JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP013
		Effective Date	01/01/2019
		Review Date	01/15/2020
	Subject **Eylea**	*Revision Date*	11/10/2021
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Eylea

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I. POLICY

Eylea (aflibercept) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

Eylea may be approved for patients who meet the following:

1. Patient is 18 years of age or older
2. Documented diagnosis of one of the following ophthalmic conditions:
   a. Neovascular (wet) age-related macular degeneration (AMD)
   b. Macular edema following retinal vein occlusion (RVO)
   c. Diabetic macular edema (DME)
   d. Diabetic retinopathy (DR)
3. Prescriber is, or in consultation with, an ophthalmologist

III. AUTHORIZATION PERIOD/LIMITATIONS

- Initial approval may be given for 6 months of therapy
- Continuation of therapy may be approved in 6-month intervals with documentation showing a beneficial response to treatment, evidence by at least one of the following:
  - Detained neovascularization
  - Improvement or stabilization in visual acuity
  - Maintenance of corrected visual acuity from prior treatment
  - Positive findings from optical coherence tomography or fluorescein angiography
- Approval dosages will be restricted to the FDA-approved dosing regimens that demonstrated efficacy. Requests for dosage increases that have not been found to provide additional efficacy will not be considered for approval.

IV. EXCLUSIONS

Eylea will **not** be covered for the following:

1. Patients with ocular or peri-ocular infections
2. Patients with active intraocular inflammation
3. Concomitant use with other anti-vascular endothelial growth factor (VEGF) agents
4. Any indications that are not FDA-approved, or clinical guideline-supported

V. RECOMMENDED DOSAGE

The following recommendations are applicable for each eye

- **AMD**: 2 mg (0.05 mL) once intravitreally every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) once every 8 weeks (every 2 months).
  - *Although Eylea may be administered every 4 weeks, additional efficacy has not been demonstrated (compared with every 8 week administration); some patients may require every 4 week (monthly) dosing after the first 12 weeks of therapy (first 3 injections). Though not as effective as every 8 week administration, some patients may also be treated every 12 weeks (3 months) after one year of effective treatment.*

- **RVO**: 2 mg (0.05 mL) once intravitreally every 4 weeks (monthly)

- **DME**: 2 mg (0.05 mL) once intravitreally every 4 weeks (monthly) for the first 5 injections, followed by 2 mg (0.05 mL) once every 8 weeks (every 2 months).
  - *Although Eylea may be administered every 4 weeks, additional efficacy has not been demonstrated (compared with every 8 week administration); some patients may require every 4 week (monthly) dosing after the first 20 weeks of therapy (first 5 injections).*

- **DR**: 2 mg (0.05 mL) once intravitreally every 4 weeks (monthly) for the first 5 injections, followed by 2 mg (0.05 mL) once every 8 weeks (every 2 months).
  - *Although may be administered every 4 weeks, additional efficacy has not been demonstrated (compared with every 8 week administration); some patients may require every 4 week (monthly) dosing after the first 20 weeks of therapy (first 5 injections).*

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code

Eylea 2 MG/0.05ML SOLN J0178 Injection, aflibercept,1 mg	J0178

VII. REFERENCES

1. Eylea [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2019 May.
2. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. N Engl J Med. 2015 Mar 26;372(13):1193-203. doi: 10.1056/NEJMoa1414264
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; January 2015. Available at www.aao.org/ppp. Accessed November 30, 2018.
4. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; November 2015. Available at www.aao.org/ppp. Accessed November 30, 2018.
5. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; December 2017. Available at www.aao.org/ppp. Accessed November 30, 2018.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
12/19/2018	Policy Creation
6/5/2019	Removed Avastin step therapy requirement and updated indications per FDA- labeling
01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020

Review Date: 12/19/2018, 01/15/2020

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