



Medicare Part B Drug Payment Model Could Adversely Impact Treatment Options for Ophthalmology Patients

The Centers for Medicare & Medicaid Services (CMS) recently released a proposed rule outlining a Medicare Part B Drug Payment Demonstration Project that seeks to evaluate alternative payment models. In the first phase, CMS seeks to test whether physician prescribing patterns will change if the current add-on (+6, which is now +4.2 due to sequestration) was replaced by 2.5 percent (approximately .86 percent with sequestration) plus an additional flat \$16.80 administrative fee. It is important to note that the current add on was congressionally mandated to cover the costs associated with procuring, storing, administering, tracking, and obtaining reimbursement for the drug and is not profit. In fact, many physicians are barely breaking even or are losing money under the current payment scenario.

While the Academy, ASRS and the Retina Society do not oppose demonstration projects to evaluate alternative payments, we feel this demonstration project is based on the following **faulty assumptions**:

- The Lower Cost Alternative (LCA) is Always Available:
 - Accessing the LCA option (Avastin®) for AMD and other ocular conditions is increasingly difficult due to new federal and state regulations on compounding and repackaging of drugs, forcing some to increase usage of more expensive drugs (Lucentis® and Eylea®).
 - Continued access to the LCA will effectively end if the U.S. Food and Drug Administration (FDA) finalizes its February 2015 draft guidance that calls for a maximum 5-day beyond use date for compounded or repackaged biologics like Avastin®.
- All Treatment Options Are Interchangeable:
 - The three available anti-VEGF drugs used to treat eye diseases, such as AMD, are not always interchangeable.
 - Some patients simply respond better to one treatment over another.
 - For some retinal diseases, such as diabetic macular edema, there is strong evidence that Eylea® and Lucentis® provide better clinical outcomes than Avastin®.
 - Vulnerable Medicare patients should not face mandatory participation in an initiative that may force them to switch from the most appropriate treatment.
- Doctors Alone Make Treatment Choices:
 - Physicians provide clinically relevant information to patients to assist them make informed health care choices.
 - Many patients are reluctant to choose a drug, such as Avastin®, that is being used off-label in a compounded form and should not be forced to do so when several FDA-approved options exist.
- Physician Prescribing Patterns Are Motivated Solely by Revenue:
 - As described above, physician prescribing patterns are influenced by multiple factors.
 - Physicians are sensitive to price differences. In an ASRS 2015 survey, 64% of respondents indicated that they currently use the LCA, Avastin®, as the first line treatment for new patients with wet AMD. BUT, when asked what drug they would choose if Avastin®, Lucentis® and Eylea® were the same price, Avastin® dropped to the last choice.

Recommended Action: The Academy, ASRS and the Retina Society do not oppose demonstration projects that evaluate appropriate alternative payments. We have long championed coverage and increased utilization of lower cost treatment options. In fact, it was the Academy that convinced Medicare carriers that coverage of off-label Avastin® was safe and effective for the treatment of several blinding ocular diseases. We have also met with CMS and insurance carriers to suggest alternative payment options that would more positively impact prescribing patterns. In light of its potential adverse impact on Medicare beneficiaries with potentially blinding disease, our organizations strongly recommend that CMS withdraw the Part B Drug Payment Model as proposed. CMS should meet with stakeholders to develop alternative models that can achieve the goal of the proposed demonstration without increasing risks for patients.



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Background:

CMS proposes a two phase demonstration that will be combined to comprise a single model. The model is estimated to span five (5) years beginning in the fall of 2016 for the first phase. The first phase focuses on adjusting the add-on to the average sales price (ASP) to something other than the current 6 percent that providers are paid to administer drugs. As proposed, CMS would pay this average sales price, plus 2.5 percent plus an additional flat \$16.80 administrative fee. There would also be a control group that would continue to be paid the current ASP, plus 6 percent. (The proposed numbers are prior to factoring in an existing 2 percent sequestration reduction currently in effect and is expected to remain in effect for the demonstration).

For the second phase, CMS is developing methods to test the impact of targeted pricing changes to payments for individual Part B drugs. It would do this using value-based purchasing strategies such as decision support tools and eliminating patient cost sharing. These would be similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. The second phase would be implemented at a later date, but no sooner than January 2017 in conjunction with the first phase.

The Use of Part B Drugs for the Treatment of AMD and Other Ophthalmic Conditions:

AMD is the leading cause of blindness in the United States, affecting more than 2 million Americans age 50 and older. As the growing baby boomer population ages, diagnosis of this disease is expected to double by 2020. Currently, there are three available treatment options for AMD that significantly reduce the devastating impact of this chronic disease by slowing vision loss, and in some cases, may even improve vision. Two options are name brand FDA-approved drugs (Lucentis® and Eylea®) which cost between \$1,800 and \$2,000 per injection. These treatments are ASP priced. The third treatment option is FDA-approved drug (Avastin®) for non-ophthalmic indications that ophthalmologists use off-label for the treatment of AMD. In order to use Avastin® for eye diseases, ophthalmologists must have the drug repackaged by a compounding facility. Avastin® is not ASP priced and ophthalmologists are typically reimbursed between \$50 and \$125 per injection, depending on the insurance carrier. All three treatments are also used to treat other conditions which significantly impair vision such as diabetic retinopathy, central retinal vein occlusion, and neovascular glaucoma.

Because AMD patients must often try multiple treatments before finding the right one for their condition, the Academy and ASRS's long-standing position is that patients and their ophthalmologists need access to all available treatment options. Overall, more than 3.6 million injections were administered to Medicare beneficiaries in 2013 according to the latest available data. According to data from the Academy's IRIS® clinical registry, in 2013 and 2014, nearly half of more than one million intravitreal injections were provided using the lower cost treatment option, Avastin®. This occurred despite the growing challenges ophthalmologists face when they try to access this drug due to new federal and state regulations on the compounding and repackaging of drugs that were outlined earlier. Ophthalmology's continued ability to utilize a lower cost alternative for the treatment of AMD and other ophthalmic conditions will be eliminated should FDA finalize its pending draft guidance.