February 14, 2019

The Honorable Alex M. Azar
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery, we want to thank you for taking time out of your busy schedule to meet with us to discuss our organizations' priorities for 2019. We appreciated the opportunity to discuss several critical issues to our members and their patients. We look forward to working with you and your staff on these issues.

As you know from our discussion and previous communications, our organizations do not support allowing Medicare Advantage (MA) plans to implement step therapy programs. However, we do appreciate the opportunity to submit recommendations, enclosed with this letter, for safeguards/guardrails that CMS should implement to provide important protections for patients and the treatments that they may need.

While we recognize and appreciate that the Department's August 2018 memo's states that MA plans new step therapy requirements "should not disrupt ongoing Part B drug therapies for enrollees," our organizations are concerned that some insurers are utilizing prior authorization (PA) to "implicitly" impose step therapy- type requirements to get around the memo's even limited patient protections (i.e. No disruption of current treatment/therapy). We have included an example to better illustrate our concerns.

> A patient was being treated with Lucentis for age-related macular degeneration under her Medicare Plus Blue plan in Michigan, but the treatment was starting to have limited effectiveness. AMD treatments under this plan require Prior Authorization, but not step therapy. However, when the patient's ophthalmologist wanted to switch the patient to Eylea, the MA plan denied the Prior Authorization request and the physician was told to use Avastin first. This denial occurred despite calls by the physician himself requesting an exception for the patient.

We ask that CMS intervene with MA plans to protect patients and ensure that PA is not used as a way around step therapy protections.

Again, thank you for meeting with us to discuss our 2019 priorities, and the Academy and ASCRS stand ready to work with you and your staff to advance our common goals. We also want to work with you to ensure that patients have timely access to the treatments they need.

Sincerely,

Michael X. Repka, MD, MV
Medical Director for Governmental Affairs
American Academy of Ophthalmology

Steve Speares
Executive Director
American Society of Cataract and Refractive Surgery

Patient Safeguards for Step Therapy Policies

- Provide a clear exception for patients who are currently stable on their therapies and prohibit them from being forced to switch medications, including those patients who switch plans. Enrollees who have taken the Part B drug (that would otherwise be subject to step therapy) within the past 365 days should be excluded from step therapy requirements.

- Specify that the provider determines if a patient "fails" a treatment, not another entity such as the insurance company.

- Mandate 72-hour appeal/24 hour expedited review time frames (AMD and other blinding eye disease reviews must be done within 24 hours)

- Exception for those whose life could be in jeopardy or physical or sensory functional irreparably harmed if treatment is delayed.

- Exception if the treatment is contraindicated.

- Exception if the provider determines the treatment is likely to cause a harmful reaction.

- Exception if the provider and patient believe the treatment is likely to impede the patient's ability to perform daily activities or responsibilities and/or adhere to the treatment plan.

- Require plans to ensure transparency about step therapy requirements directly in their explanation of coverage during the open enrollment process through plain, clear language about what it means in its for patients and what their options are.

- Require the insurance company to make the step therapy exception process readily available and understandable on its website.

- Preclude the insurance company from adopting policies that "implicitly" impose step therapy requirements through a different utilization management process such as prior authorization.

- Clarification on what constitutes a "new patient."

- Clarification that a patient with a second eye event should be considered an established patient and therefore should not