Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 1, 2026	July 6, 2026	*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/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents

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) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and

*01-26-65	09-26-65	27-26-51	33-26-54
02-26-51	11-26-50	30-26-50	
03-26-51	14-26-54	31-26-66	
08-26-65	24-26-64	32-26-50	

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/agencies/dhs/departments-offices/omap-info

quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the May 12, 2026, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Lipotropics, Other:

- Revisions to address the recent U.S. Food and Drug Administration approval of Redemplo (plozasiran), an apoC-III-directed small interfering RNA.
- Revision of the guidelines related to cholesterol goals to include non-HDL-C and apoB.
- Revisions of the guidelines related to trials of a statin.
- Revision of the guidelines related to icosapent ethyl for the treatment of hypertriglyceridemia.
- Addition of a guideline related to non-preferred proprotein convertase subtilisin/kexin type 9 inhibitors to the guidelines for renewal of a previously approved prior authorization.

The revisions to the guidelines to determine medical necessity of prescriptions for Lipotropics, Other submitted for prior authorization, 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 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/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements

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

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

2. A Lipotropics, 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/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

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

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

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

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

7. An apolipoprotein C-III (apoC-III)-directed Lipotropics, Other (e.g., olezarsen, plozasiran).

B. Review of Documentation for Medical Necessity

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

1. Is prescribed the requested Lipotropics, Other for the treatment of a diagnosis that is consistent with the U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **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 three months prior to the request for the Lipotropics, 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 non-HDL-C, LDL-C, percentage reduction of LDL-C, or apoB while adherent to treatment with the maximum tolerated dose of a high-intensity statin for greater than or equal to three months,

        ii. **Both** of the following:

            a) A temporally related intolerance[1] to a high-intensity statin 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 if clinically appropriate (e.g., dose decrease or discontinuation of the interacting drug, 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 greater than or equal to three 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 greater than or equal to three consecutive months,
        ii. A contraindication or an intolerance to ezetimibe,
        iii. An LDL-C that is greater than 25% above goal LDL-C while adherent to treatment with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for greater than or equal to three consecutive months,

[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.

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 one 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 non-HDL-C, LDL-C, percentage reduction of LDL-C, or apoB while adherent to treatment with the maximum tolerated dose of a high-intensity statin for greater than or equal to three months,

      ii. **Both** of the following:

         a) A temporally related intolerance to a high-intensity statin 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 if clinically appropriate (e.g., dose decrease or discontinuation of the interacting drug, change to an alternative statin that has a lower incidence of drug interactions)

         b) **One** of the following:

[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

(i) Therapeutic failure while adherent to treatment for greater than or equal to three 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 greater than or equal to three 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 greater than 20 mg daily or pravastatin at a dose of greater than 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. Has results of genetic testing that are positive for mutations associated with lack of response to PCSK9 inhibitors,

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. Has fasting triglycerides greater than or equal to 150 mg/dL,

b. **One** of the following:

i. Has a history of clinical atherosclerotic cardiovascular disease (ASCVD),

ii. **Both** of the following:

a) Has diabetes mellitus
b) Has at least one additional ASCVD risk factor (e.g., 50 years of age or older, cigarette smoking or stopped smoking within three months, hypertension or on antihypertensive medication, HDL-C less than or equal to 40 mg/dL for males or 50 mg/dL for females, hs-CRP greater than 3.0 mg/L, CrCl greater than 30 mL/min and less than 60 mL/min, retinopathy, micro- or macroalbuminuria, ABI less than 0.9),

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

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

i. A history of therapeutic failure of while adherent to treatment with the maximum tolerated dose of a statin for greater than or equal to three consecutive months,
ii. A history of statin intolerance after modifiable risk factors have been addressed,
iii. A contraindication to statins;

AND

10. For an apoC-III-directed Lipotropics, Other, **all** of the following:

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

b. **One** of the following:

i. For treatment of familial chylomicronemia syndrome (FCS), has **both** of the following:

a) Untreated fasting triglycerides greater than or equal to 880 mg/dL

b) **One** of the following:

(i) Results of genetic testing showing biallelic pathogenic variants in FCS-causing genes,

(ii) A North American FCS (NAFCS) score greater than or equal to 60 (i.e., definite FCS),

(iii) **Both** of the following:

a. An NAFCS score greater than or equal to 45 and less than 60 (i.e., likely FCS)
b. An FCS score (Moulin score) greater than or equal to 10 (i.e., FCS very likely)

ii. For all other diagnoses, **both** of the following:

a) Has a diagnosis that is confirmed according to applicable consensus guidelines
b) Has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines,

c. If currently using a different apoC-III-directed Lipotropics, Other, will discontinue use of that apoC-III-directed Lipotropics, Other prior to starting the requested apoC-III-directed Lipotropics, Other,

d. For Tryngolza (olezarsen), has a history of therapeutic failure of or a contraindication or an intolerance to Redemplo (plozasiran) if Redemplo (plozasiran) is approved or medically accepted for the beneficiary's diagnosis;

AND

11. 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**

12. If a prescription for a Lipotropics, 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 Lipotropics, Other that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response since starting the requested drug (e.g., decreased LDL-C, decreased triglycerides, fewer episodes of acute pancreatitis, 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, **both** of the following:

    a. Is using the requested PCSK9 inhibitor in addition to **one** of the following:

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

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

        i. A history of therapeutic failure of at least one 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

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 greater than 20 mg daily or pravastatin at a dose of greater than 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

[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

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

AND

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

8. For an apoC-III-directed Lipotropic, Other, **both** of the following:

   a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or other provider specializing in lipid disorders
   b. For Tryngolza (olezarsen), has a history of therapeutic failure of or a contraindication or an intolerance to Redemplo (plozasiran) if Redemplo (plozasiran) is approved or medically accepted for the beneficiary's diagnosis;

   AND

9. 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**

10. If a prescription for a Lipotropics, 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 Lipotropics, 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.

D. References

1. Patel SB, Belalcazar LM, Afreen S, et all. American Association of Clinical Endocrinology consensus statement: algorithm for management of adults with dyslipidemia – 2025 update. Endocrine Practice. 2025;31:1207-1238.
2. Blumenthal RS, Morris PB, Gaudino M, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/AphA/ASPC/NLA/PCNA guideline on the management of dyslipidemia: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2026;153:e00-e00.