

## **ASRS Support of Physician and Patient Choice in Treatments for Retinal Disease**

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The American Society of Retina Specialists (ASRS) is the largest retina organization in the world, representing over 3,500 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.

That ability, however, is threatened by insurer policies—in both the Medicare Advantage and private markets—aimed solely at cost savings. Payer utilization management policies, such as prior authorization and step therapy, interfere with the doctor-patient relationship and routinely restrict the use of certain anti-vascular endothelial growth factor (anti-VEGF) drugs for the treatment of potentially-blinding retinal disease. The ASRS is concerned that with the introduction of biosimilars into the retina space, these policies will proliferate and further limit patient access to the treatments retina specialists determine are most appropriate. **We are adamantly opposed to any insurer policy that mandates a certain treatment or series of treatments for retinal disease, regardless of whether the drug is an FDA-approved originator product, a biosimilar, or an off-label drug.**

#### ***Background***

The introduction of anti-VEGF treatment for chronic retinal diseases, such as age-related macular degeneration (AMD) and diabetic retinopathy, has revolutionized the way retina specialists care for their patients. In many cases, these treatments allow patients to maintain a good quality of life; prevent other high-cost medical care, such as for falls, depression, or other conditions associated with blindness; and have allowed patients of working age to remain employed and productive.

Despite these advances, there is no one-size-fits-all treatment for every patient experiencing one of these chronic retinal diseases. Retina specialists have unique training in diagnosing and considering the individual factors of a patient's disease and tailor their treatments specifically to each patient. Currently, there are several FDA-approved drugs available, of which the most-widely used are Eylea (aflibercept) and Lucentis (ranibizumab). In addition, Avastin (bevacizumab), which is off-label and repackaged for ocular use, is regularly used.

While many retina specialists use Avastin, some patients do not respond adequately to it, or may have other factors or conditions in which scenario the use of a branded FDA-approved drug manufactured for use in the eye may be more appropriate. The decision to begin with Avastin or move to a branded agent is appropriately at the discretion of the physician and patient. Retina specialists have several options for treatment patterns and dosing, depending on the individual patient. Some may follow a monthly dosing schedule, pro ne rata (as needed), or treat-and-extend method. It is difficult to predict what treatment pattern may work best for an individual patient at the outset, and whether adjustments to the regimen may be necessary as treatment progresses. In addition, all treatment options must be available because some FDA-approved drugs are not approved or covered for certain indications, such as for sickle cell retinopathy or for some pediatric patients, and retina specialists need flexibility to use Avastin off-label.

#### ***Opposition to Step Therapy***

Because of the variability in treatment options, insurer attempts to control cost through step therapy are particularly troubling. Nearly every MA plan or private insurer restricts access to FDA-approved

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branded anti-VEGF products through step therapy by requiring patients begin with and fail the use of Avastin because it is the least expensive option. It is assumed that these policies will incorporate additional step edits to include new biosimilars on the market because of their lower price points. While biosimilars may become the preferred option for some patients—just as some patients are well-managed with Avastin—the ASRS objects to any attempt by insurers to remove physician and patient discretion in drug choice through step therapy. Similarly, we oppose policies that prioritize one FDA-approved originator product over others.

Beyond our general opposition to step therapy, the ASRS is concerned that mandating the use of new products with which retina specialists have no clinical experience and that lack robust clinical literature supporting their use risks patient safety. While biosimilars are FDA-approved, they are not identical to their reference products, and the abbreviated clinical trials permitted through FDA's biosimilar approval process may not adequately identify potential adverse events that could occur in the general patient population. The risk of post-approval adverse events is not unique to biosimilars. Retina specialists' recent experience with an FDA-approved drug, Beovu (brolucizumab), which was found to cause inflammation and retinal vasculitis after it was available on the market, may make them hesitant to adopt new products on an immediate and widespread basis. Historically, retina specialists have taken a cautious approach when introducing new drugs or treatments into their patient populations, moving gradually to ensure patient safety.

The ASRS opposes *required* use of any new product, whether originator or biosimilar, especially before the real-world experience of retina specialists demonstrates its safety or efficacy. We are concerned that insurers mandating the use of new products without a proven record of clinical effectiveness and safety risk significant legal ramifications.

#### ***Opposition to Off-Label Biosimilar Use***

ASRS opposes the off-label use of Avastin biosimilars that have not been tested in the eye, and their inclusion in any payer step therapy policy. Unlike Avastin that has been effectively used off-label for over 15 years to treat retinal disease, there is no established clinical safety of current Avastin biosimilars. Furthermore, some of their excipient ingredients may be contra-indicated for ocular use. The ASRS supports the Centers for Medicare and Medicaid Services' (CMS) prohibition on the required use of off-label biosimilars as part of MA step therapy policies and recommends insurers to abide by it across all lines of business to protect patient safety. Clinical trials are currently underway for an Avastin biosimilar for ocular use. Similar to our concerns about immediate, widespread use of a new product that has no real-world clinical experience, the ASRS would oppose any inclusion of this biosimilar in a step therapy policy, but would not oppose its use in clinical settings, if FDA-approved.

#### ***Conclusion***

ASRS welcomes and encourages innovative products be introduced into the market, whether they are originators or biosimilars, as this expands the treatment options available to retina specialists; thereby ensuring patients with chronic retinal diseases have the best possible chance of maintaining the best vision possible, and therefore the best quality of life. Towards this end, we continue to believe payer-mandated use of any treatment or series of treatments is unacceptable. We urge all payers to reverse current step therapy policies that disrupt the doctor-patient relationship and restrict patient access to their preferred treatment.

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