Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2020**
Policy Number: PHW.PDL.055	**Effective Date: 01/05/2021** **Revision Date: 11/2020**
Policy Name: Lipotropics, Other	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021: policy revised according to DHS revisions effective 01/05/2021.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Lipotropics, Other

Reference Number: PHW.PDL.055
Effective Date: 01/01/2020
Last Review Date: 11/2020

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Other Lipotropics are **medically necessary** when the following criteria are met:

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.
3. A prescription for a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
4. A prescription for an adenosine triphosphate-citrate lyase (ACL) inhibitor.

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 history of a contraindication to the prescribed medication; **AND**

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

    a. Is being prescribed the PCSK9 inhibitor by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),

    b. Has documentation of results of a lipid profile within 3 months prior to the request for the PCSK9 inhibitor,

    c. Has documentation of low-density lipoprotein cholesterol (LDL-C) goal (i.e., specific LDL-C goal OR percentage reduction of LDL-C) for cardiovascular risk that is consistent with current consensus guidelines,(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)

    d. Has at least **one** of the following:

        i. A history of clinical atherosclerotic cardiovascular disease (ASCVD) (i.e., secondary prevention) -- *Clinical ASCVD consists of acute coronary syndromes, history of myocardial infarction, stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral artery disease including aortic aneurysm, all of atherosclerotic origin. (American Heart Association 2018 Cholesterol Clinical Practice Guidelines)*
        ii. **One** of the following (i.e., primary prevention):

            a) A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines *(e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society)*
            b) A diagnosis of other severe primary hypercholesterolemia (baseline [before treatment with any lipid-lowering agent] LDL-C ≥ 190 mg/dL),

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

        i. Therapeutic failure while adherent to treatment with the maximally tolerated dose of 2 different high-intensity statins for ≥ 3 consecutive months each. *Therapeutic failure of a Lipotropic, Other is defined as failure to achieve LDL-C goal for cardiovascular risk.*

        ii. **Both** of the following:

a) A temporally related intolerance (*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*) 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,

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

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

g. Will be using 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 (*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)

ii. For treatment of all other conditions, the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

h. Will not be using the requested PCSK9 inhibitor with another PCSK9 inhibitor, an ACL inhibitor, or Juxtapid (lomitapide),

i. For a non-preferred PCSK9 inhibitor, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred PCSK9 inhibitor(s) approved or medically accepted for the beneficiary's diagnosis;

6. For and ACL inhibitor, **all** of the following:

a. Is being prescribed the ACL inhibitor by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),

b. Has documentation of results of a lipid profile within 3 months prior to the request for the ACL inhibitor,

c. Has documentation of LDL-C goal (i.e., specific LDL-C goal OR percentage reduction of LDL-C) for cardiovascular risk that is consistent with current consensus guidelines (*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*)

d. Has at least one for the following:

i. A history of clinical atherosclerotic cardiovascular disease (ASCVD)-clinical ASCVD consists of acute coronary syndromes, history of myocardial infarction, stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral artery disease including aortic aneurysm, all of atherosclerotic origin. (American Heart Association 2018 Cholesterol Clinical Practice Guidelines)

ii. A diagnosis of familial hypercholesterolemia in accordance with concurrent consensus guidelines (e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society)

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

i. Therapeutic failure of a Lipotropic, Other is defined as failure to achieve LDL-C goal for cardiovascular risk while adherent to treatment with the

maximally tolerated doses of 2 different high-intensity statins for ≥ 3 consecutive months each,

ii. **Both** of the following:

a) A temporally related intolerance ((*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*) while adherent to treatment with the maximally tolerated doses of 2 different high-intensity statins for ≥ consecutive months each,

(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,

f. Has a history of **both** of the following:

i. **One** of the following:

a) Therapeutic failure while adherent to treatment with ezetimibe in combination with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥ 3 consecutive months
b) A contraindication or intolerance to ezetimibe

ii. **One** of the following:

a) Therapeutic failure while adherent to treatment with a PCSK9 inhibitor
b) A contraindication or intolerance to PCSK9 inhibitors,

g. Will be using the requested ACL inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

h. 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,

i. Will not be using the requested ACL inhibitor with a PCSK9 inhibitor;

AND

7. For Juxtapid (lomitapide), all of the following:

a. Is being prescribed Juxtapid (lomitapide) by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders,

b. Has documentation of results of a lipid profile within 3 months prior to the request for Juxtapid (lomitapide),

c. Has documentation of LDL-C goal (i.e., specific LDL-C goal OR percentage reduction of LDL-C) for cardiovascular risk that is consistent with current consensus guidelines (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),

d. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines (e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society),

e. One of the following:

i. Has a history of therapeutic failure, contraindication, or intolerance of 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%,

f. Will be using Juxtapid (lomitapide) in addition to standard lipid-lowering treatments as recommended by current consensus guidelines (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),

g. Will not be using Juxtapid (lomitapide) with a PCSK9 inhibitor;

AND

8. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure, contraindication, or 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 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 PA.CP.PMN.59 Quantity Limit Override.

   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 tolerability and a positive clinical response demonstrated by lab test results, if appropriate for the diagnosis, since starting the requested medication (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 history of a contraindication to the prescribed medication; **AND**

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

   a. Is being prescribed the PCSK9 inhibitor by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),
   b. Will be 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 (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)

ii. For treatment of all other conditions, the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

c. Will not be using the requested PCSK9 inhibitor with another PCSK9 inhibitor, an ACL inhibitor, or Juxtapid (lomitapide);

AND

5. For an ACL inhibitor, all of the following:
   a. Is being prescribed the ACL inhibitor by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),
   b. Will be using the requested ACL inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),
   c. 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,
   d. Will not be using the requested ACL inhibitor with a PCSK9 inhibitor;

AND

6. For Juxtapid (lomitapide), **both** of the following:
   a. Is being prescribed Juxtapid (lomitapide) by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),
   b. Will be using Juxtapid (lomitapide) in addition to standard lipid-lowering treatments as recommended by current consensus guidelines (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)
   c. Will not be using Juxtapid (lomitapide) with a PCSK9 inhibitor;

AND

7. If a prescription for a Lipotropic, Other 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 PA.CP.PMN.59 Quantity Limit Override.

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.

D. Dose and Duration of Therapy

Requests for prior authorization of Lipotropics, Other will be approved as follows:

1. For a PCSK9 inhibitor:
   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 12 months.

2. For an ACL inhibitor:
   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 12 months.

3. For all other Lipotropics, Other:
   a. Initial requests will be approved for up to 6 months.
   b. Renewal requests will be approved for up to 12 months.

E. References

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Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020