AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

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July 27, 2021

Troyen Brennan, MD, MPH
Executive Vice President
Chief Medical Officer
CVS Health
One CVS Drive
Woonsocket, RI 02895

Dear Dr. Brennan:

On behalf of the more than 7,700 U.S. rheumatologists and rheumatology health professionals represented by the American College of Rheumatology (ACR), I am writing to convey our alarm and dismay at the changes CVS Caremark has made to its biologic prior authorization (PA) forms in Q3 2021. These changes increase the already overwhelming paperwork burden on our members' staff without doing anything to promote our common goal of caring for patients. We request a conversation with CVS Health leaders regarding the role of prior authorizations, including the appropriateness of various components of these forms.

ACR members have years of specialty training and experience making them experts in treating musculoskeletal and autoimmune conditions. These rheumatologists are in the best position to determine the most appropriate treatment for their patients; their medical decision making should not be undermined by insurance companies or pharmacy benefit managers whose formularies are increasingly driven by rebate negotiations rather than by rational clinical criteria. However, since we recognize the role formularies play in the current healthcare environment, we feel there must be some middle ground between rheumatologists' ability to prescribe any treatment they and their patients choose, and the untenable burden of the prior authorization form CVS Caremark recently instituted. We would like to discuss several specific concerns below.

Our first concern are the clinical or lab-based questions that are not relevant to CVS Caremark's decision to approve the treatment. For example, question 5 on the Enbrel PA form asks the patient's weight. Since Enbrel dosing is not weight based, this information is not relevant. Questions 12-18 on this form ALL deal with tuberculosis exposure. ACR members have gone to medical school and are specialty trained; they know how to address tuberculosis screening. Simply asking whether the patient has been screened for TB, and if positive whether they have been treated for latent TB, should suffice. In section C, for new rheumatoid arthritis (RA) initiations, there are 7 consecutive questions (25-31) related to antibody status and inflammation levels. None of these results should impact CVS Caremark's decision to approve a requested biologic drug, since we routinely treat patients with active inflammatory disease who lack

RF/CCP, or who have normal inflammatory markers, but who still have high disease activity scores based on a HAQ, CDAI, or other activity measure.

Of greater concern and potential impact to our members and patients, is the request for "percentage of disease activity improvement in swollen or tender joints, pain, or disability". There are multiple layers of concerns with this question. First, the structure of this question does not mirror ACR guidance for disease monitoring. It is NOT appropriate to require documentation of ACR 20/50/70 percentage responses in clinical practice, as this is a study tool. Several disease activity measures (CDAI, SDAI, HAQ, etc.) are appropriate for use in clinical practice per ACR RA treatment guidelines. While many of our members utilize these measures, a) not all do, and b) different practices may use different measures - and this should be acceptable to payers. We do NOT believe it is appropriate to suddenly demand retrospective disease measures (comparing current to prior measures), without having given advance notice that such markers would be required for ongoing treatment coverage. If CVS Caremark intends to require disease activity measures, you should request a prior and current disease activity score, allowing for multiple options (i.e., HAQ, CDAI, etc.). As the term "percentage improvement" does not have clinical meaning and it is not within our members' purview to calculate an arbitrary percentage change. Moreover, patients' whose initial treatment was approved prior to the requirement for documenting improvement should be grandfathered on their current treatment. It is unfair and inappropriate to "move the goalposts" after the fact.

Additionally, many of the questions in this form require the attachment of additional documentation, which requires significant staff time to sort through years of records to find labs (RF, CCP, etc.) and documentation of treatment trials. This busywork is not reimbursed and creates barriers to treatment approval. Rather than placing the burden on our staff to provide these specific records, CVS Caremark should simply request the most recent office notes. We agree that ACR members should include documentation in their notes to justify treatment decisions. However, the burden should be on CVS Caremark to abstract charts, rather than on practices to provide numerous specific and often irrelevant data points. We would also inquire as to the motivation for the addition of these burdensome requirements to the PA process as well as the credentials of the individuals or committee responsible for creating the forms. As an aside, if CVS Caremark truly has preferred drugs, why not significantly streamline the paperwork for these agents? As it stands, the Humira form (preferred drug) greatly resembles the Enbrel form (non-preferred drug) in scope. We urge you to consider leading meaningful change amongst PBMs by reducing the burden to access preferred drugs with a more simplified 2 or 3 question PA form.

Ultimately, ACR members are at the point of care with patients –listening to their symptoms, evaluating their joints, taking their history— and their clinical decisions are informed by years of medical training. We believe PA forms should ensure these medications are being prescribed by the appropriate specialist (as opposed to primary care), that patients have had appropriate trials of conventional DMARDs prior to biologic use, and that if the request is for a non-preferred agent, there is appropriate rationale for this request. Instead, the questions in the new version of the forms suggest that rheumatologists' medical expertise is usurped by the PBM's medical decision

making. We believe there is an opportunity to work together to streamline these forms. As it stands, they are harmful to patients as they will assuredly preclude approval of many appropriate and necessary treatment courses. We would greatly appreciate the opportunity to have further discussion with you. To schedule a call or for additional information, please contact Meredith Strozier, ACR Director of Practice Advocacy at mstrozier@rheumatology.org or (404) 633-3777.

Sincerely,

Chris Phillips, MD
Chair, ACR Insurance Subcommittee