Clinical Policy: Macular Degeneration Agents

Reference Number: PHW.PDL.180
Effective Date: 01/01/2020
Last Review Date: 11/2024

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 PA Health & 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 member:

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 history of therapeutic failure of or a contraindication or an intolerance to intravitreal bevacizumab
    b. Cannot use intravitreal bevacizumab because of medical reasons as documented by the prescriber (e.g., member has neovascular (wet) age-related macular degeneration or geographic atrophy);

    AND

4. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. For a non-preferred Macular Degeneration Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Macular Degeneration Agents approved or medically accepted for the member'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 member 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 member, 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 member:

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

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

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

4. Is prescribed a dose and frequency that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. For a non-preferred Macular Degeneration Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Macular Degeneration Agents approved or medically accepted for the member'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 member 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 member, 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 member.

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.
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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

Reviews, Revisions, and Approvals	Date
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	11/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024	11/2023
Q1 2025 annual review: no changes.	11/2024