ASRS American Society of Retina Specialists

December 17, 2024

Rodrigo Cerda, MD
Independence Blue
Chief Medical Officer
1901 Market Street
Philadelphia, PA 19103-1480

Sent via email to: Rodrigo.Cerda@ibx.com

Subject: Broader Anti-VEGF Access Needed

Dear Dr. Cerda,

The American Society of Retina Specialists (ASRS)[i] advocates for physician-patient choice and access to all treatments for potentially blinding retinal disease. Retina specialists and their patients are experiencing the fourth abrupt interruption in access to bevacizumab (Avastin) in the past five years. In response, on November 25, 2024, CMS issued a memo encouraging insurers to consider halting or suspending step therapy and prior authorization requirements for alternative ophthalmic anti-vascular endothelial growth factor (VEGF) therapies to avoid access issues or treatment delays. We join CMS in urging you to suspend your Avastin step therapy policy.

We also ask for assurance that retina specialists will be able to continue to care for patients that have been switched to alternate therapies without worry of denials and burden of subsequent appeals. We are concerned that the September 30, 2024, Independence Blue, Inc., announcement to limit access to retina drugs fails to meet the best clinical standards of care. We would like the opportunity to meet with you to discuss the following issues:

- According to your website, Independence will require an Avastin-first protocol that includes several biosimilars, Alymsys, Avzivi, Mvasi, Vegzelma, Zirabev. As a reminder, these biosimilars are prohibited from being included in step therapy by the Centers for Medicare and Medicaid Services because they are not tested for treatment in the eye.

- The guidance on your website then requires Lucentis, and its biosimilars Cimerli and Byooviz, prior to accessing more durable anti-VEGF medications. **This multi-step approach to access does not align with best clinical practices and undermines the critical patient-physician relationship. Further, such policies jeopardize timely access to effective treatments, potentially leading to unrecoverable vision loss.**

Avastin Biosimilars Not Approved for Intravitreal Use

We believe, and CMS has agreed**, that it is absolutely inappropriate for plans to recommend or mandate-use of these biosimilars for injection without a prior clinical trial and testing for retinal toxicity. Untested use of intraocular medications can lead to potentially irreversible blindness due to unforeseen inflammation.**

Concerns Regarding Avastin Beyond Availability

Since Avastin is not an interchangeable treatment for certain patients' retinal disease, requiring it weakens the authority of the Food and Drug Administration (FDA) and interferes with accepted and standard-of-care medical decision-making. Patients with diabetic macular edema (DME) are more likely to suffer poorer visual outcomes when they are not able to quickly access their retina specialist's preferred treatment. The randomized Protocol T study[ii], funded by the National Eye Institute, demonstrated that patients with 20/50 or worse vision related to DME who were treated with Avastin were significantly more likely to suffer from persistent DME after six months of treatment than patients treated with Eylea or Lucentis. Our concern regarding a triple step therapy approach with an Avastin-first start, possibly followed by a ranibizumab or its biosimilars, is that patients may experience permanent vision loss while less effective treatments are being used early on.

ASRS has collected data reflecting these concerns through conducting the annual Preferences and Trends Survey, the largest survey of retina specialists practicing in the US and abroad. In 2023, when retina specialists were asked if adverse outcomes had been seen as a result of step therapy: 71 % reported lack of anatomic improvement, 63.8% reported lack of visual improvement, and approximately half of retina specialists reported worsening anatomy (50.7%), worsening vision (49.2%), and patient dissatisfaction (52.8%).[iii] Rather than risking irreversible damage to the patient's vision, evidenced-based guidance should allow patients to be treated with the available FDA-approved medications.

Scientific Studies and Practical Consideration Supporting Access to Durable Drugs

Clinical studies support the need to maintain timely access to drugs like Eylea, Eylea HD and Vabysmo to help patients gain or maintain their sight. In the VIEW trials,[iv] the largest comparison study for patients with wAMD completed comparing Eylea and Lucentis, Eylea demonstrated key advantages when compared with Lucentis. With fewer injections than Lucentis over a year, Eylea demonstrated visual acuity gains. In the TENAYA and LUCERNE studies, patients treated with Vabysmo received a median number of 10 injections over the two years verses 15 injections for those treated with Eylea, potentially decreasing the number of injections, and reducing additional out-of-pocket costs for patient co-pays.

The broader impact of multistep prior authorization policies cannot be overlooked. Injection risks include, but are not limited to: endophthalmitis, infection and retinal detachment. The latest generation of treatments may have longer durability and, thus, reduce the number of injections and risk of complications. As it stands, delaying or denying a longer-lasting treatment for any patient could worsen an Independence Blue beneficiary's quality of life and lead to higher treatment costs.

For beneficiaries, who are typically employed, the availability of durable drugs has both clinical and lifestyle benefits that minimize disruptions to their employment and lessen the treatment burden and number of co-pays that the patient is responsible for. Physicians often navigate short treatment windows along with the patient's reliance on family and friends for transportation, holidays, illnesses and staffing challenges. As patients are able to attain dosage frequencies equal or greater than 7 weeks, there would likely be better adherence to treatment

plans. Whereas delaying or denying a longer-lasting treatment for any patient could hasten a drastic change in a beneficiary's quality of life.

Economic Impact

There is also an economic impact of restrictive step therapy policies. Delays in treatment due to prior authorization and step therapy can lead to increased healthcare costs. For instance, studies indicate that patients who experience delays may require more intensive and costly interventions, ultimately burdening the healthcare system. A study presented at the 2024 ASRS annual meeting that is awaiting publication found the physician-directed real-world cost of treating patients with diabetic retinopathy was 20% lower than compared to the costs of a study on Avastin-first treatment.[v] Additionally, the administrative costs associated with managing these protocols can divert resources away from patients.

Moreover, patients may face higher out-of-pocket expenses and increased rates of medication abandonment, which can exacerbate their health conditions and lead to further economic strain. Timely access to effective treatments like Eylea and Vabysmo not only enhances patient outcomes but also reduces long-term healthcare costs.

We ask you to meet with us to discuss possible changes to Independence Blue's drug access to allow physicians to make judicious choices based on each patient's unique risk factors, clinical appearance, and economic requirements. We would be happy to schedule a meeting to discuss this issue further. Thank you for considering our request. Please do not hesitate to contact ASRS Director of Practice Management, Monica Horton, monica.horton@asrs.org with questions or to schedule a meeting.

Sincerely,

Ankoor Shah, MD
Chair, ASRS Practice Management Committee
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[i] ASRS is the largest retina organization in the world, representing over 3,000 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

[ii] The New England Journal of Medicine, The Diabetic Retinopathy Clinical Research Network, "Aflibercept, Bevacizumab, or Ranibizumab for Diabetic Macular Edema," (also known as Protocol T, Year 1), March 26, 2015. http://www.nejm.org/doi/full/10.1056/NEJMoa1414264#t=article

[iii] Hahn P. ed ASRS 2023 Preference and Trends Membership Survey, slide 39. Chicago, IL. American Society of Retina Specialists; 2023. ©2023 American Society of Retina Specialists. All rights reserved.

[iv] Peter K. Kaiser, Michael Singer, Michael Tolentino, Robert Vitti, Kristine Erickson, Namrata Saroj, Alyson J. Berliner, Karen W. Chu, Xiaoping Zhu, Zinaria Williams Liu, W. Lloyd Clark, "Long-term Safety and Visual Outcome of Intravitreal Aflibercept in Neovascular Age-Related Macular Degeneration: VIEW 1 Extension Study," https://doi.org/10.1016/j.oret.2017.01.004

[v] Cost-Effectiveness of Diabetic Macular Edema Treatment: Protocol AC Bevacizumab-First vs. Real World. 2024 American Society of Retina Specialists Annual Meeting, July 19, 2024.