



<b>ISSUE DATE</b> November 13, 2015	<b>EFFECTIVE DATE</b> October 26, 2015	<b>NUMBER</b> *See below
<b>SUBJECT</b> Prior Authorization of Lipotropics, Other - Pharmacy Service		<b>BY</b>  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994). Please send in your application(s) as soon as possible.

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of Lipotropics, Other, including the type of medical information needed to evaluate requests 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:**

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-33	09-15-31	27-15-25	
02-15-25	11-15-24	30-15-24	
03-15-25	14-15-26	31-15-32	
08-15-31	24-15-26	32-15-25	33-15-30

**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>

**DISCUSSION:**

During the September 10, 2015 meeting, the DUR Board recommended updates to the guidelines to determine medical necessity of Lipotropics, Other to ensure appropriate patient selection and drug utilization of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, a novel new class of cholesterol-lowering medications. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Lipotropics, Other are included in the attached updated provider handbook pages.

**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 chapters 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.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)
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](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

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**AND**

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 Zetia, has a history of:

- a. Therapeutic failure or intolerance of Vytorin
- OR**
- b. Intolerance or contraindication to HMG CoA Reductase Inhibitors

7. For Lovaza:

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

**AND**

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

- a. Gemfibrozil
- b. Fenofibrates
- c. Niacin

**AND**

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

8. 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**

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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**

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)

9. 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**

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- 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):
  - 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

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**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

**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

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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
    - 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,

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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 that has a lower incidence of drug interactions

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**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**

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

**OR**

- 11. 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.
- 12. 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.

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13. For renewals of a prescription for Lovaza: A request for prior authorization of a renewal of a prescription for Lovaza 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

14. 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

15. 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 PSCK9 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

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**AND**

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

**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**

- 16. 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
- 17. 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 (Iomitapide)

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- 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:
- 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

E. References

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