Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Leqvio [inclisiran], Praluent [alirocumab], Repatha [evolocumab]).

3. An adenosine triphosphate-citrate lyase (ACL) inhibitor (e.g., Nexletol [bempedoic acid], Nexlizet [bempedoic acid/ezetimibe]).

4. A microsomal triglyceride transfer protein (MTP) inhibitor (e.g., Juxtapid [lomitapide]).

5. An angiopoietin-like 3 (ANGPTL3) inhibitor (e.g., Evkeeza [evinacumab]).

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 a contraindication to the prescribed drug; **AND**

5. For treatment of a lipid disorder, has documentation of results of a lipid profile within 3 months prior to the request for the Lipotropic, Other; **AND**

6. For a PCSK9 inhibitor, **all** of the following:

    a. Has a history of **one** of the following:

        i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximum tolerated dose of a high-intensity statin for ≥3 months,

ii. **Both** of the following:

a) A temporally related intolerance[1] 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
(ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

iii. A contraindication to statins,

b. Has **one** of the following:

i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,
ii. A contraindication or an intolerance to ezetimibe,
iii. An LDL-C that is >25% above goal LDL-C while adherent to treatment with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,

c. Is prescribed 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 guidelines[2]
ii. For treatment of all other conditions, the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

d. If currently using a different PCSK9 inhibitor, will discontinue use of that PCSK9 inhibitor prior to starting the requested PCSK9 inhibitor,

[1] 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.
[2] 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

e. For a non-preferred PCSK9 inhibitor, has **one** of the following:

i. A history of therapeutic failure of at least 1 preferred PCSK9 inhibitor approved or medically accepted for the beneficiary's diagnosis
ii. A contraindication or an intolerance to the preferred PCSK9 inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

7. For an ACL inhibitor, **all** of the following:

a. Has a history of **one** of the following:

i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with the maximum tolerated dose of a high-intensity statin for ≥3 months,

ii. **Both** of the following:

a) A temporally related intolerance 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
(ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

iii. A contraindication to statins,

b. Has **one** of the following:

i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months
ii. A contraindication or an intolerance to ezetimibe,

c. Is prescribed the requested ACL inhibitor in addition to the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

d. If currently taking simvastatin or pravastatin, will not be using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

AND

8. For an ANGPTL3 inhibitor or MTP inhibitor, **all** of the following:

   a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders,

   b. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines,

   c. **One** of the following:

      i. Has a history of therapeutic failure of or a contraindication or an intolerance to 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%,

   d. Is prescribed the requested drug in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

AND

9. For icosapent ethyl, **all** of the following:

   a. **One** of the following:

      i. Has a history of clinical ASCVD,

      ii. **Both** of the following:

         a) Has diabetes mellitus
         b) Has 2 additional ASCVD risk factors (e.g., age ≥50 years, cigarette smoking, hypertension, HDL-C ≤40 mg/dL for males or ≤50 mg/dL for females, hs-CRP >3.00 mg/L, CrCl <60 mL/min, retinopathy, micro- or macroalbuminuria, ABI <0.9]),

      iii. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis,

   b. Has fasting triglycerides ≥150 mg/dL,

   c. Has **one** of the following:

      i. A history of therapeutic failure of while adherent to treatment with maximum tolerated doses of 2 different statins for ≥3 consecutive months each,
      ii. A history of statin intolerance after modifiable risk factors have been addressed,
      iii. A contraindication to statins;

AND

10. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis.

    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 a positive clinical response demonstrated by lab test results, if appropriate for the diagnosis, since starting the requested drug (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 contraindication to the prescribed drug; **AND**

4. For a PCSK9 inhibitor, is using the requested PCSK9 inhibitor in addition to **one** of the following:

   a. For treatment of HoFH, standard lipid-lowering treatments as recommended by current consensus guidelines[3]
   b. For treatment of all other conditions, the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate);

   AND

5. For an ACL inhibitor, **both** of the following:

   a. Is using the requested ACL inhibitor in addition to the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)
   b. If currently taking simvastatin or pravastatin, is not using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

   AND

6. For an ANGPTL3 inhibitor or MTP inhibitor, **both** of the following:

   a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
   b. Is using the requested drug in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

   AND

[3] 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

7. For icosapent ethyl, experienced a decrease in fasting triglycerides since starting icosapent ethyl; **AND**

8. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis.

   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

   a. 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.

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LIPOTROPICS, OTHER PRIOR AUTHORIZATION FORM *(form effective 1/6/2025)*

☐New request ☐Renewal request	Total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form:	
Dose/directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

Complete all sections that apply to the beneficiary and this request.
Check all that apply and submit documentation for each item.

INITIAL requests

1. **For treatment of ANY LIPID DISORDER:**
   ☐Has results of a lipid profile within the past 3 months

2. **For a PCSK9 INHIBITOR (eg, Leqvio, Praluent, Repatha), NEXLETOL (bempedoic acid), or NEXLIZET (bempedoic acid/ezetimibe):**
   ☐One of the following related to history of **statin** use:
   - ☐Failed to achieve goal LDL-C or percentage reduction of LDL-C with maximally tolerated dose of ONE high-intensity statin (eg, atorvastatin, rosuvastatin) for at least THREE consecutive months
   - ☐Is unable to tolerate high-intensity statins AND:
     - ☐Has a temporally related intolerance to high-intensity statins
     - ☐Tried and failed or has an intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin for at least THREE months
     - ☐Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber (eg, drug interactions, hypothyroidism, vitamin D deficiency, etc.)
   - ☐Has a contraindication to statins

   ☐One of the following related to history of **ezetimibe** use:
   - ☐Failed to achieve goal LDL-C or percentage reduction of LDL-C with ezetimibe in combination with maximally tolerated dose of the highest-tolerated intensity statin (eg, atorvastatin, rosuvastatin) for at least THREE consecutive months
   - ☐Has a contraindication or an intolerance to ezetimibe
   - ☐**For a PCSK9 inhibitor,** has an LDL-C that is >25% above goal LDL-C while adherent to treatment with the maximally tolerated dose of the highest-tolerated intensity statin for at least THREE consecutive months

   ☐One of the following:
   - ☐For a diagnosis of homozygous familial hypercholesterolemia, is prescribed the requested medication in addition to other standard lipid-lowering therapies
   - ☐For all other diagnoses, is prescribed the requested medication in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)

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☐ **For a non-preferred PCSK9 inhibitor:**
- ☐ Tried and failed a preferred PCSK9 inhibitor or has a contraindication or an intolerance to the preferred PCSK9 inhibitors approved or medically accepted for the treatment of the beneficiary's diagnosis (*Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

☐ **For Nexletol (bempedoic acid) or Nexlizet (bempedoic acid/ezetimibe):**
- ☐ If currently taking simvastatin or pravastatin, will not be using Nexletol/Nexlizet concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily

3. For EVKEEZA (evinacumab) or JUXTAPID (lomitapide):
- ☐ Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
- ☐ One of the following:
  - ☐ Tried and failed or has a contraindication or an intolerance to PCSK9 inhibitors
  - ☐ Is homozygous for LDL receptor (LDLR)-negative mutations (ie, has LDLR-negative mutations in both alleles) associated with LDLR activity below 2%
- ☐ Is prescribed the requested medication in addition to other standard lipid-lowering therapies

4. For VASCEPA (icosapent ethyl):
- ☐ One of the following:
  - ☐ Has a history of clinical atherosclerotic cardiovascular disease
  - ☐ Both of the following:
    - ☐ Has diabetes mellitus
    - ☐ Has at least 2 additional ASCVD risk factors AND *(check all that apply)*:
      - ☐ age ≥50 years
      - ☐ cigarette smoking
      - ☐ hypertension
      - ☐ hs-CRP >3.00 mg/L
      - ☐ CrCl <60 mL/min
      - ☐ HDL-C ≤40 mg/dL for males or ≤50 mg/dL for females
      - ☐ retinopathy
      - ☐ micro- or macroalbuminuria
      - ☐ ABI <0.9
      - ☐ other: _____
  - ☐ Tried and failed or has a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the treatment of the beneficiary's diagnosis (*Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*
- ☐ Has fasting triglycerides ≥150 mg/dL
- ☐ One of the following:
  - ☐ Tried and failed maximally tolerated doses of TWO different high-intensity statins for at least THREE months each
  - ☐ Has a history of statin intolerance after modifiable risk factors have been addressed (eg, drug interactions, hypothyroidism, vitamin D deficiency, etc.)
  - ☐ Has a contraindication to statins

5. For ALL OTHER NON-PREFERRED Lipotropics, Other:
- ☐ Tried and failed or has a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

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RENEWAL requests

1. **For ALL diagnoses:**
   - ☐ Experienced 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.)

2. **For a PCSK9 INHIBITOR (eg, Leqvio, Praluent, Repatha):**
   - ☐ For a diagnosis of homozygous familial hypercholesterolemia, is using the requested PCKS9 inhibitor in addition to other standard lipid-lowering treatments
   - ☐ For all other diagnoses, is using the requested PCSK9 inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)

3. **For NEXLETOL (bempedoic acid) or NEXLIZET (bempedoic acid/ezetimibe):**
   - ☐ Is using the requested medication in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate)
   - ☐ If currently taking simvastatin or pravastatin, will not be using Nexletol/Nexlizet concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily

4. **For EVKEEZA (evinacumab) or JUXTAPID (lomitapide):**
   - ☐ Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
   - ☐ Is using the requested medication in addition to other standard lipid-lowering treatments

5. **For ALL OTHER NON-PREFERRED Lipotropics, Other:**
   - ☐ Tried and failed or has a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary's diagnosis *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: