

ISSUE DATE December 6, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Macular Degeneration Agents – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary 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 and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Macular Degeneration Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for

*01-19-116	09-19-112	27-19-111	33-19-113
02-19-110	11-19-109	30-19-108	
03-19-109	14-19-108	31-19-116	
08-19-119	24-19-111	32-19-108	

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 Web site at
<https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the September 13, 2019, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of Macular Degeneration Agents:

- Revision of the guidelines related to therapeutic failure, intolerance, or contraindication to intravitreal bevacizumab;
- Revision of the guidelines for prescribed dose and frequency to be consistent with FDA-approved labeling and medical literature;
- Revision of the guidelines for a non-preferred Macular Degeneration Agent to take into account the beneficiary's diagnosis; and
- Revision of the guidelines for renewal of a prior authorization.

The revisions to the guidelines to determine medical necessity of Macular Degeneration Agents, as recommended by the DUR Board, 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 that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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, intolerance, or contraindication 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);
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 history of therapeutic failure, intolerance, or contraindication of 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 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 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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MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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