ASRS American Society of Retina Specialists

February 3, 2017

Laurence Clark, MD
National Government Services
5000 Brittonfield Pkway, Suite 100
East Syracuse, NY 13057

Dear Dr. Clark,

On behalf of the American Society of Retina Specialists, the largest retinal organization in the world, representing nearly 3,000 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases, we write to request a change in payment policy to allow for flexibility in treating patients with severe neovascular Age-related Macular Degeneration (AMD), a disease that results in a gradual loss of vision usually to the level of legal blindness without treatment.

It has come to our attention that injections of anti-vascular endothelial growth factor (anti-VEGF) medicines are being denied as not reasonable and necessary based on an arbitrary interpretation of the FDA approved guidance. Specifically, "If code C9257 or J0178 or J2778 or J9035 are billed within 25 days of each other, frequency of injections will cause denial." Consequently, these restrictions are compromising the vision of a small percentage of patients (less than 5%) who have well-documented aggressive conditions and need injections more often. Additionally, physicians report that they were not informed of this policy changes.

Patients with severe forms of neovascular AMD may be well-controlled two to three weeks after their injection treatment, but beyond three weeks experience increased leakage and/or bleeding leading to vision loss. This small group of patients has a carefully documented need for an increased frequency of treatment, yet Medicare payment for this reasonable and necessary care is being denied.

Lucentis® (ranibizumab) is a Medicare Part B-covered drug approved by the Food and Drug Administration (FDA) for the treatment of neovascular AMD. The randomized studies that led to the FDA's approval of ranibizumab allowed a range of treatment visits between 23 and 37 days.

EYLEA (aflibercept), is also a Medicare Part B-covered drug approved by the FDA for the treatment of neovascular AMD. The EYLEA US Prescribing Information (USPI) indicates that EYLEA is approved for both monthly (2 mg q4) and every 2 months (2 mg q8) dosing, following three initial monthly doses.

Bevacizumab (Avastin ®), is approved by the FDA as a treatment for different types of cancer. Its use to treat neovascular age-related AMD, is considered an "off-label" use and therefore does not have an FDA approved treatment window.

In addition, it is often logistically impossible for patients and physicians to be available at exactly 28 days. Transportation for patients, travel, Federal holidays and physician schedule limitations all create scheduling conflicts that can prevent a patient from returning at exactly 28 days. Mutual availability may necessitate an appointment less than 28 days as the next available time could exceed 35 days. Rather than risking irreversible damage to the patient's vision, evidenced-based guidance should allow patients to be treated in the same window of time used in the studies that led to FDA-approval.

Given that each patient is unique, it is incumbent on the physician to individualize treatment to what works for each patient. We ask you to review any payment edits or policies that automatically reject payments and implement a more evidenced-based approach that would offer flexibility in caring for our patients with neovascular AMD. If you would like to further discuss this issue, we welcome a meeting. We appreciate your consideration of this matter and look forward to working with you to develop a policy that allows physicians to provide the highest quality care to patients. If we can provide any additional information, please contact Monica Horton, ASRS Director of Practice Management at monica.horton@asrs.org.

Sincerely,

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