

National Committee for Quality Assurance/
Physician Consortium for Performance Improvement® (PCPI)/
American College of Rheumatology

DRAFT – FOR PUBLIC COMMENT

Rheumatoid Arthritis
Clinician Performance Measurement Set

June 2008

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Physician Performance Measures (Measures) and related data specifications developed by the American Medical Association (AMA) in collaboration with the Physician Consortium for Performance Improvement® (PCPI) and the National Committee for Quality Assurance (NCQA), pursuant to government sponsorship under Subcontract No. 6414-07-089 with Mathematica Policy Research under Contract HHSM-500-2005-000251(0004) with Centers for Medicare and Medicaid Services.

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Purpose of Measures:

These clinical performance measures, developed by the American College of Rheumatology, the National Committee for Quality Assurance, and the Physician Consortium for Performance Improvement® (PCPI), are designed to assess whether appropriate processes of care were delivered. The measures are appropriate for accountability if appropriate methodological, statistical, and implementation rules are achieved.

Accountability Measures:

Measure #1: Tuberculosis Screening

Measure #2: Appropriate Use of Biologic Disease Modifying Anti-Rheumatic Drugs (DMARDs)

Measure #3: Periodic Assessment of Disease Activity

Measure #4: Functional Status Assessment

Measure #5: Glucocorticoid Dose

Measure #6: Assessment and Classification of Disease Prognosis

Intended Audience and Patient Population:

These measures are designed for use by physicians and eligible health professionals where appropriate, and for calculating reporting or performance measurement at the individual clinician level.

Measures 1 through 6 are designed for any clinician caring for patients aged 18 years and older with a diagnosis of rheumatoid arthritis.

Measure Specifications

NCQA seeks to specify measures for implementation using multiple data sources, including paper medical record, administrative (claims) data, and particular emphasis on Electronic Health Record Systems (EHRS). Draft specifications to report on these measures for Rheumatoid Arthritis using administrative (claims) data are included in this document. We have identified codes for these measures, including ICD-9 and CPT (Evaluation & Management Codes, Category I and where Category II codes would apply). Specifications for additional data sources, including EHRS, will be fully developed at a later date. We welcome comments on the draft specifications included in addition to the measure language.

Measure Exclusions:

For *process measures*, there are three categories of reasons for which a patient may be excluded from the denominator of an individual measure:

- **Medical reasons**
Includes:
 - not indicated (absence of organ/limb, already received/performed, other)
 - contraindicated (patient allergic history, potential adverse drug interaction, other)
- **Patient reasons**
Includes:
 - patient declined
 - social or religious reasons
 - other patient reasons
- **System reasons**
Includes:
 - resources to perform the services not available
 - insurance coverage/payor-related limitations
 - other reasons attributable to health care delivery system

These measure exclusion categories are not available uniformly across all measures; for each measure, there must be a clear rationale to permit an exclusion for a medical, patient, or system reason. The exclusion of a patient may be reported by appending the appropriate modifier to the CPT Category II code designated for the measure:

- **Medical reasons**: modifier 1P
- **Patient reasons**: modifier 2P
- **System reasons**: modifier 3P

Although this methodology does not require the external reporting of more detailed exclusion data, NCQA recommends that clinicians document the *specific* reasons for exclusion in patients' medical records for purposes of optimal patient management and audit-readiness. NCQA also advocates the systematic review and analysis of each clinician's exclusions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that clinicians have identified as meeting the criteria for exclusion.

Please refer to documentation for each individual measure for information on the acceptable exclusion categories and the codes and modifiers to be used for reporting.

Measures #1-6 in the Rheumatoid Arthritis measurement set are process measures.

For outcome measures, NCQA specifically identifies all acceptable reasons for which a patient may be excluded from the denominator. Each specified reason is reportable with a CPT Category II code designated for that purpose.

There are no outcome measures in the Rheumatoid Arthritis measurement set.

NCQA continues to evaluate and likely will evolve its methodology for handling exclusions as it gains experience in the use of the measures. NCQA welcomes comments on its exclusions methodology.

Data Capture and Measure Calculation

NCQA intends for clinicians to collect data on each patient eligible for a measure. Feedback on measures should be available to clinicians by patient to facilitate patient management and in aggregate to identify opportunities for improvement across a clinician's patient population.

Measure calculations will differ depending on whether a rate is being calculated for performance or reporting purposes.

The method of calculation for performance follows these steps: first, identify the patients who meet the eligibility criteria for the denominator (PD); second, identify which of those patients meet the numerator criteria (A); and third, for those patients who do not meet the numerator criteria, determine whether an appropriate exclusion applies and subtract those patients from the denominator (C). (see examples below)

The methodology also enables implementers to calculate the rates of exclusions and to further analyze both low and high rates, as appropriate (see examples below).

The method of calculation for reporting differs. One program which currently focuses on reporting rates is the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting Initiative (PQRI). Currently, under that program design, there will be a reporting denominator determined solely from claims data (CPT and ICD-9), which in some cases result in a reporting denominator that is much larger than the eligible population for the performance denominator. Additional components of the reporting denominator are explained below.

The components that make up the numerator for reporting include all patients from the eligible population for which the clinician has reported, including: the number of patients who meet the numerator criteria (A), the number of patients for whom valid exclusions apply (C) and also the number of patients who do not meet the numerator criteria (D). These components, where applicable, are summed together to make up the inclusive reporting numerator. The calculation for reporting will be the reporting numerator divided by the reporting denominator (see examples below).

Calculation for Performance

For performance purposes, this measure is calculated by creating a fraction with the following components:

Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:

Number of patients meeting numerator criteria

Performance Denominator (PD) Includes:

Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (C) Include:

Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

Performance Calculation

$$\frac{A \text{ (\# of patients meeting numerator criteria)}}{PD \text{ (\# patients in denominator)} - C \text{ (\# patients with valid denominator exclusions)}}$$

It is also possible to calculate the percentage of patients excluded overall, or excluded by medical, patient, or system reason where applicable:

Overall Exclusion Calculation

$$\frac{C \text{ (\# of patients with any valid exclusion)}}{PD \text{ (\# patients in denominator)}}$$

OR

Exclusion Calculation by Type

$$\frac{C_1 \text{ (\# patients with medical reason)}}{PD \text{ (\# patients in denominator)}}$$

$$\frac{C_2 \text{ (\# patients with patient reason)}}{PD \text{ (\# patients in denominator)}}$$

$$\frac{C_3 \text{ (\# patients with system reason)}}{PD \text{ (\# patients in denominator)}}$$

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator

Reporting Numerator includes each of the following components, where applicable. (There may be instances where there are no patients to include in A, C, D, or E).

A. Number of patients meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9 and CPT Category I coding alone) AND numerator criteria

C. Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

D. Number of patients not meeting numerator criteria and without a valid exclusion

E. All other patients not meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9 and CPT Category I coding alone)

Reporting Denominator (RD) Includes:

RD. Denominator criteria (identifiable through ICD-9 and CPT Category I coding)

Reporting Calculation

$$\frac{A(\text{\# of patients meeting additional denominator criteria AND numerator criteria}) + C(\text{\# of patients with valid exclusions}) + D(\text{\# of patients NOT meeting numerator criteria}) + E(\text{\# of patients not meeting additional denominator criteria})}{RD \text{ (\# of patients in denominator)}}$$

Candidate Measure Summary form

Project Name: Clinician Measure Development
 Submitter Name: NCQA
 Date Completed: 4/10/08

The purpose of this template is to provide a brief, high-level description of the candidate measure as well as the measure attributes using the measure evaluation criteria and subcriteria. This information will be used by the Technical Expert Panel to evaluate the proposed measures. In addition, if this measure is one of the final measures in the measure set, much of the information documented here can be transferred into the Measures Management System "Measure Information Form" as well as the National Quality Forum measure submission form. Complete one form for each measure.

Measure Set:	Rheumatoid Arthritis
Measure Name <i>(should be brief, concise):</i>	Rheumatoid Arthritis: Tuberculosis Screening
Measure Description:	Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted prior to the first prescription of biologic disease-modifying antirheumatic drug (DMARD) therapy.

Technical Specifications

Denominator

Denominator Statement: Patients 18 years and older with a diagnosis of rheumatoid arthritis (RA) and a first prescription for biologic disease-modifying antirheumatic therapy (DMARD)

Denominator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – Patient with a first-time prescription for biologic DMARD therapy for RA

AND

ICD-9-CM Diagnosis code: 714.0, 714.1, 714.2, 714.81

Definition:

Biologic DMARD therapy: Adalimumab, Etanercept, Infliximab, Abatacept, Anakinra (Rituximab is excluded)

Exclusions:

CPT Cat-II code (in development): XXXXF – Patient not receiving biologic DMARD therapy for RA

Medical reason: patient positive for TB and documentation of past treatment; patient who has recently completed a course of anti-TB therapy

XXXXF-1P

Numerator

Numerator Statement: Number of patients with documentation of a TB screening performed and results interpreted within six months prior to initiation of biologic DMARD therapy

Numerator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – TB screening performed and results interpreted within six months prior to first prescription of biologic DMARD therapy for RA

Exclusions: None

Type of Measure: Process

Data source: Medical Record, Administrative Claims, Electronic Medical Record, Administrative Claims supplemented by Medical Records, Pharmacy Claims

Unit of Measurement: Clinician

Measure Care Setting: Ambulatory

Measure Source:

- New
- Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)
- Adopted (if adopted, provide name of original measure)

Measure Justification

Rationale: (describe succinctly the overall reasoning behind the use of this measure):

Before initiating biologic DMARDs for a patient with RA, it is essential to screen the patient for tuberculosis, as research has documented a higher incidence of TB after anti-TNF α therapy. All patients being considered for biologic DMARD should receive a tuberculin skin test, even if the patient has previously received the BCG vaccination. Test results, in addition to patient risk for TB and other tests, should be used to assess the patient's risk for latent TB infection. This is a patient safety measure.¹

I. Importance

- a. Describe how measure addresses a national health goal or priority area **OR** focuses on high impact aspect of health care (**epidemiological relevance, financial relevance, policy relevance**)

Policy relevance

Improving quality in rheumatoid arthritis care falls under the IOM priority area of Living with Illness/Disability. The other area of policy relevance is the changing landscape of medical risks versus benefits of the therapeutic options for RA treatment. This is especially important with the introduction of biopharmaceuticals.

Clinical or Epidemiologic Relevance

RA is a multisystem disorder of unknown etiology, characterized by chronic destructive synovitis. The current national estimate of prevalence of RA, using 2005 population estimates from the Census Bureau, is that 1,293,000 American adults age \geq 18 years (0.6%) have RA. This estimate is lower than prior estimates due to stricter disease classification

criteria. The prevalence in women is approximately double that in men (1.06% vs. 0.61%), and the average age of persons with prevalent RA has increased steadily over time, from 63.3 years in 1965 to 66.8 years in 1995, suggesting that RA is becoming a disease of older adultsⁱⁱ.

Financial relevance

The costs of RA are increasing because of the introduction and increasing use of biologic therapy. The mean total annual direct medical care cost in 2001 for a patient with RA was \$9,519. Drug costs were \$6,324 (66% of the total), while hospitalization costs were only \$1,573 (17%). Approximately 25% of patients received biologic therapy. The mean total annual direct cost for patients receiving biologic agents was \$19,016 per year, while the costs for those not receiving biologic therapy was \$6,164. The remaining 16% of total costs includes outpatient services such as outpatient surgery, physician and health professional encounters, x-rays, MRI and CT scans and other laboratory testing. Medicare patients incur a high rate of out-of-pocket drug costs; 46% of Medicare patients paid greater than 25% of their drug expenses. The key clinical factors in predicting future costs are functional disability and comorbidityⁱⁱⁱ.

- b. Describe how data demonstrate considerable variation **OR** poor performance across providers **OR** population groups. (**Opportunity for improvement**)

While there are a limited number of studies that investigate gaps in care for patients with rheumatoid arthritis, the research that does exist identifies opportunities for improvement in several care areas: 1) there is a lack of adherence to RA guidelines, most noticeably in the use of disease-modifying antirheumatic drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

One study analyzed quality of care for 1,355 patients with rheumatoid arthritis using data from a national health plan. Using process measures, the study found that patients with rheumatoid arthritis often did not receive the recommended care suggested by clinical guidelines (for each person-year, recommended processes of care for rheumatoid arthritis were performed an average 62% of the time). The study also found that the quality of care provided to patients with RA varied according to provider type (patients seeing a rheumatologist had higher quality care than those seeing a primary care physician).^{iv} Similar results were reported by a cohort study of 1,025 patients with RA. Based on certain outcome measures (including pain rating, number of painful joints, and functional status), patients with a rheumatologist as their RA physician had significantly better outcomes than patients whose main RA physician was a non-rheumatologist.^v

Variation and room for improvement will be demonstrated for this measure during pilot testing.

II. Scientific Acceptability

- a. Describe how the specific outcome, intermediate outcome, process, or structure is consistent with/clinical practice guidelines. Provide guideline citation with USPSTF grade of evidence/recommendation. Discuss any contradictory guidelines or evidence. **(Strength of evidence base)**

The American College of Rheumatology

The TFP recommended routine tuberculosis screening to identify latent TB infection (LTBI) in patients being considered for therapy with biologics. The evidence for TB testing is based on a documented higher incidence of TB following ant-TNF α therapy. To begin, clinicians should ask all RA patients being considered for biologic DMARDs about their potential risk factors for TB infection (see below) and, irrespective of prior Bacillus-Calmette- Guérin (BCG) vaccination, use a Tuberculin Skin Test (TST) as a diagnostic aid to assess their patient's probability of LTBI. (Level of Evidence: Not Rated)

British Society for Rheumatology

There have been a large number of cases of tuberculosis (TB) reported in association with the use of infliximab, and studies that demonstrate a significantly higher rate of TB in patients on this treatment compared with controls. Cases of TB have also been reported in association with etanercept and adalimumab. Reactivation of latent TB is highest in the first 12 months of treatment, so particular vigilance is required during this time. With infliximab, the majority of cases occurred within three cycles of treatment, with a median of 12 weeks after starting treatment, suggesting reactivation of latent TB as the main factor predisposing to TB in these cases. The following are the British Society for Rheumatology's recommended guidelines for patients with RA: Prior to commencing treatment with anti-TNF, all patients should be screened for TB in accordance with the British Thoracic Society (BTS) guidelines. Active TB needs to be adequately treated before anti-TNF therapy can be started; prior to commencing anti-TNF therapy, consideration of prophylactic anti-TB therapy (as directed by the BTS guidelines) should be given to patients with evidence of potential latent disease (past history of TB treatment or abnormal chest X-ray raising the possibility of TB) after consultation with a local TB specialist; all patients commenced on anti-TNF therapies need to be closely monitored for TB. This needs to continue for 6 months after discontinuing infliximab treatment due to the prolonged elimination phase of infliximab; patients on anti-TNF therapy who develop symptoms suggestive of TB should receive full anti-TB chemotherapy, but may continue with their anti-TNF therapy if it is clinically indicated; anti-TNF therapy should only be resumed in accordance with the BTS guidelines and after agreement in collaboration with a TB specialist.^{vi} (Level of Evidence C)

- b. Describe the science underlying the measure concepts; the extent to which the scientific evidence underlying the measure is stable. **(Stability)**

According to the Expert Workgroup, this is an area where the scientific evidence underlying the measure is relatively stable.

- c. Describe measure reliability testing and results, using a methodology appropriate to the measure type. If the measure has not been tested, plans for testing have been presented. **(Reliability)**

Full evaluation of reliability and validity can only be assessed through large scale implementation of measures. This is a lengthy and expensive process, and has not been requested by CMS. However, NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development.

- d. Describe process for evaluating the face validity as representing the quality of care. Describe testing of the measure providing evidence of the validity of conclusion about quality and the data from testing OR use of the measure demonstrate variation OR poor performance. If the measure has not been tested, plans for testing have been presented. **(Validity)**

NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development to demonstrate variation and room for improvement. We tested face validity through evaluation by an Expert Workgroup, and will further collect comments on face validity through a broadly publicized public comment process and focus group interviews with clinicians.

- e. Describe rationale including evidence-base as to why any exclusions are necessary and appropriate. **(Precision of specifications)**

No exclusions.

- f. **(Outcome measures)** Summarize the testing done to determine the need (or non need) for risk adjustment and the statistical performance of the risk adjustment method. **(Adequacy of Risk Adjustment)**

N/A – process measure.

- g. If results are stratified by population characteristics, to detect disparities in care/outcome, describe rationale including evidence. **(Adequacy of Risk Adjustment)**

While many measures can be sensitive to disparities, these measures have not been specifically tested or specified for ability to detect disparities in care.

III. Usability

- a. Describe how measure is/can be actionable by users such as providers, public, purchasers etc. **(Actionability)**

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives. We also expect the results from these measures to be relevant and usable by payers for value-based purchasing, and by consumers through report cards.

- b. Describe how the measure provides a distinctive or additive value to existing measures **(Actionability)**

These measures address areas of care that are not currently addressed in existing measure sets.

- c. If measure is in current use, describe how real difference in performance can be identified/interpreted with comparative data. **(Actionability)**

Measure is not in current use.

- d. Describe testing done to determine if information produced by the measure is meaningful and understandable to audiences. **(Actionability)**

We are not planning to conduct formal usability testing to determine if the information produced by the measure is meaningful and understandable to audiences.

- e. Describe the extent to which processes and outcomes related to this measure are under the control of the entity being measured. **(Controllability)**

These provider-level measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives, and are assumed to be under the influence or control of the clinician being measured.

- f. Describe the extent to which the measure is adaptable to multiple populations or can be applied across various healthcare settings. **(Adaptability)**.

This measure has been specified for use in the population and setting described above, and has not been evaluated for use beyond the specified population and setting.

IV. Feasibility

- a. Describe the where and how during routine care delivery data can be obtained and if electronic information can be used for this measure. **(Burden of data collection)**

The measure has been specified to rely largely on administrative data collected during routine care and billing. Additional data elements will be collected through CPT Category II codes, which are coded at the point of care. We do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- b. Describe how the testing OR use of the measure demonstrates the data collection strategy (timing, frequency, and sampling) can be implemented. **(Burden of data collection)**

The feasibility of data collection will be evaluated during pilot testing

- c. Describe how the information provided by the measure outweighs the cost/burden of data collection. (**Cost/benefit**)

We have not directly evaluated either the value of the measure or the cost of data collection. However, we do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- d. The data items are auditable (i.e., to detect errors or inaccuracies). (**Potential for unintended consequences - misrepresentation**)

Instructions will be explicit that reporting this quality measure requires accompanying documentation in the medical record. All elements required for reporting must also be documented in the medical record. For example, use of exclusions requires specific documentation explaining the justification for exclusion.

- e. Describe how patient confidentiality is protected. (**Protects confidentiality**)

Confidentiality is an aspect of measure implementation, and not a property of the measure itself. We would expect that implementers of the measure would have appropriate safeguards in place to address the confidentiality of any data collected.

- f. Describe if this measure is harmonized with related measures. Describe how this measure is applicable to multiple levels, settings, and data sources? (**Harmonization**)

This measure was designed to reflect a comparable measure for TB screening for patients with HIV.

References

ⁱ Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis Rheum* 2008;59(6): 762---784.

ⁱⁱ Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. *Arth Rheum*. 2008; 58(1): 15-25.

ⁱⁱⁱ Michaud K, Messer J, Choi HK, Wolfe F. Direct medical costs and their predictors in patients with rheumatoid arthritis. *Arth Rheum*. 2003; 48(10): 2750-2762.

^{iv} MacLean CH, Louie R, Leake B, et al. Quality of care for patients with rheumatoid arthritis. *JAMA*. 2000; 284:984–992.

^v Yelin E, Such C, Criswell L, et al. Outcomes for persons with rheumatoid arthritis with a rheumatologist versus nonrheumatologist as the main physician for this condition. *Med Care*. 1998; 36:513–522.

^{vi} Ledingham J, Deighton C, on behalf of the British Society for Rheumatology Standards, Guidelines and Audit Working Group (SGAWG). Update on the British Society for Rheumatology guidelines for prescribing TNF α blockers in adults with rheumatoid arthritis (update of previous guidelines of April 2001). *Rheumatology*. 2005; 44: 157-163.

Candidate Measure Summary form

Project Name: Clinician Measure Development
 Submitter Name: NCQA
 Date Completed: 4/28/08

The purpose of this template is to provide a brief, high-level description of the candidate measure as well as the measure attributes using the measure evaluation criteria and subcriteria. This information will be used by the Technical Expert Panel to evaluate the proposed measures. In addition, if this measure is one of the final measures in the measure set, much of the information documented here can be transferred into the Measures Management System "Measure Information Form" as well as the National Quality Forum measure submission form. Complete one form for each measure.

Measure Set:	Rheumatoid Arthritis
Measure Name (should be brief, concise):	Rheumatoid Arthritis: Appropriate Use of Biologic Disease Modifying Anti-Rheumatic Drugs (DMARDs)
Measure Description:	Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis who have documentation of guideline criteria for appropriate use of biologic DMARDs prior to the first prescription.

Technical Specifications

Denominator

Denominator Statement: Patients 18 years and older with a diagnosis of Rheumatoid Arthritis (RA) and a first prescription for a biologic DMARD

Denominator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – Patient with first-time prescription for biologic DMARD therapy for RA

AND

ICD-9-CM Diagnosis code: 714.0, 714.1, 714.2, 714.81

Exclusions:

CPT Cat-II code (in development): XXXXF – Patient not receiving biologic DMARD therapy for RA

Medical reason (e.g., patient is not a candidate for non-biologic DMARDs due to any of the following: liver disease, alcohol use, renal insufficiency, GI intolerance, toxicity to non-biologic DMARDs)

XXXXF-1P

Numerator

Numerator Statement: Patients with documentation of guideline criteria for appropriate use of biologic DMARDs during the one month prior to a first prescription

Numerator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – Documentation of high disease activity AND disease duration ≥ 3 months documented in the one month prior to first prescription for a biologic DMARD

OR

CPT Cat-II code (in development): XXXXF – Documentation of high disease activity AND duration for < 3 months and features of poor prognosis in the one month prior to first prescription for a biologic DMARD

OR

CPT Cat-II code (in development): XXXXF – Documentation of moderate disease activity AND disease duration ≥ 6 months and features of poor prognosis in the one month prior to first prescription for a biologic DMARD

Definition:

Disease duration: time from symptom onset

Exclusions: None

Type of Measure: Process

Data source: Medical Record, Administrative Claims, Electronic Medical Record, Administrative Claims supplemented by Medical Records

Unit of Measurement: Clinician

Measure Care Setting: Ambulatory

Measure Source:

New

Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)

Adopted (if adopted, provide name of original measure)

Measure Justification

Rationale: (describe succinctly the overall reasoning behind the use of this measure):

While the majority of patients with diagnosed RA should have a prescription for a disease modifying anti-rheumatic drug (DMARD), the rate and costs of biologic DMARDs are rising rapidly. Recently developed recommendations from the American College of Rheumatology provide guidance on the judicious use of biologic DMARDs and suggest appropriateness criteria for consideration prior to a new prescription based on clinical evidence and expert panel input.¹

I. Importance

- a. Describe how measure addresses a national health goal or priority area **OR** focuses on high impact aspect of health care (**epidemiological relevance, financial relevance, policy relevance**)

Before publishing an endorsed quality indicator set in 2006, the American College of Rheumatology assessed rates for the quality indicators in a population of 568 patients with RA. While rates were high for certain quality indicators (98% of patients received at least one joint examination), the rates for other indicators were substantially lower. Seventy four percent of patients received a physician global assessment and 79% received a patient global assessment. Treatment rates were also not optimal – 85% of patients received a disease modifying antirheumatic drug (DMARD). Despite guideline recommendations that suggest a patient should receive some adjustment in treatment after six months of maintained or increased disease activity, only 50% of patients in the study received a DMARD adjustment after at least one documented increase in disease activity. For patients who had a documented increase in disease activity twice within one year, 64% received a DMARD adjustment.ⁱⁱ In another study of 377 patients with RA, 50% of patients with persistent disease activity received a change in DMARD medication or dose within six months of meeting criteria for severe disease activity (the rate was 23% for those meeting criteria for moderate disease activity). Within one year of meeting criteria for severe disease activity, 68% of patients had received a change in DMARD medication or dose (the rate was 34% for those meeting criteria for moderate disease activity).ⁱⁱⁱ

Policy relevance

Improving quality in rheumatoid arthritis care falls under the IOM priority area of Living with Illness/Disability. The other area of policy relevance is the changing landscape of medical risks versus benefits of the therapeutic options for RA treatment. This is especially important with the introduction of biopharmaceuticals.

Clinical or Epidemiologic Relevance

RA is a multisystem disorder of unknown etiology, characterized by chronic destructive synovitis. The current national estimate of prevalence of RA, using 2005 population estimates from the Census Bureau, is that 1,293,000 American adults age ≥ 18 years (0.6%) have RA. This estimate is lower than prior estimates due to stricter disease classification criteria. The prevalence in women is approximately double that in men (1.06% vs. 0.61%), and the average age of persons with prevalent RA has increased steadily over time, from 63.3 years in 1965 to 66.8 years in 1995, suggesting that RA is becoming a disease of older adults^{iv}.

Financial relevance

The costs of RA are increasing because of the introduction and increasing use of biologic therapy. The mean total annual direct medical care cost in 2001 for a patient with RA was \$9,519. Drug costs were \$6,324 (66% of the total), while hospitalization costs were only \$1,573 (17%). Approximately 25% of patients received biologic therapy. The mean total annual direct cost for patients receiving biologic agents was \$19,016 per year, while the costs for those not receiving biologic therapy was \$6,164. The remaining 16% of total costs includes outpatient services such as outpatient surgery, physician and health professional encounters, x-rays, MRI and CT scans and other laboratory testing. Medicare patients incur a high rate of out-of-pocket drug costs; 46% of Medicare patients paid greater than 25% of

their drug expenses. The key clinical factors in predicting future costs are functional disability and comorbidity^v.

- b. Describe how data demonstrate considerable variation **OR** poor performance across providers **OR** population groups. (**Opportunity for improvement**)

While there are a limited number of studies that investigate gaps in care for patients with rheumatoid arthritis, the research that does exist identifies opportunities for improvement in several care areas: 1) there is a lack of adherence to RA guidelines, most noticeably in the use of disease-modifying antirheumatic drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

One study analyzed quality of care for 1,355 patients with rheumatoid arthritis using data from a national health plan. Using process measures, the study found that patients with rheumatoid arthritis often did not receive the recommended care suggested by clinical guidelines (for each person-year, recommended processes of care for rheumatoid arthritis were performed an average 62% of the time). The study also found that the quality of care provided to patients with RA varied according to provider type (patients seeing a rheumatologist had higher quality care than those seeing a primary care physician).^{vi} Similar results were reported by a cohort study of 1,025 patients with RA. Based on certain outcome measures (including pain rating, number of painful joints, and functional status), patients with a rheumatologist as their RA physician had significantly better outcomes than patients whose main RA physician was a non-rheumatologist.^{vii}

II. Scientific Acceptability

- a. Describe how the specific outcome, intermediate outcome, process, or structure is consistent with/clinical practice guidelines. Provide guideline citation with USPSTF grade of evidence/recommendation. Discuss any contradictory guidelines or evidence. (**Strength of evidence base**)

American College of Rheumatology

Patients must:

1. Fulfill the 1987 criteria of the American College of Rheumatology classification criteria for a diagnosis of RA.
2. Have active RA (have a DAS28 score of >5.1). Measurements of disease activity should be made at two points, 1 month apart confirming on-going active disease.
3. Have failed standard therapy as defined by failure to respond or tolerate adequate therapeutic trials of at least two standard disease-modifying anti-rheumatic drugs (DMARDs)— intramuscular gold, hydroxychloroquine, sulphasalazine, penicillamine, azathioprine, methotrexate or leflunomide). One of the failed or not tolerated therapies must be methotrexate.

Adequate therapeutic trial is defined as:

(a) Treatment for at least 6 months, with at least 2 months at a standard target dose unless significant toxicity limited the dose tolerated.

(b) Treatment for less than 6 months where treatment was withdrawn because of drug intolerance or toxicity, but normally after at least 2 months at therapeutic doses.

There may be circumstances when other DMARDs are relatively contraindicated, so that anti-TNF therapy may be considered very early in the course of the disease, and in patients in whom methotrexate has not been used. There are data to support these approaches with anti-TNF therapies working well in trials of early RA and in DMARD-naïve patients. However, it is anticipated that in clinical practice it will be rare that circumstances arise necessitating use of anti-TNF therapy as a first-line therapyⁱ.

National Institute for Health and Clinical Excellence

The tumour necrosis factor alpha (TNF-a) inhibitors adalimumab, etanercept and infliximab are recommended as options for the treatment of adults who have both of the following characteristics: Active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart; Have undergone trials of two disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated). A trial of a DMARD is defined as being normally of 6 months, with 2 months at standard dose, unless significant toxicity has limited the dose or duration of treatment.^{viii} (Level of evidence C)

- b. Describe the science underlying the measure concepts; the extent to which the scientific evidence underlying the measure is stable. **(Stability)**

According to the Expert Workgroup, this is an area where the scientific evidence underlying the measure is stable enough to develop measures.

- c. Describe measure reliability testing and results, using a methodology appropriate to the measure type. If the measure has not been tested, plans for testing have been presented. **(Reliability)**

Full evaluation of reliability and validity can only be assessed through large scale implementation of measures. This is a lengthy and expensive process, and has not been requested by CMS. However, NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development.

- d. Describe process for evaluating the face validity as representing the quality of care. Describe testing of the measure providing evidence of the validity of conclusion about quality and the data from testing OR use of the measure demonstrate variation OR poor performance. If the measure has not been tested, plans for testing have been presented. **(Validity)**

NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development to demonstrate variation and room for improvement. We tested face validity through evaluation by an Expert Work Group and will

further collect comments on face validity through a broadly publicized public comment process and focus group interviews with clinicians.

- e. Describe rationale including evidence-base as to why any exclusions are necessary and appropriate. (**Precision of specifications**)

Medical Exclusion: The work group determined there are one or more clinical reasons for excluding a patient from the denominator of this measure. There are clinical reasons why a patient might be started on a biologic-DMARD, but does not meet the established guideline criteria. These reasons include the patient not being a candidate for a non-biologic DMARD due to any of the following: liver disease, alcohol use, renal insufficiency, GI intolerance, toxicity to non-biologic DMARDs

- f. (**Outcome measures**) Summarize the testing done to determine the need (or non need) for risk adjustment and the statistical performance of the risk adjustment method. (**Adequacy of Risk Adjustment**)

N/A – process measure

- g. If results are stratified by population characteristics, to detect disparities in care/outcome, describe rationale including evidence. (**Adequacy of Risk Adjustment**)

While many measures can be sensitive to disparities, these measures have not been specifically tested or specified for the ability to detect disparities in care.

III. Usability

- a. Describe how measure is/can be actionable by users such as providers, public, purchasers etc. (**Actionability**)

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives. We also expect the results from these measures to be relevant and usable by payers for value-based purchasing, and by consumers through report cards.

- b. Describe how the measure provides a distinctive or additive value to existing measures (**Actionability**)

These measures address areas of care that are not currently addressed in existing measure sets.

- c. If measure is in current use, describe how real difference in performance can be identified/interpreted with comparative data. (**Actionability**)

Measure is not in current use.

- d. Describe testing done to determine if information produced by the measure is meaningful and understandable to audiences. (**Actionability**)

We are not planning to conduct formal usability testing to determine if the information produced by the measure is meaningful and understandable to audiences.

- e. Describe the extent to which processes and outcomes related to this measure are under the control of the entity being measured. (**Controllability**)

These provider-level measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives, and are assumed to be under the influence or control of the clinician being measured.

- f. Describe the extent to which the measure is adaptable to multiple populations or can be applied across various healthcare settings. (**Adaptability**).

This measure has been specified for use in the population and setting described above, and has not been evaluated for use beyond the specified population and setting.

IV. Feasibility

- a. Describe the where and how during routine care delivery data can be obtained and if electronic information can be used for this measure. (**Burden of data collection**)

The measure has been specified to rely largely on administrative data collected during routine care and billing. Additional data elements will be collected through CPT Category II codes, which are coded at the point of care. We anticipate that the cost or administrative burden for this measure is equivalent to the burden associated with other NCQA or PCPI measures used in similar settings.

- b. Describe how the testing OR use of the measure demonstrates the data collection strategy (timing, frequency, and sampling) can be implemented. (**Burden of data collection**)

The feasibility of data collection will be evaluated during pilot testing

- c. Describe how the information provided by the measure outweighs the cost/burden of data collection. (**Cost/benefit**)

We have not directly evaluated either the value of the measure or the cost of data collection. However, we do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- d. The data items are auditable (i.e., to detect errors or inaccuracies). (**Potential for unintended consequences - misrepresentation**)

Instructions will be explicit that reporting this quality measure requires accompanying documentation in the medical record. All elements required for reporting must also be documented in the medical record. For example, use of exclusions requires specific documentation explaining the justification for exclusion.

- e. Describe how patient confidentiality is protected. (**Protects confidentiality**)

Confidentiality is an aspect of measure implementation, and not a property of the measure itself. We would expect that implementers of the measure would have appropriate safeguards in place to address the confidentiality of any data collected.

- f. Describe if this measure is harmonized with related measures. Describe how this measure is applicable to multiple levels, settings, and data sources? (**Harmonization**)

There are no similar measures with which to harmonize.

References

ⁱ Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis Rheum* 2008;59(6): 762--784.

ⁱⁱ Kahn KL, Maclean CH, Wong AL, et al. Assessment of American College of Rheumatology quality criteria for rheumatoid arthritis in a prequality criteria patient cohort. *Arthritis Rheum*. 2007; 57:707–715.

ⁱⁱⁱ Kahn KL, MacLean CH, Liu H, et al. Application of explicit process of care measurement to rheumatoid arthritis: moving from evidence to practice. *Arthritis Rheum*. 2006; 55:884–891.

^{iv} Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. *Arth Rheum*. 2008; 58(1): 15-25.

^v Michaud K, Messer J, Choi HK, Wolfe F. Direct medical costs and their predictors in patients with rheumatoid arthritis. *Arth Rheum*. 2003; 48(10): 2750-2762.

^{vi} MacLean CH, Louie R, Leake B, et al. Quality of care for patients with rheumatoid arthritis. *JAMA*. 2000; 284:984–992.

^{vii} Yelin E, Such C, Criswell L, et al. Outcomes for persons with rheumatoid arthritis with a rheumatologist versus nonrheumatologist as the main physician for this condition. *Med Care*. 1998; 36:513–522.

^{viii} National Institute for Health and Clinical Excellence. 2007. Available online at <http://www.nice.org.uk/guidance/index.jsp?action=download&o=37916>. [Accessed March 27, 2008]

Candidate Measure Summary form

Project Name: Clinician Measure Development
 Submitter Name: NCQA
 Date Completed: 4/28/08

The purpose of this template is to provide a brief, high-level description of the candidate measure as well as the measure attributes using the measure evaluation criteria and subcriteria. This information will be used by the Technical Expert Panel to evaluate the proposed measures. In addition, if this measure is one of the final measures in the measure set, much of the information documented here can be transferred into the Measures Management System "Measure Information Form" as well as the National Quality Forum measure submission form. Complete one form for each measure.

Measure Set:	Rheumatoid Arthritis
Measure Name <i>(should be brief, concise):</i>	Rheumatoid Arthritis: Periodic Assessment of Disease Activity
Measure Description:	Percentage of patients 18 years and older with at least one outpatient visit and a diagnosis of rheumatoid arthritis (RA) with assessment and classification of disease activity

Technical Specifications

Denominator

Denominator Statement: Patients 18 years and older with at least one outpatient visit and a diagnosis of Rheumatoid Arthritis (RA)

Denominator Inclusions/Exclusions:

Inclusions:

ICD-9-CM Diagnosis code: 714.0, 714.1, 714.2, 714.81

AND

Visit code: 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99455, 99456

Exclusions:

Outpatient visits for injections and/or infusions.

Numerator

Numerator Statement: Disease activity assessed by a standardized descriptive or numeric scale or composite index into one of the following categories: low, moderate or high, at least once during the measurement year

Numerator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – RA disease activity, low

OR

CPT Cat-II code (in development): XXXXF – RA disease activity, moderate

OR

CPT Cat-II code (in development): XXXXF – RA disease activity, high

Exclusions: None

Definition:

Standardized descriptive or numeric scales and/or composite indexes could include but are not limited to: DAS28, SDAI, CDAI, RADA, RAPID

Type of Measure: Process

Data source: Medical Record, Administrative Claims, Electronic Medical Record, Administrative Claims supplemented by Medical Records

Unit of Measurement: Clinician

Measure Care Setting: Ambulatory

Measure Source:

- New
- Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)
- Adopted (if adopted, provide name of original measure)

Measure Justification

Rationale: (describe succinctly the overall reasoning behind the use of this measure):

After establishing a diagnosis of RA, risk assessment is crucial for guiding optimal treatment. For the purposes of selecting therapies, physicians should consider the patient's disease activity at the time of the treatment decisions.¹

I. Importance

- a. Describe how measure addresses a national health goal or priority area **OR** focuses on high impact aspect of health care (**epidemiological relevance, financial relevance, policy relevance**)

Policy relevance

Improving quality in rheumatoid arthritis care falls under the IOM priority area of Living with Illness/Disability. The other area of policy relevance is the changing landscape of medical risks versus benefits of the therapeutic options for RA treatment. This is especially important with the introduction of biopharmaceuticals.

Clinical or Epidemiologic Relevance

RA is a multisystem disorder of unknown etiology, characterized by chronic destructive synovitis. The current national estimate of prevalence of RA, using 2005 population estimates from the Census Bureau, is that 1,293,000 American adults age ≥ 18 years (0.6%) have RA. This estimate is lower than prior estimates due to stricter disease classification criteria. The prevalence in women is approximately double that in men (1.06% vs. 0.61%), and the average age of persons with prevalent RA has increased steadily over time, from 63.3 years in 1965 to 66.8 years in 1995, suggesting that RA is becoming a disease of older adultsⁱⁱ.

Financial relevance

The costs of RA are increasing because of the introduction and increasing use of biologic therapy. The mean total annual direct medical care cost in 2001 for a patient with RA was \$9,519. Drug costs were \$6,324 (66% of the total), while hospitalization costs were only \$1,573 (17%). Approximately 25% of patients received biologic therapy. The mean total annual direct cost for patients receiving biologic agents was \$19,016 per year, while the costs for those not receiving biologic therapy was \$6,164. The remaining 16% of total costs includes outpatient services such as outpatient surgery, physician and health professional encounters, x-rays, MRI and CT scans and other laboratory testing. Medicare patients incur a high rate of out-of-pocket drug costs; 46% of Medicare patients paid greater than 25% of their drug expenses. The key clinical factors in predicting future costs are functional disability and comorbidityⁱⁱⁱ.

- b. Describe how data demonstrate considerable variation **OR** poor performance across providers **OR** population groups. (**Opportunity for improvement**)

While no published data regarding a quality gap or variation in performance are available for this measure topic, the work group was in consensus that this is an aspect of care that is not regularly performed for all patients. Through implementation and testing of this measure, it is expected that we will be able to collect data that will help us demonstrate whether or not a gap in care or variation in performance exists.

II. Scientific Acceptability

- a. Describe how the specific outcome, intermediate outcome, process, or structure is consistent with/clinical practice guidelines. Provide guideline citation with USPSTF grade of evidence/recommendation. Discuss any contradictory guidelines or evidence. (**Strength of evidence base**)

Several indices to measures RA disease activity have been developed each of which has advantages and disadvantages. Evidence-based guidelines require clear definitions of disease activity to make rationale therapeutic choices, but it is not possible or appropriate to mandate use of a single disease activity score for the individual physician, and different studies have used different definitions. Therefore, the TFP was asked to consider a combined estimation of disease activity, which allowed reference too many past definitions. With these instruments as our guide, we rated RA disease activity in an ordinal manner as low, moderate, or high, as previously requested by the CEP.^{iv}

- b. Describe the science underlying the measure concepts; the extent to which the scientific evidence underlying the measure is stable. (**Stability**)

According to the Expert Workgroup, this is an area where the scientific evidence underlying the measure is stable enough to develop measures.

- c. Describe measure reliability testing and results, using a methodology appropriate to the measure type. If the measure has not been tested, plans for testing have been presented. **(Reliability)**

Full evaluation of reliability and validity can only be assessed through large scale implementation of measures. This is a lengthy and expensive process, and has not been requested by CMS. However, NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development.

- d. Describe process for evaluating the face validity as representing the quality of care. Describe testing of the measure providing evidence of the validity of conclusion about quality and the data from testing OR use of the measure demonstrate variation OR poor performance. If the measure has not been tested, plans for testing have been presented. **(Validity)**

NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development to demonstrate variation and room for improvement. We tested face validity through evaluation by an Expert Work Group and will further collect comments on face validity through a broadly publicized public comment process and focus group interviews with clinicians.

- e. Describe rationale including evidence-base as to why any exclusions are necessary and appropriate. **(Precision of specifications)**

None

- f. **(Outcome measures)** Summarize the testing done to determine the need (or non need) for risk adjustment and the statistical performance of the risk adjustment method. **(Adequacy of Risk Adjustment)**

N/A – process measure

- g. If results are stratified by population characteristics, to detect disparities in care/outcome, describe rationale including evidence. **(Adequacy of Risk Adjustment)**

While many measures can be sensitive to disparities, these measures have not been specifically tested or specified for the ability to detect disparities in care.

III. Usability

- a. Describe how measure is/can be actionable by users such as providers, public, purchasers etc. **(Actionability)**

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives. We also expect

the results from these measures to be relevant and usable by payers for value-based purchasing, and by consumers through report cards.

Describe how the measure provides a distinctive or additive value to existing measures (**Actionability**)

These measures address areas of care that are not currently addressed in existing measure sets.

- b. If measure is in current use, describe how real difference in performance can be identified/interpreted with comparative data. (**Actionability**)

Measure is not in current use.

- c. Describe testing done to determine if information produced by the measure is meaningful and understandable to audiences. (**Actionability**)

We are not planning to conduct formal usability testing to determine if the information produced by the measure is meaningful and understandable to audiences.

- d. Describe the extent to which processes and outcomes related to this measure are under the control of the entity being measured. (**Controllability**)

These provider-level measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives, and are assumed to be under the influence or control of the clinician being measured.

- e. Describe the extent to which the measure is adaptable to multiple populations or can be applied across various healthcare settings. (**Adaptability**).

This measure has been specified for use in the population and setting described above, and has not been evaluated for use beyond the specified population and setting.

IV. Feasibility

- a. Describe the where and how during routine care delivery data can be obtained and if electronic information can be used for this measure. (**Burden of data collection**)

The measure has been specified to rely largely on administrative data collected during routine care and billing. Additional data elements will be collected through CPT Category II codes, which are coded at the point of care. We anticipate that the cost or administrative burden for this measure is equivalent to the burden associated with other NCQA or PCPI measures used in similar settings.

- b. Describe how the testing OR use of the measure demonstrates the data collection strategy (timing, frequency, and sampling) can be implemented. **(Burden of data collection)**

The feasibility of data collection will be evaluated during pilot testing

- c. Describe how the information provided by the measure outweighs the cost/burden of data collection. **(Cost/benefit)**

We have not directly evaluated either the value of the measure or the cost of data collection. However, we do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- d. The data items are auditable (i.e., to detect errors or inaccuracies). **(Potential for unintended consequences - misrepresentation)**

Instructions will be explicit that reporting this quality measure requires accompanying documentation in the medical record. All elements required for reporting must also be documented in the medical record. For example, use of exclusions requires specific documentation explaining the justification for exclusion.

- e. Describe how patient confidentiality is protected. **(Protects confidentiality)**

Confidentiality is an aspect of measure implementation, and not a property of the measure itself. We would expect that implementers of the measure would have appropriate safeguards in place to address the confidentiality of any data collected.

- f. Describe if this measure is harmonized with related measures. Describe how this measure is applicable to multiple levels, settings, and data sources? **(Harmonization)**

There are no similar measures with which to harmonize.

References

ⁱ Saag KG, Teng GG, Patkar NM, Anuntiyoy J, Finney C, Curtis JR, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis Rheum* 2008;59(6): 762---784.

ⁱⁱ Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. *Arth Rheum*. 2008; 58(1): 15-25.

ⁱⁱⁱ Michaud K, Messer J, Choi HK, Wolfe F. Direct medical costs and their predictors in patients with rheumatoid arthritis. *Arth Rheum*. 2003; 48(10): 2750-2762.

^{iv} Saag KG, Teng GG, Patkar NM, Anuntiyoy J, Finney C, Curtis JR, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis Rheum* 2008;59(6): 762---784.

Candidate Measure Summary form

Project Name: Clinician Measure Development
 Submitter Name: NCQA
 Date Completed: 4/10/08

The purpose of this template is to provide a brief, high-level description of the candidate measure as well as the measure attributes using the measure evaluation criteria and subcriteria. This information will be used by the Technical Expert Panel to evaluate the proposed measures. In addition, if this measure is one of the final measures in the measure set, much of the information documented here can be transferred into the Measures Management System "Measure Information Form" as well as the National Quality Forum measure submission form. Complete one form for each measure.

Measure Set:	Rheumatoid Arthritis
Measure Name <i>(should be brief, concise)</i> :	Rheumatoid Arthritis: Functional Status Assessment
Measure Description:	Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have functional status assessed at least once during the measurement year.

Technical Specifications

Denominator

Denominator Statement: Patients 18 years and older with a diagnosis of rheumatoid arthritis (RA)

Denominator Inclusions/Exclusions:

Inclusions:

ICD-9-CM Diagnosis code: 714.0, 714.1, 714.2, 714.81

Exclusions: None

Numerator

Numerator Statement: Patients with functional status assessed (documentation of an assessment using a standardized descriptive or numeric scale, standardized questionnaire, or notation of assessment of the impact of RA on patient activities of daily living) at least once during the measurement year

Definition:

Examples of tools used to assess functional status include: Health Assessment Questionnaire (HAQ), Modified HAQ, HAQ-2; American College of Rheumatology's Classification of Functional Status in Rheumatoid Arthritis

Activities of Daily Living: could include a description of any of the following: dressing/grooming, rising from sitting, walking/running/ability to ambulate, stairclimbing, reaching, gripping, shopping/running errands/house or yard work.

Numerator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – Functional status assessed

Exclusions: None

Type of Measure: Process

Data source: Medical Record, Administrative Claims, Electronic Medical Record, Administrative Claims supplemented by Medical Records

Unit of Measurement: Clinician

Measure Care Setting: Ambulatory

Measure Source:

- New
- Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)
- Adopted (if adopted, provide name of original measure)

Measure Justification

Rationale: (describe succinctly the overall reasoning behind the use of this measure):

Functional limitations are a significant and disruptive complication for patients living with RA. Assessments of functional limitations are used to assess prognosis and guide treatment and therapy decisions. Functional status should be assessed at the baseline and each follow-up visit, using questionnaires such as the Arthritis Impact Measurement Scales or the Health Assessment Questionnaire. Regardless of the assessment tool used, it should indicate whether a functional decline is due to inflammation, mechanical damage, or both, as treatment strategies will vary accordingly.ⁱ

I. Importance

- a. Describe how measure addresses a national health goal or priority area OR focuses on high impact aspect of health care (**epidemiological relevance, financial relevance, policy relevance**)

Policy relevance

Improving quality in rheumatoid arthritis care falls under the IOM priority area of Living with Illness/Disability. The other area of policy relevance is the changing landscape of medical risks versus benefits of the therapeutic options for RA treatment. This is especially important with the introduction of biopharmaceuticals.

Clinical or Epidemiologic Relevance

RA is a multisystem disorder of unknown etiology, characterized by chronic destructive synovitis. The current national estimate of prevalence of RA, using 2005 population estimates from the Census Bureau, is that 1,293,000 American adults age ≥ 18 years (0.6%) have RA. This estimate is lower than prior estimates due to stricter disease classification criteria. The prevalence in women is approximately double that in men (1.06% vs. 0.61%), and the average age of persons with prevalent RA has increased steadily over time, from 63.3 years in 1965 to 66.8 years in 1995, suggesting that RA is becoming a disease of older adultsⁱⁱ.

Financial relevance

The costs of RA are increasing because of the introduction and increasing use of biologic therapy. The mean total annual direct medical care cost in 2001 for a patient with RA was \$9,519. Drug costs were \$6,324 (66% of the total), while hospitalization costs were only \$1,573 (17%). Approximately 25% of patients received biologic therapy. The mean total annual direct cost for patients receiving biologic agents was \$19,016 per year, while the costs for those not receiving biologic therapy was \$6,164. The remaining 16% of total costs includes outpatient services such as outpatient surgery, physician and health professional encounters, x-rays, MRI and CT scans and other laboratory testing. Medicare patients incur a high rate of out-of-pocket drug costs; 46% of Medicare patients paid greater than 25% of their drug expenses. The key clinical factors in predicting future costs are functional disability and comorbidityⁱⁱⁱ.

- b. Describe how data demonstrate considerable variation **OR** poor performance across providers **OR** population groups. (**Opportunity for improvement**)

While there are a limited number of studies that investigate gaps in care for patients with rheumatoid arthritis, the research that does exist identifies opportunities for improvement in several care areas: 1) there is a lack of adherence to RA guidelines, most noticeably in the use of disease-modifying antirheumatic drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

One study analyzed quality of care for 1,355 patients with rheumatoid arthritis using data from a national health plan. Using process measures, the study found that patients with rheumatoid arthritis often did not receive the recommended care suggested by clinical guidelines (for each person-year, recommended processes of care for rheumatoid arthritis were performed an average 62% of the time). The study also found that the quality of care provided to patients with RA varied according to provider type (patients seeing a rheumatologist had higher quality care than those seeing a primary care physician).^{iv} Similar results were reported by a cohort study of 1,025 patients with RA. Based on certain outcome measures (including pain rating, number of painful joints, and functional status), patients with a rheumatologist as their RA physician had significantly better outcomes than patients whose main RA physician was a non-rheumatologist.^v

Variation and room for improvement will be demonstrated for this measure during pilot testing

II. Scientific Acceptability

- a. Describe how the specific outcome, intermediate outcome, process, or structure is consistent with/clinical practice guidelines. Provide guideline citation with USPSTF grade of evidence/recommendation. Discuss any contradictory guidelines or evidence. (**Strength of evidence base**)

American College of Rheumatology Guidelines

The management of RA is an iterative process, and patients should be periodically reassessed for evidence of disease or limitation of function with significant alteration of joint anatomy. Baseline evaluation of disease activity and damage in patients with rheumatoid arthritis through evaluation of functional status or quality of life assessments using standardized questionnaires, a physician's global assessment of disease activity, or patient's global assessment of disease activity. The initial evaluation of the patient with RA should document symptoms of active disease (i.e., presence of joint pain, duration of morning stiffness, degree of fatigue), functional status, objective evidence of disease activity (i.e., synovitis, as assessed by tender and swollen joint counts, and the ESR or CRP level), mechanical joint problems, etc.

At each follow up visit, the physician must assess whether the disease is active or inactive. Symptoms of inflammatory (as contrasted with mechanical) joint disease, which include prolonged morning stiffness, duration of fatigue, and active synovitis on joint examination, indicate active disease and necessitate consideration of changing the treatment program. Occasionally, findings of the joint examination alone may not adequately reflect disease activity and structural damage; therefore, periodic measurements of the ESR or CRP level and functional status, as well as radiographic examinations of involved joints should be performed. Functional status may be determined by questionnaires such as the Arthritis Impact Measurement Scales (32) or the Health Assessment Questionnaire (33). It is important to determine whether a decline in function is the result of inflammation, mechanical damage, or both; treatment strategies will differ accordingly.

- b. Describe the science underlying the measure concepts; the extent to which the scientific evidence underlying the measure is stable. **(Stability)**

According to the Expert Workgroup, this is an area where the scientific evidence underlying the measure is relatively stable.

- c. Describe measure reliability testing and results, using a methodology appropriate to the measure type. If the measure has not been tested, plans for testing have been presented. **(Reliability)**

Full evaluation of reliability and validity can only be assessed through large scale implementation of measures. This is a lengthy and expensive process, and has not been requested by CMS. However, NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development.

- d. Describe process for evaluating the face validity as representing the quality of care. Describe testing of the measure providing evidence of the validity of conclusion about quality and the data from testing OR use of the measure demonstrate variation OR poor performance. If the measure has not been tested, plans for testing have been presented. **(Validity)**

NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development to demonstrate variation and room for improvement. We tested face validity through evaluation by an Expert Workgroup, and will further collect comments on face validity through a broadly publicized public comment process and focus group interviews with clinicians.

- e. Describe rationale including evidence-base as to why any exclusions are necessary and appropriate. (**Precision of specifications**)

No exclusions.

- f. (**Outcome measures**) Summarize the testing done to determine the need (or non need) for risk adjustment and the statistical performance of the risk adjustment method. (**Adequacy of Risk Adjustment**)

N/A – process measure.

- g. If results are stratified by population characteristics, to detect disparities in care/outcome, describe rationale including evidence. (**Adequacy of Risk Adjustment**)

While many measures can be sensitive to disparities, these measures have not been specifically tested or specified for ability to detect disparities in care.

III. Usability

- a. Describe how measure is/can be actionable by users such as providers, public, purchasers etc. (**Actionability**)

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives. We also expect the results from these measures to be relevant and usable by payers for value-based purchasing, and by consumers through report cards.

- b. Describe how the measure provides a distinctive or additive value to existing measures (**Actionability**)

These measures address areas of care that are not currently addressed in existing measure sets.

- c. If measure is in current use, describe how real difference in performance can be identified/interpreted with comparative data. (**Actionability**)

Measure is not in current use.

- d. Describe testing done to determine if information produced by the measure is meaningful and understandable to audiences. (**Actionability**)

We are not planning to conduct formal usability testing to determine if the information produced by the measure is meaningful and understandable to audiences.

- e. Describe the extent to which processes and outcomes related to this measure are under the control of the entity being measured. (**Controllability**)

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives, and are assumed to be under the influence or control of the clinician being measured.

- f. Describe the extent to which the measure is adaptable to multiple populations or can be applied across various healthcare settings. (**Adaptability**).

This measure has been specified for use in the population and setting described above, and has not been evaluated for use beyond the specified population and setting.

IV. Feasibility

- a. Describe the where and how during routine care delivery data can be obtained and if electronic information can be used for this measure. (**Burden of data collection**)

The measure has been specified to rely largely on administrative data collected during routine care and billing. Additional data elements will be collected through CPT Category II codes, which are coded at the point of care. We do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- b. Describe how the testing OR use of the measure demonstrates the data collection strategy (timing, frequency, and sampling) can be implemented. (**Burden of data collection**)

The feasibility of data collection will be evaluated during pilot testing

- c. Describe how the information provided by the measure outweighs the cost/burden of data collection. (**Cost/benefit**)

We have not directly evaluated either the value of the measure or the cost of data collection. However, we do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- d. The data items are auditable (i.e., to detect errors or inaccuracies). (**Potential for unintended consequences - misrepresentation**)

Instructions will be explicit that reporting this quality measure requires accompanying documentation in the medical record. All elements required for reporting must also be

documented in the medical record. For example, use of exclusions requires specific documentation explaining the justification for exclusion.

- e. Describe how patient confidentiality is protected. (**Protects confidentiality**)

Confidentiality is an aspect of measure implementation, and not a property of the measure itself. We would expect that implementers of the measure would have appropriate safeguards in place to address the confidentiality of any data collected.

- f. Describe if this measure is harmonized with related measures. Describe how this measure is applicable to multiple levels, settings, and data sources? (**Harmonization**)

This measure is structured to be similar to the Osteoarthritis Pain and Functional Status measure, however; because the denominator criteria are different, we have only harmonized the numerator criteria.

References

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- ⁱ American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. *Arth Rheum*. 2002; 46(2):328-346.
- ⁱⁱ Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. *Arth Rheum*. 2008; 58(1): 15-25.
- ⁱⁱⁱ Michaud K, Messer J, Choi HK, Wolfe F. Direct medical costs and their predictors in patients with rheumatoid arthritis. *Arth Rheum*. 2003; 48(10): 2750-2762.
- ^{iv} MacLean CH, Louie R, Leake B, et al. Quality of care for patients with rheumatoid arthritis. *JAMA*. 2000; 284:984–992.
- ^v Yelin E, Such C, Criswell L, et al. Outcomes for persons with rheumatoid arthritis with a rheumatologist versus nonrheumatologist as the main physician for this condition. *Med Care*. 1998; 36:513–522.

Candidate Measure Summary form

Project Name: Clinician Measure Development
 Submitter Name: NCQA
 Date Completed: 4/10/08

The purpose of this template is to provide a brief, high-level description of the candidate measure as well as the measure attributes using the measure evaluation criteria and subcriteria. This information will be used by the Technical Expert Panel to evaluate the proposed measures. In addition, if this measure is one of the final measures in the measure set, much of the information documented here can be transferred into the Measures Management System "Measure Information Form" as well as the National Quality Forum measure submission form. Complete one form for each measure.

Measure Set:	Rheumatoid Arthritis
Measure Name (should be brief, concise):	Rheumatoid Arthritis: Glucocorticoid Dose
Measure Description:	Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis (RA) with documentation of glucocorticoid dose at least once during the measurement year

Technical Specifications

Denominator

Denominator Statement: Patients 18 years and older with a diagnosis of rheumatoid arthritis (RA).

Denominator Inclusions/Exclusions:

Inclusions:

ICD-9-CM Diagnosis code: 714.0, 714.1, 714.2, 714.81

Exclusions:

Medical reason (i.e., glucocorticoid prescription is for a medical condition other than RA)
 XXXXF-1P

Numerator

Numerator Statement: Percentage of patients with documentation of glucocorticoid dose at least once during the measurement year (measure is stratified by prednisone equivalent dose category: 1-4mg, 5-9mg, 10-19mg, and >20mg)

Numerator Inclusions/Exclusions:

Inclusions:

- CPT Cat-II code (in development): XXXXF – No glucocorticoid prescription
- CPT Cat-II code (in development): XXXXF – Prednisone equivalent dose; 1-4mg
- CPT Cat-II code (in development): XXXXF – Prednisone equivalent dose; 5-9mg
- CPT Cat-II code (in development): XXXXF – Prednisone equivalent dose; 10-19mg
- CPT Cat-II code (in development): XXXXF – Prednisone equivalent dose; ≥20mg

Definitions:

Prednisone equivalents can be determined using the following:

1 mg of prednisone = 1 mg of prednisolone; 5 mg of cortisone; 4 mg of hydrocortisone; 0.8 mg of triamcinolone; 0.8 mg of methylprednisolone; 0.15 mg of dexamethasone; 0.15 mg of betamethasoneⁱ

Exclusions: None

Type of Measure: Process

Data source: Medical Record, Administrative Claims, Electronic Medical Record, Administrative Claims supplemented by Medical Records

Unit of Measurement: Clinician

Measure Care Setting: Ambulatory

Measure Source:

New

Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)

Adopted (if adopted, provide name of original measure)

Measure Justification

Rationale: (describe succinctly the overall reasoning behind the use of this measure):

Glucocorticoids are an important part of RA treatment as they inhibit inflammation and may control synovitis. However, long-term use of glucocorticoids, especially at high doses, should be avoided, due to the potential health complications. Monitoring length and dose of glucocorticoid treatment for patients with RA is integral to making other clinical decisions (e.g., prescribing vitamin D and calcium supplements, initiating antiresorptive therapy, ordering a dual energy X-ray absorptiometry scan to assess bone mineral density, and tapering the steroid dose)^{ii,iii}.

I. Importance

- a. Describe how measure addresses a national health goal or priority area **OR** focuses on high impact aspect of health care (**epidemiological relevance, financial relevance, policy relevance**)

Policy relevance

Improving quality in rheumatoid arthritis care falls under the IOM priority area of Living with Illness/Disability. The other area of policy relevance is the changing landscape of medical risks versus benefits of the therapeutic options for RA treatment. This is especially important with the introduction of biopharmaceuticals.

Clinical or Epidemiologic Relevance

RA is a multisystem disorder of unknown etiology, characterized by chronic destructive synovitis. The current national estimate of prevalence of RA, using 2005 population

estimates from the Census Bureau, is that 1,293,000 American adults age ≥ 18 years (0.6%) have RA. This estimate is lower than prior estimates due to stricter disease classification criteria. The prevalence in women is approximately double that in men (1.06% vs. 0.61%), and the average age of persons with prevalent RA has increased steadily over time, from 63.3 years in 1965 to 66.8 years in 1995, suggesting that RA is becoming a disease of older adults^{iv}.

Financial relevance

The costs of RA are increasing because of the introduction and increasing use of biologic therapy. The mean total annual direct medical care cost in 2001 for a patient with RA was \$9,519. Drug costs were \$6,324 (66% of the total), while hospitalization costs were only \$1,573 (17%). Approximately 25% of patients received biologic therapy. The mean total annual direct cost for patients receiving biologic agents was \$19,016 per year, while the costs for those not receiving biologic therapy was \$6,164. The remaining 16% of total costs includes outpatient services such as outpatient surgery, physician and health professional encounters, x-rays, MRI and CT scans and other laboratory testing. Medicare patients incur a high rate of out-of-pocket drug costs; 46% of Medicare patients paid greater than 25% of their drug expenses. The key clinical factors in predicting future costs are functional disability and comorbidity^v.

- b. Describe how data demonstrate considerable variation **OR** poor performance across providers **OR** population groups. (**Opportunity for improvement**)

While there are a limited number of studies that investigate gaps in care for patients with rheumatoid arthritis, the research that does exist identifies opportunities for improvement in several care areas: 1) there is a lack of adherence to RA guidelines, most noticeably in the use of disease-modifying antirheumatic drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

One study analyzed quality of care for 1,355 patients with rheumatoid arthritis using data from a national health plan. Using process measures, the study found that patients with rheumatoid arthritis often did not receive the recommended care suggested by clinical guidelines (for each person-year, recommended processes of care for rheumatoid arthritis were performed an average 62% of the time). The study also found that the quality of care provided to patients with RA varied according to provider type (patients seeing a rheumatologist had higher quality care than those seeing a primary care physician).^{vi} Similar results were reported by a cohort study of 1,025 patients with RA. Based on certain outcome measures (including pain rating, number of painful joints, and functional status), patients with a rheumatologist as their RA physician had significantly better outcomes than patients whose main RA physician was a non-rheumatologist.^{vii}

II. Scientific Acceptability

- a. Describe how the specific outcome, intermediate outcome, process, or structure is consistent with/clinical practice guidelines. Provide guideline citation with USPSTF grade of evidence/recommendation. Discuss any contradictory guidelines or evidence. **(Strength of evidence base)**

The 1993 American College of Rheumatology guidelines acknowledge the importance of the use and the tracking of glucocorticoid as a RA symptom reliever. The benefits of low-dose systemic glucocorticoids, however, should always be weighed against their adverse effects. The adverse effects of long-term oral glucocorticoids at low doses are protean and include osteoporosis, hypertension, weight gain, fluid retention, hyperglycemia, cataracts, and skin fragility, as well as the potential for premature atherosclerosis. These adverse effects should be considered and should be discussed in detail with the patient before glucocorticoid therapy is begun. For long term disease control, the glucocorticoid dosage should be kept to a minimum. For the majority of patients with RA, this means equal or less than 10 mg of prednisone per day.^{viii}

- b. Describe the science underlying the measure concepts; the extent to which the scientific evidence underlying the measure is stable. **(Stability)**

According to the Expert Workgroup, this is an area where the scientific evidence underlying the measure is stable enough to develop measures.

- c. Describe measure reliability testing and results, using a methodology appropriate to the measure type. If the measure has not been tested, plans for testing have been presented. **(Reliability)**

Full evaluation of reliability and validity can only be assessed through large scale implementation of measures. This is a lengthy and expensive process, and has not been requested by CMS. However, NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development.

- d. Describe process for evaluating the face validity as representing the quality of care. Describe testing of the measure providing evidence of the validity of conclusion about quality and the data from testing OR use of the measure demonstrate variation OR poor performance. If the measure has not been tested, plans for testing have been presented. **(Validity)**

NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development to demonstrate variation and room for improvement. We tested face validity through evaluation by an Expert Work Group and will further collect comments on face validity through a broadly publicized public comment process and focus group interviews with clinicians.

- e. Describe rationale including evidence-base as to why any exclusions are necessary and appropriate. **(Precision of specifications)**

Medical Exclusion: The work group determined there are one or more clinical reasons for excluding a patient from the denominator of this measure. Examples of these clinical reasons include the patient utilizing a glucocorticoid for a reason other than RA treatment.

- f. (**Outcome measures**) Summarize the testing done to determine the need (or non need) for risk adjustment and the statistical performance of the risk adjustment method. (**Adequacy of Risk Adjustment**)

N/A – process measure

- g. If results are stratified by population characteristics, to detect disparities in care/outcome, describe rationale including evidence. (**Adequacy of Risk Adjustment**)

While many measures can be sensitive to disparities, these measures have not been specifically tested or specified for the ability to detect disparities in care.

III. Usability

- a. Describe how measure is/can be actionable by users such as providers, public, purchasers etc. (**Actionability**)

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives. We also expect the results from these measures to be relevant and usable by payers for value-based purchasing, and by consumers through report cards.

- b. Describe how the measure provides a distinctive or additive value to existing measures (**Actionability**)

These measures address areas of care that are not currently addressed in existing measure sets.

- c. If measure is in current use, describe how real difference in performance can be identified/interpreted with comparative data. (**Actionability**)

Measure is not in current use.

- d. Describe testing done to determine if information produced by the measure is meaningful and understandable to audiences. (**Actionability**)

We are not planning to conduct formal usability testing to determine if the information produced by the measure is meaningful and understandable to audiences.

- e. Describe the extent to which processes and outcomes related to this measure are under the control of the entity being measured. (**Controllability**)

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives, and are assumed to be under the influence or control of the clinician being measured.

- f. Describe the extent to which the measure is adaptable to multiple populations or can be applied across various healthcare settings. (**Adaptability**).

This measure has been specified for use in the population and setting described above, and has not been evaluated for use beyond the specified population and setting.

IV. Feasibility

- a. Describe the where and how during routine care delivery data can be obtained and if electronic information can be used for this measure. (**Burden of data collection**)

The measure has been specified to rely largely on administrative data collected during routine care and billing. Additional data elements will be collected through CPT Category II codes, which are coded at the point of care. We do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- b. Describe how the testing OR use of the measure demonstrates the data collection strategy (timing, frequency, and sampling) can be implemented. (**Burden of data collection**)

The feasibility of data collection will be evaluated during pilot testing

- c. Describe how the information provided by the measure outweighs the cost/burden of data collection. (**Cost/benefit**)

We have not directly evaluated either the value of the measure or the cost of data collection. However, we do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- d. The data items are auditable (i.e., to detect errors or inaccuracies). (**Potential for unintended consequences - misrepresentation**)

Instructions will be explicit that reporting this quality measure requires accompanying documentation in the medical record. All elements required for reporting must also be documented in the medical record. For example, use of exclusions requires specific documentation explaining the justification for exclusion.

- e. Describe how patient confidentiality is protected. (**Protects confidentiality**)

Confidentiality is an aspect of measure implementation, and not a property of the measure itself. We would expect that implementers of the measure would have appropriate safeguards in place to address the confidentiality of any data collected.

- f. Describe if this measure is harmonized with related measures. Describe how this measure is applicable to multiple levels, settings, and data sources? (**Harmonization**)

There are no similar measures with which to harmonize.

References

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- ⁱ Wei L, MacDonal TM, Walker BR. Taking glucocorticoids by prescription is associated with subsequent cardiovascular disease. *Ann Intern Med.* 2004; 141:764-770.
- ⁱⁱ Khanna D, Arnold EL, Pencharz JN, et al. Measuring process of arthritis care: The Arthritis Foundation's quality indicator set for rheumatoid arthritis. *Semin Arthritis Rheum.* 2006; 35:211-237.
- ⁱⁱⁱ Luqmani R, Hennell S, Estrach C, et al. British Society for Rheumatology and British Health Professionals in Rheumatology guideline for the management of rheumatoid arthritis (the first 2 years). *Rheumatology.* 2006:1-16.
- ^{iv} Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. *Arth Rheum.* 2008; 58(1): 15-25.
- ^v Michaud K, Messer J, Choi HK, Wolfe F. Direct medical costs and their predictors in patients with rheumatoid arthritis. *Arth Rheum.* 2003; 48(10): 2750-2762.
- ^{vi} MacLean CH, Louie R, Leake B, et al. Quality of care for patients with rheumatoid arthritis. *JAMA.* 2000; 284:984-992.
- ^{vii} Yelin E, Such C, Criswell L, et al. Outcomes for persons with rheumatoid arthritis with a rheumatologist versus nonrheumatologist as the main physician for this condition. *Med Care.* 1998; 36:513-522.
- ^{viii} American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. *Arth Rheum.* 2002; 46(2): 339.

Candidate Measure Summary form

Project Name: Clinician Measure Development
 Submitter Name: NCQA
 Date Completed: 4/28/08

The purpose of this template is to provide a brief, high-level description of the candidate measure as well as the measure attributes using the measure evaluation criteria and subcriteria. This information will be used by the Technical Expert Panel to evaluate the proposed measures. In addition, if this measure is one of the final measures in the measure set, much of the information documented here can be transferred into the Measures Management System "Measure Information Form" as well as the National Quality Forum measure submission form. Complete one form for each measure.

Measure Set:	Rheumatoid Arthritis
Measure Name <i>(should be brief, concise):</i>	Rheumatoid Arthritis: Assessment and Classification of Disease Prognosis
Measure Description:	Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis (RA) with assessment and classification of disease prognosis at least once during the measurement period.

Technical Specifications

Denominator

Denominator Statement: Patients 18 years and older with a diagnosis of Rheumatoid Arthritis (RA)

Denominator Inclusions/Exclusions:

Inclusions:

ICD-9-CM Diagnosis code: 714.0, 714.1, 714.2, 714.81

Exclusions: None

Numerator

Numerator Statement: Patients with at least one documented assessment and classification (good/poor) of disease prognosis utilizing clinical markers of poor prognosis during the measurement period.

Numerator Inclusions/Exclusions:

Inclusions:

CPT Cat-II code (in development): XXXXF – Disease prognosis assessed, poor prognosis documented

OR

CPT Cat-II code (in development): XXXXF – Disease prognosis assessed, good prognosis documented

Definitions: Prognostic Classification should be based upon at a minimum the following markers of poor prognosis: functional limitation (e.g., HAQ Disability Index), extraarticular disease (e.g. vasculitis, Sjorgen’s syndrome, RA lung disease, rheumatoid nodules), RF positivity, positive anti-CCP antibodies (both characterized dichotomously, per CEP recommendation), and/or bony erosions by radiography.

Exclusions: **None**

Type of Measure: **Process**

Data source: **Medical Record, Administrative Claims, Electronic Medical Record, Administrative Claims supplemented by Medical Records**

Unit of Measurement: **Clinician**

Measure Care Setting: **Ambulatory**

Measure Source:

- New
- Adapted (if adapted, provide name of original measure and original specifications as an attachment; summarize the changes that were made to the measure)
- Adopted (if adopted, provide name of original measure)

Measure Justification

Rationale: (describe succinctly the overall reasoning behind the use of this measure):

After establishing a diagnosis of RA, risk assessment is crucial for guiding optimal treatment. For the purposes of selecting therapies, physicians should consider the presence of these prognostic factors at the time of the treatment decisionsⁱ.

I. Importance

- a. Describe how measure addresses a national health goal or priority area OR focuses on high impact aspect of health care (**epidemiological relevance, financial relevance, policy relevance**)

Over the last two decades, the movement to assess, report and improve healthcare quality for many chronic conditions has gained significant momentum. However, consistent with trends seen in the U.S. healthcare system as a whole, significant deficits in healthcare quality have been identified in the rheumatic conditions. Management of rheumatoid arthritis (RA) has changed dramatically over the last decade. Paradigms have shifted to the control of early disease and physicians have a broader and more effective array of treatment optionsⁱⁱ.

Policy relevance

Improving quality in rheumatoid arthritis care falls under the IOM priority area of Living with Illness/Disability. The other area of policy relevance is the changing landscape of medical risks versus benefits of the therapeutic options for RA treatment. This is especially important with the introduction of biopharmaceuticals.

Clinical or Epidemiologic Relevance

RA is a multisystem disorder of unknown etiology, characterized by chronic destructive synovitis. The current national estimate of prevalence of RA, using 2005 population estimates from the Census Bureau, is that 1,293,000 American adults age ≥ 18 years (0.6%) have RA. This estimate is lower than prior estimates due to stricter disease classification

criteria. The prevalence in women is approximately double that in men (1.06% vs. 0.61%), and the average age of persons with prevalent RA has increased steadily over time, from 63.3 years in 1965 to 66.8 years in 1995, suggesting that RA is becoming a disease of older adultsⁱⁱⁱ.

Financial relevance

The costs of RA are increasing because of the introduction and increasing use of biologic therapy. The mean total annual direct medical care cost in 2001 for a patient with RA was \$9,519. Drug costs were \$6,324 (66% of the total), while hospitalization costs were only \$1,573 (17%). Approximately 25% of patients received biologic therapy. The mean total annual direct cost for patients receiving biologic agents was \$19,016 per year, while the costs for those not receiving biologic therapy was \$6,164. The remaining 16% of total costs includes outpatient services such as outpatient surgery, physician and health professional encounters, x-rays, MRI and CT scans and other laboratory testing. Medicare patients incur a high rate of out-of-pocket drug costs; 46% of Medicare patients paid greater than 25% of their drug expenses. The key clinical factors in predicting future costs are functional disability and comorbidity^{iv}.

- b. Describe how data demonstrate considerable variation **OR** poor performance across providers **OR** population groups. (**Opportunity for improvement**)

While there are a limited number of studies that investigate gaps in care for patients with rheumatoid arthritis, the research that does exist identifies opportunities for improvement in several care areas: 1) there is a lack of adherence to RA guidelines, most noticeably in the use of disease-modifying antirheumatic drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

One study analyzed quality of care for 1,355 patients with rheumatoid arthritis using data from a national health plan. Using process measures, the study found that patients with rheumatoid arthritis often did not receive the recommended care suggested by clinical guidelines (for each person-year, recommended processes of care for rheumatoid arthritis were performed an average 62% of the time). The study also found that the quality of care provided to patients with RA varied according to provider type (patients seeing a rheumatologist had higher quality care than those seeing a primary care physician).^v Similar results were reported by a cohort study of 1,025 patients with RA. Based on certain outcome measures (including pain rating, number of painful joints, and functional status), patients with a rheumatologist as their RA physician had significantly better outcomes than patients whose main RA physician was a non-rheumatologist.^{vi}

II. Scientific Acceptability

- a. Describe how the specific outcome, intermediate outcome, process, or structure is consistent with/clinical practice guidelines. Provide guideline citation with USPSTF grade of

evidence/recommendation. Discuss any contradictory guidelines or evidence. **(Strength of evidence base)**

We have based the selection of measurement topics on review of draft guidelines developed by the American College of Rheumatology. These guidelines are currently in press and will be formally published in early June, 2008.

Through literature reviews the guideline developers gathered that before the selection of the treatment regimen, first an assessment of prognosis is required. Poor prognosis is suggested by earlier age at disease onset, high titer of RF, elevated ESR, and swelling of >20 joints. Extraarticular manifestations of RA, such as rheumatoid nodules, Sjogren's syndrome, episcleritis and scleritis, interstitial lung disease, pericardial involvement, systemic vasculitis, and Felty's syndrome, may also indicate a worse prognosis. Since studies have demonstrated that treatment with DMARDs may alter the disease course in patients with recent-onset RA, particularly those with unfavorable prognostic factors, aggressive treatment should be initiated as soon as the diagnosis has been established. (Level C evidence)

Assessment of prognosis should be performed at baseline, before starting medications, to assess organ dysfunction due to comorbid diseases. The literature agrees that a thorough assessment includes recording a complete blood cell count, electrolyte levels, creatinine levels, hepatic enzyme levels (AST- aspartate aminotransferase, ALT- alanine aminotransferase, and albumin), and performing a urinalysis and stool guaiac. If necessary prognosis at baseline should rule out other diseases; this may be repeated during disease flares to rule out septic arthritis through synovial fluid analysis^{vii} (Level C evidence)

- b. Describe the science underlying the measure concepts; the extent to which the scientific evidence underlying the measure is stable. **(Stability)**

According to the Expert Workgroup, this is an area where the scientific evidence underlying the measure is stable enough to develop measures.

- c. Describe measure reliability testing and results, using a methodology appropriate to the measure type. If the measure has not been tested, plans for testing have been presented. **(Reliability)**

Full evaluation of reliability and validity can only be assessed through large scale implementation of measures. This is a lengthy and expensive process, and has not been requested by CMS. However, NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development.

- d. Describe process for evaluating the face validity as representing the quality of care. Describe testing of the measure providing evidence of the validity of conclusion about quality and the data from testing OR use of the measure demonstrate variation OR poor performance. If the measure has not been tested, plans for testing have been presented. **(Validity)**

NCQA and PCPI plan to pilot test this measure in accordance with standard testing protocols as a further stage of measure development to demonstrate variation and room for improvement. We tested face validity through evaluation by an Expert Work Group and will further collect comments on face validity through a broadly publicized public comment process and focus group interviews with clinicians.

- e. Describe rationale including evidence-base as to why any exclusions are necessary and appropriate. (**Precision of specifications**)

None

- f. (**Outcome measures**) Summarize the testing done to determine the need (or non need) for risk adjustment and the statistical performance of the risk adjustment method. (**Adequacy of Risk Adjustment**)

N/A – process measure

- g. If results are stratified by population characteristics, to detect disparities in care/outcome, describe rationale including evidence. (**Adequacy of Risk Adjustment**)

While many measures can be sensitive to disparities, these measures have not been specifically tested or specified for the ability to detect disparities in care.

III. Usability

- a. Describe how measure is/can be actionable by users such as providers, public, purchasers etc. (**Actionability**)

These measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives. We also expect the results from these measures to be relevant and usable by payers for value-based purchasing, and by consumers through report cards.

- b. Describe how the measure provides a distinctive or additive value to existing measures (**Actionability**)

These measures address areas of care that are not currently addressed in existing measure sets.

- c. If measure is in current use, describe how real difference in performance can be identified/interpreted with comparative data. (**Actionability**)

Measure is not in current use.

- d. Describe testing done to determine if information produced by the measure is meaningful and understandable to audiences. (**Actionability**)

We are not planning to conduct formal usability testing to determine if the information produced by the measure is meaningful and understandable to audiences.

- e. Describe the extent to which processes and outcomes related to this measure are under the control of the entity being measured. (**Controllability**)

These provider-level measures are derived from clinical guidelines, which are generally actionable by the relevant clinicians in terms of feedback and quality improvement initiatives, and are assumed to be under the influence or control of the clinician being measured.

- f. Describe the extent to which the measure is adaptable to multiple populations or can be applied across various healthcare settings. (**Adaptability**).

This measure has been specified for use in the population and setting described above, and has not been evaluated for use beyond the specified population and setting.

IV. Feasibility

- a. Describe the where and how during routine care delivery data can be obtained and if electronic information can be used for this measure. (**Burden of data collection**)

The measure has been specified to rely largely on administrative data collected during routine care and billing. Additional data elements will be collected through CPT Category II codes, which are coded at the point of care. We anticipate that the cost or administrative burden for this measure is equivalent to the burden associated with other NCQA or PCPI measures used in similar settings.

- b. Describe how the testing OR use of the measure demonstrates the data collection strategy (timing, frequency, and sampling) can be implemented. (**Burden of data collection**)

The feasibility of data collection will be evaluated during pilot testing

- c. Describe how the information provided by the measure outweighs the cost/burden of data collection. (**Cost/benefit**)

We have not directly evaluated either the value of the measure or the cost of data collection. However, we do not anticipate that the cost or administrative burden for this measure would be significantly different than the burden associated with other NCQA or PCPI measures that are used in similar settings.

- d. The data items are auditable (i.e., to detect errors or inaccuracies). (**Potential for unintended consequences - misrepresentation**)

Instructions will be explicit that reporting this quality measure requires accompanying documentation in the medical record. All elements required for reporting must also be

documented in the medical record. For example, use of exclusions requires specific documentation explaining the justification for exclusion.

- e. Describe how patient confidentiality is protected. (**Protects confidentiality**)

Confidentiality is an aspect of measure implementation, and not a property of the measure itself. We would expect that implementers of the measure would have appropriate safeguards in place to address the confidentiality of any data collected.

- f. Describe if this measure is harmonized with related measures. Describe how this measure is applicable to multiple levels, settings, and data sources? (**Harmonization**)

There are no similar measures with which to harmonize.

References

ⁱ Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis Rheum* 2008;59(6): 762---784.

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