pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 8, 2023	January 8, 2024	*See below

SUBJECT

Prior Authorization of Macular Degeneration Agents – Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Macular Degeneration Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Macular Degeneration Agents will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Macular Degeneration Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T)

*01-23-45	09-23-44	27-23-35	33-23-42
02-23-33	11-23-33	30-23-36	
03-23-31	14-23-32	31-23-46	
08-23-48	24-23-41	32-23-31	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).
- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 13, 2023, meeting, the P&T Committee recommended the following revisions to the medical necessity guidelines for Macular Degeneration Agents:

- Addition of a guideline to address the recent approval by the U.S. Food and Drug Administration of Syfovre (pegcetacoplan) for the treatment of geographic atrophy secondary to age-related macular degeneration.
- Addition of a guideline for the determination of medical necessity of a request for renewal of a prescription for a non-preferred Macular Degeneration Agent.

The revisions to the guidelines to determine medical necessity of prescriptions for Macular Degeneration Agents submitted for prior authorization were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Macular Degeneration Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Macular Degeneration Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 beneficiary:

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., beneficiary 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 beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Macular Degeneration Agents at: https://papdl.com/preferred-drug-list; **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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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 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 beneficiary's diagnosis. See the PDL for the list of preferred Macular Degeneration Agents at: https://papdl.com/preferred-drug-list; **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 the Quantity Limits Chapter. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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 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 beneficiary.

D. 5-Day Supply

The Department does not consider the receipt of a Macular Degeneration Agent to be an

emergency situation and therefore will NOT cover a 5-day supply of a Macular Degeneration Agent pending approval of a request for prior authorization.

E. References

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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.