



Search...



Clinical Updates – Clinical Updates

ASRS Fights Novitas Decision to Interpret Eylea Usage More Frequently than q8 as "Off Label"

ASRS is fighting a recent decision by Novitas Solutions, a Medicare Administrator Contractor, to interpret the Aflibercept (Eylea) FDA label as to not cover Eylea use more frequently than 8 weeks after the initial load. This interpretation came to our attention as a result of a Medicare utilization audit in which Novitas indicated that it is seeking recoupment of reimbursement for Eylea doses that it deems as "off label" under this definition.

The current FDA label states the following:

"The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks."

ASRS Board member, David Brown, discussed this issue with Wiley Chambers, Deputy Director for the Division of Transplant and Ophthalmology at the FDA, and was assured that it was not the intention of the FDA label to restrict Eylea use to every 8 weeks, and the label was specifically designed to permit monthly dosing in patients. ASRS is trying to coordinate a meeting between the FDA and CMS to resolve the misinterpretation.

In the meantime, Regeneron is aware of the situation and has submitted a revised label to the FDA for clarification. A response is expected shortly.

Please contact the ASRS if you are being audited for "off label" use of Eylea.

(Posted May 24, 2016)

EXHIBIT
10
BROWN
April 26, 2022

Home Clinical Education Publications Annual Meeting Practice Advocacy Sections
Patients Member Services

FIND A RETINA SPECIALIST RETINA CAREER CENTER ABOUT ASRS FOUNDATION CORPORATE JOIN
THE ASRS SIGN IN

AMERICAN SOCIETY OF RETINA SPECIALISTS

20 North Wacker Drive, Suite 2030, Chicago, Illinois 60606 (312) 578-8760 phone info@asrs.org



© 2022 The American Society of Retina Specialists. All rights reserved. Privacy statement. Terms of use.