

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
LIPOTROPICS, OTHER

Proposed Effective Date: January 5, 2026

Revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Lipotropics, Other

A. Revisions to 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/en/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 APOC-III-directed antisense oligonucleotide (ASO) (e.g., olezarsen).**

B. Revisions to 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 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**

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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 LDL-C or percentage reduction of LDL-C 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 intolerance¹ to two 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 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:

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.

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- 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,
- 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 guidelines²
 - 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 LDL-C or percentage reduction of LDL-C 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 two 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)

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

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(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 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:

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- 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%,~~ **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. **One** of the following:
 - i. Has a history of clinical ASCVD,
 - ii. **Both** of the following:
 - a) Has diabetes mellitus
 - b) Has two additional ASCVD risk factors (e.g., 50 years of age or older, cigarette smoking, hypertension, HDL-C less than or equal to 40 mg/dL for males or 50 mg/dL for females, hs-CRP greater than 3.00 mg/L, CrCl 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 the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis,
 - b. Has fasting triglycerides greater than or equal to 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 two different statins for greater than or equal to three consecutive months each,
 - 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 ASO, both of the following:**

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- 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 one of the following:
 - a) Results of genetic testing showing biallelic pathogenic variants in FCS-causing genes,
 - b) A North American FCS score greater than or equal to 60 (i.e., definite FCS),
 - c) An FCS score greater than or equal to 10 (i.e., FCS very likely)
 - ii. For all other diagnoses, 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;

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 ~~demonstrated by lab test results, if appropriate for the diagnosis,~~ 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**

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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 guidelines³
 - 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 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
 - 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 ASO, is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or other provider specializing in lipid disorders; 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.

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

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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

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