CSRO
Coalition of State Rheumatology Organizations

BOARD OF DIRECTORS

Officers

Madelaine A. Feldman, MD, FACR
President

Gary Feldman, MD
Vice President

Michael Saitta, MD, MBA
Treasurer

Michael S. Brooks, MD, FACP, FACR
Secretary

Directors

Kostas Botsoglou, MD
Director

Mark Box, MD
Director

Aaron Broadwell, MD
Director

Adrienne Burford Foggs, MD
Director

Sarah Doaty, MD
Director

Harry Gewanter, MD, FAAP, MACR
Director

Adrienne Hollander, MD
Director

Robert Levin, MD
Director

Amar Majjhoo, MD
Director

Gregory Schimizzi, MD
Director

Michael Schweitz, MD
Director

Joshua Stolow, MD
Director

Headquarter Office

Ann Marie Moss
Executive Director

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202
P: (414) 918-9825 | F: (414) 276-3349
Email: info@csro.info | Website: www.csro.info

March 25, 2022

Acumen, LLC.
Contractor for the Centers for Medicare and Medicaid Services (CMS)
MACRA Episode-Based Cost Measures
Submitted via email to: macra-episode-based-cost-measures-info@acumenllc.com and Qualtrics upload

**RE: Call for Public Comment on Wave 5 Measure Development – Rheumatoid Arthritis**

Dear Sir or Madam:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

Today, we write to share feedback on the development of episode-based cost measures in the Rheumatoid Arthritis (RA) clinical area as part of the MACRA Episode-Based Cost Measures (Wave 5) Call for Public Comments. Generally, these comments are consistent with our prior feedback on Wave 4, but have been updated to address new questions being posed and reflect innovations in this disease area.

## General Comments

We appreciate the challenge in developing an episode-based cost measure for RA (e.g., identifying the patient cohort and accounting for certain costs) and understand why the Centers for Medicare and Medicaid Services (CMS) prioritized other clinical areas during Wave 4. As we've noted in prior comments, there are no appropriate resource use measures for rheumatologists under the Quality Payment Program (QPP) Merit-Based Incentive Payment System (MIPS) and Advance Alternative Payment Model (AAPM) tracks. Given the agency will soon implement a MIPS Value Pathway (MVP) for Advancing Rheumatology Patient Care in CY 2023, we agree it would be useful to attempt development of a more applicable measure of costs in RA.

As it did during Wave 4, Acumen highlights potential opportunities for improvement associated with variation in treatment (i.e., drug options) and efficient monitoring/imaging/therapy, including for adverse effects to treatments. With respect to treatment options, we previously shared that RA medications span across Part B ("medical" or "physician-administered") and Part D ("pharmacy" or "self-administered"), and emphasized that all pharmaceutical costs must be considered when evaluating resource use for RA. We appreciate that Acumen discussed the inclusion of Part D drugs as part of its Wave 4 Frequently Asked Questions (FAQ) document, which states that "Part D should be considered on a case-by-case basis," and that "[m]easures where

Part D makes up a substantial portion of care or where assessing clinician performance may be incomplete without Part D could be candidates for including Part D drugs."

Unfortunately, the list of "trigger codes" that would start an episode only includes physician-administered drugs, without any mention of self-administered drugs (see screenshot below), which is inconsistent with sentiments outlined above.

| Episode Group | Type of Episode Group | Code Type | Code | Code Description |
|---|---|---|---|---|
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | 80193 | Measurement of leflunomide |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J0129 | Injection, abatacept, 10 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered) |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J0135 | Injection, adalimumab, 20 mg |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J0717 | Injection, certolizumab pegol, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered) |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J0718 | Injection, certolizumab pegol, 1 mg |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J1438 | Injection, etanercept, 25 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered) |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J1602 | Injection, golimumab, 1 mg, for intravenous use |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J1745 | Injection, infliximab, excludes biosimilar, 10 mg |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J3262 | Injection, tocilizumab, 1 mg |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J9311 | Injection, rituximab 10 mg and hyaluronidase |
| Rheumatoid Arthritis | Chronic | CPT/HCPCS | J9312 | Injection, rituximab, 10 mg |

Measuring the use of Part B drugs alone inappropriately penalizes physicians whose patient population may require office-administered medications, and puts them at a disadvantage over their peers who may prescribe more self-administered drugs covered under Part D, since the former would appear more costly than the latter. Worse, it has the potential to influence treatment decisions as physicians are perversely incentivized to prescribe Part D drugs when Part B drugs may be more appropriate for the patient. **Any resource use measurement for RA must include both physician- and self-administered drugs.**

## Response to Key Questions

***Question 1: Stakeholders have suggested focusing on newly diagnosed rheumatoid arthritis patients. Since this would result in lower beneficiary and cost coverage, is there a way to define a broader (yet still clinically coherent) patient cohort that could represent a viable measure? For example, are there opportunities for improvement in later stages of the disease?***

Focusing on newly diagnosed RA patients is a reasonable first-step toward measuring RA costs-of-care. This would allow the agency and its contractor, with feedback from stakeholders and the Technical Expert Panel (TEP), to address anticipated challenges with measuring Part B and Part D drugs, among other potential challenges. Once the expected "kinks" have been addressed, expanding the measure denominator – or developing additional measures – to account for patients in later stages of RA disease would be more reasonable.

***Question 2: Using claims data, how should the measure account for differences in costs due to rheumatoid arthritis severity or patients' responses to medication? Some example approaches include: linking severity to prescription/dialogic use, using the claims based index of rheumatoid arthritis severity (CIRAS), using the presence of extraarticular manifestations (e.g., pulmonary, ocular), and looking for the presence of other comorbidities or services (e.g., coronary artery disease, lymphoma, lung disease, vasculitis, and side effects from medications).***

We noted previously that accounting for differences in RA severity are accomplished with the use of disease activity indices (subjective) and blood-based testing (objective). Commonly used disease activity indices include the Routine Assessment of Patient Index Data 3 (RAPID3), Clinical Disease Activity Index

(CDAI) for RA, and Simple Disease Activity Index (SDAI) for RA. These patient reported outcome tools are frequently used alongside objective assessments and laboratory testing, such as erythrocyte sedimentation (sed) rate, C-reactive protein (CRP), complete blood count (CBC), rheumatoid factor (RF), antibodies to cyclic citrullinated peptides (CCP), and occasionally multi-biomarker tests designed for RA. Together with the clinical judgement of the rheumatologist, these tools can help in the assessment of disease activity and point the way to the best treatment for the patient.

Regarding certain types of services or diagnoses available via claims that may be useful in identifying various levels of severity, we suggest considering the continued use of steroids, the presence of comorbidities, such as premature coronary artery disease (CAD), lymphoma, interstitial lung disease, vasculitis, and side effects from medications (e.g., corticosteroids), as well as consultations with other specialties, a history of orthopedic surgery, particularly joint replacements. and certain other laboratory findings (double positive RF and CCP), and imaging (radiographic progression).

With regard to patients' responses to medications, we note that innovations in precision medicine have led to the development of new predictive drug response testing tools in RA. As we shared in comments to CMS' Molecular Diagnostics (MolDX) program, there are no published studies to suggest the optimal sequence of different therapies following non-biologic DMARDs. The rheumatologist's clinical assessment and shared decision making with the patient is the best approach but can result in several treatment failures before the optimal regimen is found. This new predictive drug response testing may aid in finding the best medication sooner, allowing patients to achieve remission earlier, potentially reducing their risk of comorbid conditions such as coronary heart disease and lymphoma.

## Concluding Remarks

Regardless of whether CMS prioritizes RA for Wave 5 or postpones to a later time, we again emphasize that cost and resource use measurement should not bias treatment decisions, nor penalize them for delivering clinically appropriate care in the best interest of their patients. Again, whether the solution is to remove Part B drug costs or to incorporate Part D drug costs, ***the most important thing is that episode-based cost measures do not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the patient.***

*****

Thank you for considering our comments on the development of RA-focused episode-based cost measures for use in MACRA. Please do not hesitate to contact us, should you require additional information.

Sincerely,

Madelaine A. Feldman, MD
President
CSRO