

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 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
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.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>

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 the following:

1. For Welchol, whether the recipient has a history of intolerance to bile acid sequestrants.
2. For Zetia, whether the recipient has a history of:
 - a. Therapeutic failure or intolerance of Vytorin
 - OR**
 - b. Intolerance or contraindication to HMG CoA Reductase Inhibitors
3. For Lovaza, whether the recipient is 18 years of age or older and:
 - a. Has a documented Triglyceride level > 500 mg/dL
 - AND**
 - b. Has a history of therapeutic failure or contraindication to:

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- 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
4. For Kynamro (mipomersen sodium) and Juxtapid (lomitapide), whether the recipient:
- a. Has a diagnosis of homozygous familial hypercholesterolemia (HoFH) supported by medical history and laboratory findings

AND

- b. 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

- c. 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

- d. Has documentation of adherence to a low-fat, low cholesterol diet

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AND

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

AND

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

AND

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

AND

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

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

OR

- 6. 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.
- 7. 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.
- 8. 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

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AND

- b. No significant increase in LDL-C and ALT measures
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 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

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

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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 Kynamro (mipomersen sodium) or Juxtapid (lomitapide) as follows:

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