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Robert B. Nelson, P.A.-C
Executive Director

January 31, 2018

The Honorable Chuck Schumer
Minority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

Dear Minority Leader Schumer,

I am Robert Nelson, the Executive Director at Island Eye Surgicenter in Westbury, New York, and I am writing to urge your support for pending legislation that will extend the pass-through period for innovative drugs and devices from 3 to 5 years. Passage of this legislation will remove a barrier to appropriate care for Medicare beneficiaries who receive cataract surgery. OMIDRIA is a groundbreaking and important FDA-approved drug that is regularly used in cataract surgery at our facility. As of the first of this year, OMIDRIA's pass-through period expired and CMS began packaging reimbursement for OMIDRIA into the facility procedure payment. No longer could we cover the cost of this important medication. Island Eye Surgicenter is a New York State licensed and Medicare Certified Ambulatory Surgery Center specializing in eye surgery. We opened in 1999. With six operating rooms, nearly seventy surgeons on staff, a commitment to clinical research and a national reputation for clinical excellence, Island Eye is frequently on the forefront of important issues like this one. Several of our surgeons are nationally and internationally recognized for their contributions to clinical research and surgical invention. At the core of our mission is a commitment to providing our patients with the absolute best surgical care available. OMIDRIA has become essential in the care of our cataract surgery patients, and this change in reimbursement virtually eliminates payment for OMIDRIA when it is used. As a result, it is inaccessible to our surgeons and staff who are trying to deliver the best care for their patients. More importantly, it now subjects our patients to alternative medications that are frequently compounded, often used Off-Label and do not have the assurance of an FDA Approved label.

This is not a problem specific to cataract surgery but, rather, negatively affects innovation across all therapeutic areas and medical specialties. The current 3-year duration of pass-through limits the calculation of the reimbursement amount for a product following expiration of its pass-through period to data generated only during its first year (or less) on the market. By extending pass-through to 5 years, CMS will have much more data on which to base the product's ultimate reimbursement.

OMIDRIA was introduced into our facility in 2015 and our surgeons have found it to be highly effective in maintaining pupil size (a critical need in cataract surgery) and in reducing pain and inflammation resulting from cataract surgery. Our surgeons conducted a sentinel study comparing OMIDRIA to our previous standard for maintaining pupil size in cataract surgery, and found that OMIDRIA reduces both complication rates and the need for iris-damaging pupil expanding devices frequently needed when pupil dilation is either not achieved or not maintained during the surgery. These results are clinically meaningful and statistically significant and were recently published in a peer-reviewed manuscript (Rosenberg, et al. *Clin Ophthalmology.* 2018; 12:21-28). OMIDRIA is the only FDA-approved product of its kind and, because it is manufactured according to the FDA's Good Manufacturing Practices, our facility can feel confident that the drug is safe for patients and does not carry the risks, including that of blindness, associated with compounded products. With OMIDRIA, cataract surgery is safer and provides our surgeons with the confidence that they can achieve better patient outcomes.

CMS's decision to no longer pay for OMIDRIA, despite its proven clinical relevance and many letters from ophthalmic surgeons requesting that payment continues, means that after only three short years our facility has been forced financially to forego use of this very helpful drug. The unfortunate result means that our surgeons, nurses, and other facility personnel devote more time, resources and cost to addressing complications in surgery, and additional visits that could have been avoided. Most importantly, the resulting impact on patient care and outcomes is particularly concerning.

As part of Medicare extenders, I urge you to support an extension to the pass-through period for OMIDRIA and other drugs that are inappropriately packaged in with surgical procedures. This extension of the pass-through period to 5 years is supported by leading ophthalmic societies that include world class ophthalmic surgeons and nationally recognized ambulatory surgery center administrators. Specifically, American Society of Cataract and Refractive Surgery (ASCRS), Outpatient Ophthalmic Surgery Society (OOSS), American Society of Retina Specialists (ASRS), and Society for Excellence in Eyecare (SEE) all support this extension as well as the separate payment for drugs that are used at physicians' discretion in surgery. In the interests of the millions of seniors who undergo cataract surgery every year, I implore you and your colleagues to address this issue as quickly as possible. Fixing this problem is good for Medicare beneficiaries, good for your constituents and good policy!

Thank you for your support.

Respectfully,

R. Nelson PA-C

Robert B. Nelson, PA-C
Executive Director
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