

ISSUE DATE November 12, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below
SUBJECT Prior Authorization of Lipotropics, Other – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary 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 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 delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Lipotropics, Other to the appropriate managed care organization.

*01-20-33	09-20-32	27-20-28	33-20-29
02-20-26	11-20-26	30-20-25	
03-20-26	14-20-27	31-20-33	
08-20-36	24-20-26	32-20-25	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type.</p> <p>Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.</p>

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the August 12, 2020, meeting, the P&T Committee recommended a revision to the guidelines to determine medical necessity of Lipotropics, Other to address the place in therapy of adenosine triphosphate-citrate lyase (ACL) inhibitors. Bempedoic acid was recently approved by the U.S. Food and Drug Administration and is the first drug in the ACL inhibitor class to receive approval. Bempedoic acid is being added to the Statewide PDL as non-preferred.

The revisions to the guidelines to determine medical necessity of Lipotropics, Other, 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 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>

MEDICAL ASSISTANCE HANDBOOK
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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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
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,

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- 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,¹
- d. Has at least **one** of the following:
 - i. A history of clinical atherosclerotic cardiovascular disease (ASCVD)² (i.e., secondary prevention)
 - ii. **One** of the following (i.e., primary prevention):
 - a) A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines³
 - b) A diagnosis of other severe primary hypercholesterolemia (baseline [before treatment with any lipid-lowering agent] LDL-C \geq 190 mg/dL),
- e. Has a history of **one** of the following:
 - i. Therapeutic failure⁴ while adherent to treatment with the maximally tolerated doses of 2 different high-intensity statins for \geq 3 consecutive months each,
 - ii. **Both** of the following:
 - a) A temporally related intolerance⁵ 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,

¹ 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

² 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)

³ e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society

⁴ Therapeutic failure of a Lipotropic, Other is defined as failure to achieve LDL-C goal for cardiovascular risk.

⁵ 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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- 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 guidelines⁶
 - 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;

AND

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

⁶ 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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- 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,⁷
- d. Has at least **one** of the following:
 - i. A history of clinical atherosclerotic cardiovascular disease (ASCVD)⁸
 - ii. A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines,⁹
- e. Has a history of **one** of the following:
 - i. Therapeutic failure¹⁰ 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 intolerance¹¹ 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

⁷ 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

⁸ 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)

⁹ e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society

¹⁰ Therapeutic failure of a Lipotropic, Other is defined as failure to achieve LDL-C goal for cardiovascular risk.

¹¹ 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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- (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,¹²
 - d. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines,¹³

¹² 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

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- 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 (Iomitapide) in addition to standard lipid-lowering treatments as recommended by current consensus guidelines,¹⁴
- g. Will not be using Juxtapid (Iomitapide) 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 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 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**

¹³ e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society

¹⁴ 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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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 guidelines¹⁵
 - 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,¹⁶
 - c. Will not be using Juxtapid (lomitapide) with a PCSK9 inhibitor;

AND

¹⁵ 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

¹⁶ 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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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 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.

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.

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