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Coalition of State Rheumatology Organizations

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555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414.918.9825
Email: info@csro.info
Website: www.csro.info

February 26, 2025

Stephanie Carlton
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 2018 Step Therapy Memorandum

Dear Ms. Carlton:

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 ask for your assistance with improving access to biosimilar medications for seniors with rheumatic disease. Biosimilars are vital therapies for treating chronic rheumatologic conditions such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and lupus, among other diseases. These lower-cost therapies alleviate pain and dysfunction while reducing costly disease-related complications, including joint damage, surgery and hospitalizations.

In our comments on the Contract Year (CY) 2026 Medicare Advantage and Part D Prescription Drug Plan Policy and Technical Changes and the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (PFS), we shared concerns about beneficiary access to biosimilars that are reimbursed at rates below their acquisition costs, or "underwater," making them unaffordable for physicians – and even hospitals – to "buy and bill" and administer. We explained that the low average sales price (ASP) for these medications is the result of excessive rebates paid to health plans and their pharmacy benefit managers (PBMs) by certain biosimilar manufacturers to secure preferred formulary placement, but which artificially depress the ASP. Although the *Inflation Reduction Act* temporarily increased the ASP add-on for some biosimilars from 6% to 8%, the increased add-on does not sufficiently bridge the gap between rheumatologists' costs and Medicare reimbursement, leaving physicians – and some hospitals – financially "underwater." We understand that CMS does not have the statutory authority to modify the ASP payment methodology; this will require a legislative solution that, unfortunately, will be complicated by limitations on key data points and a considerable price tag.

We also shared that CMS' memorandum to Medicare Advantage Organizations (MAOs), *Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage*, is preventing enrollees from accessing an alternative therapy (e.g., another more affordable biosimilar or the reference biologic) when the underwater biosimilar is preferred ("fail first") in the step therapy protocol. If physicians can't afford to purchase and administer the preferred biosimilar in their office, the enrollee must be referred to another site of care, usually a hospital. Moving

treatment to a hospital significantly increases the cost of care and adds unnecessary patient safety risk to immune-compromised patients. Further, due to the reimbursement challenges noted above, if the hospital is underwater on the mandated biosimilar, they refuse to take the patient. This leaves enrollees without any access to therapy. It is important to highlight that beneficiaries with original Medicare (and usually a supplement) are ***not*** subject to step therapy protocols, meaning the physician can choose to administer another affordable biosimilar or the reference product, as appropriate.

Misalignment in access to medications across Medicare Advantage and original Medicare needs to be corrected quickly, particularly as more enrollees choose Medicare Advantage for their health needs. This could be achieved if CMS withdrew its step therapy policy or, at a minimum, revised it to mandate enrollee access to another biosimilar or the reference product that the physician's practice can afford to administer. It would also provide Congress with the necessary time to work with stakeholders, including CMS, on a longer-term solution to biosimilar reimbursement challenges.

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Thank you for considering our feedback on this important issue to your beneficiaries, and our patients. We would be pleased to share a number of options that Congress could establish to improve ASPs for biosimilars. Please do not hesitate to contact us at info@csro.info should you require additional information or to set a meeting with our leadership.

Sincerely,

Aaron Broadwell, MD, FACR
President

Madelaine A. Feldman, MD, FACR
Vice President, Advocacy & Government Affairs