Bristol Myers Squibb™

July 13, 2025

VIA ELECTRONIC SUBMISSION

Washington Prescription Drug Affordability Board
626 8th St. Ave. SE
Olympia, WA 98501
HCA_WA_PDAB@hca.wa.gov

Re: Prescription Drug Prioritized Shortlist

Dear Members of the Washington Prescription Drug Affordability Board:

Bristol Myers Squibb ("BMS") appreciates the opportunity to submit written comments to the Washington Prescription Drug Affordability Board (the "Board") on its subset of prescription drugs to prioritize for affordability review. **For the reasons below, we respectfully ask that ORENCIA® (abatacept) be removed from the prioritized shortlist and not subject to the affordability review process.**

Bristol Myers Squibb's Commitment to Washington Patients

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through lifesaving, innovative medicines. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, cardiovascular disease, and neuroscience—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change. BMS supports public policies that promote patient access to new and effective medical treatments and help ensure patients benefit from the innovation that defines the U.S. health care system, and we have long supported efforts in Washington to meaningfully enhance patient access and improve affordability by lowering out-of-pocket costs for patients.

In light of ORENCIA's clinical importance, demonstrated patient affordability, designation as an orphan drug, and the anticipated entry of biosimilar competition, we respectfully urge the Board to remove ORENCIA from the prioritized shortlist for affordability review. As outlined in the sections that follow, we are concerned that the current methodology used to prioritize drugs for review may not appropriately reflect actual affordability challenges for patients and risks creating unintended consequences for access to essential therapies. We offer the following background and rationale in support of this request.

Background on ORENCIA

ORENCIA is a first-in-class T cell costimulation modulator indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA), and the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) or with active psoriatic arthritis (PsA).[1] RA, the most prevalent condition treated by ORENCIA, is a chronic autoimmune disease that causes inflammation around the body and commonly presents with pain in the joints. Left untreated, RA can cause severe damage to the joints and their surrounding tissue, leading to profound disability. It can also lead to complications in other organ systems including the heart, lungs, and nervous system.[2] Common symptoms include chronic pain, stiffness, tenderness, heat and swelling in the joints. RA can make it hard to move and perform daily activities. Notably, women are two to three times more likely to suffer from RA.[3]

There are several factors which make ORENCIA clinically unique in the rheumatology class. ORENCIA is the only approved RA treatment that addresses the root cause of the inflammatory response, T-cell activation. ORENCIA may be the last line of defense against RA, as patients are often required to try and fail with other medications before being prescribed ORENCIA. Importantly, ORENCIA is one of the safest medications in a class where adverse events (AEs), such as infections and certain types of cancers, are common. AEs have been shown to occur much less frequently with patients taking ORENCIA, which leads to lower health system costs and better patient adherence.[4] Given that patients with RA often suffer from comorbid conditions involving the heart, lungs, and other systems, there is a proven need for a medication that can be used safely in a sicker patient population. Finally, due to its strong efficacy and safety profiles, ORENCIA is one of the most durable medications in its class, with patients often remaining on therapy and continuing to see benefits over several years.

In addition to the clinical benefits of ORENCIA, its economic benefits have also been well-documented. Studies show that patients treated with abatacept had lower odds of hospitalization and emergency department (ED) visits than those treated with a first-line TNF inhibitor.[5] Decreasing the odds of these costly interventions not only lessens the burden on patients, but also provides significant savings to the health care system overall. Other studies have shown that, when compared to other common treatment options for RA, ORENCIA is more cost effective at both 10 years and over patients' entire lifetimes.[6,7]

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[1] ORENCIA® (apixaban) Package Insert. Bristol-Myers Squibb Company, Princeton, NJ https://packageinserts.bms.com/pi/pi_ORENCIA.pdf.
[2] Rheumatoid Arthritis. World Health Organization. June 28, 2023.
[3] *Id.*
[4] Han X, Park S, Schmier J, et al. Adverse event-related costs associated with abatacept and upadacitinib for moderate-to-severe rheumatoid arthritis. Poster presentation at: International Society for Pharmacoeconomics and Research (ISPOR) 2021; May 17-20. Virtual Meeting.
[5] Klink A, et al. Am J Manag Care. 2019;25(10):e288-e295.
[6] Vera-Llonch M, et al. Cost-effectiveness of abatacept in patients with moderately to severely active rheumatoid arthritis and inadequate response to methotrexate. Rheumatology. 2008; 47:535-541.
[7] Vera-Llonch M, et al. Cost-effectiveness of abatacept in patients with moderately to severely active rheumatoid arthritis and inadequate response to tumor necrosis factor antagonists. J Rheumatol. 2008; 35:1745-1753

The Prioritized Shortlist Places Excess Weight on Prescription Volume and Insurer Spending Data

We believe that ORENCIA should be removed from the prioritized shortlist of prescription drugs as its inclusion is inappropriately weighed more heavily on its volume of use by clinicians and patients in Washington and the costs to insurance companies. Washington law states that the Board "must determine whether the prescription drug has led or will lead to excess costs to patients" and instructs the Board to consider multiple factors in determining which prescription drugs to prioritize for affordability review.[8] We are concerned that the current methodology and criteria used by the Board to identify prescription drugs for affordability review may not accurately prioritize those prescription drugs that may pose affordability challenges for patients, as the listing of ORENCIA reflects. We believe this inclusion places disproportionate weight on payer-level data rather than direct patient benefit.

In developing the shortlist, the Board has elected to rely on a weight rank calculation using a variety of data inputs. Notably, nearly half of the weighted rank is calculated using the total amounts paid by insurers for the drug and the volume of patients who had a claim for the drug in a given year.[9] This methodology may inadvertently deprioritize the very factors – broad clinical utility and patient access – that reflect a medicine's value to patients and providers. An overreliance on payer-level costs also overlooks the most meaningful measure of affordability – whether patients can both obtain and adhere to the medications they need. To help address any affordability challenges that may exist for patients, a copay assistance program is available through which eligible, commercially-insured patients can pay as little as $5 per month for ORENCIA.[10]

ORENCIA's Designation as an Orphan Drug by the FDA

In addition to its many clinical and economic benefits for patients suffering from various forms of arthritis, ORENCIA also received designation by the Food and Drug Administration (FDA) as an orphan drug in December 2021 as a prophylactic treatment of acute graft versus host disease (aGvHD) for patients undergoing hematopoietic stem cell transplantation (HSCT). This designation underscores ORENCIA's critical role in addressing rare, potentially life-threatening conditions. The Prescription Drug Affordability Boards (PDABs) in Colorado and Oregon acknowledge the vital importance of facilitating access to treatments for rare diseases by exempting orphan-designated drugs from affordability reviews. We urge the Board to carefully review the potential detrimental impacts that imposing an affordability review and upper payment limit (UPL) determination could have. Such actions could significantly hamper access for patients relying on ORENCIA for stem cell transplantation, potentially undermining the benefits provided by this essential therapy.

[8] RCW 70.405.040
[9] Please refer to "Methodology for Selecting Prescription Drugs for Affordability Review" available here: https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-affordability-board#affordability-reviews.
[10] ORENCIA On Call™ patient assistance program and savings card. Bristol Myers Squibb Company (July 2025). https://www.orencia.com/support-savings.

ORENCIA's Limited Remaining Market Exclusivity

ORENCIA's patent exclusivity in the United States concluded in 2021. Despite the inherently complex and extended development and regulatory pathways associated with biosimilars, especially for first-in-class, sophisticated biologics such as ORENCIA, biosimilar competitors are actively progressing through development stages and have demonstrated positive results in clinical trials. Of note, the Board's authority to enforce upper payment limits (UPLs) does not take effect until January 2027. Consequently, biosimilar competition for ORENCIA is highly probable either prior to, or contemporaneously with, the implementation of UPL determinations. Given this anticipated competitive landscape, we strongly urge the Board to prioritize its evaluation efforts on drugs lacking imminent biosimilar competition. Concentrating on drugs where generic alternatives do not exist or are not projected to be available at the time of UPL determinations would optimize the Board's resources and efficacy in safeguarding patient access to affordable medications.

Conclusion

BMS is committed to promoting policies that protect Washington patients and enable them to better afford their medicines. We share the Board's goal of lowering out-of-pocket costs for patients and believe this is best achieved through reforms that directly target patient affordability, such as requiring PBMs to pass negotiated savings to patients at the pharmacy counter. Considering the preceding arguments, **we strongly urge the Board to remove ORENCIA from the prioritized shortlist of prescription drugs**.

Thank you for the opportunity to provide comments and for considering our concerns. Should you have any questions or concerns, please contact Richard Meyers, Director, State & Federal Policy at richard.meyers@bms.com and Anne Murray, Director, State & Local Government Affairs, U.S. Policy & Government Affairs at anne.murray@bms.com.

Sincerely,

/s/ Anne Murray

Director, State & Local Government Affairs
Bristol Myers Squibb