pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 15, 2020	January 5, 2021	*See below

SUBJECT

Prior Authorization of Complement Inhibitors – 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 Complement Inhibitors 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 Complement Inhibitors 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 efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists

*01-20-51	09-20-50	27-20-46	33-20-47
02-20-44	11-20-44	30-20-43	
03-20-44	14-20-45	31-20-51	
08-20-54	24-20-45	32-20-43	

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.

through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the October 21, 2020, meeting, the DUR Board recommended revisions to the guidelines to determine medical necessity of prescriptions for Complement Inhibitors to address a recent expanded indication approved by the U.S. Food and Drug Administration for Soliris (eculizumab). In addition to the treatment of paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome, and generalized myasthenia gravis, Soliris (eculizumab) is now also approved for the treatment of neuromyelitis optica spectrum disorder.

The revisions to the guidelines to determine medical necessity of prescriptions for Complement Inhibitors, 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 Complement Inhibitors 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 Complement Inhibitors) 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

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 Complement Inhibitors

A. Prescriptions That Require Prior Authorization

All prescriptions for Complement Inhibitors must be prior authorized.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Complement Inhibitor, 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 insert OR is a medically-accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

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

4. Is prescribed the Complement Inhibitor by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, nephrologist, neurologist, etc.); **AND**

5. Received appropriate vaccinations as recommended in the FDA-approved package labeling unless contraindicated; **AND**

6. For the treatment of a diagnosis of generalized myasthenia gravis (gMG), **all** of the following:

    a. Has a positive serologic test for anti-AChR antibodies,

    b. Has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy,

    c. Has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy,

    d. **One** of the following:

        i. Failed treatment over 6 months or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy
        ii. Has a documented history of contraindication or intolerance to ISTs,

    e. **One** of the following:

i. Failed treatment with plasma exchange or intravenous immunoglobulin (IVIG)
ii. Has a documented history of contraindication or intolerance plasma exchange or IVIG;

AND

7. For the treatment of neuromyelitis optica spectrum disorder, has a history of therapeutic failure, intolerance, or contraindication to rituximab; **AND**

8. If a prescription for a Complement Inhibitor 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. 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 COMPLEMENT INHIBITORS: The determination of medical necessity of a request for renewal of a prior authorization for a Complement Inhibitor that was previously approved will take into account whether the beneficiary:

1. Had a documentation of tolerability and a positive clinical response to the requested medication; **AND**

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

3. Is prescribed the Complement Inhibitor by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, nephrologist, neurologist, etc.); **AND**

4. If a prescription for a Complement Inhibitor 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. 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 guideline listed above but, in the professional judgment of the physician reviewer, the service is 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 Complement Inhibitor. 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. Dose and Duration of Therapy

Requests for prior authorization of a Complement Inhibitor will be approved as follows:

1. Initial requests for prior authorization of a Complement Inhibitor will be approved for up to 3 months.

2. Renewals of requests for prior authorization of a Complement Inhibitor will be approved for up to 6 months.

E. References

1. Complement-mediated hemolytic uremic syndrome. UpToDate. Accessed February 5, 2018.
2. Diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. UpToDate. Accessed February 5, 2018.
3. Legendre CM, Licht C, Muus P, et.al. Terminal Complement Inhibitor Eculizumab in Atypical Hemolytic-Uremic Syndrome. *N Engl J Med* 2013; 368:2169-81.
4. Soliris prescribing information. Alexion Pharmaceuticals, Inc. June 2019.
5. National Institute of Neurological Disorders and Stroke Website. Myasthenia Gravis Fact Sheet. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myasthenia-Gravis-Fact-Sheet. Accessed February 5, 2018.
6. Myasthenia Gravis Foundation of America Website. Health Professionals. http://www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx. Accessed February 5, 2018.
7. Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. Lancet Neurol. 2017 Oct 20.
8. Diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. UpToDate. Accessed February 5, 2019.
9. Ultomiris prescribing information. Alexion Pharmaceuticals, Inc. October 2019.