



Eylea (afibercept) Injection

Revision: 2

Policy Number: M-0037

Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

FDA

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Central Retinal Vein Occlusion

Coding Information:

HCPCS Code(s)

J0178	Injection, Aflibercept, 1mg
-------	-----------------------------

ICD-9 Code(s)

362.52	Exudative senile macular degeneration
362.35	Central retinal vein occlusion

Limitations:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

Background:

Aflibercept is a recombinant fusion protein that acts as a decoy receptor to bind up vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PIGF).



Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

FDA Black Box Warning:

Severely compromised wound healing may occur; discontinuation is required. Suspend therapy for at least 4 weeks prior to elective surgery, and do not resume for at least 4 weeks following major surgery and until the surgical wound is fully healed. Severe and sometimes fatal hemorrhage, including gastrointestinal hemorrhage, has been reported; monitoring is required. Do NOT administer if severe hemorrhage. Gastrointestinal perforation including fatalities may occur; discontinuation is required

References:

1. Eylea. In: Clinical Pharmacology. Tampa (FL): Gold Standard. [updated 12/18/11; accessed 09/24/12]. <http://clinicalpharmacology-ip.com.ezproxy.samford.edu/Forms/Monograph/monograph.aspx?cpnum=3746&sec=mondesc>.
2. Eylea. In: Micromedex 2.0. Greenwood Village (CO): Thompson Reuters. [updated 08/29/12; accessed 09/24/12]. http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/8181D0/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/75A66C/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=930048&contentSetId=100&title=Aflibercept&servicesTitle=Aflibercept&topicId=contraindicationsWarningsSection&subtopicId=contraindicationsSection.
3. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2012
4. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L32013). Available at: <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32013&ContrId=268&ver=27&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Alabama&CptHcpcsCode=j0178&bc=gAAAABAAAAAAAA%3d%3d&>. Accessed on June 4, 2014.

This policy has been developed by VIVA Health to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. Treating providers are solely responsible for medical advice and treatment of members. This document contains confidential and proprietary information of VIVA Health and cannot be reproduced, distributed or printed without permission from VIVA Health. This page contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with VIVA Health. This policy may be updated and is subject to change.



Document History:

Date Written: 11/14/12

Effective Date: 1/1/13

Revision 1: 8/30/13

Revision 2: 6/4/2014

Internal Review: 6/11/2014

External Review: 6/17/2014

For the Archived Policy, please go

to <http://www.vivaprovider.com/Resources/CoveragePolicies.aspx> and click on the Archived Policies Link.

This policy has been developed by VIVA Health to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. Treating providers are solely responsible for medical advice and treatment of members. This document contains confidential and proprietary information of VIVA Health and cannot be reproduced, distributed or printed without permission from VIVA Health. This page contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with VIVA Health. This policy may be updated and is subject to change.