

December 17, 2014

Dr. Roy A. Beveridge, M.D.
Senior Vice President and Chief Medical Officer
Humana
500 West Main Street
Louisville, KY 40202

Re: Lucentis (ranibizumab) and Eylea (aflibercept injection) Pharmacy Coverage Policies

Dear Dr. Beveridge:

On behalf of the American Society of Retina Specialists (ASRS), we would like to express our concern about Humana's step therapy policy aimed at restricting the use of medications to treat age-related macular degeneration (AMD) and other retinal diseases.

The ASRS is the largest retinal organization in the world, representing over 2400 fellowship trained members. Retina specialists are 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.

Effective January 1, 2015, Humana will require that patients have prior therapy, contraindication, or intolerance to Avastin (bevacizumab) before they can receive Lucentis or Eylea. We believe that it is inappropriate for any insurer to require the off-label use of Avastin before the use of two available FDA approved agents (Lucentis and Eylea) is considered. Currently, of the three utilized anti-VEGF agents, only Lucentis and Eylea have specific FDA approval. Avastin not only does not have specific FDA approval, it must be used in a compounded form. These three anti-VEGF agents are not interchangeable and their efficacy, safety, and clinical usage should determine which agent is the appropriate drug for a specific disease presentation in the setting of an individual patient's comorbidities and risk.

Recent clinical data have focused on the potential benefits of each of these three agents when care is directed by a retinal specialist and targeted to the individual patient and the specific anatomic and visual response of that patient. The concept of tiered therapy, when each of the three anti-VEGF agents has been found to have unique anatomic responses, negates the importance of targeted patient care whereby the retinal specialist selects the most effective drug for each unique patient. Ultimately, the retinal specialist utilizes clinical judgment to select the best drug to use for treatment. This ability to individualize treatment and select the most efficacious agent for each patient is the key to the major improvements we have gained in recovering and maintaining visual acuity and retinal function in our patients with blinding diseases of the retina.

Furthermore, we believe this policy should be rescinded at a minimum until such time as the U.S. Food and Drug Administration (FDA) has promulgated the compounding pharmacy rules that will determine whether Avastin will continue to be available in a compounded form and, if so, what entities will be permitted to “repackage” it. During this time of uncertainty, many retina specialists have already reported difficulty obtaining compounded Avastin. This problem will likely increase now that the FDA is cracking down on compounding pharmacies that have been dispensing compounded drugs without a patient-specific prescription for office use even in states that do not require one.

We are certain that our members’ patients who are enrolled in Humana’s commercial plans will be shocked to learn that they will no longer have access to FDA-approved drugs for diabetic macular edema. As part of our “Buyer Beware” campaign, we will be alerting our membership so they can discuss this policy change with their patients as soon as possible.

In summary, we strongly urge Humana to reverse its step therapy policy and allow retina specialists and their patients to make wise and judicious choices based on the patient’s unique risk factors, clinical appearance, availability of compounded drugs, and economic requirements.

We look forward to a response from you. Please do not hesitate to contact the ASRS if you have any questions. Thank you for your consideration.

Sincerely,

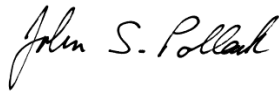
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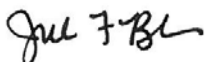
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