**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 2522

**Measure Title**: Rheumatoid Arthritis: Tuberculosis Screening

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/1/2019

|  |
| --- |
| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

|  |
| --- |
| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

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

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the 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*): Click here to name the intermediate outcome

Process: Tuberculosis screening prior to initiating newly prescribed biologic DMARD therapy for patients with RA.

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**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 is a patient safety measure pertaining to commonly used therapies (specific biologic DMARDs) in rheumatoid arthritis. Administrative data suggest that over 1 in 4 individuals with RA receive biologic DMARDs (*Zhang J, Xie F, Delzell E, et al. Trends in the Use of Biologic Therapies among Rheumatoid Arthritis Patients Enrolled in the U.S. Medicare Program. Arthritis care & research. Jun 10 2013*). Over 1.3 million individuals in the United States have RA (*Helmick CG, Felson DT, Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Arthritis and rheumatism. Jan 2008;58(1):15-25*); therefore this measure is expected to apply to over 300,000 Americans with RA. Biologic therapies can reactivate latent tuberculosis, leading to significant morbidity and even mortality.

The path between the *process* of care and *adverse health outcomes* is illustrated below:

TB risk 🡪 TB screening prior to initiating biologic DMARD therapy 🡪 Identification of latent Tb, which can be reactivated by immunosuppressive therapies, such as DMARDs **→** Treatment of latent Tb **→** Decreased risk of TB reactivation or worsening of active TB when initiating biologic DMARD therapy 🡪 Optimize RA outcomes by avoiding serious adverse events, such Tb reactivation

**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(SR) 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

The 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis reviewed the literature and, based upon the absence of new data, the voting panel re-endorsed the recommendations previously published in the 2008 recommendations and in the 2012 update. Singh, et al, 2016, page 14: “The panel endorsed the recommendations previously published in the 2008 recommendations and in the 2012 update to be included in the 2015 recommendations (Table 3 and Figure 6). The panel indicated that in the absence of significant new knowledge, development of an alternate recommendation was not warranted with one exception: the Voting Panel recommended that the same TB screening algorithm as described for biologics should be followed for patients receiving tofacitinib.” Therefore, we have provided all relevant reference citations and recommendations below:

Singh J et al.2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis*. Arthritis Rheumatol. 2016 Dec;68(1):1-26*).

Singh, 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. AC&R 2012;64(5):625-639. The following recommendations are all Level C Evidence, except for initiation of biologic agents in patients being treated for latent tuberculosis infection (LTBI), where the Level of Evidence is B

Saag, et al., American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. AC&R 2008;59(6):762-784: (\*\*Grades not assigned to these recommendations)

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. * Singh, et al * 2008 * AC&R 2008;59(6):762-784 * [**http://rheumatoidarthritis.semarthritisrheumatism.com/Content/PDFs/RR-2008-Guidelines.pdf**](http://rheumatoidarthritis.semarthritisrheumatism.com/Content/PDFs/RR-2008-Guidelines.pdf) |
| 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. | * In Table 2: “Latent TB infection prior to initiation of latent TB treatment, or active TB disease prior to completing a standard regiment of anti-TB therapy” were “contraindications to starting or resuming therapy with … biologic DMARDs in RA patients” * Page 776: “The TFP recommended routine TB screening to identify latent TB infection in patients being considered for therapy with biologic agents (Figure 4). The evidence for TB testing is based on a documented higher incidence of TB following anti-TNF-alpha therapy (references 117, 122). To begin, the TFP recommended that clinicians should ask all RA patients being considered for biologic DMARD therapy about their potential risk factors for TB infection (see below) and, irrespective of prior BCG vaccination, should use a TB skin test as a diagnostic aid to assess the patient’s probability of latent TB infection (Figure 4).” * Page 776: “These ACR recommendations defer the decision to initiate anti-TB therapy to physicians possessing sufficient expertise in TB management. In general, patients with latent TB infection should begin preventive therapy before starting their anti-TNF-alpha therapy (Reference 248). The CDC suggests that the preferred regimen for management of latent TB infection is a 9-month course of daily isoniazid (Reference 245). The CDC also suggests delaying anti-TNF-alpha therapy until isoniazid treatment has been initiated but does not specify an optimal time period of delay (Reference 249). Observational studies suggest anti-TNF-alpha therapy can be safely started 1 month after starting isoniazid treatment (Reference 250,251). The British Thoracic Society also has provided recommendations on this issue (Reference 252). Treatment with isoniazid does not eliminate all cases of anti-TNF-alpha –associated TB, and clinicians should remain vigilant for active TB in any anti-TNF\_–treated patient in whom constitutional or chronic respiratory symptoms develop during anti-TNF-alpha therapy.” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Grades not assigned to these recommendations |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | N/A |
| Provide all other grades and definitions from the recommendation grading system | N/A |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | N/A |
| 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? | Singh, et al., AC&R 2012;64(5):625-639: This is an update to the 2008 ACR RA treatment Guidelines. The following recommendations are all Level C Evidence, except for initiation of biologic agents in patients being treated for LTBI, where Level of Evidence is B   * Page 634: “The panel recommends screening to identify LTBI in all RA patients being considered for therapy with biologic agents, regardless of the presence of risk factors for LTBI (diamond A of Figure 3) (Reference 14). It recommends that clinicians assess the patient’s medical history to identify risk factors for TB (specified by the CDC) (Table 2).” * Figure 3 illustrates the recommendations for TB screening methods * Page 636: “If the RA patient has active or latent TB based on the test results, the panel recommends appropriate antitubercular treatment and consideration of referral to a specialist. Treatment with biologic agents can be initiated or resumed after 1 month of latent TB treatment with antitubercular medications and after completion of the treatment of active TB, as applicable (Figure 3; below).”   **Figure 3. Recommendations for TB Screening methods.**  Figure 3. Recommendations for TB Screening methods. The figure shows the process providers should follow to test for TB. The first step is TST or IGRA. If positive, do a chest radiograph. If positive, sputum for AFB. If positive, active TB should be treated. If latent TB is discovered, complete at least one month treatment for latent TB. All this should be done prior to a patient starting (or resuming) a biologic.   * Page 638: “Because these recommendations were heavily informed by CDC guidance and minimal additional information was found in the broader literature search, our TB screening and vaccination recommendations are concordant with the CDC recommendations.”   The recommendations are all Level C Evidence, except for initiation of biologic agents in patients being treated for LTBI, which are Level of Evidence B. The strength of evidence was assigned using methods from the American College of Cardiology (*Hunt SA, et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2005;112:e154–235*). The evidence was rated by an Expert Panel using the RAND Appropriateness Method, which requires median ratings of 7-9 and no disagreement; Tb screening recommendations had high agreement. From the guideline, “Level C evidence often denoted a circumstance where medical literature addressed the general topic under discussion but it did not address the specific clinical situations or scenarios reviewed by the panel. Since many recommendations had multiple components (in most cases, multiple medication options), a range is sometimes provided for the level of evidence; for others, the level of evidence is provided following each recommendation.”  Definitions for this grading scheme:  Level A. If data are derived from multiple randomized clinical trials or metanalyses.  Level B. If data are derived from a single randomized trial or non-randomized studies.  Level C. If recommendation is based on consensus opinion of experts, case studies, or standard-of-care |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**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.**