August 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare and Medicaid Services
Department of Health and Human Services

Via Email (chiquita.brooks-lasure@cms.hhs.gov)

Dear Administrator Brooks-LaSure:

The undersigned organizations, representing a broad range of providers and patient advocates nationwide, write to you today to express our grave concerns regarding the inadequate (or "underwater") reimbursement of certain part B biosimilars by the Centers for Medicare and Medicaid Services (CMS) and its impact on the quality of care that patients receive. Specifically, we request a meeting with you and strongly call for CMS to address the issue of underwater biosimilars to any extent possible and work with Congress where necessary to amend Section 1847a of the Social Security Act to include an 8% add-on to the actual acquisition cost and/or removal of manufacturer rebates to pharmacy benefit managers (PBMs) from the ASP equation.[1]

Biologics are vitally important therapeutic options for patients with certain chronic diseases, such as cancer, arthritis, and glaucoma. In addition to reducing pain and dysfunction related to inflammatory, genetic, and ocular diseases, these medications reduce costly disease-related complications, including cardiovascular diseases, metabolic syndromes, and expensive procedures and surgeries. Biologics also reduce costs by preventing missed work, improving work performance, and avoiding long-term disability. Biosimilars undergo rigorous testing to demonstrate no clinically meaningful differences exist in safety or efficacy compared to their reference products, which are the original brand-name biologics. These less costly versions of existing biologics have the potential to promote a sustainable, robust market that encourages competition, cost savings, and better serves patients.

As biosimilars are a market-based solution to help with the affordability of specialty drugs in the US, there is a real opportunity for patients to be part of the savings. However, PBMs have exerted disproportionate sway on formularies. They have pressured pharmaceutical companies to offer significant rebates to get their biosimilar versions on formularies. Manufacturers that agree to these high rebate demands then report the rebates to CMS as part of their quarterly ASP reporting, and in turn experience a subsequent reduction in their ASP, resulting in significantly decreased reimbursement for their products.

Unfortunately, the drop in ASP has not been matched by a similar drop in the acquisition costs for some commonly used biosimilars, thus putting physicians who buy and bill these drugs underwater when they infuse them. The resulting financial pressure obliges practices to choose to

[1] https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm

either administer the drug to the patient at a loss, transfer their administration site to a hospital, or switch the patient's therapy. This scenario delays care and risks compromising patient safety.

Please note that the scenario we are describing is distinct from the one which was addressed by a provision in the Inflation Reduction Act whereby CMS was concerned that providers might avoid administering biosimilars due to reduced profit margin on cheaper drugs, and so it was provided to calculate an 8% add-on from the cost of the more expensive originator drug rather than the cheaper biosimilar. That scenario assumed that providers could acquire the cheaper drug without being reimbursed at a loss. We are describing a scenario where providers would be, in the most extreme scenario, more than 100% underwater on reimbursement. As such, even with the originator-based add-on, most providers would be administering these drugs at a loss.

As you know, the ASP serves as the basis for CMS (and private payer) reimbursement of these drugs via the ASP+6 equation. We have seen that the rebates paid by manufacturers, which are not passed along to the providers who are purchasing the drug, are reducing the ASP to a level at or below the acquisition cost of the medication. This problem is occurring across multiple suppliers, indicating an industry-wide phenomenon. In many regions of the country, biosimilars are no longer accessible to patients for this reason. Ironically, the lowest cost medication, the biosimilar, cannot be used due to this problem, and this will increase Medicare expenditures significantly. This is highly unfair to providers and patients alike. As such, we reiterate the following requests:

1) CMS must address the issue of underwater biosimilars to any extent possible and work with Congress where necessary to amend Section 1847a of the Social Security Act to include an 8% add-on to the actual acquisition cost and/or removal of rebates.
2) We would like to have a meeting with you and relevant stakeholders at CMS to discuss how this can be adequately achieved.

We strongly believe that the development and approval of biosimilars marks a critical moment for the healthcare economy. Biologic drugs have transformed the lives of many patients, but with a high economic cost. If biosimilars can affect cost savings with similar effectiveness to the originators, it will be a win-win for all parties. We are pointing out to CMS, however, that due to flaws in the part B reimbursement system, the uptake of these drugs is being hampered, and unless a solution is achieved, we worry that the same underwater situation will plague future biosimilars.

Conclusion

The coalition is dedicated to working with CMS to ensure that all patients have access to high quality care and that all providers are reimbursed fairly for providing it. We look forward to partnering with CMS and Congress on this endeavor and serving as a resource as rules and regulations on biosimilars are developed. Please contact Colby Tiner, MA, at ctiner@rheumatology.org if you have any questions.

Sincerely,
Organizations

Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
Alliance for Safe Biologic Medicines
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
Arthritis Foundation
Association of Women in Rheumatology
California Rheumatology Alliance
Chicago Rheumatism Society
Coalition of State Rheumatology Organizations
Colorado Rheumatology Association
Connecticut Rheumatology Association
Crohn's and Colitis Foundation
Digestive Health Physicians Association
Florida Society of Rheumatology
Georgia Society of Rheumatology
Infusion Providers Alliance
Kentuckiana Rheumatology Alliance
Lupus and Allied Diseases Association
Maryland Society for the Rheumatic Diseases
Massachusetts, Maine, and New Hampshire Rheumatology Association
Michigan Rheumatism Society
Midwest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Managers
New York State Rheumatology Society
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
North Carolina Rheumatology Association
Ohio Rheumatology Association
Philadelphia Rheumatism Society
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Society of New Mexico
Spondylitis Association of America
State of Texas Association of Rheumatologists
Tennessee Rheumatology Society
Virginia Society of Rheumatology
Washington State Rheumatology Alliance
West Virginia State Rheumatology Society
Wisconsin Rheumatology Association