AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Suite 400
20 F Street, NW
Washington, DC 20001-6701

Tel: 202.737.6662
Fax: 202.737.7061
www.aao.org

May 25th, 2012

Patrick Conway, M.D., MSc
Chief Medical Officer
Office of Clinical Standards and Quality

Louis B. Jacques, M.D.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Request for Rescission of Medicare National Coverage Determination (NCD)
Manual Section Number 80.3.1 Title Verteporfin
Effective Date 4/1/2004

Dear Drs. Conway and Jacques:

The above referenced NCD has recently come to the attention of the American Academy of Ophthalmology as being extremely outdated and is being inappropriately used against ophthalmologists who are following the current standard of care that now applies for the use of ocular photodynamic therapy (OPTD) and the associated drug treatment, verteporfin that accompanies it. The Academy, is the world's largest association of eye physicians and surgeons—Eye M.D.s—with 21,000 members in the United States. **We would request that CMS immediately review and rescind this NCD.**

When the original coverage decision was developed over ten years ago for OPDT and verteprofin it was prior to the emergence of intravitreal anti-VEGF therapy as an alternate treatment for age-related macular degeneration (AMD) and other retinal diseases. In the early 2000's when OPTD coverage decision was initiated, it was the only recognized treatment for the blinding consequences of AMD. Once intravitreal delivery of the newer drugs (bevacizumab and ranubizamab) became established, they became the standard of care for the millions of Americans facing the vision loss of AMD. Now, OPDT and verteporfin, are only considered as a last resort once a patient has failed the newer intravitreal drug treatments.

This is born out in Medicare claims data for utilization of OPDT which is reported with CPT Code 67221 Destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy (includes intravenous infusion) which has decreased tenfold since 2001 when it was billed more than 84,300 times in the Medicare population and declining to 8,500 claims in 2011.

When the NCD was written back in 2004, an initial fluoroscein angiographic image was ordered to determine if the lesions were considered classic subfoveal choroidal neovascularization lesions. Then the patients were followed monthly with additional angiograms to determine the need for retreatment. Today, since the only patients receiving OPDT are those that have failed anti-vegF treatment, their lesions are advanced and no longer require fluorescein angiography to determine retreatment.

Recently, one of Medicare's Recovery Audit Contractor's performing a data mining review comparing claims data to NCD provisions found that retina practices were not additionally billing for the follow-up fluoroscein angiography. That contractor sent letters to several retina practices in its region request a refund of the payment for the verteporfin citing the lack of a simultaneous claim for CPT Code 92235 Fluoroscein angiography. However the provision of that services and submission of such a claim would be a waste of Medicare resources under the current standard of care.

It is unfortunate that this audit is essentially saying that the last resort treatment for these patients who are facing complete blindness must be repaid to Medicare. In reality, Medicare has saved substantial dollars because the use of follow-up fluorescein angiography is no longer necessary when OPDT and verteporfin are provided to these end-stage patients.

We would urge CMS to consider an expedited review and implementation of this rescission request. For additional information, please contact Ms. Cherie L. McNett, Director of Health Policy at 202-737-6662 or via email at cmcnett@aaodc.org. Thank you for your assistance in this important matter.

Sincerely,

Michael X. Repka, M.D.
Medical Director for Government Affairs