

ISSUE DATE July 8, 2016	EFFECTIVE DATE July 11, 2016	NUMBER *See below
SUBJECT Prior Authorization of Lipotropics, Other - Pharmacy Services		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISE to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Lipotropics, Other for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is removing the specific guideline to determine medical necessity of Zetia from the handbook as Zetia is now designated as preferred.

*01-16-24	09-16-22	27-16-22	
02-16-21	11-16-21	30-16-21	
03-16-21	14-16-22	31-16-26	
08-16-22	24-16-24	32-16-20	33-16-21

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

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

SECTION II
Lipotropics, Other

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I. Requirements for Prior Authorization of Lipotropics, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for a Lipotropic, Other that meets any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Lipotropic, Other.
See Preferred Drug List (PDL) for the list of preferred Lipotropics, Other at: www.papdl.com
2. A prescription for a Lipotropic, Other with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:
http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf
3. A prescription for a preferred PCSK9 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 recipient:

1. Is being treated for a condition that is:
 - a. Consistent with U.S. Food and Drug Administration (FDA) approved package labeling, national medical compendia, or peer-reviewed medical literature

AND

- b. Documented by medical history and laboratory results

AND

2. Is being prescribed a dose that is consistent with package labeling

AND

3. Is age appropriate according to package labeling

AND

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4. Does not have a contraindication to the prescribed Lipotropic, Other

AND

5. For Welchol, has a history of intolerance to bile acid sequestrants

6. For Omega-3 Products:

- a. Has a documented triglyceride level > 500 mg/dL

AND

- b. Has a history of therapeutic failure or contraindication to:

- i. Gemfibrozil
- ii. Fenofibrates
- iii. Niacin

AND

- c. Obtained lab values for TG, LDL-C and ALT at baseline that will be monitored during therapy

7. For Kynamro (mipomersen sodium) and Juxtapid (lomitapide):

- a. Has a history of therapeutic failure (defined as failure to achieve goal LDL reduction for cardiovascular risk), contraindication or intolerance to standard lipid lowering agents

AND

- b. Is being prescribed Kynamro (mipomersen sodium) or Juxtapid (lomitapide):

- i. By or in consultation with a physician specializing in metabolic lipid disorders

AND

- ii. By a prescriber enrolled with the respective REMS program

AND

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- iii. As adjunctive treatment for HoFH with therapeutic doses of standard lipid lowering agents

AND

- c. Has documentation of counseling on, or adherence to, standard lipid-lowering lifestyle interventions, including physical activity and a low-fat, low cholesterol diet

AND

- d. Has baseline liver function tests (ALT, AST, alkaline phosphatase, total bilirubin)

AND

- e. For Juxtapid (lomitapide), has a documented history of therapeutic failure, contraindication or intolerance to Kynamro (mipomersen sodium)

- 8. For a PCSK9 Inhibitor:

- a. Has documentation of counseling on, or adherence to, standard lipid-lowering lifestyle interventions, including physical activity and a low fat, low cholesterol diet

AND

- b. Has documentation of a baseline lipid profile within one (1) month prior to the request for the PCSK9 inhibitor

AND

- c. Has documentation of goal LDL cholesterol (LDL-C) that is consistent with peer-reviewed medical literature

AND

- d. Will not be taking the requested PCSK9 inhibitor with another PCSK9 inhibitor

AND

- e. For the treatment of homozygous familial hypercholesterolemia (HoFH):

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- i. Is being prescribed the requested PCSK9 inhibitor by, or in consultation with, a physician specializing in metabolic lipid disorders

AND

- ii. Has a documented history of trial and failure to meet goal LDL-C with other lipid-lowering medications

AND

- iii. Will be taking the requested PCSK9 inhibitor in addition to other lipid-lowering medications

OR

- f. For the treatment of heterozygous familial hypercholesterolemia (HeFH):

- i. Is being prescribed the requested PCSK9 inhibitor by, or in consultation with, a physician specializing in metabolic lipid disorders

AND

- ii. Has a documented history of trial and failure to meet goal LDL-C with at least one (1) of the following:
 - a) Adherence to treatment for at least three (3) consecutive months with the highest-available dose of two different high-intensity statins in addition to standard doses of ezetimibe (Zetia)

OR

- b) An intolerance to the highest available doses of high-intensity statins that occurred after:
 - 1) The following comorbid conditions that may enhance statin intolerance have been ruled out:
 - A. Hypothyroidism
 - B. Vitamin D deficiency
 - C. Acute or chronic renal failure
 - D. Obstructive liver disease

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AND

- 2) All possible drug interactions with statins were addressed by one of the following:
 - A. The dose of the interacting non-statin drug was decreased
 - B. The interacting non-statin drug was discontinued
 - C. The interacting statin was changed to an alternative statin that has a lower incidence of drug interactions

AND

- 3) Adherence to treatment for at least three (3) consecutive months with one of the following:
 - A. A lower dose of high-intensity statins
 - B. The maximally-tolerated dose of moderate-intensity statins
 - C. The lowest approved daily dose of statins
 - D. Alternate-day dosing of statins

AND

- iii. Will be taking the requested PCSK9 inhibitor in addition to the maximally-tolerated dose of the highest-intensity tolerated statin

OR

- g. For the treatment of clinical atherosclerotic cardiovascular disease (ASCVD):
 - i. Has at least one of the following:
 - a) Acute coronary syndrome
 - b) A history of myocardial infarction (MI)
 - c) Stable or unstable angina
 - d) Coronary or other revascularization

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- e) A history of stroke
- f) A history of transient ischemic attack
- g) Peripheral artery disease

AND

- ii. Is being prescribed the PCSK9 inhibitor by, or in consultation with, a cardiologist, lipidologist, endocrinologist, or other provider specializing in lipid disorders

AND

- iii. Has a documented history of trial and failure to meet goal LDL-C with at least one of the following:
 - a) Adherence to treatment for at least three (3) consecutive months with the highest available dose of two different high-intensity statins in addition to standard doses of ezetimibe (Zetia)

OR

- b) An intolerance to the highest available doses of high-intensity statins that occurred after:
 - 1) The following comorbid conditions that may enhance statin intolerance have been ruled out:
 - A. Hypothyroidism
 - B. Vitamin D deficiency
 - C. Acute or chronic renal failure
 - D. Obstructive liver disease

AND

- 2) All possible drug interactions with statins were addressed by one of the following:
 - A. The dose of the interacting non-statin drug was decreased
 - B. The interacting non-statin drug was discontinued
 - C. The interacting statin was changed to an alternative statin

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that has a lower incidence of drug interactions

AND

3) Adherence to treatment for at least three (3) consecutive months with one of the following:

- A. A lower dose of high-intensity statins
- B. The maximally-tolerated dose of moderate-intensity statins
- C. The lowest approved daily dose of statins
- D. Alternate-day dosing of statins

AND

iv. Will be taking the requested PCSK9 inhibitor in addition to the maximally-tolerated dose of the highest-intensity tolerated statin

AND

h. For a non-preferred PCSK9 inhibitor, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred PCSK9 inhibitor(s)

AND

9. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure, contraindication or intolerance to the preferred Lipotropics, Other.

OR

10. The recipient 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 recipient.

11. In addition, if a prescription for either a preferred or non-preferred Lipotropic, Other is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary

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will also take into account the guidelines set forth in the Quantity Limits Chapter.

12. For renewals of a prescription for an Omega-3 Product: A request for prior authorization of a renewal of a prescription for an Omega-3 Product that was previously approved will take into account the recipient's clinical response, including:
- a. A documented improvement in TG level

AND

- b. No significant increase in LDL-C and ALT measures
13. For renewals of prescriptions for Kynamro (mipomersen sodium) or Juxtapid (lomitapide): Requests for prior authorization of renewals of prescriptions for Kynamro (mipomersen sodium) or Juxtapid (lomitapide) that were previously approved will take into account whether the recipient:
- a. Has documented decrease in LDL-C

AND

- b. Received routine liver function tests since initiating the requested medication

AND

- c. Does not have a contraindication to the prescribed agent

AND

- d. Is being prescribed a dose of the requested medication that is appropriate according to package labeling
14. For renewals of a prescription for a PCSK9 inhibitor: Requests for prior authorization of renewals of prescriptions for a PCSK9 inhibitor that were previously approved will take into account whether the recipient:
- a. Has a documented decrease in LDL-C since starting the PCSK9 inhibitor

AND

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- b. Does not have a contraindication to the prescribed agent

AND

- c. Is prescribed a dose of the requested medication that is appropriate according to package labeling

AND

- d. For the treatment of HoFH:
 - i. Is being prescribed the requested PCSK9 inhibitor by, or in consultation with, a physician specializing in metabolic lipid disorders

AND

- ii. Will continue treatment with other lipid-lowering therapies

OR

- e. For the treatment of HeFH:
 - i. Is being prescribed the requested PCSK9 inhibitor by, or in consultation with, a physician specializing in metabolic lipid disorders

AND

- ii. Will continue treatment with the maximally-tolerated dose of the highest-intensity tolerated statin

OR

- f. For the treatment of ASCVD:
 - i. Is prescribed the PCSK9 inhibitor by, or in consultation with, a cardiologist, lipidologist, endocrinologist, or other provider specializing in lipid disorders

AND

- ii. Will continue treatment with the maximally-tolerated dose of the highest-intensity tolerated statin

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AND

- g. Has documentation of counseling on, or adherence to, lipid-lowering medications and standard lifestyle interventions, including physical activity and a low fat, low cholesterol diet

OR

- 15. Does not meet the clinical review guidelines above, but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient
- 16. In addition, if a prescription for either a preferred or non-preferred 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.

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 the request for a prescription for a Lipotropic, Other. If the applicable guidelines in Section B are met, the reviewer will prior authorize the prescription. If the applicable 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 recipient.

D. Dose and Duration of Therapy

The Department will limit authorization of prescriptions for Lipotropics, Other as follows:

- 1. For Kynamro (mipomersen sodium) or Juxtapid (lomitapide)
 - a. 6 months of therapy for an initial approval of Kynamro (mipomersen sodium) or Juxtapid (lomitapide)
 - b. Up to 12 months of therapy for a renewal of Kynamro (mipomersen sodium) or Juxtapid (lomitapide)
- 2. For a PCSK9 inhibitor:

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- a. Two months of therapy for an initial approval of a PCSK9 inhibitor
- b. Up to six months of therapy for a renewal of a PCSK9 inhibitor

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