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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 Survey Monkey upload

RE: Call for Comment on Wave 4 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 4) Call for Comments.

Broad Comments

According to Acumen, the RA clinical area would focus on a chronic condition measure that would apply to rheumatologists and primary care clinicians that manage care for patients with the condition. Acumen notes that RA is a priority given its prevalence in Medicare, as well as potential opportunities for improvement due to variations in treatment and management options (e.g., drug therapies), monitoring, and adverse effects. CSRO agrees. As we've noted in prior comments to the Centers for Medicare and Medicaid Services (CMS) on its Quality Payment Program (QPP), there are no appropriate cost/resource measures for rheumatologists under the current cost measures used in the QPP programs (i.e., the Merit-Based Incentive Payment System (MIPS) and Advance Alternative Payment Models (AAPMs)).

Of note, Acumen highlights a potential improvement opportunity associated with variations in treatment, with a focus on available drug therapies. First and foremost, we note that RA medication options span across Parts B (medical) and Part D (pharmacy). To date, CMS has yet to implement a mechanism that could account for *all pharmaceutical costs* when evaluating physician resource use, although this has been discussed in the context of certain Bundled Payments for Care Improvement (BPCI) models (e.g., Inflammatory Bowel Disease, or IBD). Our understanding is that CMS faces challenges including Part D costs in resource use measurement, which puts physicians who administer Part B drugs in their office at a significant disadvantage compared to those who order/prescribe drugs covered under Part D, since the former would appear to have higher Medicare expenditures than the latter. CMS has previously noted that

use of the Hierarchical Condition Categories (HCC) model may account for some conditions that require Part B drugs and are therefore more costly, but we contend that it does not distinguish between the *appropriateness* of Part D drugs versus Part B drugs and unduly punishes physicians who ultimately determine that Part B drugs are most appropriate for their patient. Under the current MIPS cost measures, the methodology 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. We are concerned the RA measure in development will face the same challenges and concerns.

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.***

Response to Key Questions

Question 1: What are ways to account for different severity levels for Rheumatoid Arthritis? Are there considerations like the specialty of the attributed clinician (e.g., internal medicine versus rheumatology) that may help inform different severity levels? We may use techniques like risk adjusting or sub-grouping for services that are indicative of various levels of severity. Are there certain types of services or diagnoses available via claims that may be useful in identifying various levels of severity?

To account for different severity levels in RA patients, rheumatologists use 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 biomarker testing, such as erythrocyte sedimentation (sed) rate, C-reactive protein (CRP), rheumatoid factor (RF), antibodies of cyclic citrullinated peptides (CCP), antibodies to mutated citrullinated vimentin (MCV), and other multi-biomarker tests designed for RA. Together, these tools help rheumatologists better direct treatment and are usually proportional to the aggressiveness of the treatment needed.

Regarding certain types of services or diagnoses available via claims that may be useful in identifying various levels of severity, we suggest considering 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, and certain other laboratory, imaging and neurodiagnostic services.

Question 2: Are there any concerns regarding the attribution of Rheumatoid Arthritis episodes to clinicians from certain specialties (e.g., internal medicine versus rheumatology)? For reference, chronic condition measure attribution for clinicians includes the requirement that the clinician within the attributed clinician group must bill at least 30% of "primary care" evaluation and management (E&M) codes with a relevant chronic condition diagnosis and/or chronic condition-related Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) codes for related services with a relevant chronic condition diagnosis on Part B Physician/Supplier claim lines during the episode (along with other requirements).

Regarding attribution, rheumatologists have the requisite expertise to accurately and appropriately diagnose, treat, and manage the care of RA patients. When primary care providers misdiagnose these

conditions, or refer these patients for intervention by a rheumatologist too late, disease progression is heightened and more difficult to control; costs to the Medicare program and beneficiaries are increased; and, beneficiary outcomes and quality of life are diminished until control is regained, if at all. All patients suspected of RA should see a rheumatologist; less severe cases are occasionally managed by primary care providers with input from rheumatologists.

Question 3: For a cost measure focused on the ongoing treatment and care for Rheumatoid Arthritis, what are some areas for opportunity for improvement a measure may be able to capture regarding care and potential mitigation of complications?

There are several opportunities to improve care and mitigate complications in RA. First and foremost is ensuring patients suspected of or diagnosed with RA should have a consultative visit with a rheumatologist and initiative treatment as soon as possible to mitigate long term complications and disability. Primary care providers have less expertise in the diagnosis, treatment and management of RA, and should not be routinely relied upon.

Another opportunity is ensuring rheumatologists are mindful of American College of Rheumatology (ACR) guidelines, which suggests that newly diagnosed RA patients with mild to moderate disease are given 12 weeks of disease-modifying antirheumatic drugs (DMARDs) prior to starting biologic therapy. There should be exceptions for patients who can't take DMARDs or have highly active disease requiring more aggressive treatment. This would improve quality of care by decreasing side effects of combining medications and decrease cost of giving expensive drugs, unless indicated, early in RA disease. Related, another potential opportunity is for biologic naïve patients that fail DMARD therapy to start treatment with a biosimilar drug, which have significantly lower costs.

Finally, a key opportunity is using tools that predict response to medications. While patients suffering from RA have benefited greatly from pharmaceutical innovations, it can take a few "trials" to find the drug option that is best suited based on the patient's clinical circumstances and characteristics. Of note, the current RA guidelines from the ACR are not prescriptive; rather, they serve as a tool and encourage treatment recommendations to be made through shared decision-making processes, accounting for patients' values, preferences, and comorbidities. Anticipated innovations in precision diagnostics, including those that identify individuals with a molecular signature of inadequate response to certain drug therapies, may enable rheumatologists to better target treatments with the goal of early disease control, which translates into improved outcomes with lower overall costs.

Question 4: Are there any other concerns that may be present with assessing the chronic care for patients with Rheumatoid Arthritis? If so, what are some potential approaches to address these concerns for a cost measure?

As noted above, we continue to have concerns about perceived limitations that have prevented CMS from including both Part B and Part D drugs in its cost and resource use measurement, which CMS has discussed in the context of its Total Per Capita Costs and Medicare Spending Per Beneficiary cost measures, and other episode-of-care models. If the RA episode-based cost measure only accounts for Part B drug costs, it will inadvertently penalize physicians who prescribe them. Consequently, it may drive physicians toward prescribing more Part D drugs to lower drug spending attributable to them, which may not be in the best interest of patients clinically *or* monetarily.

We maintain 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.***

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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

Michael C. Schweitz, MD
Federal Advocacy Chair
CSRO