

**Lipid Lowering Agents**  
**Effective 10/02/2023**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
Exchange	Phone: 855-582-2022	Fax: 855-245-2134	
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	Evkeeza is available under medical benefit only. Leqvio is available under pharmacy and medical benefits.		

**Overview**

No PA	Drugs that require PA
<b>Fibric Acid Derivatives</b>	
Antara® # (fenofibrate 30 mg, 90 mg capsule) fenofibric acid tablet Lipofen® (fenofibrate 50 mg, 150 mg capsule) ‡ fenofibrate capsule, 54 mg and 160 mg tablet Lipid® # (gemfibrozil) Tricor® # (fenofibrate 48 mg, 145 mg tablet) Trilipix® # (fenofibric acid capsule)	Fenoglide® (fenofibrate 40 mg, 120 mg tablet) (QL > 1 unit/day) †
<b>PCSK9 Inhibitors</b>	
	Praluent® (alirocumab) Repatha® (evolocumab)
<b>Statins</b>	
	Altoprev® (lovastatin extended-release) (QL > 1.5 units/day for 20 mg and 40 mg; QL > 1 unit/day for 60 mg) Atorvaliq (atorvastatin suspension) Crestor® # (rosuvastatin 5 mg, 10 mg, 20 mg) >1.5 units/day† Crestor® # (rosuvastatin 40 mg) > 1 unit/day † Ezallor® (rosuvastatin sprinkle capsule) > 1 unit/day Flolipid® (simvastatin suspension) §

	fluvastatin (QL > 1.5 units/day for 20 mg; QL > 2 units/day for 40 mg) † Lescol XL® (Fluvastatin extended-release) (QL > 1 unit/day) † Lipitor® # (atorvastatin 10 mg, 20 mg, 40 mg) > 1.5 units/day † Lipitor® # (atorvastatin 80 mg) > 1 unit/day † Livalo® (pitavastatin calcium) (QL > 1.5 units/day for 1 mg, 2 mg; QL > 1 unit/day for 4 mg) lovastatin 10 mg, 20 mg >1.5 units/day lovastatin 40 mg > 2 units/day pravastatin 10 mg, 20 mg, 40 mg >1.5 units/day pravastatin 80 mg > 1 unit/day Zocor® # (simvastatin 5 mg, 10 mg, 20 mg, 40 mg) > 1.5 units/day † Zocor® # (simvastatin 80 mg) > 1 unit/day † Zypitamag® (pitavastatin magnesium) (QL > 1.5 units/day for 2 mg; QL > 1 unit/day for 4 mg)
<b>Combination Lipid Lowering Agents</b>	
	Caduet® (amlodipine/atorvastatin) (QL > 1 unit/day) † Roszet® (rosuvastatin/ezetimibe) ‡ Vytorin® # (ezetimibe/simvastatin) > 1 unit/day†
<b>Miscellaneous Lipid Lowering Agents</b>	
cholestyramine/aspartame †† cholestyramine/sucrose †† Colestid® # (colestipol) Lovaza® # (omega-3 acid ethyl esters) Niaspan® # (niacin extended-release tablet) vitamin B-3 (niacin) * Welchol® # (colesevelam) Zetia® # (ezetimibe)	Evkeeza® (evinacumab-dgnb) <sup>MB</sup> Leqvio® (inclisiran) <sup>DUAL</sup> Juxtapid® (lomitapide) Nexletol® (bempedoic acid) (QL > 1 unit/day) Nexlizet® (bempedoic acid/ezetimibe) (QL > 1 unit/day) Vascepa® (icosapent ethyl) † <sup>BP</sup>

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalents

<sup>BP</sup> Brand Preferred over generic equivalents. In general, requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

<sup>MB</sup> This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The Plan does not pay for this drug to be dispensed through the retail pharmacy.

<sup>DUAL</sup> This drug is available through both pharmacy and medical benefits

\*The generic OTC and, if any, generic prescription versions of the drug are payable without prior authorization

†Available as an A-rated generic. Both brand and A-rated generic require PA.

‡Available as an authorized generic

†† A branded generic(s) is available in this formulation.

§This agent does not participate in federal rebate

#### Approvable Diagnosis:

- Primary hyperlipidemia
- Primary prevention of cardiovascular events
- Hypercholesterolemia in a member with a previous history of any cardiovascular event



- HeFH
- HoFH
- Primary dysbetalipoproteinemia
- Hypertriglyceridemia

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

### OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

#### **Fenoglide\*** (fenofibrate 40 mg, 120 mg tablet)

**ALL** of the following:

1. Diagnosis of hypertriglyceridemia, hypercholesterolemia, or mixed dyslipidemia
2. Medical records documenting an inadequate response or adverse reaction to a therapeutically equivalent fenofibrate formulation available without prior authorization
3. **ONE** of the following:
  - a. Requested quantity is  $\leq 1$  unit/day
  - b. Medical necessity for the requested agent above quantity limits

#### **Praluent\*** (alirocumab)

#### **Repatha\*** (evolocumab)

**ALL** of the following:

1. **ONE** of the following:
  - a. Praluent: Member is  $\geq 18$  years of age
  - b. Repatha: Member has a diagnosis of HeFH or HoFH and is  $\geq 10$  years of age OR member is  $\geq 18$  years of age
2. Diagnosis is hypercholesterolemia with **ONE** of the following:
  - a. For members with a diagnosis of HeFH or HoFH, current LDL-C is  $\geq 70$  mg/dL
  - b. For members with a previous history of a cardiovascular event (with or without HeFH or HoFH), current LDL-C is  $\geq 55$  mg/dL
  - c. For members with primary hyperlipidemia (without a history of a cardiovascular event and/or HeFH/HoFH), baseline LDL-C is  $\geq 190$  mg/dL, and current LDL-C is  $\geq 70$  mg/dL
3. **ONE** of the following\*:
  - a. Paid claims or physician attestation of inadequate response (defined as  $\geq$  the last 3 months) to a high intensity statin in combination with ezetimibe
  - b. Adverse reaction or contraindication to ezetimibe $\ddagger$  AND inadequate response (defined as  $\geq$  the last 3 months) to high intensity statin monotherapy
  - c. Adverse reaction to ONE high intensity statin or contraindication to ALL high intensity statins
4. Appropriate dosing
5. **ONE** of the following:
  - a. Praluent: Requested quantity is 2 pens or syringes/28 days
  - b. Repatha: Requested quantity is 2 autoinjectors or syringes/28 days or 1 to 2 on-body infuser systems/28 days



*\*If the prescriber documents that the member has experienced an adverse reaction to a high intensity statin or has a contraindication to high intensity statins, requests may be approved without the requirement for ezetimibe monotherapy*

*‡Please see Appendix I: Special Considerations in Lipid Lowering Therapy for requests that document that less costly trials will be associated with inadequate lipid lowering.*

**Caduet®** (amlodipine/atorvastatin)

**ALL** of the following:

1. **ONE** of the approvable diagnoses (list above)
2. Medical necessity for use of the combination product instead of the commercially available separate agents
3. **ONE** of the following:
  - a. Requested quantity is  $\leq 1$  tablet/day
  - b. Medical necessity for the requested agent above quantity limits (See Appendix II: Requests above the quantity limit)
  - c. If the request is above the maximum, FDA-approved dose, inadequate response (defined as  $\geq$  the last 3 months) to atorvastatin 80 mg daily

**Altoprev®** (lovastatin extended-release)

**fluvastatin**

**Lescol XL®** (fluvastatin extended-release)

**Livalo®** (pitavastatin calcium)

**Zypitamag®** (pitavastatin magnesium)

**ALL** of the following:

1. **ONE** of the approvable diagnoses (list above)
2. **ONE** of the following:
  - a. Paid claims or physician attestation of inadequate response (defined as  $\geq$  the last 3 months) or an adverse reaction to ONE or contraindication to ALL high intensity statins
  - b. A well-defined clinical rationale for not trying a high intensity statin
3. **ONE** of the following:
  - a. Request is within quantity limit for strength requested
  - b. Medical necessity for the requested agent above quantity limits (See Appendix II: Requests above the quantity limit)
  - c. If the request is above the maximum, FDA-approved dose, inadequate response (defined as  $\geq$  the last 3 months) to atorvastatin 80 mg daily

*Above Quantity Limits*

**Crestor®** (rosuvastatin)

**Lipitor®** (atorvastatin)

**lovastatin**

**pravastatin**

**Vytorin®** (ezetimibe/simvastatin)

**Zocor®** (simvastatin)

**ALL** of the following:

1. **ONE** of the approvable diagnoses (list above)
2. Medical necessity for the requested agent above quantity limits (See Appendix II: Requests above the quantity limit)



**Atorvaliq**<sup>®</sup> (atorvastatin suspension)

**Ezallor**<sup>®</sup> (rosuvastatin sprinkle capsule)

**Flolipid**<sup>®</sup> (simvastatin suspension)

**ALL** of the following:

1. **ONE** of the approvable diagnoses (list above)
2. Medical necessity for the requested formulation as noted by one of the following:
  - a. Member has severe dysphagia AND is currently only utilizing formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets)
  - b. Member utilizes tube feeding (G-tube/J-tube)
  - c. Member is < 13 years of age
3. Appropriate dosing
4. For Ezallor, requested quantity is ≤ one sprinkle capsule/day
5. For Atorvaliq, clinical rationale for the use of the requested agent instead of Ezallor
6. For FloLipid, requests must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

**Roszet**<sup>®</sup> (rosuvastatin/ ezetimibe)

**ALL** of the following:

1. Diagnosis of hypercholesterolemia or HoFH
2. Clinical rationale for use of the combination product over the commercially available separate agents
3. Request is within quantity limit of 1 unit/day  
Requests must meet the above criteria and the prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product (as per the Non-FDA approved and Non-rebate Medications guideline)

**Evkeeza**<sup>®</sup> (evinacumab-dgnb)<sup>MB</sup>

**ALL** of the following:

1. Diagnosis of HoFH confirmed by **ONE** of the following:
  - a. Laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations
  - b. **BOTH** of the following:
    - i. Baseline LDL-C ≥ 400 mg/dL
    - ii. Current LDL-C ≥ 100 mg/dL
  - c. **ONE** of the following:
    - i. Member had evidence of xanthoma before 10 years of age
    - ii. Evidence of HeFH in both parents
2. Member is ≥ 5 years of age
3. Prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided
4. **ONE** of the following:
  - a. Agent to be used as add-on therapy with a high-intensity statin, ezetimibe, and PCSK9 inhibitor
  - b. Contraindication or other well-defined clinical rationale for omitting one or more of the standard lipid-lowering therapies: statin, ezetimibe, and PCSK9 inhibitors
5. Member's current weight (use to verify correct dosing)
6. Appropriate dosing

**Leqvio**<sup>®</sup> (inclisiran)



**ALL** of the following:

1. Diagnosis is hypercholesterolemia with **ONE** of the following:
  - a. For members with a diagnosis of HeFH, current LDL-C is  $\geq 70$  mg/dL
  - b. For members with a previous history of a cardiovascular event (with or without HeFH), current LDL-C is  $\geq 55$  mg/dL
2. Member is  $\geq 18$  years of age
3. Prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided
4. Paid claims or physician attestation of inadequate response (defined as  $\geq$  the last 3 months) or adverse reaction to **ONE** or contraindication to **BOTH** of the following\*:
  - a. Praluent® (alirocumab)
  - b. Repatha® (evolocumab)
5. **ONE** of the following†:
  - a. Paid claims or physician attestation of inadequate response (defined as  $\geq$  the last 3 months) to combination therapy with a high intensity statin and ezetimibe
  - b. Adverse reaction or contraindication to ezetimibe AND inadequate response (defined as  $\geq$  the last 3 months) to high intensity statin monotherapy
  - c. Adverse reaction to ONE high intensity statin or contraindication to ALL high intensity statins
6. Appropriate dosing

\*Requests looking to bypass the required trial with Praluent® (alirocumab) or Repatha® (evolocumab) may be approved if the prescriber documents concerns with the member using self-injections (due to non-adherence or low health literacy)

† If the prescriber documents that the member has experienced an adverse reaction to a high intensity statin or has a contraindication to high intensity statins, requests may be approved without the requirement for ezetimibe monotherapy

**Juxtapid®** (lomitapide)

**ALL** of the following:

1. Diagnosis of HoFH confirmed by **ONE** of the following:
  - a. Laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations
  - b. **BOTH** of the following:
    - i. Baseline LDL-C  $\geq 400$  mg/dL
    - ii. Current LDL-C  $\geq 100$  mg/dL
  - c. **ONE** of the following:
    - i. Member had evidence of xanthoma before 10 years of age
    - ii. Evidence of HeFH in both parents
2. Member is  $\geq 18$  years of age
3. Prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided
4. **ONE** of the following:
  - a. Paid claims or physician attestation of inadequate response (defined as  $\geq$  the last 3 months) or adverse reaction to ONE or contraindication to ALL high intensity statins
  - b. Clinical rationale for not trying a high intensity statin
5. **ONE** of the following:
  - a. Agent to be used as add-on therapy with a high-intensity statin
  - b. Contraindication to statin therapy



6. Physician attestation of inadequate response or adverse reaction to **ONE** additional non-statin lipid lowering agent or contraindication to ALL non-statin lipid lowering agents

**Nexleto<sup>®</sup>** (bempedoic acid)

**Nexlizet<sup>®</sup>** (bempedoic acid/ezetimibe)

**ALL** of the following:

1. Diagnosis of hypercholesterolemia with ONE of the following:
  - a. For members with a diagnosis of HeFH, current LDL-C is  $\geq 70$  mg/dL
  - b. For members with a previous history of a cardiovascular event (with or without HeFH or HoFH), current LDL-C is  $\geq 55$  mg/dL
2. Member is  $\geq 18$  years of age
3. Prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided
4. **ONE** of the following\*:
  - a. Paid claims or physician attestation of inadequate response (defined as  $\geq$  the last 3 months) to combination therapy with a high intensity statin and ezetimibe
  - b. Adverse reaction or contraindication to ezetimibe AND inadequate response (defined as  $\geq$  the last 3 months) to high intensity statin monotherapy
  - c. Adverse reaction to ONE high intensity statin or contraindication to ALL high intensity statins
5. Requested quantity is  $\leq 1$  tablet/day

\*If the prescriber documents that the member has experienced an adverse reaction to a high intensity statin or has a contraindication to high intensity statins, requests may be approved without the requirement for ezetimibe monotherapy

**Vascepa<sup>®</sup>** (icosapent ethyl)<sup>BP</sup>

**ONE** of the following:

1. Diagnosis of hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors)
  - a. Triglyceride level  $\geq 500$  mg/dL
  - b. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication (e.g., elevated LDL levels ( $\geq 100$  mg/dL) to omega-3 acid ethyl esters
  - c. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to a fibric acid derivative (i.e., fenofibrate or gemfibrozil)
  - d. **ONE** of the following:
    - i. For icosapent ethyl 1 g capsule, requested quantity is  $\leq 4$  capsules/day
    - ii. For icosapent ethyl 0.5 g capsule, requested quantity is  $\leq 8$  capsules/day
    - iii. Medical necessity for the requested agent above quantity limits (See Appendix II: Requests above the quantity limit)
2. Diagnosis of cardiovascular risk reduction
  - a. **ONE** of the following:
    - i. Member has established cardiovascular disease (e.g., prior MI, hospitalization for high-risk NSTEMI-ACS cerebrovascular or carotid disease: prior ischemic stroke, carotid artery disease, PAD)
    - ii. Member has diabetes mellitus with at least one risk factor for CVD (e.g. age [women  $\geq 65$  years, men  $\geq 55$  years], smoker, HTN, low HDL-C [ $\leq 40$  mg/dL for men and  $\leq 50$  mg/dL for women], renal dysfunction [CrCl  $>30$  and  $< 60$  mL/min], retinopathy, micro- or macroalbuminuria, high-sensitivity C-reactive protein (hs-CRP)  $>3.0$  mg/dL, or ankle-brachial index  $< 0.9$  without symptoms of intermittent claudication)



- b. Triglyceride level  $\geq$  135 mg/dL
- c. **ONE** of the following:
  - i. Requested agent will be used in combination with a statin
  - ii. Clinical rationale why member cannot take a statin
- d. **ONE** of the following:
  - i. For icosapent ethyl 1 gm capsule, requested quantity is  $\leq$  4 capsules/day
  - ii. For icosapent ethyl 0.5 gm capsule, requested quantity is  $\leq$  8 capsules/day
  - iii. Medical necessity for the requested agent above quantity limits (See Appendix II: Requests above the quantity limit)

### **Continuation of Therapy**

Reauthorization should be reviewed for the following information:

#### **Atorvaliq, Ezallor, FloLipid:**

Prescriber must provide documentation of continued medical necessity for the requested formulation instead of tablets as noted by **ONE** of the following:

- a. Member has severe dysphagia AND is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets)
- b. Member utilizes tube feeding (G-tube/J-tube)
- c. Member is <13 years of age

#### **Evkeeza® (evinacumab-dgnb)**

- 1. **ONE** of the following:
  - a. Decrease in LDL-C from baseline and the member appears to be adherent to the regimen.
  - b. Decrease in LDL-C from baseline and evidence of non-adherence to one or more agent(s) in the regimen.
- 2. Updated member weight (use to verify correct dosing; may take this information over the phone if missing on PA request)

#### **Leqvio® (inclisiran)**

- 1. Member appears to be adherent to Leqvio®, statin and/or ezetimibe therapy (consistent with regimen noted on initial approval) (at least 60 days of therapy within the last 90 days for the statin and ezetimibe)
- 2. **ONE** of the following:
  - a. Decrease in LDL-C from baseline and the member appears to be adherent to the regimen.
  - b. Decrease in LDL-C from baseline and evidence of non-adherence.
  - c. If there is no decrease or an increase in LDL-C, or if an updated LDL-C is not provided and there is evidence of non-adherence.

#### **PCSK9 Inhibitors (Praluent®, Repatha®)**

Prescriber must provide documentation of a positive response to therapy.

#### **All Other Agents:**

Reauthorization by prescriber will infer a positive response to therapy.

### **Limitations**

- 1. Initial approvals will be granted for the following:
  - a. PCSK9 Inhibitors (Praluent®, Repatha®), Evkeeza® and Leqvio®: 6 months





- b. All other agents: 1 year
- 2. Reauthorizations will be granted for the following:
  - a. Evkeeza® and Leqvio®:
    - i. Decrease in LDL-C from baseline and member is adherent: 12 months
    - ii. Decrease in LDL-C from baseline and non-adherence: 6 months
    - iii. No decrease or an increase in LDL-C or updated LDL-C not provided and non-adherence: 6 months
  - b. All other agents: 1 year
- 3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
- 4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at [www.mass.gov/druglist](http://www.mass.gov/druglist).
- 5. The following quantity limits apply:

Fenoglide (fenofibrate 40 mg, 120 mg tablet)	30 tablets per 30 days
Praluent (alirocumab)	2 pens or syringes per 28 days
Repatha (evolocumab)	2 autoinjectors or syringes per 28 days
Altoprev (lovastatin extended-release)	20 mg, 40 mg: 45 capsules per 30 days 60 mg: 30 capsules per 30 days
Crestor (rosuvastatin)	5 mg, 10 mg, 20 mg: 45 tablets per 30 days 40 mg: 30 tablets per 30 days
Ezallor (rosuvastatin sprinkle capsule)	30 capsules per 30 days
fluvastatin	20 mg: 45 capsules per 30 days 40 mg: 60 capsules per 30 days
Lescol XL® (fluvastatin extended-release)	30 capsules per 30 days
Livalo (pitavastatin calcium)	1 mg, 2 mg: 45 tablets per 30 days 4 mg: 30 tablets per 30 days
Lipitor (atorvastatin)	10 mg, 20 mg, 40 mg: 45 tablets per 30 days 80 mg: 30 tablets per 30 days
Livalo (pitavastatin calcium)	1 mg, 2 mg: 45 tablets per 30 days 4 mg: 30 tablets per 30 days
lovastatin	10 mg, 20 mg: 45 tablets per 30 days 40 mg: 60 tablets per 30 days
pravastatin	10 mg, 20 mg, 40 mg: 45 tablets per 30 days 80 mg: 30 tablets per 30 days
Zocor (simvastatin)	5 mg, 10 mg, 20 mg, 40 mg: 45 tablets per 30 days 80 mg: 30 tablets per 30 days
Zypitamag (pitavastatin magnesium)	2 mg: 45 tablets per 30 days 4 mg: 30 tablets per 30 days



Caduet (amlodipine/atorvastatin)	30 tablets per 30 days
Vytorin (ezetimibe/simvastatin)	30 tablets per 30 days
Nexletol (bempedoic acid)	30 tablets per 30 days
Nexlizet (bempedoic acid/ezetimibe)	30 tablets per 30 days

## Appendix

### I. Special Considerations in Lipid Lowering Therapy

<b>Contraindication to Statin Therapy</b>
The following should be considered for <b>approval</b> when reviewing requests: <ul style="list-style-type: none"> <li>• Elevated serum transaminases with statin use</li> <li>• Elevated baseline serum transaminases (due to liver disease or other etiology) <ul style="list-style-type: none"> <li>○ All statins are cautioned in patients with liver disease; however, pravastatin has been studied in this population and is generally recommended at low doses</li> </ul> </li> </ul>

### II. Requests above the quantity limit

Quantity limits should allow for the use of most commonly requested doses that are not commercially available. For statin therapy, if the requested dose is above the FDA-approved limits listed below, then an atorvastatin trial is required at an appropriate dose (80 mg) and duration (3 months).

<b>Drug</b>	<b>Maximum FDA-Approved Dose<sup>†</sup></b>
<b>Statins</b>	
Altoprev <sup>®</sup> 20 mg, 40 mg, 60 mg (lovastatin extended-release)	60 mg/day
Crestor <sup>®</sup> 5 mg, 10 mg, 20 mg, 40 mg (rosuvastatin)	40 mg/day
Ezallor <sup>®</sup> 5 mg, 10 mg, 20 mg, 40 mg (rosuvastatin sprinkle capsule)	40 mg/day
Lescol <sup>®</sup> 20 mg, 40 mg (fluvastatin)	80 mg/day
Lescol XL <sup>®</sup> 80 mg (fluvastatin extended-release)	80 mg/day
Livalo <sup>®</sup> 1 mg, 2 mg, 4 mg (pitavastatin)	4 mg/day
Lipitor <sup>®</sup> 10 mg, 20 mg, 40 mg, 80mg (atorvastatin)	80 mg/day
lovastatin 10 mg, 20 mg, 40 mg	80 mg/day
pravastatin 10 mg, 20 mg, 40 mg 80 mg	80 mg/day
Roszet <sup>®</sup> 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, 40 mg/10 mg. (rosuvastatin/ezetimibe)	40 mg/10 mg/day
Vytorin <sup>®</sup> 10/10 mg, 10/20 mg, 10/40 mg, 10/80 mg (ezetimibe/simvastatin)	10 mg/80 mg/day
Zocor <sup>®</sup> 5 mg, 10 mg, 20 mg, 40 mg, 80 mg (simvastatin)	80 mg/day
Zypitamag <sup>®</sup> 2 mg, 4 mg (pitavastatin)	4 mg/day
<b>Other Agents</b>	
Fenoglide <sup>®</sup> 40 mg, 120 mg (fenofibrate)	120 mg/day
Vascepa <sup>®</sup> 0.5 g, 1 g (icosapent ethyl)	4 g/day

<sup>†</sup>Doses that are not available commercially are bolded.

### References

1. Third report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). Circulation. 2002 Dec 17;106(25):3143-421.
2. Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Lloyd-Jones DM, Blum CB 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. *J Am Coll Cardiol*. 2013 Nov 7.

3. Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary. *Circulation*. 2018 Nov 10:CIR0000000000000624.
4. Livalo® [package insert]. Montgomery (AL): Kowa Pharmaceuticals America, Inc.; 2020 Sep.
5. Lescol® [package insert]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2017 Aug.
6. Lescol XL® [package insert]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2020 Sep.
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### Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Criteria was named as Lipid Lowering Agents. Note: Praluent and Repatha was combined to this criteria. Effective 4/1/23.

07/12/23 – Reviewed and updated for P&T. Formatting updates to drug table. Clarified approvable diagnoses. Praluent and Repatha criteria updated to become less restrictive. Appendix criteria for special populations who are statin intolerant was removed and now combined with its respective criteria. Low cost alternative trials language have been simplified throughout the policy. Praluent and Repatha trial may be bypassed for Leqvio if there are concerns with member using self injections. Caduet®(amlodipine/atorvastatin) was updated to only require medical necessity for use of the combination product instead of the commercially available separate agents. Evkeeza had an age expansion to members aged 5 and older. New drug, Atorvaliq, was added. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23

09/13/23 – Reviewed and updated for P&T. Leqvio has been added to pharmacy benefit with PA and will remain on medical benefit with PA. Effective 10/2/23

