ASRS American Society of Retina Specialists

December 2, 2014

Glenn M. Hackbarth, J.D.
Chairman
Medicare Payment Advisory Commission
425 I Street, N.W., Suite 701
Washington, DC 20001

Dear Chairman Hackbarth:

The American Society of Retina Specialists (ASRS) supports MedPAC's exploration of payment strategies to create incentive for providers to consider comparative effectiveness evidence of drugs and other health services. The ASRS is the largest retinal organization in the world, representing 2700 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases.

We believe the following points raised by the Commissioners during recent deliberations would serve as the basis for a good litmus test for evaluating such proposals:

- Providing sufficient incentive for providers to maximize health outcomes and value while reducing costs;
- Ensuring that payment policies do not compromise quality of care or limit patients' treatment options;
- Assessing the impact of such payment policies on low-income patients; and
- Implementing a sufficiently transparent and adequate exceptions process to allow providers to prescribe more expensive products when it is medically necessary.

Retina specialists use expensive Medicare Part B drugs, Lucentis and Eylea, to save patients' vision. The ASRS and its members have devoted tremendous resources to support efficacy and comparative effectiveness clinical research and the dissemination of results. For example, the Treat-and-Extend Protocol, now widely used in the treatment of macular degeneration and diabetic retinopathy, allows retina specialists to treat less frequently than indicated on the medication package inserts of both Lucentis and Eylea. This protocol yields significant savings in terms of treatment burden and cost, yet maintains excellent vision outcomes.

The Society has a long history of advocating for safely compounded Avastin, a less costly alternative to Lucentis and Eylea. Our commitment to more cost effective patient care was evident in 2007 when ASRS successfully persuaded Genentech to reverse its efforts to restrict Avastin sales for ophthalmic use. We have and continue to urge the Food and Drug and Administration (FDA) to preserve the repackaging of Avastin and enable outsourcing 503B facilities to repackage Avastin without a patient-specific prescription. We, as a specialty, have a proven track record of striving for the most efficacious, safe and cost efficient treatment strategy in the management of numerous sight-threatening conditions.

As you consider new payment polices, we ask the Commission to bear in mind that the treatment of macular degeneration, diabetic retinopathy, and retinal vein occlusion is constantly evolving. Any policy must be sufficiently flexible to adapt to new evidence, such as the soon to be published results of the Diabetic Retinopathy Clinical Research (DRCR) Protocol T research, which evaluated the clinical efficacy of the anti-VEGF treatments for diabetic edema. While all of the drugs used to treat retinal disorders should be at the retina specialist's disposal, they are not equal. Currently, of the three anti-VEGF agents used by retina specialists, only Lucentis and Eylea have specific FDA approval for ophthalmic conditions. Avastin is used off-label for ophthalmic conditions and must be used in a compounded form. Clinical response varies among the three anti-VEGF agents in individual patients. While all three anti-VEGF agents have similar efficacy in

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many patients, various trials have demonstrated differences in subsets of patients. Therefore, retina specialists must evaluate each patient and select the appropriate treatment agent accordingly. Ultimately, the retina specialist utilizes clinical judgment and the patient's response to a particular drug to select the best treatment. The ability to individualize treatment is critical to safely maximizing recovery and maintaining visual function in our patients with blinding diseases of the retina. Since the intravitreal treatment of macular conditions does not follow a one-size-fits-all protocol, ASRS has serious concerns that a bundled per-episode payment model could promote under-treatment of macular degeneration and diabetic retinopathy, which is already the major culprit of vision loss due to these conditions in the United States and Europe. We, therefore, urge MedPAC to consider an incentive system that will encourage physicians to provide the best care for each individual patient and lower costs as much as possible.

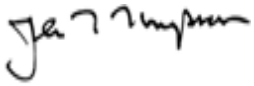
During your ongoing deliberations, we believe it is important for MedPAC to recognize that ASP +6% (now +4.2% due to sequestration) is not an add-on that equates to profit and, therefore, should not be reduced, eliminated, or repurposed as an incentive or bonus payment program. We would also highlight that Avastin, in its compounded form, is not paid based on ASP+6%, but rather at the local carrier discretion based on either WAC or invoice pricing.

As you know, ASP is based on actual market price data and accounts for the majority of rebates and discounts. Congress mandated a six percent add-on to ASP to cover any shortfall that the physician may incur between ASP and actual acquisition cost or any overhead for the costs of purchasing, handling and administering the drug. In fact, MedPAC acknowledged this in its 2007 Report to Congress on the Impact of Changes in Medicare Payment for Part B Drugs, noting that ASP may not include wholesale fees or state and local taxes that physicians pay. For example, in Minnesota, sequestration and local taxes reduce the "actual" reimbursement of Medicare Part B drugs to ASP +2%. Of the remaining 2%, a significant portion, if not all, goes to cover other administrative costs such as inventory management, refrigeration, drug security, prescribing, and cataloging. In addition, retina specialists incur significant costs assisting patients with insurance related issues, including obtaining pre-qualification and co-pay assistance. Nonetheless, retina specialists often need to write off unpaid co-pay debt and the cost of unused drugs.

Finally, please keep in mind that until the FDA authorizes the new outsourcing facilities to repackage Avastin without a prescription, many retina specialists and their patients are subjected to additional burdens that result from retina specialists not having a supply of Avastin on hand to treat patients on the same day as diagnosis/evaluation, like they can with Lucentis and Eylea. For that reason, as payment policies are developed it is important to coordinate with the FDA.

We appreciate MedPAC's efforts to maintain the best care for patients while lowering costs, and offer our assistance in providing data to support your efforts. Please contact Jill Blim, ASRS Executive Vice President, at jill.blim@asrs.org, if you have any questions or feel we can be of assistance.

Sincerely,



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