Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 09/01/2019**
Policy Number: PHW.PDL.180	**Effective Date: 01/01/2020** **Revision Date: 11/01/2019**
Policy Name: Macular Degeneration Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Macular Degeneration Agents

Reference Number: PHW.PDL.180
Effective Date: 01/01/2020
Last Review Date: 11/01/2019

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Macular Degeneration Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Macular Degeneration Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Macular Degeneration Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Macular Degeneration Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA) approved package labeling, or a medically accepted indication

AND

2. Is prescribed the medication by a retinal specialist

AND

3. One of the following:
   a. Has a documented history of therapeutic failure, intolerance, or contraindication to intravitreal bevacizumab
   b. Cannot use intravitreal bevacizumab because of clinical reasons as documented by the prescriber (e.g., beneficiary has neovascular (wet) age-related macular degeneration);

AND

4. Is prescribed a dose and frequency that is consistent with FDA-approved package labeling or nationally recognized compendia or is medically accepted;

AND

5. For a non-preferred Macular Degeneration Agent, has a documented history of therapeutic failure, intolerance, or contraindication of the preferred Macular Degeneration Agents approved or medically accepted for the beneficiary's diagnosis.

AND

6. If a prescription for a Macular Degeneration Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MACULAR DEGENERATION AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Macular Degeneration Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed the medication by a retinal specialist; **AND**

2. Has documentation of previous date(s) of administration; **AND**

3. Has documentation of tolerability and a positive clinical response based on the prescriber's assessment; **AND**

4. Is prescribed a dose and frequency ~~according to~~ that is consistent with FDA-approved
package labeling or nationally recognized compendia or is medically accepted; **AND**

5. If a prescription for a Macular Degeneration Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B above, to assess the medical necessity of the request for a prescription for a Macular Degeneration Agent. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. **Approval Duration:**

Avastin (bevacizumab) intravitreal	**12 months**
Eylea (aflibercept)	**6 months**
Lucentis (ranibizumab)	**6 months**
Visudyne (verteporfin)	**6 months**
Macugen (pegaptanib)	**6 months**

E. References

1. Martin et.al. Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration. New England Journal of Medicine 2011;364:1897-908.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2017. Available at: www.aao.org/ppp.
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2015. Available at: www.aao.org/ppp.
4. Ocular Histoplasmosis Syndrome. Basic and Clinical Science Course - Excerpt. American Academy of Ophthalmology.
5. Bakri, S.J, Thorne, J.E, et.al. Safety and Efficacy of Anti-Vascular Endothelial Growth Factor Therapies for Neovascular Age-Related Macular Degeneration. A Report by the American Academy of Ophthalmology. Ophthalmology 2019;126:55-63.
6. Arroyo, J.G. et.al, Age-related macular degeneration: Treatment and prevention. Up To Date, accessed May 29, 2019.
7. Bevacizumab. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed May 29, 2019.
8. Eylea prescribing information. Regeneron Pharmaceuticals, Inc. May 2019.
9. Lucentis prescribing information. Genentech, Inc. March 2018.
10. Macugen prescribing information. Valeant Pharmaceuticals International, Inc. July 2016.
11. Visudyne prescribing information. Valeant Pharmaceuticals International, Inc.

February 2017.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020