MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy

Antihyperlipidemics Policy

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Policy Number: 013

BCBSA Reference Number: None

Related Policies

- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621
- Medical Benefit Prior Authorization Medication List, #034

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: Prescription drugs are covered to the extent that these types of services are generally covered by each member's benefit design. The Formulary Exception/Prior Authorization form is included as part of this document for the physicians to submit for patients who do not meet Prior Authorization criteria.

Physicians may also call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients at (800)366-7778.

Please refer to the chart below for the formulary status of the medications affected by this policy.

Drug	Formulary Information
	Standard
	Formulary Status
Evkeeza ™ (evinacumab)	PA Required
Juxtapid ® (lomitapide)	PA Required
Kynamro ™ (mipomersen)	PA Required
Leqvio ® (inclisiran)	PA Required
Nexletol ™ (bempedoic acid)	PA Required
Nexlizet ™ (bempedoic acid and ezetimibe)	PA Required
Praluent ®^ (alirocumab)	PA Required
Repatha ™^ (evolocumab)	PA Required

^ - This Drug is part of Medications covered only under the pharmacy benefit program.

*Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and step criteria below are met.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We may cover **Evkeeza™** (evinacumab) for a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) when **ALL** of the following criteria is met:

- Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe, **AND**
- Current (<12 months ago) Cholesterol labs with values, **AND**
- Current treatment with Praluent® or Repatha™, unless clinically contraindicated to PCSK9s, **AND**
- This medication is part of the Med UM program.

We may cover **Juxtapid**® (lomitapide) for a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) when **ALL** of the following criteria is met:

- Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe, **AND**
- Required to be filled at an in-network specialty pharmacy, **AND**
- Current (<12 months ago) Cholesterol labs with values

OR

- Used LDL apheresis where available

We may cover **Kynamro**® (mipomersen) for a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) when **ALL** of the following criteria is met:

- Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe, **AND**
- Required to be filled at an in-network specialty pharmacy, **AND**
- Current (<12 months ago) Cholesterol labs with values.

We may cover **Leqvio** ® (inclisiran) for a confirmed diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) or In adults with established cardiovascular disease, it is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization When **ALL** of the following criteria is met:

- Patient has been evaluated in a lipid program staffed by a board certified cardiologist or endocrinologist, **And**
- Patient is ≥18 years old, **And**
- Current (<12 months ago) LDL lab value, **And**
- Used as adjunct therapy to diet and maximally tolerated statin therapy, **OR**
  Previous treatment failure with 3 statin medications – at least 2 of which are high-potency – in combination with ezetimibe (**claims will be verified when there is not a break in coverage**), **And**
- If stable on high-potency statin in combination with ezetimibe additional trials of statins will not be required, **And**
- Previous treatment failure with Praluent ®

Initial requests meeting the above criteria will be given a 3 month (encompassing one 6-month shot) initial approval.
Continuation of Therapy:
We will re-approve **Leqvio** ® (inclisiran) for 1 year when all the following criteria are met:

- Adherence to current therapy verified with claims data, **AND**
- Current (<3 months ago) submitted lab values show maintained improvement in LDL levels.

We do **NOT** cover **Leqvio** ® (inclisiran) for any other diagnoses not listed above.

We cover **Nexletol**™ (bempedoic acid) or **Nexlizet**™ (bempedoic acid and ezetimibe) for a confirmed diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) or in adults with established atherosclerotic cardiovascular disease when **ALL** of the following criteria is met:

- Member has been evaluated in a lipid program staffed by a board-certified cardiologist or endocrinologist, **AND**
- Current (<12 months ago) LDL lab value, **AND**
- Used as adjunct therapy to diet and maximally tolerated statin therapy (**claims will be verified when there is not a break in coverage**)

We cover **Praluent**® (alirocumab) for a confirmed diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH), or In adults with established cardiovascular disease (primary hyperlipidemia), it is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization When **ALL** of the following criteria is met:

- Member has been evaluated in a lipid program staffed by a board-certified cardiologist or endocrinologist
- Current (<12 months ago) LDL lab value, **AND**
- Used as adjunct therapy to diet and maximally tolerated statin therapy **OR**
  Previous treatment failure with 3 statin medications – at least 2 of which are high-potency – in combination with ezetimibe (**claims will be verified when there is not a break in coverage**) , **AND**
- If stable on high-potency statin in combination with ezetimibe additional trials of statins will not be required

Initial requests meeting the above criteria will be given a 3-month initial approval.
Continuation of Therapy:
We may re-approve **Praluent**® (alirocumab) for 1 year when all the following criteria are met:

- Adherence to current therapy verified with claims data, **AND**
- Current (<3 months ago) submitted lab values show maintained improvement in LDL levels.

We may cover **Repatha ™** (evolocumab) for a confirmed diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH), or In adults with established cardiovascular disease, it is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization When **ALL** of the following criteria is met:

- Member has been evaluated in a lipid program staffed by a board certified cardiologist or endocrinologist, **AND**
- Current (<12 months ago) LDL lab value, **AND**
- Used as adjunct therapy to diet and maximally tolerated statin therapy **OR**
  Previous treatment failure with 3 statin medications – at least 2 of which are high-potency – in combination with ezetimibe (**claims will be verified when there is not a break in coverage**), **AND**
- If stable on high-potency statin in combination with ezetimibe additional trials of statins will not be required, **AND**
- Previous treatment failure with Praluent®

Initial requests meeting the above criteria will be given a 3-month initial approval.
Continuation of Therapy:
We will re-approve **Repatha™** (evolocumab) for 1 year when all the following criteria are met:

- Adherence to current therapy verified with claims data, **AND**
- Current (<3 months ago) submitted lab values show maintained improvement in LDL levels.

We do NOT cover **Praluent**® (Alilocumab), **Repatha™** (evolocumab) or any other PCSK9 medication for any other diagnoses not listed above.

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for some of the above medications (as noted in criteria) at one of the providers in our retail specialty pharmacy network, see link below:

Link to Specialty Pharmacy List

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Prior Authorization Information

Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.

Policy History

Date	Action
4/2022	Updated to include Leqvio ® to the policy.
7/2021	Updated to add Evkeeza to the policy and included the new indication for Praluent ®.
8/2020	Updated to specify which meds are required to be filled at an in-network specialty pharmacy.
6/2020	Updated to include Nexletol™ & Nexlizet™ to the policy.
10/2019	Updated to Clarified Criteria.
7/2019	Updated new Praluent® indication.
11/2018	Updated to Clarified Criteria.
2/2018	Updated to include new Repatha Indication.
10/2017	Updated to change Walgreens Specialty Name.
7/2017	Updated to add AllCare to Pharmacy Specialty list.
6/2017	Updated address for Pharmacy Operations.
1/2017	Updated to remove Step from policy and add criteria for Juxtapid® and Kynamro™.
6/2016	Updated to remove Advicor & Simcor due to loss of FDA approval & add Rosuvastatin to step 1.
4/2016	Updated to include PCSK9's into the new Prior Authorization section of policy.
2/2014	Removal of Curascript name from specialty pharmacy section.
1/2014	Updated to add Juxtapid® & Kynamro™ to step 2 and reference 4, 5, 6, and 7. Also updated to include Liptruzet™* in step 3. Updated ExpressPAth language.
1/2013	Updated to move Lipitor to non-covered and consolidate Steps 3 & 4 into one Step 3
8/2012	Updated to add fluvastatin to Step 1
4/2012	Reviewed 4/2012 MPG-Cardiology and Pulmonology, no changes in coverage were made.

11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Updated to move Lipitor® 80mg from Step 1 to Step 3.
12/2011	Updated to add amlodipine/atorvastatin to step 1.
12/2011	Updated to add atorvastatin to step 1.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
11/2011	Updated to move Vytorin® to Step 4 and non-covered status.
11/2010	Updated to include coverage criteria for new FDA approved product Livalo®.
4/2010	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
2/2010	Updated with formulary change and Express PA information.
9/2009	Policy updated to change 180 day look back period to 130 days and to remove Medicare Part D criteria from Medical Policy.
4/2009	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2009	Updated to remove non-formulary designation of Step 4.
9/2008	Updated to include Simcor to medical policy.
4/2008	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
2/2008	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
7/2007	Updated to move Zocor and Pravachol brand names to Step 2 except Medicare HMO & PPO formulary and revision of request form.
4/2007	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
2/2007	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
2/2003	New policy, effective 2/2003, describing covered and non-covered indications.

References

1. Callister T. Q., Raggi P., Cooil B., Lippolis N. J., Russo D. J. Effect of HMG-CoA Reductase Inhibitors on Coronary Artery Disease as Assessed by Electron-Beam Computed Tomography N Engl J Med 1998; 339:1972-1978, Dec 31, 1998.
2. Charles R. Harper, MD; Terry A. Jacobson, MD New Perspectives on the Management of Low Levels of High-Density Lipoprotein Cholesterol Archives of Internal Medicine / volume:159 (page: 1049)
3. Thomas A. Pearson, MD, PhD, MPH; Irene Laurora, PharmD; Henry Chu, MS; Stephanie Kafonek, MD The Lipid Treatment Assessment Project (L-TAP): A Multicenter Survey to Evaluate the Percentages of Dyslipidemic Patients Receiving Lipid-Lowering Therapy and Achieving Low-Density Lipoprotein Cholesterol Goals Archives of Internal Medicine / volume:160 (page: 459)
4. Juxtapid® [package insert]. Cambridge, MA: Aeggerion Pharmaceutical, Inc.; December 2012.
5. J Atheroscler Thromb, 2012; 19:1043-1060 Mariko Harada-Shiba et al. Guidelines for the Management of Familial Hypercholesterolemia.
6. Liptruzet™ [package insert]. Whitehouse Station, NJ: Merck & Co, Inc.; May 2013.
7. Kynamro™ [package insert]. Cambridge, MA: Genzyme Corporation.; 2013.
8. Praluent® [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC.; July 2015.
9. Repatha® [package insert]. Thousand Oaks, California: Amgen Inc.; Aug 2015.
10. Nexletol™ [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc.; Mar 2020.
11. Nexlizet™ [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc.; Mar 2020.
12. Evkeeza™ [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; Feb 2021.
13. Leqvio ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; Apr 2022.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:
http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf