

## Aflibercept: **Eylea®; Eylea® HD** **(Intravitreal)**

**Effective Date:** 01/01/2020

**Dates Reviewed:** 04/10/2019, 9/18/2019, 12/18/2019, 1/29/2020, 5/20/2021, 10/21/2021, 6/16/2022, 7/27/2023, 12/07/2023, 01/04/2024, 05/01/2024

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

### I. Length of Authorization <sup>1</sup>

Coverage will be provided for 6 months and may be renewed annually, unless otherwise specified.

- Coverage for Retinopathy of Prematurity (ROP) will be provided initially for a total of 2 doses (1 dose per eye) and may be renewed as re-treatment for up to an additional 4 doses (2 doses per eye) (*Refer to Section IV for re-treatment criteria*)

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

Eylea:

- 2 mg/0.05 mL injection: 1 vial/pre-filled syringe per eye every 28 days

Eylea HD:

- 8 mg/0.07 mL injection: 1 vial/kit per eye every 28 days

#### B. Max Units (per dose and over time) [HCPCS Unit]:

Diagnosis	Eylea		Eylea HD	
	Initial Dosing	Maintenance Dosing	Initial Dosing	Maintenance Dosing
Neovascular age-related macular degeneration (AMD)	4 units every 28 days x 3 doses	4 units every 28-56 days	16 units every 28 days x 3 doses	16 units every 56 to 112 days
Macular edema following retinal vein occlusion (RVO)	4 units every 28 days	4 units every 28 days	N/A	N/A
Diabetic Macular Edema (DME)/ Diabetic Retinopathy (DR)	4 units every 28 days x 5 doses	4 units every 28-56 days	16 units every 28 days x 3 doses	16 units every 56 to 112 days
Retinopathy of Prematurity (ROP)	0.8 units x 1 dose (1 vial = 2 units)	0.8 units every 10 days x 2 doses (2 vials = 4 units)	N/A	N/A

*(Max units are based on administration to both eyes)*

### III. Summary of Evidence

Clinical trials have demonstrated the efficacy and safety of aflibercept (Eylea/Eylea HD) in the treatment of neovascular (wet) age-related macular degeneration (nAMD). Key findings from clinical trials include significant improvements in visual acuity, reduction in central retinal thickness, and decreased progression of choroidal neovascularization compared to placebo. Eylea has been shown to maintain or improve visual function and quality of life in patients with neovascular AMD. Eylea HD every 12 and 16 weeks demonstrated non-inferiority to Eylea every

8 weeks in the treatment of nAMD, diabetic macular edema (DME) and diabetic retinopathy (DR) with similar improvements in visual acuity or disease severity.

#### IV. Initial Approval Criteria <sup>1-15</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**
- Prescribed by or in consultation with Retina Specialist; **AND**

##### Universal Criteria <sup>1</sup>

- Patient has a definitive diagnosis of one of the following:
  - Neovascular (Wet) Age-Related Macular Degeneration (nAMD) †\*
  - Macular Edema following Retinal Vein Occlusion (RVO) † (*Eylea Only*)
  - Diabetic Macular Edema (DME) †\*
  - Diabetic Retinopathy (DR) †\*
  - Retinopathy of Prematurity (ROP) † Φ (*Eylea Only*); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment (*Note: NOT applicable to patients with Retinopathy of Prematurity*); **AND**
- The patient meets one of the following:
  - For patients with ROP, the patient meets both of the following:
    - The patient is a premature infant with a maximum gestational age at birth of 32 weeks OR a birth weight of >800 to 1500 g; **AND**
    - The patient must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab; **OR**
  - For patients with DR, the patient must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab; **OR**
  - For patients with AMD or RVO, they must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or Byooviz; **OR**
  - For patients with DME and baseline visual acuity of 20/50 or worse, they must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or ranibizumab (Lucentis); **OR**
  - For patients with DME and baseline visual acuity better than 20/50, the patient must have an inadequate treatment response, intolerance, or contraindication to treatment with bevacizumab; **AND**
- For Eylea HD requests, the patient must have an inadequate treatment response, intolerance, or contraindication to treatment with Eylea; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active intraocular inflammation; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., brolocizumab-dblb, ranibizumab or ranibizumab via ocular implant, pegaptanib, bevacizumab, faricimab-svoa, etc.); **AND**

- Patients that are currently on treatment with Eylea (afibercept) can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

**\*Eylea Only:** *Patients with an insufficient response during initial therapy for AMD, DME & DR administered every 4 weeks may continue with dosing every 4 weeks. Patients with an inadequate response to maintenance therapy administered every 8 weeks may increase the dosing frequency up to every 4 weeks. (Refer to Section V)*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

## V. Renewal Criteria <sup>1-15</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events; **AND**

### Retinopathy of Prematurity (ROP) (Eylea Only)

- Patient still has the presence of active ROP requiring treatment; **AND**
- At least 10 days have elapsed since receiving initial treatment

### All Other Indications

- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition

## VI. Dosage/Administration <sup>1,2</sup>

Indication	Dose
Neovascular (Wet) AMD	<p><b><u>Eylea Only</u></b></p> <p><u>Initiation:</u> Administer 2 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months)</p> <p><u>Maintenance:</u> Administer 2 mg intravitreally per affected eye once every 8 weeks (2 months); however, Eylea may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly)</p> <ul style="list-style-type: none"> <li>• Additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (approximately monthly) dosing after the first 12 weeks (3 months).</li> <li>• Patients may also be treated with one dose every 12 weeks after one year of effective therapy</li> </ul>
	<p><b><u>Eylea HD Only</u></b></p> <p>The recommended dose is 8 mg administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.</p>

Macular Edema following RVO	<p><b><u>Eylea Only</u></b> Administer 2 mg intravitreally per affected eye once every 4 weeks (approximately every 25 days, monthly)</p>
Diabetic Macular Edema (DME) & Diabetic Retinopathy (DR)	<p><b><u>Eylea Only</u></b> <b><u>Initiation:</u></b> Administer 2 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days, monthly) for the first 5 injections <b><u>Maintenance:</u></b> Administer 2 mg intravitreally per affected eye once every 8 weeks (2 months); however, Eylea may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly)</p> <ul style="list-style-type: none"> <li>Additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).</li> </ul>
	<p><b><u>Eylea HD Only</u></b> The recommended dose is 8 mg administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.</p>
Retinopathy of Prematurity (ROP)	<p><b><u>Eylea Only</u></b> Administer 0.4 mg intravitreally per affected eye.</p> <ul style="list-style-type: none"> <li>Injections may be given bilaterally on the same day.</li> <li>Injections may be repeated in each eye and the treatment interval between doses injected into the same eye should be at least 10 days.</li> <li><b><u>NOTE:</u></b> Treatment for this indication is ONLY applicable to the single-dose vial kit. Do NOT use the pre-filled syringe for the treatment of ROP.</li> </ul>

## VII. Billing Code/Availability Information

### HCPCS Code(s):

- J0178 – Injection, aflibercept, 1 mg; 1 billable unit = 1 mg (*Eylea Only*)
- J0177 – Injection, aflibercept hd, 1mg; 1 billable unit = 1 mg (*Eylea HD*)

### NDC(s):

- Eylea 2 mg/0.05 mL Solution for Injection, single-dose vial kit or single-dose pre-filled syringe: 61755-0005-xx
- Eylea 8 mg/0.07 mL Solution for Injection, single-dose vial kit: 61755-0050-xx
- Eylea 8 mg/0.07 mL Solution for Injection, single-dose vial: 61755-0051-xx

## VIII. References

- Eylea [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; February 2023. Accessed April 2024.
- Eylea HD [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; August 2023. Accessed April 2024.
- Diabetic Retinopathy Clinical Research Network, Wells JA, Glassman AR, Ayala AR, Jampol LM, Aiello LP, Antoszyk AN, Arnold-Bush B, Baker CW, Bressler NM, Browning DJ, Elman MJ, Ferris FL, Friedman SM,

- Melia M, Pieramici DJ, Sun JK, Beck RW. Aflibercept, Bevacizumab, or Ranibizumab for Diabetic Macular Edema. *N Engl J Med.* 2015 Mar 26; 372(13): 1193–1203. DOI: 10.1056/NEJMoa1414264
4. John A. Wells JA, Adam R. Glassman, Lee M. Jampol, Lloyd Paul Aiello, Andrew N. Antoszyk, Carl W. Baker, Neil M. Bressler, David J. Browning, Crystal G. Connor, Michael J. Elman, Frederick L. Ferris, Scott M. Friedman, Michele Melia, Dante J. Pieramici, Jennifer K. Sun, Roy W. Beck, for the Diabetic Retinopathy Clinical Research Network. Association of Baseline Visual Acuity and Retinal Thickness with 1-year Efficacy of Aflibercept, Bevacizumab, and Ranibizumab for Diabetic Macular Edema. *JAMA Ophthalmol.* 2016 Feb;134(2):127-34. doi: 10.1001/jamaophthalmol.2015.4599
  5. Heier JS, Brown DM, Chong V, et al. Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. *Ophthalmology.* 2012 Dec;119(12):2537-48.
  6. Szabo SM, Hedegaard M, Chan K, et al. Ranibizumab vs. aflibercept for wet age-related macular degeneration: network meta-analysis to understand the value of reduced frequency dosing. *Curr Med Res Opin.* 2015 Nov;31(11):2031-42.
  7. Gillies MC, Nguyen V, Daien V, et al. Twelve-Month Outcomes of Ranibizumab vs. Aflibercept for Neovascular Age-Related Macular Degeneration: Data from an Observational Study. *Ophthalmology.* 2016 Dec;123(12):2545-2553.
  8. Barthelmes D, Campain A, Nguyen P, et al. Effects of switching from ranibizumab to aflibercept in eyes with exudative age-related macular degeneration. *Br J Ophthalmol.* 2016 Dec;100(12):1640-1645.
  9. Solomon SD, Chew E, Duh EJ, et al. Diabetic Retinopathy: A Position Statement by the American Diabetes Association. *Diabetes Care.* 2017 Mar;40(3):412-418.
  10. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Diabetic Retinopathy PPP – Update 2019. Oct 2019.
  11. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Retinal Vein Occlusions PPP – Update 2019. Oct 2019.
  12. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2019. Oct 2019.
  13. Royal College of Ophthalmologists. Clinical Guidelines – Retinal Vein Occlusion (RVO) Guidelines – July 2015. Accessed at <https://www.rcophth.ac.uk/standards-publications-research/clinical-guidelines>.
  14. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, Bevacizumab, or Ranibizumab for Diabetic Macular Edema: Two-Year Results from a Comparative Effectiveness Randomized Clinical Trial. *Ophthalmology* 2016;123(6):1351-9. doi.org/10.1016/j.ophtha.2016.02.022.
  15. Stahl A, Sukgen EA, Wu WC, et al.; FIREFLEYE Study Group. Effect of Intravitreal Aflibercept vs Laser Photocoagulation on Treatment Success of Retinopathy of Prematurity: The FIREFLEYE Randomized Clinical Trial. *JAMA.* 2022 Jul 26;328(4):348-359. doi: 10.1001/jama.2022.10564.
  16. National Government Services, Inc. Local Coverage Article: Billing and Coding: Ranibizumab and biosimilars, Aflibercept, Brolucizumab-dblb and Faricimab-svoa (A52451). Centers for Medicare & Medicaid Services, Inc. Updated on 03/24/2023 with effective date of 04/01/2023. Accessed August 2023.
  17. Palmetto GBA. Local Coverage Article (LCA): Billing and Coding: Aflibercept (EYLEA®) (A53387). Centers for Medicare & Medicaid Services, Inc. Updated on 04/12/2021 with effective date of 04/22/2021. Accessed August 2023.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema

ICD-10	ICD-10 Description
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema
E08.3211	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye
E08.3212	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye
E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3291	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, right eye
E08.3292	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, left eye
E08.3293	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3299	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E08.3311	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E08.3312	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3391	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E08.3392	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E08.3393	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3399	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E08.3411	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye
E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3491	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, right eye
E08.3492	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, left eye
E08.3493	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3499	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye
E08.3512	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye
E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral
E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye



ICD-10	ICD-10 Description
E08.3591	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye
E08.3592	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, left eye
E08.3593	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, bilateral
E08.3599	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, unspecified eye
E08.37X1	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, right eye
E08.37X2	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, left eye
E08.37X3	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, bilateral
E08.37X9	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, unspecified eye
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy without macular edema
E09.3211	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3291	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E09.3292	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E09.3293	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E09.3299	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3391	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E09.3392	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E09.3393	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E09.3399	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye

ICD-10	ICD-10 Description
E09.3491	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E09.3492	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E09.3493	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E09.3499	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E09.3511	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E09.3512	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E09.3591	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E09.3592	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E09.3593	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E09.3599	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E09.37X1	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E09.37X2	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E09.37X3	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E09.37X9	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye



ICD-10	ICD-10 Description
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye

ICD-10	ICD-10 Description
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.319	Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3291	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E13.3292	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E13.3293	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3299	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3391	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E13.3392	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E13.3393	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3399	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral

ICD-10	ICD-10 Description
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3491	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E13.3492	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E13.3493	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3499	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E13.3591	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E13.3592	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E13.3593	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E13.3599	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E13.37X1	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E13.37X2	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E13.37X9	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
H34.8110	Central retinal vein occlusion, right eye, with macular edema
H34.8120	Central retinal vein occlusion, left eye, with macular edema
H34.8130	Central retinal vein occlusion, bilateral, with macular edema
H34.8190	Central retinal vein occlusion, unspecified eye, with macular edema
H34.8310	Tributary (branch) retinal vein occlusion, right eye, with macular edema
H34.8320	Tributary (branch) retinal vein occlusion, left eye, with macular edema
H34.8330	Tributary (branch) retinal vein occlusion, bilateral, with macular edema
H34.8390	Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema
H35.1	Retinopathy of prematurity
H35.10	Retinopathy of prematurity, unspecified
H35.101	Retinopathy of prematurity, unspecified, right eye
H35.102	Retinopathy of prematurity, unspecified, left eye
H35.103	Retinopathy of prematurity, unspecified, bilateral
H35.109	Retinopathy of prematurity, unspecified, unspecified eye
H35.111	Retinopathy of prematurity, stage 0, right eye
H35.112	Retinopathy of prematurity, stage 0, left eye
H35.113	Retinopathy of prematurity, stage 0, bilateral
H35.119	Retinopathy of prematurity, stage 0, unspecified eye
H35.121	Retinopathy of prematurity, stage 1, right eye
H35.122	Retinopathy of prematurity, stage 1, left eye
H35.123	Retinopathy of prematurity, stage 1, bilateral
H35.129	Retinopathy of prematurity, stage 1, unspecified eye

ICD-10	ICD-10 Description
H35.131	Retinopathy of prematurity, stage 2, right eye
H35.132	Retinopathy of prematurity, stage 2, left eye
H35.133	Retinopathy of prematurity, stage 2, bilateral
H35.139	Retinopathy of prematurity, stage 2, unspecified eye
H35.141	Retinopathy of prematurity, stage 3, right eye
H35.142	Retinopathy of prematurity, stage 3, left eye
H35.143	Retinopathy of prematurity, stage 3, bilateral
H35.149	Retinopathy of prematurity, stage 3, unspecified eye
H35.151	Retinopathy of prematurity, stage 4, right eye
H35.152	Retinopathy of prematurity, stage 4, left eye
H35.153	Retinopathy of prematurity, stage 4, bilateral
H35.159	Retinopathy of prematurity, stage 4, unspecified eye
H35.161	Retinopathy of prematurity, stage 5, right eye
H35.162	Retinopathy of prematurity, stage 5, left eye
H35.163	Retinopathy of prematurity, stage 5, bilateral
H35.169	Retinopathy of prematurity, stage 5, unspecified eye
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

<b>Jurisdiction(s):</b> 6, K	<b>NCD/LCD/LCA Document (s):</b> A52451
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52451&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52451&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP</a>	
<b>Jurisdiction(s):</b> J, M	<b>NCD/LCD/LCA Document (s):</b> A53387
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a53387&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a53387&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP</a>	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

**Policy Rationale:**

Aflibercept (Eylea®/Eylea HD®) was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use aflibercept (Eylea®/Eylea HD®) according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.