



ISSUE DATE January 6, 2016	EFFECTIVE DATE January 20, 2016	NUMBER *See below
SUBJECT Prior Authorization of Macular Degeneration Agents - Pharmacy Service	BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs	

IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (Department) is adding the Macular Degeneration Agents class of drugs to the Preferred Drug List (PDL).
2. Inform providers that all Macular Degeneration Agents will require prior authorization.
3. Issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Macular Degeneration Agents, including the type of medical information needed to evaluate requests for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department's Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to

*01-16-04	09-16-04	27-16-04	
02-16-04	11-16-04	30-16-04	
03-16-04	14-16-04	31-16-04	
08-16-04	24-16-04	32-16-04	33-16-04

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>

new drugs in therapeutic classes already included in the Preferred Drug List (PDL), changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred, new quantity limits, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the November 3, 2015 meeting, the P&T Committee recommended that the Department add the Macular Degeneration Agents class of drugs to the PDL and require prior authorization of all Macular Degeneration Agents. The Committee also proposed guidelines to determine medical necessity of Macular Degeneration Agents which were subject to public review and comment, and subsequently approved for implementation by the Department. The revised clinical review guidelines to determine the medical necessity of Macular Degeneration Agents are included in the attached updated provider handbook pages.

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 chapters 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

SECTION II

Macular Degeneration Agents

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Macular Degeneration Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Macular Degeneration Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a preferred or non-preferred Macular Degeneration Agent, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of Macular Degeneration Agents at:
http://www.providersynergies.com/services/documents/PAM_PDL_20100223.pdf
2. A prescription for a Macular Degeneration Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:
http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

B. 5-Day Supply

The Department does not consider a delay in the receipt of a Macular Degeneration Agent to present an immediate need and does not cover 5-day supplies of Macular Degeneration Agents pending approval of a request for prior authorization.

C. Clinical Review Guidelines and 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 condition that is U.S. Food and Drug Administration (FDA) approved, or a medically accepted indication

AND

2. Is prescribed the medication by a retinal specialist

AND

3. If being treated for neovascular (wet) age-related macular degeneration, has a documented history of therapeutic failure, intolerance, or contraindication to intravitreal bevacizumab

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AND

4. Is prescribed a dose and frequency according to package labeling

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

OR

6. Does not meet the clinical review guidelines above, but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient
7. In addition, if a prescription for either a preferred or non-preferred Macular Degeneration Agent is in 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.

FOR RENEWALS OF PRESCRIPTIONS FOR MACULAR DEGENERATION AGENTS - The determination of medical necessity of requests for prior authorization of renewals of prescriptions for a Macular Degeneration Agents, that were previously approved, will take into account whether the recipient:

1. Has documented improvement or stabilization in visual acuity

AND

2. Is prescribed the medication by a retinal specialist

AND

3. Is prescribed a dose and frequency according to package labeling

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C above, to assess the medical necessity of the request for a prescription for a Macular Degeneration Agent. If the guidelines in Section C are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior

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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.

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. Arroyo, J.G. et.al, Age-related macular degeneration: Treatment and prevention. Up To Date, accessed October 19, 2015.
3. Eylea prescribing information. Regeneron Pharmaceuticals, Inc. July, 2015.
4. Lucentis prescribing information. Genentech, Inc. February, 2015.
5. Macugen prescribing information. Gilead Sciences, Inc. October, 2011.