ASRS American Society of Retina Specialists

November 16, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Acting Administrator Slavitt:

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 National Coverage Determination 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 several claims processing contractors have Local Coverage Determinations (LCDs) specifying limitations on ranibizumab (brand name Lucentis®) injections, one of the key drugs used to slow or prevent the progression of vision loss related to AMD. These LCDs indicate that the additional Lucentis ® injections are denied as not reasonable and necessary based on an arbitrary interpretation of the FDA approved package insert. Specifically, these strict LCD payment policies restrict injection treatments to every 28 days and are compromising the vision of a small percentage of patients (less than 5%) who have well-documented aggressive conditions and need injections more often.

Lucentis® 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. 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.

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 that CMS develop a National Coverage Determination 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,

Mark S. Humayun, MD, PhD
President

John S. Pollack, MD
President-Elect

Carl C. Awh, MD
Treasurer

Philip J. Ferrone, MD
Secretary

Timothy G. Murray, MD, MBA
Chair, Council on Governance

Jeffrey S. Heier, MD
Chair, Council on Education

Tarek S. Hassan, MD
Immediate Past President

John T. Thompson, MD
Council on Health Policy

20 North Wacker Drive
Suite 2030
Chicago, IL 60606

phone 312 578 8760
fax 312 578 8763
www.asrs.org