Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

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November 12, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Lipotropics, Other – Pharmacy Services

BY

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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.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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 Lipotropics, Other 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 Lipotropics, Other 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 Lipotropics, Other to the appropriate managed care organization.

BACKGROUND:

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

*01-25-17	09-25-17	27-25-17	33-25-17
02-25-17	11-25-17	30-25-17	
03-25-17	14-25-17	31-25-17	
08-25-18	24-25-17	32-25-17	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- 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 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Lipotropics, Other:

- Deletion of the guidelines for a proprotein convertase subtilisin/kexin type 9 inhibitor related to a history of clinical atherosclerotic cardiovascular disease (ASCVD), a diagnosis of familial hypercholesterolemia, or a diagnosis of other severe hypercholesterolemia.
- Deletion of the guidelines for an adenosine triphosphate-citrate lyase inhibitor related to a history of clinical ASCVD, a diagnosis of familial hypercholesterolemia, or a diagnosis of other severe hypercholesterolemia.
- Deletion of the dose and duration of therapy guidelines.

The revisions to the guidelines to determine medical necessity of prescriptions for Lipotropics, Other submitted for prior authorization, as recommended by the P&T Committee, 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 Lipotropics, Other 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 Lipotropics, Other) 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Lipotropics, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Lipotropics, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Lipotropic, Other. See the Preferred Drug List (PDL) for the list of preferred Lipotropics, Other at: https://papdl.com/preferred-drug-list.

2. A Lipotropic, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

3. A proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Leqvio [inclisiran], Praluent [alirocumab], Repatha [evolocumab]).

4. An adenosine triphosphate-citrate lyase (ACL) inhibitor (e.g., Nexletol [bempedoic acid], Nexlizet [bempedoic acid/ezetimibe]).

5. A microsomal triglyceride transfer protein (MTP) inhibitor (e.g., Juxtapid [lomitapide]).

6. An angiopoietin-like 3 (ANGPTL3) inhibitor (e.g., Evkeeza [evinacumab]).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropic, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested Lipotropic, Other for the treatment of 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 a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

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

4. Does not have a contraindication to the prescribed drug; **AND**

5. For treatment of a lipid disorder, has documentation of results of a lipid profile within 3 months prior to the request for the Lipotropic, Other; **AND**

6. For a PCSK9 inhibitor, **all** of the following:

    a. Has a history of **one** of the following:

        i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximum tolerated dose of a high-intensity statin for ≥3 months,

        ii. **Both** of the following:

            a) A temporally related intolerance[1] to 2 high-intensity statins that occurred after **both** of the following:

                (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)

                (ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):

                    a. Dose decrease of the interacting non-statin drug,
                    b. Discontinuation of the interacting non-statin drug,
                    c. Change to an alternative statin that has a lower incidence of drug interactions

            b) **One** of the following:

                (i) Therapeutic failure while adherent to treatment for ≥3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
                (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

        iii. A contraindication to statins,

    b. Has **one** of the following:

        i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,
        ii. A contraindication or an intolerance to ezetimibe,

[1] Temporally related intolerance of a statin is defined as the occurrence of symptoms and/or lab abnormalities upon initiation of a statin, resolution of symptoms and/or lab abnormalities upon discontinuation of a statin, and recurrence of symptoms and/or lab abnormalities after rechallenge with the same statin at the same dose.

iii. An LDL-C that is >25% above goal LDL-C while adherent to treatment with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,

c. Is prescribed the requested PCSK9 inhibitor in addition to **one** of the following:

i. For treatment of homozygous familial hypercholesterolemia (HoFH), standard lipid-lowering treatments as recommended by current consensus guidelines[2]
ii. For treatment of all other conditions, the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

d. If currently using a different PCSK9 inhibitor, will discontinue use of that PCSK9 inhibitor prior to starting the requested PCSK9 inhibitor,

e. For a non-preferred PCSK9 inhibitor, has **one** of the following:

i. A history of therapeutic failure of at least 1 preferred PCSK9 inhibitor approved or medically accepted for the beneficiary's diagnosis
ii. A contraindication or an intolerance to the preferred PCSK9 inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

7. For an ACL inhibitor, **all** of the following:

a. Has a history of **one** of the following:

i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximum tolerated dose of a high-intensity statin for ≥3 months,

ii. **Both** of the following:

a) A temporally related intolerance to 2 high-intensity statins that occurred after **both** of the following:

(i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)

(ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):

[2] e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society

a. Dose decrease of the interacting non-statin drug,
b. Discontinuation of the interacting non-statin drug,
c. Change to an alternative statin that has a lower incidence of drug interactions

b) **One** of the following:

(i) Therapeutic failure while adherent to treatment for ≥3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
(ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

iii. A contraindication to statins,

b. Has **one** of the following:

i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months
ii. A contraindication or an intolerance to ezetimibe,

c. Is prescribed the requested ACL inhibitor in addition to the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

d. If currently taking simvastatin or pravastatin, will not be using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

AND

8. For an ANGPTL3 inhibitor or MTP inhibitor, **all** of the following:

a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders,

b. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines,

c. **One** of the following:

i. Has a history of therapeutic failure of or a contraindication or an intolerance to PCSK9 inhibitors
ii. Is homozygous for LDL receptor (LDLR)-negative mutations (i.e., has LDLR-negative mutations in both alleles) associated with LDLR activity below 2%,

d. Is prescribed the requested drug in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

AND

9. For icosapent ethyl, **all** of the following:

   a. **One** of the following:

      i. Has a history of clinical ASCVD,

      ii. **Both** of the following:

         a) Has diabetes mellitus
         b) Has 2 additional ASCVD risk factors (e.g., age ≥50 years, cigarette smoking, hypertension, HDL-C ≤40 mg/dL for males or ≤50 mg/dL for females, hs-CRP >3.00 mg/L, CrCl <60 mL/min, retinopathy, micro- or macroalbuminuria, ABI <0.9]),

      iii. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis,

   b. Has fasting triglycerides ≥150 mg/dL,

   c. Has **one** of the following:

      i. A history of therapeutic failure of while adherent to treatment with maximum tolerated doses of 2 different statins for ≥3 consecutive months each,
      ii. A history of statin intolerance after modifiable risk factors have been addressed,
      iii. A contraindication to statins;

   AND

10. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis; **AND**

11. If a prescription for a Lipotropic, Other 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.

    NOTE: If the beneficiary does not meet the clinical review guidelines 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 LIPOTROPICS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for a Lipotropic, Other that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response demonstrated by lab test results, if appropriate for the diagnosis, since starting the requested drug (e.g., decreased LDL-C, decreased triglycerides, etc.); **AND**

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

3. Does not have a contraindication to the prescribed drug; **AND**

4. For a PCSK9 inhibitor, is using the requested PCSK9 inhibitor in addition to **one** of the following:

    a. For treatment of HoFH, standard lipid-lowering treatments as recommended by current consensus guidelines[3]
    b. For treatment of all other conditions, the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate);

    AND

5. For an ACL inhibitor, **both** of the following:

    a. Is using the requested ACL inhibitor in addition to the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)
    b. If currently taking simvastatin or pravastatin, is not using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

    AND

6. For an ANGPTL3 inhibitor or MTP inhibitor, **both** of the following:

    a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
    b. Is using the requested drug in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

[3] e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society

AND

7. For icosapent ethyl, experienced a decrease in fasting triglycerides since starting icosapent ethyl; **AND**

8. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis; **AND**

9. If a prescription for a Lipotropic, Other 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.

   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 Lipotropic, Other. 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.

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