Highmark Wholecare
Pharmacy Division
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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 Lipotropics, 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., alirocumab, evolocumab, inclisiran).

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

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

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

6. An apolipoprotein C-III (apoC-III)-directed Lipotropics, Other (e.g., olezarsen, plozasiran).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropics, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested Lipotropics, Other for the treatment of a diagnosis that is consistent with the U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **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 three months prior to the request for the Lipotropics, 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 non-HDL-C, LDL-C, percentage reduction of LDL-C, or apoB while adherent to treatment with the maximum tolerated dose of a high-intensity

statin for greater than or equal to three months,

ii. **Both** of the following:

a) A temporally related intolerance[1] to a high-intensity statin 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 if clinically appropriate (e.g., dose decrease or discontinuation of the interacting drug, 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 greater than or equal to three 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 greater than or equal to three consecutive months,
ii. A contraindication or an intolerance to ezetimibe,
iii. An LDL-C that is greater than 25% above goal LDL-C while adherent to treatment with the maximum tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for greater than or equal to three 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 one 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 non-HDL-C, LDL-C, percentage reduction of LDL-C, or apoB while adherent to treatment with the maximum tolerated dose of a high-intensity statin for greater than or equal to three months,

ii. **Both** of the following:

a) A temporally related intolerance to a high-intensity statin 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 if clinically appropriate (e.g., dose decrease or discontinuation of the interacting drug, 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 greater than or equal to three 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 greater than or equal to three 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 greater than 20 mg daily or pravastatin at a dose of greater than 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. Has results of genetic testing that are positive for mutations associated with lack of response to PCSK9 inhibitors,

   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. Has fasting triglycerides greater than or equal to 150 mg/dL,

   b. **One** of the following:

      i. Has a history of clinical atherosclerotic cardiovascular disease (ASCVD),

      ii. **Both** of the following:

         a) Has diabetes mellitus
         b) Has at least one additional ASCVD risk factor (e.g., 50 years of age or older, cigarette smoking or stopped smoking within three months, hypertension or on antihypertensive medication, HDL-C less than or equal to 40 mg/dL for males or 50 mg/dL for females, hs-CRP greater than 3.0 mg/L, CrCl greater than 30 mL/min and less than 60 mL/min, retinopathy, micro- or macroalbuminuria, ABI less than 0.9),

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

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

i. A history of therapeutic failure of while adherent to treatment with the maximum tolerated dose of a statin for greater than or equal to three consecutive months,
ii. A history of statin intolerance after modifiable risk factors have been addressed,
iii. A contraindication to statins;

AND

10. For an apoC-III-directed Lipotropics, Other, **all** of the following:

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

b. **One** of the following:

i. For treatment of familial chylomicronemia syndrome (FCS), has **both** of the following:

a) Untreated fasting triglycerides greater than or equal to 880 mg/dL

b) **One** of the following:

(i) Results of genetic testing showing biallelic pathogenic variants in FCS-causing genes,

(ii) A North American FCS (NAFCS) score greater than or equal to 60 (i.e., definite FCS),

(iii) **Both** of the following:

a. An NAFCS score greater than or equal to 45 and less than 60 (i.e., likely FCS)
b. An FCS score (Moulin score) greater than or equal to 10 (i.e., FCS very likely)

ii. For all other diagnoses, **both** of the following:

a) Has a diagnosis that is confirmed according to applicable consensus guidelines
b) Has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines,

c. If currently using a different apoC-III-directed Lipotropics, Other, will discontinue use of that apoC-III-directed Lipotropics, Other prior to starting the requested apoC-III-directed Lipotropics, Other,

d. For Tryngolza (olezarsen), has a history of therapeutic failure of or a contraindication or an intolerance to Redemplo (plozasiran) if Redemplo (plozasiran) is approved or medically accepted for the beneficiary's diagnosis;

AND

11. 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 Lipotropics, Other that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response since starting the requested drug (e.g., decreased LDL-C, decreased triglycerides, fewer episodes of acute pancreatitis, 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, **both** of the following:

    a. Is using the requested PCSK9 inhibitor in addition to **one** of the following:

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

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

        i. A history of therapeutic failure of at least one 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

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)

[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

b. If currently taking simvastatin or pravastatin, is not using the requested ACL inhibitor concomitantly with simvastatin at a dose of greater than 20 mg daily or pravastatin at a dose of greater than 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

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

8. For an apoC-III-directed Lipotropic, Other, **both** of the following:

   a. Is prescribed the requested drug by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or other provider specializing in lipid disorders
   b. For Tryngolza (olezarsen), has a history of therapeutic failure of or a contraindication or an intolerance to Redemplo (plozasiran) if Redemplo (plozasiran) is approved or medically accepted for the beneficiary's diagnosis;

   AND

9. 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

I. 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 Lipotropics, 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 7/6/2026)*

☐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):

☐Has at least ONE of the following **diagnoses**:
- ☐A history of clinical atherosclerotic cardiovascular disease
- ☐Familial hypercholesterolemia
- ☐Severe hypercholesterolemia (baseline LDL-C ≥190 mg/dL)

☐ONE of the following related to history of **statin** use:
- ☐Failed to achieve goal non-HDL-C, LDL-C, percentage reduction of LDL-C, or apoB with maximally tolerated dose of a high-intensity statin (eg, atorvastatin, rosuvastatin) for at least 3 consecutive months
- ☐Is unable to tolerate high-intensity statins AND:
  - ☐Has a temporally related intolerance to a high-intensity statin
  - ☐Tried and failed or has an intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin for at least 3 months
  - ☐Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber (eg, hypothyroidism, vitamin D deficiency, etc.)
  - ☐All possible drug interactions with statins were addressed (eg, dose decrease or discontinuation of the interacting drug, change to an alternative statin that has a lower incidence of drug interactions)
- ☐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 3 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 3 consecutive months

☐ONE of the following:
- ☐For a diagnosis of homozygous familial hypercholesterolemia, is prescribed the requested drug in addition to other standard lipid-lowering therapies
- ☐For all other diagnoses, is prescribed the requested drug 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
  - ☐ Has results of genetic testing that are positive for mutations associated with lack of response to PCSK9 inhibitors
- ☐ Is prescribed the requested medication in addition to other standard lipid-lowering therapies

4. For VASECPA (icosapent ethyl):
- ☐ ONE of the following:
  - ☐ Has a history of clinical atherosclerotic cardiovascular disease (ASCVD)
  - ☐ BOTH of the following:
    - ☐ Has diabetes mellitus
    - ☐ Has at least one additional ASCVD risk factor *(check all that apply)*:
      - ☐ age ≥50 years
      - ☐ retinopathy
      - ☐ micro- or macroalbuminuria
      - ☐ hs-CRP >3.0 mg/L
      - ☐ ABI <0.9
      - ☐ HDL-C ≤40 mg/dL for males or ≤50 mg/dL for females
      - ☐ current smoker or stopped smoking within 3 months
      - ☐ hypertension or taking antihypertensive medication
      - ☐ CrCl >30 mL/min and <60 mL/min
      - ☐ other: _____
  - ☐ Tried and failed or has a contraindication or an intolerance to a preferred fibric acid derivative 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 a statin for at least 3 months
  - ☐ 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 an APOC-III-DIRECTED Lipotropics, Other (eg, Redemplo, Tryngolza):
- ☐ Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or other provider specializing in lipid disorders
- ☐ **For a diagnosis of familial chylomicronemia syndrome (FCS),** BOTH of the following:
  - ☐ Untreated fasting triglycerides ≤880 mg/dL
  - ☐ ONE of the following:
    - ☐ Results of genetic testing showing biallelic pathogenic variations in FCS-causing genes
    - ☐ A North American FCS score ≥60 (i.e., definite FCS)
    - ☐ BOTH of the following:
      - ☐ A North American FCS score ≥45 and <60 (i.e., likely FCS)
      - ☐ An FCS score (Moulin score) ≥10 (i.e., FCS very likely)
- ☐ **For a diagnosis other than FCS:**
  - ☐ Has a diagnosis that is confirmed according to applicable consensus guidelines
  - ☐ Tried and failed or has a contraindication or intolerance to first-line therapy(ies) if applicable according to consensus treatment guidelines

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☐ **For TRYNGOLZA (olezarsen):**
- ☐ Tried and failed or has a contraindication or an intolerance to Redemplo (plozasiran) if Redemplo is approved or medically accepted for the beneficiary's diagnosis

6. 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.)*

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)

☐ **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.)*

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 an APOC-III-DIRECTED Lipotropics, Other (eg, Redemplo, Tryngolza):

☐ Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or other provider specializing in lipid disorders

☐ **For TRYNGOLZA (olezarsen):**
- ☐ Tried and failed or has a contraindication or an intolerance to Redemplo (plozasiran) if Redemplo is approved or medically accepted for the beneficiary's diagnosis

6. 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**:

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