


ISSUE DATE July 23, 2018	EFFECTIVE DATE July 23, 2018	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:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994

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 and providing services in the fee-for-service delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to Lipotropics, Other to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the following:

*01-18-14	09-18-15	27-18-13	33-18-14
02-18-09	11-18-09	30-18-09	
03-18-09	14-18-10	31-18-15	
08-18-16	24-18-10	32-18-09	

<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 Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>
--

- New drugs in therapeutic classes already included on 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 the PDL; and
- Guidelines to determine medical necessity.

DISCUSSION:

During the May 16, 2018, meeting, the P&T Committee recommended a change in the status of Welchol Powder and omega-3 acid ethyl esters from non-preferred to preferred. DHS proposed to remove the guidelines to determine the medical necessity of Welchol and omega-3 products as they would no longer require prior authorization. The proposed deletions were subject to public review and comment, and subsequently approved for implementation by DHS with updated handbook pages that reflect these changes.

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. DHS 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 non-preferred Lipotropic, Other. See Preferred Drug List (PDL) for the list of preferred Lipotropics, Other at: www.papdl.com.
2. 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 beneficiary:

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

5. 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

- 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)

6. For a PCSK9 Inhibitor:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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):

- 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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, 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:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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

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

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

8. 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.

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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.

9. 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 beneficiary:

- 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.

10. 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 beneficiary:

- a. Has a documented decrease in LDL-C since starting the PCSK9 inhibitor

AND

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

AND

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

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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

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

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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 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 beneficiary.

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:
 - a. Two months of therapy for an initial approval of a PCSK9 inhibitor

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- b. Up to six months of therapy for a renewal of a PCSK9 inhibitor

E. References

1. Praluent (alirocumab) package insert. Bridgewater, NJ: sanofi-aventis; July 2015.
2. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129:S1-S45.
3. Al-Rasadi K, Al-Waili K, Al-Sabti HA, et al. Criteria for diagnosis of familial hypercholesterolemia: a comprehensive analysis of the different guidelines, appraising their suitability in the Omani Arab population. *Oman Med J*. 2014;29(2):85-91.
4. Robinson JG. Management of familial hypercholesterolemia: a review of the recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Manag Care Pharm*. 2013;19(2):139-149.
5. Nordestgaard BG, Chapman MJ, Humphries SE, et al. Familial hypercholesterolemia is underdiagnosed and undertreated in the general population: guidance for clinicians to prevent coronary artery disease. *Eur Heart J*. 2013;34:3478-3490.
6. Rosenson RS, Baker SK. Statin myopathy. In: UpToDate [Internet Database]. Freeman MW, Rind DM, eds. Waltham, MA: UpToDate. Updated 2015 July 10.
7. Stroes E, Colquhoun D, Sullivan D, et al. Anti-PCSK9 antibody effectively lowers cholesterol in patients with statin intolerance: the GAUSS-2 randomized, placebo-controlled phase 3 clinical trial of evolocumab. *J Am Coll Cardiol*. 2014;63(23):2541-2548.
8. Moriarty PM, Jacobson TA, Bruckert E, et al. Efficacy and safety of alirocumab, a monoclonal antibody to PCSK9, in statin-intolerant patients: design and rationale of ODYSSEY ALTERNATIVE, a randomized phase 3 trial. *J Clin Lipidol*. 2014;8:554-561.
9. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. *N Engl J Med*. 2015;372(25):2387-2397.
10. Colhoun HM, Robinson JG, Farnier M, et al. Efficacy and safety of alirocumab, a fully human PCSK9 monoclonal antibody, in high cardiovascular risk patients with poorly controlled hypercholesterolemia on maximally tolerated doses of statins: rationale and design of the ODYSSEY COMBO I and II trials. *BMC Cardiovasc Disord*. 2014;14(121):1-10.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

11. Rind DM, Hayward RA. Intensity of lipid lowering therapy in secondary prevention of cardiovascular disease. In: UpToDate [Internet Database]. Freeman MW, Park L, eds. Waltham, MA: UpToDate. Updated 2015 June 25.
12. Rosenson RS, Baker SK, Jacobson TA, et al. An assessment by the Statin Muscle Safety Task Force: 2014 update. *J Clin Lipidol*. 2014;8:S58-S71.
13. Bays H, Cohen DE, Chalasani N, Harrison SA. An assessment by the Statin Liver Safety Task Force: 2014 update. *J Clin Lipidol*. 2014;8:S47-S57.
14. Guyton JR, Bays HE, Grundy SM, Jacobson TA. An assessment by the Statin Intolerance Panel: 2014 update. *J Clin Lipidol*. 2014;8:S72-S81.
15. American College of Cardiology. ACC Statin Intolerance App. <http://www.acc.org/StatinIntoleranceApp>. (accessed 2015 Aug 7).
16. U.S. National Institutes of Health. Alirocumab. <https://clinicaltrials.gov/ct2/results?term=alirocumab&Search=Search>. Accessed 2015 Aug 12.
17. PL Detail-Document, PCSK9 inhibitors for high cholesterol. Pharmacist's Letter/Prescriber's Letter. August 2015.
18. PL Detail-Document, Statin-associated muscle symptoms. Pharmacist's Letter/Prescriber's Letter. June 2012.
19. Kastelein JJ, Robinson JG, Farnier M, et al. Efficacy and safety of alirocumab in patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy: design and rationale of the ODYSSEY FH studies. *Cardiovasc Drugs Ther*. 2014;28:281-289.
20. Goff DC Jr, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129(suppl 2):S49-S73.
21. Downs JR, O'Malley RG. Management of dyslipidemia for cardiovascular disease risk reduction: synopsis of the 2014 U.S. Department of Veterans Affairs and U.S. Department of Defense clinical practice guideline. *Ann Intern Med*. 2015;163:291-297.
22. Mittleman MA, Taylor WC, Smetana G, Burns RB. Treatment of blood cholesterol to reduce risk for atherosclerotic cardiovascular disease. *Ann Intern Med*. 2015;163:280-290.
23. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 – executive summary. *J Clin Lipidol*. 2014;8:473-488.
24. Cholesterol Treatment Trialists' (CTT) Collaboration. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170000 participants in 26 randomised trials. *Lancet*. 2010;376(9753):1670-1681.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

25. Repatha (evolocumab) package insert. Thousand Oaks, CA: Amgen. August 2015.