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January 3, 2023

Roberta Capp, MD, MHS
Chief Medical Officer,
VP Clinical Operations and Innovations
Blue Cross Blue Shield of North Carolina
4615 University Drive Durham, NC 27707

Dear Roberta,

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of over 30 state and regional professional rheumatology societies, formed by physicians to advocate for access to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease.

Our member societies represent providers of rheumatologic care in North Carolina and other states treating patients insured by Blue Cross Blue Shield of North Carolina (BCBS NC). It is with this in mind that we write to you regarding recent changes to your medical drug coverage policy[1] for Actemra (tocilizumab) in the treatment of rheumatoid arthritis and Orencia (abatacept) in the treatment of psoriatic arthritis (PSA) and rheumatoid arthritis (RA) that went into effect this on January 1, 2023.

We are concerned with the step therapy requirements mandating the use of an infliximab product (specifically only Avsola or Inflectra[2]) and Simponi Aria (all tumor necrosis factor inhibitors – TNFi) prior to the use of IV Actemra in patients with rheumatoid arthritis (RA) or IV Orencia in patients with RA and psoriatic arthritis (PSA). *There is also mandated failure of two subcutaneous TNFis, specifically, Enbrel, Humira, and/or Simponi before utilizing Orencia SC[3] (RA & PSA) or Actemra SC[4] (RA).* **Often the rationale for such step therapy policies is that these "steps" result in the lowest *cost*. Unfortunately, it is the lowest cost for the insurance company, as a**

[1] https://www.bluecrossnc.com/providers/medical-policies-and-coverage/medical-policy-updates/notification-drug-policy-revisions-1

[2] https://www.bluecrossnc.com/providers/medical-policies-and-coverage/medical-policy-updates/notification-drug-policy-revisions-0

[3] https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/formulary/Orencia_SubQ_Criteria.pdf#search=psoriatic%20arthritis

[4] https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/formulary/Actemra_Pharmacy_Criteria.pdf#search=Actemra%20subcutaneous%20subcutaneously

result of the highest rebate, not for the patient. This does not lower costs for patients and in fact such policies have been shown to increase out of pocket costs for patients from lack of disease control and non-adherence.

According to the most recent ACR RA treatment guidelines[5], it is recommended to switch to a different class of either biologic (b) DMARDS or targeted synthetics (ts) DMARDS for patients taking a bDMARD or tsDMARD who are not responding to that class. Not only is your policy in direct contraindication to ACR guidelines, it subjects a patient to 9 months of high disease activity when you include the 3 month failure to methotrexate. This can lead to not only irreversible joint damage but to other consequences of chronic inflammation such as anemia, cardiac disease and certain malignancies.

There are other important questions that are not answered in this medical policy that are of utmost importance involving **patients who are stable on either IV Orencia or IV Actemra and those that have already failed subcutaneous TNFis.**

If this **revised medical policy** is mandating a **non-medical switch** for stable RA and PSA patients, that would be going against everything that good medical care necessitates. We strongly support the American College of Rheumatology (ACR) position paper on patient's access to biologics, which specifically states that policies should allow for grandfathering of patients whose disease is well controlled on stable therapy.[6]

The North Carolina Step Therapy bill (S58-3-221) grants exceptions to step therapy if the required drug is expected to cause a harmful reaction to the patient. If a patient is stable or they have tried that class before and failed it, the likelihood of harm to the patient is high if they are FORCED to leave their stabilizing medicine or FORCED to revisit a class of drug that has failed them before. This would need to be brought before the NC Department of Insurance as it will be obvious that BCBS is not following the criteria of the NC Step Therapy bill. North Carolina legislators will also be interested in hearing how the spirit of their bill is being violated, resulting in harm to their constituents with chronic systemic inflammatory arthritis.

The journey that patients with rheumatic diseases go through to find a treatment regimen that properly manages their diseases is one filled with trial and error and uncertainty. The cost of losing control of their disease[7] is high in terms of quality of life, disease progression, and downstream healthcare utilization. It is for these reasons that caution should be a paramount principle guiding disease management once a patient's condition has been successfully stabilized.

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[5] https://www.rheumatology.org/Portals/0/Files/2021-ACR-Guideline-for-Treatment-Rheumatoid-Arthritis-Early-View.pdf

[6] https://www.rheumatology.org/Portals/0/Files/Patient%20Access%20to%20Biologics%20aka%20Model%20Biologics.pdf

[7] https://admin.allianceforpatientaccess.org/wp-content/uploads/2020/01/AfPA-How-NMS-Hurts-Patients.pdf

At the very least, **CSRO requests that you exempt patients from any revised policy who are currently stable on their present medication**. We also ask that you **reconsider the mandated 2 IV TNFi failure** and additionally, if patients have already failed 2 **subcutaneous tumor necrosis factor inhibitors there would be no reason for them to fail a 3rd TNFI, regardless of the mode of administration**. Mandating a 3rd TNFi for **non medical reasons** (IV or subc) would make it clear that a patient's well-being is not being considered in your policies.

We hope that you will reconsider/delay this revised medical policy on IV Actemra and IV Orencia, and we will be happy to join the North Carolina Rheumatology Association is discussing with you an appropriate resolution to this issue. CSRO and NCRA are both committed to having a constructive dialogue in order to reach an acceptable resolution that would maintain the health and well-being of patients covered by BCBS NC at the center of the conversation. To coordinate a conversation, I can be reached at MadelaineFeldman@gmail.com; please include CSRO's Executive Director, Ann Marie Moss, on correspondence.

Sincerely,

Madelaine A. Feldman, MD FACR
Coalition of State Rheumatology Organizations
Vice President, Advocacy & Government Affairs

Cc: **North Carolina Department of Insurance - Consumer Services Division**
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