Reference number(s)
2507-A

STANDARD MEDICARE PART B MANAGEMENT

EYLEA (aflibercept)
EYLEA HD (aflibercept)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Eylea is indicated for the treatment of:
A. Neovascular (wet) age-related macular degeneration
B. Macular edema following retinal vein occlusion
C. Diabetic macular edema
D. Diabetic retinopathy
E. Retinopathy of Prematurity

Eylea HD is indicated for the treatment of:
A. Diabetic macular edema
B. Diabetic retinopathy
C. Neovascular (wet) age-related macular degeneration

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Neovascular (wet) age-related macular degeneration
Authorization of 12 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

B. Macular edema following retinal vein occlusion
Authorization of 12 months may be granted for treatment of macular edema following retinal vein occlusion.

C. Diabetic macular edema
Authorization of 12 months may be granted for the treatment of diabetic macular edema.

D. Diabetic retinopathy
Authorization of 12 months may be granted for the treatment of diabetic retinopathy.

E. Retinopathy of Prematurity
Authorization of 12 months may be granted for the treatment of retinopathy of prematurity.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when ALL of the following criteria are met:
A. The member is currently receiving therapy with Eylea.
B. Eylea is being used to treat an indication enumerated in Section II.
C. The medication has been effective for treating the diagnosis or condition.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Eylea
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Eylea are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCE

1. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; February 2023.
2. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals; August 2023