November 22, 2024

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
H-232, The Capitol
Washington, DC 20515

The Honorable Charles Schumer
Majority Leader
U.S. Senate
S-221, The Capitol
Washington, DC 20515

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
H-204, The Capitol
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
S-230, The Capitol
Washington, DC 20515

RE: Inadequate reimbursement of certain Medicare Part B biosimilars

Dear Speaker Johnson, Majority Leader Schumer, Minority Leader McConnell, and Minority Leader Jeffries:

The undersigned organizations of the Underwater Biosimilars Coalition ("The Coalition") are committed to improving access to provider-administered medications, including biosimilars. The Coalition is comprised of over 40 organizations representing a broad range of providers and patient advocates nationwide. We write to express our grave concerns regarding the inadequate (or "underwater") reimbursement of certain Medicare Part B biosimilars under the current average sales price (ASP) methodology and its impact on access to care, and to recommend potential solutions intended to broaden the use of these lower-cost therapies.

Background

Biosimilars, which typically provide a lower cost version of existing biologics, are vitally important therapeutic options for patients with certain chronic diseases, such as cancer, arthritis, and macular degeneration. In addition to reducing pain and dysfunction related to inflammatory, genetic, and ocular diseases, these medications reduce the frequency of costly disease-related complications, including cardiovascular diseases, metabolic syndromes, and expensive procedures and surgeries. Biosimilars undergo rigorous testing to demonstrate comparable safety and efficacy to their reference products (i.e., brand biologics). Biosimilars have the potential to promote a sustainable, robust market that encourages competition, cost savings, and better patient care.

As biosimilars are a market-based solution to help with the affordability of specialty drugs in the U.S., there is a real opportunity for savings to the entire healthcare system, including the Medicare program and patient out-of-pocket costs. However, insurers and their pharmacy benefit managers (PBMs) have exerted disproportionate sway on drug formularies by pressuring pharmaceutical companies to offer significant rebates in exchange for preferred formulary placement, including "fail first" status. These rebates are reflected in manufacturers' quarterly ASP reporting to the Centers for Medicare and Medicaid Services (CMS), and they have artificially lowered the ASP to the point that many providers' acquisition costs substantially exceed Medicare and other private health plan payments.

Problem

Many physician practices that directly administer drugs, including biosimilars, to patients in outpatient facilities engage in a practice known as "buy and bill." These practices pre-purchase drugs and bill the payer for reimbursement once the medication is administered to the patient. Margins for practices engaged in buy and bill are thin. Recognizing the need for drug administration to cover overhead costs such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance, CMS established drug reimbursement at 6% above ASP. In the case of "underwater biosimilars," not only are our members NOT afforded the small margins that help defray overhead costs, but they are not even reimbursed enough to cover the cost of the drug itself.

Unfortunately, the ASP for most biosimilar therapies continues to fall short of many providers' acquisition costs – even for the earliest biosimilars – forcing providers into an untenable position. Their choices include: administering the drug at a financial loss, transferring care to another site of service (e.g. a hospital), or switching the patient's therapy when they are stable on current therapy, which may be further complicated by "step therapy" requirements imposed by payers, including Medicare Advantage plans. Not only do these options increase financial pressure on providers, but they also contribute to higher costs to the healthcare system, Medicare, and patients, and lower the quality of care. For example, administering drugs in a hospital setting increases costs for both payers and patients, while altering treatment disrupts continuity of care and can result in suboptimal outcomes, potentially leading to worsened health conditions.

Congress increased the ASP "add-on" from 6% to 8% for qualifying biosimilar therapies for five years in Section 11403 of the *Inflation Reduction Act* (IRA), Public Law 117-169. According to CMS, this temporary add-on payment has been implemented to promote greater competition within the biologic/biosimilar marketplace and to increase access to and utilization of biosimilars. However, this does not extend to all biosimilars on the market.

Unfortunately, even with this increased ASP +8% "add-on" rate, physicians are still underwater because the ASP is so artificially low. As Congress continues to explore opportunities to increase access to biosimilars, it's imperative to address provider "underwater" biosimilar reimbursements, which will remain an obstacle to full biosimilar integration into the market if providers are unable to offer these vital medications to patients.

Importantly, this scenario seems at odds with bipartisan interest in reducing drug prices and expanding access to lower-cost alternatives, such as biosimilars.

Potential Solutions

Following meetings with CMS leadership, it is clear that resolving this challenge requires legislative action, as CMS does not have the necessary authority to meaningfully improve reimbursement for these drugs. Our coalition recommends the following options to raise the ASP for underwater biosimilars for Congressional consideration:

1) Amend Section 1847A(b) of the Social Security Act (SSA) to temporarily provide an 8% add-on to the providers' acquisition cost of all biosimilar products;
2) Amend Section 1847A(c)(4) to extend the Secretary's authority to use wholesale acquisition cost (WAC) + 3% until ASP reaches sustainable levels, as determined by the Secretary; or

3) Amend Section 1847A(c)(3) to permanently remove manufacturer rebates from the ASP methodology for biosimilars.

The Coalition believes that the development and approval of biosimilars marks a critical moment for the healthcare economy. Biologic drugs have transformed the lives of many patients, and their biosimilars can affect cost savings with comparable effectiveness. However, due to flaws in the ASP methodology, uptake of these drugs is hampered – a challenge that will continue to plague future biosimilars absent congressional action.

Conclusion

The Coalition is dedicated to working with Congress 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 you on this endeavor and serving as a resource to address "underwater" biosimilars. 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