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Coalition of State Rheumatology Organizations

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December 13, 2021

Willard Harms, MD
Vice President, Medical Affairs

Gerald Isreal, Jr.
Chief Pharmacy Officer & Assistant Vice President

Blue Cross Blue Shield of South Carolina
P.O. Box 100300
Columbia, SC 29202-3300

Re: Updates to Coverage Policy for Intravenous (IV) Simponi Aria and (IV) Orencia

Dr. Harms and Mr Isreal:

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 rheumatology care in South Carolina and other states treating patients insured by Blue Cross Blue Shield (BCBS) and Blue Choice of South Carolina.

It is with this in mind that we write to you regarding recent changes to your coverage policy for IV Simponi Aria and IV Orencia, scheduled to go into effect January 1, 2022. Specifically, we are concerned that the exclusion of medical coverage for IV Simponi Aria and IV Orencia, with sole coverage for the self-injectable version, will negatively impact the patients treated by our members.

We are most concerned about those patients that are presently stable on the IV formulations of these medications or those that have already failed the subcutaneous formulations. We strongly support the American College of Rheumatology (ACR) position, which specifically states that policies should allow for grandfathering of patients whose disease is well controlled on stable therapy.[1]

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

As you know, your medical policy already has steps in place for coverage of IV Simponi Aria, with patients having to have tried and failed two self-injectable therapies[2] before getting coverage for IV Simponi Aria. These patients have already shown lack of responsiveness or adverse event to two subcutaneous (SC) preparations, and consequently, the SC mandate makes little sense if their physician chooses to change route of administration and wishes to use the IV preparation of either of these two medications based on previous issues with SC formulations.

A survey by the Global Healthy Living Foundation revealed that nearly 40% of patients who are supposed to be self-administering subcutaneous medication rely on family and friends to inject them. This often leads to non-adherence, resulting in loss of disease control. Lack of adherence to treatment is a significant contributor to avoidable health care costs in this country.[3] For some patients, the choice of an IV formulation is made to assure that the patient is taking their medication when they are supposed to, and not taking it if they have an infection or any other reason that would require skipping the medication. This is especially important given our current pandemic climate, and that patients on immunomodulating therapy are in the highest infection risk category.

There are clearly efficacy benefits for some patients on IV medications versus a SC formulation. Weight-based dosing is an improvement over flat dosing, particularly in patients with higher BMIs. Faster onset of relief with IV medications improves adherence, and as stated by the ACR, there are "unique indications, risks and target patient populations to warrant using[4]" different formulations determined by shared decision making between the patient and their physician.

Most concerning is that your current policy mandates patients who are stable on IV Simponi Aria or IV Orencia to change to a SC formulation for a non-medical reason, known as non-medical switching, which increases the likelihood of a loss of disease control. The American College of Rheumatology disapproves of non-medical switching[5] because of the potential harm to stable patients, a position we and other rheumatology organizations strongly support.

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 is high in terms of quality of life, disease progression, and downstream healthcare utilization. A study published in the Journal of Rheumatology that switched patients from IV abatacept (Orencia) to the SC formulation resulted in nearly 30% of patients losing control of their disease and having to return to the IV formulation.

Cost control is often cited as a reason for switching patients. However, non-medical switching is

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[2] http://www.cam-policies.com/internet/cmpd/cmp/mdclplcy.nsf/DispContent/946A02CCC87EF52D8525811E0069B560?opendocument

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/

[4] https://www.rheumatology.org/Portals/0/Files/Complexity of Biologics.pdf

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

a poor way to achieve that for the patient populations in question, as it leads to larger downstream costs that swamp any up-front savings for the plans.[6] **These cost-motivated switches increase plan enrollees' health care utilization, disrupt the course of care, and, as a result, increase related health care costs.**[7] It is for these reasons that caution should be a paramount principle guiding management of their disease once a patient's condition has been successfully stabilized.

CSRO requests that, at the very least, BCBS and Blue Choice of South Carolina exempt patients who are currently stable on IV Simponi Aria or IV Orencia from the new coverage policy. We also would like to discuss the broader implications of your discontinuation of medical coverage for the IV preparations of medications that are beneficial for many patients.

We request a reply by this Friday, December 17 to schedule a meeting before December 24. Please email me at MadelaineFeldman@gmail.com with your availability, and thank you for your partnership in the care of rheumatology patients.

Sincerely,

Madelaine Feldman, MD, FACR
President – Coalition of State Rheumatology Organizations

Sent via email

CC: South Carolina Department of Insurance (consumers@doi.sc.gov)

[6] https://www.ecco-ibd.eu/index.php/publications/congress-abstract-s/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html
[7] http://allianceforpatientaccess.org/wp-content/uploads/2016/10/IfPA_Cost-Motivated-Treatment-Changes_October-2016.pdf.