MASSACHUSETTS

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

Pharmacy Medical Policy
Antihyperlipidemics Policy

Table of Contents

Policy Number: 013

BCBSA Reference Number: N/A

Related Policies

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

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**11/1/2023**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☒ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **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 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This is a comprehensive policy covering prior authorization and quantity limit requirements for anti-hyperlipidemic agents.

Policy

No Requirements

BCBSMA formulary coverage options for anti-hyperlipidemic agents that do not have any coverage requirements include:

- Atorvastatin
- Colesevelam
- Colestipol
- Ezetimibe
- Ezetimibe-Simvastatin
- Fenofibrate
- Fluvastatin
- Gemfibrozil
- Icosapent Ethyl
- Lovastatin
- Niacin ER
- Omega-3 Ethyl Ester
- Pravastatin
- Rosuvastatin
- Simvastatin

Prior Authorization Criteria

Length of Approval	12 months, unless otherwise specified in prior authorization criteria
Formulary Status	All requests must meet the Prior Authorizations requirement. For non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Formulary status/requirements of the medications affected by this policy:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement	Additional Considerations
Evkeeza ™ (evinacumab)	Covered, PA	PA required. See below for criteria.	N/A
Juxtapid ® (lomitapide)	Covered, PA		
Nexletol ™ (bempedoic acid)	Covered, PA, QCD		
Nexlizet ™ (bempedoic acid and ezetimibe)	Covered, PA, QCD		
Leqvio ® (inclisiran) *	Covered, PA		*SPBO - Pharmacy benefit coverage only
Praluent ® (alirocumab) *	Covered, PA, QCD		
Repatha ™ (evolocumab) *	NCNF, PA, QCD	PA and Non formulary criteria required	

PA – Prior Authorization; QCD – Quality Care Dosing (refer to policy #621b); SPBO – Specialty Pharmacy access; NFNC – Non-formulary, non-covered

Evkeeza ™

Evkeeza may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. A confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH); **AND**
2. Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe; **AND**
3. Recent cholesterol labs with values (<12 months ago); **AND**
4. Current treatment with Praluent® or Repatha™, unless clinically contraindicated to PCSK9s.

Juxtapid ®

Juxtapid may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. A confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH); **AND**
2. Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe; **AND**
3. Recent cholesterol labs (< 12 months) with values OR used LDL apheresis.

Leqvio ®

Leqvio may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

Initial Request

1. A confirmed diagnosis of:
    a. Primary hyperlipidemia; **OR**
    b. Heterozygous Familial Hypercholesterolemia (HeFH); **OR**
    c. Established cardiovascular disease; **AND**
2. Age ≥18 years old; **AND**
3. Evaluation in a lipid program staffed by a board-certified cardiologist or endocrinologist; **AND**
4. Recent LDL labs with values (<12 months); **AND**
5. Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe; **OR** Previous treatment failure with 3 statin medications (at least 2 of which are high potency) in combination with ezetimibe; **AND**
6. Previous treatment failure with Praluent

Initial approval duration: ***3 months (encompassing one 6-month shot) initial approval.***

Continuation Request:

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

Continued coverage duration: ***12 months approval.***

Nexletol ™ and Nexlizet ™

Nexletol or **Nexlizet** may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. A confirmed diagnosis of:
    a. Heterozygous Familial Hypercholesterolemia (HeFH); OR
    b. Established cardiovascular disease; **AND**
2. Age >18 years old; **AND**
3. Evaluation in a lipid program staffed by a board-certified cardiologist or endocrinologist; **AND**
4. Recent LDL labs with values (<12 months); **AND**

5. Used as adjunct therapy to diet and maximally tolerated statin therapy.

Praluent ®

Praluent may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

Initiation Requests

1. A confirmed diagnosis of:
   a. Heterozygous Familial Hypercholesterolemia (HeFH); **OR**
   b. Homozygous Familial Hypercholesterolemia (HoFH); **OR**
   c. Established cardiovascular disease; **AND**
2. Evaluation in a lipid program staffed by a board-certified cardiologist or endocrinologist; **AND**
3. Recent LDL labs with values (<12 months); **AND**
4. Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe; **OR**
5. Previous treatment failure with 3 statin medications (at least 2 of which are high potency) in combination with ezetimibe.

Initial approval duration: ***3 months approval.***

Continuation Requests

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

Continued coverage duration: ***12 months approval.***

Repatha ™

Repatha may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

Initiation Requests

1. A confirmed diagnosis of:
   a. Heterozygous Familial Hypercholesterolemia (HeFH); **OR**
   b. Homozygous Familial Hypercholesterolemia (HoFH); **OR**
   c. Established cardiovascular disease; **AND**
2. Evaluation in a lipid program staffed by a board-certified cardiologist or endocrinologist; **AND**
3. Recent LDL labs with values (<12 months); **AND**
4. Used as adjunct therapy to diet and maximally tolerated statin therapy in combination with ezetimibe OR previous treatment failure with 3 statin medications (at least 2 of which are high potency) in combination with ezetimibe; **AND**
5. Previous treatment failure with Praluent

Initial approval duration: ***3 months approval.***

Continuation Requests

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

Continued coverage duration: ***12 months approval.***

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

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

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
11/2023	Reformatted Policy.
10/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A. Updated indication for Leqvio to include primary hyperlipidemia
7/2023	Reformatted Policy.
1/2023	Updated to remove Kynamro ® from the policy as it was withdrawn from the market.
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.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

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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.