reliability score for the measure. The distribution of these practice-level scores is reported in Table 2a below.

Table 2a. Reliability scores for the Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy measure among practices participating in the RISE registry, January 2017-December 2017.

Mean Reliability	Min Reliability	1st Quartile Reliability	Median Reliability	3rd Quartile Reliability	Max Reliability	Proportion of lowest quartile performers with reliability ≥0.9	Proportion of middle 50% performers with reliability ≥0.9	Proportion of highest quartile performers with reliability ≥0.9
0.90	0.03	0.95	0.98	0.99	1.00	0.73	0.91	0.77

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Based on standard interpretations of reliability, these findings support strong reliability of the measure result. For the few extreme outliers with poor reliability, the poor performance is likely due to small case volumes and can, if needed, be addressed by flagging or suppressing any measure results based on very few observations.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☒ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☐ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Below, we discuss 2 different aspects of validity that are relevant to the proposed measure. These include: 1) Validity of critical data elements, obtained through comparison of automated e-measure data compared to a front-end total EHR data abstraction, as well as the validation performed during the RISE registry onboarding and yearly audit processes, and 2) Systematic assessment of face validity using the ACR's quality measure development process.

1. Critical data element validity. Data abstracted from randomly sampled patient records were used to calculate parallel forms reliability for the measure. Patient charts for abstraction were selected from visits for rheumatoid arthritis for adult patients with two or more face-to-face encounters for rheumatoid arthritis during the measurement period.

We examined whether EHR specifications and data exported electronically from the EHR were valid when compared to a front-end chart abstraction of the entire EHR by trained reviewers. From the population in which the e-measure was applied, we created a simple random sample for front-end abstraction. For the characteristics of sampled patients, please see Table 2 above.

Reviewers recorded relevant data elements using a structured data entry process. Overall performance rates using the automatically exported data as specified by the e-measure were compared to the front-end abstraction results by calculating a kappa coefficient, a statistical measure of inter-rater agreement.

For the QDM data element "Diagnosis: Rheumatoid Arthritis" front-end chart review found disagreement in 11.7% of cases compared to the automated report. These instances resulted from the provider improperly coding the patient's diagnosis as RA, when in fact the patient had another diagnosis. These data are consistent with the scientific literature in which the validity of case definitions for RA using related automated algorithms have been examined (*Chung CP, A systematic review of validated methods for identifying patients with rheumatoid arthritis using administrative or claims data. Vaccine. 2013 Dec 30;31 Suppl 10:K41-61; Carroll RJ et al. Portability of an algorithm to identify rheumatoid arthritis in electronic health records. J Am Med Inform Assoc. 2012 Jun;19(e1):e162-9*; *Liao KP, Electronic medical records for discovery research in rheumatoid arthritis. Arthritis Care Res. 2010 Aug;62(8):1120-7*). Conclusions from this literature are that algorithms, such as the one used here, in which more than one code for RA is required, including a diagnosis from a rheumatologist, have good sensitivity and specificity.

As noted in section 1.2, this measure has been implemented in the ACR's RISE registry. RISE uses computer programming to extract data from the EHR systems of participating providers, analyze the data and provide feedback through an analytic dashboard on a provider's performance on this measure. Through the implementation process, providers must confirm that all data used to calculate the measure performance is accurate and valid. The dashboard is updated on a monthly basis and allows providers to track their performance over time. This allows providers to regularly assess the accuracy of their measure performance score. If providers discover any inconsistencies, they work directly with RISE registry technical experts to identify and correct the source of the issue.

While ACR is transparent about the specifications, this is functionally a registry measure, similar to STS' NQF-endorsed measures that cannot be reproduced by other entities, and thus the quality of the output (and the validity of normalized values) is performed through iterative work between the practices, the registry tech vendor and our third-party data analytic centers that review the data collected by the vendor during set-up of the practices and on a regular basis.

Furthermore, the RISE dashboard allows providers to see how their performance on each quality measure, including the Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy measure, compares to the average performance of all RISE providers. During the onboarding process, practices not only evaluate their own data to ensure that each element is accurate and valid; they also evaluate their performance against the registry average. Because all practices in RISE go through the same onboarding process, practices are able to verify that any difference in their measure performance as compared to the registry average is due to differences in quality of care.

The RISE registry also conducts yearly audits to verify the accuracy of the patient data extracted from the EHR systems of a random sample of participating practices. The most recent audit was conducted in 2018 on data from January 2017 to December 2017. Random sampling technique was used for a sample size of 13 TIN/NPI combinations. For each TIN/NPI sample, a minimum of 40-50 patients were reviewed for audit purposes. Providers reviewed and reported back on the accuracy of data for all reportable measures applicable to the patient, including data relevant to this measure.

2. Systematic assessment of face validity. Systematic assessment of face validity was performed using a multi-stakeholder expert panel that formally rated validity of the proposed measure using a scale based on the RAND Appropriateness Method. *Panelists participated in an open and transparent process in which they were specifically asked to address whether the scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality*.

The American College of Rheumatology has worked for the last several years to develop a rigorous measure development process that leverages the considerable investment in producing guidelines and also input from stakeholders throughout the health care system in the area of rheumatoid arthritis (RA). *The following information is provided to place the Expert Panel ratings, used to assess face validity, in context*. The major elements of the measure development process are listed here. Reviewers are referred to materials in the supplemental appendix for further details.

- First, the ACR assembled a **Working Group** of 7 experts in RA, quality measurement, and health services research meeting its conflict of interest policies (requiring that a majority of group members, including the principal investigator, have no links to any company or commercial entity that makes a drug, device or product in the area of RA). The Work Group was tasked with drafting potential quality measures based on 2012 ACR Guidelines for the management of RA (*Singh JA, Furst DE, Bharat A et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39*). Measures were drafted in an iterative fashion over a period of six months.
- Preliminary measures were presented to a separate multi-stakeholder **Expert Panel** of 16 for formal ratings. The group was comprised of patients with RA, practicing rheumatologists whose primary

responsibility is patient care, an orthopedic surgeon nominated by the American Academy of Orthopedic Surgery, an Internal Medicine specialist nominated by the American College of Physicians, a member of the American Rheumatology Health Professional's Association, a payer representative (a Medical Director for a large public payer program), and methodological experts with expertise in quality measure development. For each measure, the panel was asked to review the scientific evidence and vote prior to meeting. These results were then presented to the panel and a facilitated discussion using initial ratings was undertaken during a meeting. Members voted again after deliberating. Results were analyzed according the RAND Appropriateness Method (mean scores of 7-9 indicate good agreement if criteria for disagreement are absent; *see Brook RH. The RAND/UCLA appropriateness method. In: McCormick KA, Moore SR, Siegel RA, editors. Methodology perspectives. Rockville (MD): US Department of Health and Human Services; 1994. p. 59–70*). Panel ratings on the measure are provided below. Table 3 summarizes the results of the rating procedure. ***The median score for validity was 9 (indicating excellent validity).***

Table 3. Data from the American College of Rheumatology's Rheumatoid Arthritis Quality Measures Project Expert Panel Rating Process for DMARD Measure.[1,2]

Median score for validity	Median score for feasibility	# of raters with validity score ≤ 3	# of raters with validity score ≥ 7	# of raters total	% invalid (score ≤ 3)
9	8	1	13	14	7.14%

1. *Panelists were provided with the following instructions*: "Your validity ratings should reflect whether you believe that the measure can be used to reflect the quality of care for RA. Questions to consider in determining your validity ratings should include:

a. Is there adequate scientific evidence or professional consensus to support the indicator?

b. Are there identifiable health benefits to patients who receive care specified by the indicator?

c. Based on your professional experience, would you consider providers with significantly higher rates of adherence to the indicator higher quality providers?

d. Are the majority of factors that determine adherence to the indicator under the control of the physician or health care system?"

2. *Measure scale definitions*: For validity, 1=definitely NOT valid to 9=definitely valid; for feasibility, 1=definitely NOT feasible; 9=definitely feasible.

- In addition to the formal validity assessment by experts, additional vetting was performed in several ways. First, the ACR requested **public comment** on the measure, publicizing the comment period through email communication with ACR members and communicating with the leadership of other stakeholder groups. Public comments were reviewed and did not identify any additional issues concerns with the measure.
- Finally, the **ACR Quality Measures Subcommittee, ACR Quality of Care Committee** and **ACR Board of Directors** approved the measures.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

1. Critical data element validity.

Sample Size: 162

Kappa Overall, Range, % Agreement: .67, (.44, .89), 95.1%

Kappa, Range, % Agreement Denominator: 1.00, (1.0, 1.0), 100%

Kappa, Range, % Agreement Numerator: .67, (.44, .89), 95.1%

Kappa, Range, % Agreement Exceptions: 1.00 (1.0, 1.0), 100%*

*100% agreement that there are no exceptions

Recommended guidelines for interpreting Kappa values from the National Quality Forum's Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties

Kappa values range between 0 and 1. 0 and are interpreted as degree of agreement beyond chance. By convention, a kappa > .70 is considered acceptable inter-rater reliability, but this depends on the researcher's purposes[23]	
0	No better than chance
0.01-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.0	Almost perfect[23]

Please see above section for details of additional validity testing results.

Table 3a below contains the results from the registry audit conducted in 2018.

Table 3a. Results of RISE registry audit of data from January 2017-December 2017.

Number of NPI/TIN audited	Number of Patients	Expected count of Responses	Number of Correct Responses	Number of Incorrect Responses	% Success	% Fail
13	644	698	684	14	97.99%	2.01%

2 Systematic assessment of face validity.

Table 3. Data from the American College of Rheumatology's Rheumatoid Arthritis Quality Measures Project Expert Panel Rating Process for Disease Activity Measure.[1,2]

Median score for validity	Median score for feasibility	# of raters with validity score ≤ 3	# of raters with validity score ≥ 7	# of raters total	% invalid (score ≤ 3)
9	8	1	13	14	7.14%

1. *Panelists were provided with the following instructions*: "Your validity ratings should reflect whether you believe that the measure can be used to reflect the quality of care for RA. Questions to consider in determining your validity ratings should include:

a. Is there adequate scientific evidence or professional consensus to support the indicator?

b. Are there identifiable health benefits to patients who receive care specified by the indicator?

c. Based on your professional experience, would you consider providers with significantly higher rates of adherence to the indicator higher quality providers?

d. Are the majority of factors that determine adherence to the indicator under the control of the physician or health care system?"

2. *Measure scale definitions*: For validity, 1=definitely NOT valid to 9=definitely valid; for feasibility, 1=definitely NOT feasible; 9=definitely feasible.

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Critical data element validity. The kappa statistic of 0.67 for overall performance indicates substantial agreement between the automated report and the front-end chart abstraction. Individual data elements were found to be highly reliable.

Manual audit validity testing results in a random sampling of practices indicated a very high (98%) accuracy.

Systematic assessment of validity. Ratings by a multi-stakeholder group in which the RAND/UCLA rating scale was applied found excellent validity of this measure, with a mean score of 9, and no disagreement.

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section* 2b3

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

The current measure adds e-specifications to an NQF-endorsed measure (DMARD use in RA, stewarded by the National Committee for Quality Assurance). Exclusions of the current measure are consistent with those in previous versions of this measure that are currently widely used and accepted in the U.S. health care system. Exclusions are based on the scientific literature and include:

1) Pregnancy, Active. This is clinically justified for a number of reasons. These include that most DMARDs are either frankly teratogenic (e.g. methotrexate, leflunomide) or are inadequately studied in pregnant women, and that many individuals with RA may experience lower levels of disease activity during pregnancy and therefore may not require drug therapy. In addition, even in the case of active disease, women may reasonably decide to minimize medication use to reduce potential harm to the fetus (*Makol A. Rheumatoid arthritis and pregnancy: safety considerations in pharmacological management. Drugs. 2011 Oct 22;71(15):1973-87*).
2) HIV, Active. This is clinically justified since the safety of immunosuppressive drugs is inadequately studied in individuals with HIV/AIDS.
3) Rheumatoid Arthritis, inactive. This is clinically justified and based on clinical guidelines (*Singh J et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39*). The course of RA is variable, and some patients may achieve remission off of drug therapy.

To identify these exclusions, an automated query was generated to identify:

Patients Aged 18 and older -> Patients with Diagnosis, RA -> Patients with two or more encounters during the measurement period –> Patients with a diagnosis Pregnancy, Active and/or HIV, Active, and/or Rheumatoid Arthritis, Inactive. *Running this query did not reveal any patients who met this exclusion criterion in our testing sites*.

These exclusions are expected to be relatively uncommon based on available scientific literature, but are included to increase both the scientific and face validity of the DMARD measure. For example, in a national sample of Medicare fee-for-service enrollees with rheumatoid arthritis, **HIV/AIDS** was only identified in 6 individuals among a cohort of over 20,000 patients with RA (*Yazdany J et al. Glucocorticoid monotherapy among Medicare beneficiaries with rheumatoid arthritis. Arthritis Care & Research, in press*). In addition, because the mean age of individuals with RA in the United States is currently 67 years and expected to rise as our population ages (*Helmick CG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Arthritis Rheum. 2008 Jan;58(1):15-25*), **pregnancy** exclusions are expected to be present but not common.

Although precise population-based estimates are not available, studies to date suggest that up to 10% of individuals with RA may achieve a **drug-free remission** over the course of their disease (*van der Woude D. Sustained drug-free remission in rheumatoid arthritis after DAS-driven or non-DAS-driven therapy: a comparison of two cohort studies. Rheumatology (Oxford). 2012 Jun;51(6):1120-8*).

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

See response above, including data from testing sites and also national benchmark data on these exclusions.

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

These exclusions are expected to be present, but not common. They are clinically justified and lend scientific and face validity to the measure. Members of our Expert Panels felt strongly that these exclusions should be included to increase acceptability of the DMARD measure among practicing clinicians.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4**.**

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with risk factors**

☐ **Stratification by risk categories**

☐ **Other,**

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

2b3.9. Results of Risk Stratification Analysis:

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

Performance varied between sites. Performances ranged from 88-90% in sites that have established workflow to collect data on DMARD therapy.

Variation between providers, health plans and geographic regions have also been documented when this measure has been applied across the U.S. population (*Schmajuk G et al. Receipt of disease-modifying antirheumatic drugs among patients with rheumatoid arthritis in Medicare managed care plans. JAMA. 2011 Feb 2;305(5):480-6* and *Schmajuk G et al. Patterns of disease-modifying antirheumatic drug use in rheumatoid arthritis patients after 2002: a systematic review. Arthritis Care Res (Hoboken). 2013 Dec;65(12):1927-35*).

We also evaluated the variation in measure performance in 2017 among 107 RISE practices, representing 98.2% of all practices fully enrolled in RISE at the beginning of 2017.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Data from the literature suggest that there is significant variation on DMARD use within the U.S. health care system. Schmajuk et al. (*JAMA. 2011 Feb 2;305(5):480-6*) describe that overall performance on the analogous HEDIS DMARD measure in the Medicare managed care population was 67% in 2008. The largest difference in performance was based on age, with older individuals being less likely to receive a DMARD. Blacks, those with low personal incomes, and those residing in zip codes with low socioeconomic status also had significantly lower DMARD use. In addition, performance varied widely by health plan, ranging from 16% to 87%. Additional studies, including a systematic review have also documented variation (*Schmajuk G, Solomon DH, Yazdany J. Patterns of disease-modifying antirheumatic drug use in rheumatoid arthritis patients after 2002: a systematic review. Arthritis Care Res (Hoboken). 2013 Dec;65(12):1927-35*). Available studies also demonstrate that variation is significantly less for those under the care of a rheumatologist. This is consistent with data from the ACR's Rheumatology Clinical Registry, in which performance was 92.5% among participating rheumatologists in 2011 (*Yazdany J et al. Uptake of the American College of Rheumatology's Rheumatology Clinical Registry (RCR): Quality Measure Summary Data". Annual Scientific Meeting. American College of Rheumatology. Arthritis Rheum, 2013 abstract supplement*).

Table 4. Variation in performance on Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy measure in the RISE registry, January 2017-December 2017.

Practices	Total Denominator	Mean Denominator	Denominator range	Total Numerator	Mean Numerator	Numerator Range	Average Practice Performance (%)	25th, 50th, 75th, 100th percentile
107	94872	886.65	18-4017	86446	807.91	18-3737	90.47%	89.00, 93.03, 95.42, 100

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

Application of this measure in the U.S. health care system for the last decade (2005-2014) suggests that DMARD use is a disparities-sensitive measure with significant variation across providers and health care settings; see above.

The results demonstrate that variation in the use of DMARDs has decreased over time, supporting the impact of this measure. A more than 10 percentage point interquartile range supports persistent performance variation and a continued need for improvement in performance overall; the modest drop in average success from prior assessments (mean performance 92.5% in 2012 to 90.5% in 2017) likely reflects both changing demographics and a shift from non-EHR-based measure versions used in the past. Given that the measure exclusions account for the situations where use of DMARDs would be clinically inappropriate, optimal clinical performance for this measure should be 100%, as this measure reflects the ACR guidelines for care of RA patients.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note: *This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

Identification of missing data was included as part of the earlier critical data element validity testing described in section 2b1.

With the RISE registry, there is no missing data. As described in section 1.2, during the implementation process, providers work with the registry's technical experts to review the data elements necessary for measure performance calculations and direct the technical team on how to find those data elements in the practice's EHR system. The technical team is them able to extract the necessary data from both structured and unstructured fields. This ensures that accurate measure performance can be calculated no matter how the information is documented (in free text or as a scanned pdf).

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

In 5.6% of the patient sample, missing medication data (DMARD) were noted.

As noted above, the data abstraction approach ensures there is no missing data. See 2b6.3.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

Because there is currently heterogeneity in the U.S. electronic health record systems in medication capture, we expect that missing medication data (DMARD) may be a problem in some settings. In one study, up to 15% of medications taken by patients were not captured by the electronic health record (*Orrico KB. Sources and types of discrepancies between electronic medical records and actual outpatient medication use. J Manag Care Pharm. 2008 Sep;14(7):626-31*). As medication reconciliation procedures improve, the extent of missing data will likely decrease over time.

However, this is not a concern with data in the RISE registry. Because of the method of data mining used to calculate measure performance in the registry, the absence of a necessary data element, such as a lab test, a medication or a disease activity assessment, is not indicative of missing data. Rather, it indicates that the provider did not perform the expected action.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in a combination of electronic sources

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

As noted in S.3.2., the ACR made a conscious decision to move away from an eCQM in order to provide the most flexible route to electronic health record data-based measurement and avoid forcing individual practitioners to change their workflow and documentation to satisfy requirements for HQMF specifications. The ACR will continue to monitor developments in coding and HQMF specifications to determine if the updates would provide the necessary flexibility to make this measure an eCQM.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment: RA_Feasibility_Survey_Responses_-_Data_Element_Scores.xls

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

Testing did not uncover any additional issues with this measure.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

N/A

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting Payment Program Regulatory and Accreditation Programs Professional Certification or Recognition Program	Quality Improvement (external benchmarking to organizations) RISE Registry http://www.riseregistry.org Quality Improvement (Internal to the specific organization) RISE Registry http://www.riseregistry.org

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Program: The Rheumatology Informatics System for Effectiveness (RISE) registry
Sponsor: American College of Rheumatology
Purpose: To help prepare rheumatologists for the significant challenges of a rapidly changing healthcare environment, including adapting to new payment and delivery models, meeting evolving certification requirements, and using EHR data to assess quality of care.
Geographic area: United States
Number of entities and patients: As of January 3, 2019, 937 rheumatology providers participated in RISE, representing 1,787,394 patients
Level of measurement: provider and practice
Setting: Solo practice, single-specialty group practice, multi-specialty group practice

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

The measure as specified was part of CMS's PQRS payment program. However, they declined to carryover this measure when they transitioned to the MIPS payment program. We will be meeting with CMS and plan to discuss how to make this measure acceptable for use in MIPS.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

This measure continues to be tracked in the ACR's RISE registry. While the main purpose of the registry has been to help providers meet federal reporting requirements, the ACR is actively pursuing opportunities with

private payers to track performance on a variety of quality measures, including this measure, through the RISE registry in order to identify high quality providers and determine payment reimbursement. In particular, the ACR is working to develop a value recognition program that sets high quality thresholds for each measure that providers must meet as opposed to having providers compete against their peers. Discussions around the specific program details and timeline are ongoing and contain sensitive information. However, the ACR has a vested interest in developing and implementing this additional use of the RISE registry as quickly as possible. In addition, we are actively working with CMS to ensure as many of the ACR's measures as possible are either designated as QCDR measures or as MIPS measures.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

For information on feedback from those being measured during measure development, please refer to the validity testing in section 2.

For implementation, those being measure are deeply involved in the process. Measure performance is shared with rheumatology providers via the ACR's RISE registry. Participating providers work closely with the registry technology vendor to ensure data is being extracted from their EHR correctly and portrayed accurately via the registry's analytic dashboard. Through the RISE dashboard, providers are able to see their individual overall performance on the measure, their practice's overall performance on the measure, and the average performance of all RISE users on the measure. Each provider is also able to drill down into their measure performance to see the patients who qualify for the denominator and the numerator. Furthermore, providers have direct access to the human readable measure specifications in the dashboard. If they have any questions or concerns about how the measure is being calculated or the specifications in general, they are able to contact both ACR staff and the registry technology vendor staff directly. This allows providers the ability to confirm the accuracy of their measure performance, review how their own practices impact their measure performance, and get any questions on measure interpretation answered directly by the measure owner.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

The analytic dashboard for all RISE providers is updated every month following the most recent data extraction. All providers have constant access to their analytic dashboard to review the measure specifications and their measure performance. ACR and vendor staff are available during regular business hours to answer their questions over the phone or via e-mail.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

RISE users communicate directly with the registry technology vendor and ACR staff over the phone and via e-mail.

4a2.2.2. Summarize the feedback obtained from those being measured.

When communicating with staff, they have said that this and the other measures included in the registry to be very helpful in understanding the quality of care they provide patients. When a provider first joins the RISE registry, most often they note that they expected higher performance on their measures. However, through their work with the registry technology vendor and the analytic dashboard, they are able to see an objective analysis of their data and realize that they are not providing as high of quality care as they assumed. The other most common feedback received on this measure is focused on ways to identify the various data elements in the measure. For example, a provider may use a different tool than approved for use in the measure or document a lab result in a different way than expected.

4a2.2.3. Summarize the feedback obtained from other users

As far as we are aware, this measure has only been implemented in the RISE registry. As mentioned in 4a1.2., this measure was previously used by RISE participants for PQRS reporting. However, when CMS transitioned to MIPS, they did not carryover this measure. We will be meeting with CMS and plan to discuss how to make this measure acceptable for use in MIPS. Because of this, we have not yet received feedback from other entities.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

As noted, RISE providers have direct communication with the registry vendor and ACR staff. They are able to ask questions and share concerns directly with the ACR and receive prompt feedback. As needed, ACR staff are able to take questions and concerns to a team of rheumatology volunteers with expertise in quality measurement. Feedback from ACR and the quality measure experts is then used to improve the guidance on quality measure implementation for both the registry technology vendor and the provider.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

The relatively high performance over time reflects intense attention paid to DMARD treatment by rheumatology societies and evidence supporting the value of early, aggressive use of DMARDs. It may also reflect the increasing numbers of DMARDs available to the US market (enabling patients who have failed other DMARDs to try new DMARDs), as well as increased direct to consumer advertising (resulting in higher patient acceptance rates and likely greater patient-driven discussions about initiating DMARDs. Even with this improvement, the variation in results indicates continued need for monitoring and assessing performance on this measure, especially as more practices continue to join RISE.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

As noted in S.3.2, we found that many providers were documenting key aspects of the measure data elements in free text or other non-standardized formats. Only a portion of providers have laboratory data and/or prescription data integrated into their outpatient electronic health record, further complicating the ability to pull HQMF-formatted specifications.

We are unaware of any negative or unintended impacts on patients due to measurement.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

We received positive feedback from several participating providers. This included both the benefits of better understanding provider variation within practices as well as identification of higher-risk patients such as those with frequent disease flares.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

Measure Title: Rheumatoid Arthritis DMARD Therapy

Owner: NCQA

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

The current NQF-endorsed DMARD measure is specified for claims-based reporting. Our measure is specified for use with EHR data and intended for use in electronic reporting options. Also, the NCQA´s DMARD measure does not include "Rheumatoid Arthritis, Inactive" as an exclusion. This exclusion has been incorporated into this submission. Furthermore, measure is built for plan-level analysis, whereas our measure focuses on provider- and practice-level performance. The ACR would be happy to work with NCQA to harmonize the measures.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

The current NQF-endorsed DMARD measure is specified for claims-based reporting. Our measure is specified for use with EHR data and intended for use in electronic reporting options. Also, the NCQA´s DMARD measure does not include "Rheumatoid Arthritis, Inactive" as an exclusion. This exclusion has been incorporated into this submission. Furthermore, the NCQA´s measure is built for plan-level analysis, whereas our measure focuses on provider- and practice-level performance. The ACR would be happy to work with NCQA to harmonize the measures.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment **Attachment:** Appendix.xlsx

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): AMERICAN COLLEGE OF RHEUMATOLOGY

Co.2 Point of Contact: RACHEL, MYSLINSKI, RMYSLINSKI@RHEUMATOLOGY.ORG, 404-633-3777-824

Co.3 Measure Developer if different from Measure Steward: AMERICAN COLLEGE OF RHEUMATOLOGY

Co.4 Point of Contact: RACHEL, MYSLINSKI, RMYSLINSKI@RHEUMATOLOGY.ORG, 404-633-3777-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

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Boston University

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released:

Ad.3 Month and Year of most recent revision:

Ad.4 What is your frequency for review/update of this measure?

Ad.5 When is the next scheduled review/update for this measure?

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Ad.8 Additional Information/Comments: