



Louisiana

HMG-CoA Reductase Inhibitors and HMG-CoA Reductase Inhibitor Combination Drugs

Policy # 00339

Original Effective Date: 01/09/2013

Current Effective Date: 07/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

For Patients with "Step Therapy" (generic before brand) ONLY:

Based on review of available data, brand name HMG-CoA reductase inhibitors (statins) and brand name HMG-CoA reductase inhibitor combination drugs, including, but not limited to Lipitor^{®‡} (atorvastatin), Livalo^{®‡} (pitavastatin), Vytorin^{®‡} (simvastatin/ezetimibe), Lescol^{®‡} (fluvastatin), Lescol^{®‡} XL (fluvastatin extended release), Caduet^{®‡} (atorvastatin/amlodipine), FloLipid^{®‡} (simvastatin oral suspension), Ezallor^{™‡} Sprinkle (rosuvastatin), Zypitamag^{®‡} (pitavastatin), Roszet^{®‡} (rosuvastatin/ezetimibe) and its branded generic (Rosuvastatin/Ezetimibe), Atorvaliq^{®‡} (atorvastatin), and Altoprev^{®‡} (lovastatin) may be considered to be **eligible for coverage**** when one of the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name HMG-CoA reductase inhibitors and brand name HMG-CoA reductase inhibitor combination drugs when one of the following criteria is met:

- Patient has tried and failed one generic HMG-CoA reductase inhibitor (e.g., atorvastatin, lovastatin, pravastatin, fluvastatin, simvastatin, rosuvastatin); OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient; OR

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- The requested drug is FloLipid or Ezallor Sprinkle; AND
 - Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets or capsules; AND
 - Patient is NOT currently taking any medication in tablet or capsule form.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name HMG-CoA reductase inhibitors and brand name HMG-CoA reductase inhibitor combination drugs when patient selection criteria are not met to be **not medically necessary**.**

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients with "Prior Authorization" ONLY:

Based on review of available data, the Company may consider brand/generic Livalo (pitavastatin), Zypitamag (pitavastatin), Altoprev (lovastatin), Crestor[®]† (rosuvastatin), FloLipid (simvastatin), Atorvaliq (atorvastatin), Roszet (rosuvastatin/ezetimibe) and its branded generic (Rosuvastatin/Ezetimibe), and Ezallor Sprinkle (rosuvastatin) to be **eligible for coverage**** when the below patient selection criteria are met for the requested drug:

Patient Selection Criteria

Coverage eligibility will be considered for brand/generic Livalo (pitavastatin), Zypitamag (pitavastatin), FloLipid (simvastatin), Altoprev (lovastatin), Atorvaliq (atorvastatin), Roszet (rosuvastatin/ezetimibe) and its branded generic (Rosuvastatin/Ezetimibe), or Crestor (rosuvastatin) when the following criteria are met for the requested drug:

- For Crestor requests: Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (one of which MUST be generic rosuvastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient.

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- For Livalo requests: Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (one of which MUST be generic pitavastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient.
- For Altoprev, Zypitamag, or generic pitavastatin requests: Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (e.g., atorvastatin, lovastatin, pravastatin, fluvastatin, simvastatin, rosuvastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient.
- For FloLipid, Ezallor Sprinkle, or Atorvaliq requests: Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets or capsules AND patient is NOT currently taking any medication in tablet or capsule form.
- For Roszet or its branded generic requests:
 - Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (one of which MUST be generic rosuvastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient; AND
 - Patient has tried and failed generic ezetimibe unless there is clinical evidence or patient history that suggests the use of generic ezetimibe will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand/generic Livalo (pitavastatin), Zypitamag (pitavastatin), FloLipid (simvastatin), Ezallor Sprinkle (rosuvastatin), Altoprev (lovastatin), Atorvaliq (atorvastatin), Roszet (rosuvastatin/ezetimibe) and its branded generic (Rosuvastatin/Ezetimibe), or Crestor (rosuvastatin) when the patient selection criteria for the requested drug are not met to be **not medically necessary**.**

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When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients with BOTH "Prior Authorization" AND "Step Therapy":

Based on review of the available data, brand name HMG-CoA reductase inhibitors (statins) and brand name HMG-CoA reductase inhibitor combination drugs, including, but not limited to Lipitor (atorvastatin), Livalo (pitavastatin), Zypitamag (pitavastatin), FloLipid (simvastatin), Ezallor Sprinkle (rosuvastatin), Atorvaliq (atorvastatin), Vytorin (simvastatin/ezetimibe), Lescol (fluvastatin), Lescol XL (fluvastatin extended release), Caduet (atorvastatin/amlodipine), Roszet (rosuvastatin/ezetimibe) and its branded generic (Rosuvastatin/Ezetimibe), Altoprev (lovastatin), and generic pitavastatin may be considered to be **eligible for coverage**** when the below patient selection criteria are met for the requested drug:

Patient Selection Criteria

Coverage eligibility will be considered for brand name HMG-CoA reductase inhibitors, brand name HMG-CoA reductase inhibitor combination drugs, and generic pitavastatin when the following criteria are met for the requested drug:

- For Altoprev, Zypitamag, or generic pitavastatin requests: Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (e.g., atorvastatin, lovastatin, pravastatin, fluvastatin, simvastatin, rosuvastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient.
- For Crestor requests: Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (one of which MUST be generic rosuvastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient.
- For Livalo requests: Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (one of which MUST be generic pitavastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient.

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- For FloLipid, Ezallor Sprinkle, or Atorvaliq requests: Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets or capsules AND patient is not currently taking any medication in tablet or capsule form.
- For Roszet or its authorized generic requests:
 - Patient has tried and failed at least TWO generic HMG-CoA reductase inhibitor products (one of which MUST be generic rosuvastatin) unless there is clinical evidence or patient history that suggests the use of the generic HMG-CoA reductase inhibitor products will be ineffective or cause an adverse reaction to the patient; AND
 - Patient has tried and failed generic ezetimibe unless there is clinical evidence or patient history that suggests the use of generic ezetimibe will be ineffective or cause an adverse reaction to the patient.
- For ALL other requests: Patient has tried and failed one generic HMG-CoA reductase inhibitor (e.g., atorvastatin, lovastatin, pravastatin, Fluvastatin, simvastatin, rosuvastatin) unless there is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name HMG-CoA reductase inhibitors, brand name HMG-CoA reductase inhibitor combination drugs, and generic pitavastatin when patient selection criteria are not met to be **not medically necessary**.**

Background/Overview

HMG Co-A reductase inhibitors (statins) and statin combination drugs are used to treat lipid abnormalities. There are various products in this class that have a generic equivalent. Products without a commercially available generic equivalent are Zypitamag, FloLipid, Roszet, Atorvaliq, and Altoprev. However, there are alternative generic statins available that produce similar cholesterol lowering effects as these products. There are also generic alternatives available for CYP 3A4 drug interaction concerns (e.g., pravastatin). FloLipid is the first commercially available liquid formulation of a statin and is appropriate for patients who are unable to swallow medications in tablet or capsule form. Ezallor Sprinkle was designed as another option for patients who have difficulty swallowing. These capsules may be opened and sprinkled on applesauce or dissolved in water prior to administration. Atorvaliq is a third available oral suspension form of a statin and contains the active ingredient atorvastatin.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above-mentioned caveat, there is no advantage of using a brand name HMG Co-A reductase inhibitor (statin) or brand name statin combination drug over the available generic statins or generic statin combination drugs. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs. In the instance where there is not a generic equivalent, there are generic alternatives available that produce similar clinical outcomes in this drug class.

References

1. Express Scripts HMG-CoA Reductase Inhibitor (HMG) Enhanced Step Therapy. 5/2018.
2. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the 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). *JAMA*. 2001;285(19):2486-2497.
3. Grundy SM, Cleeman JI, Bairey CN, et al; Coordinating Committee of the National Cholesterol Education Program. Implications from recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. *Circulation*. 2004;110:227-239.

Policy History

Original Effective Date: 01/09/2013

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01/03/2013 Medical Policy Committee review

01/09/2013 Medical Policy Implementation Committee approval. New policy.

02/19/2013 Format revision. Coding section removed.

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11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. Removed Crestor from step therapy program.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Added prior authorization to Livalo, Altoprev, and Crestor. Split into PA, step, and step/PA.
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Added new products, Flolipid and Zypitamag. Replaced the word “TWO” with “the” to clarify the criteria. For Patients With “Prior Authorization” ONLY and For Patients With BOTH “Prior Authorization” AND “Step Therapy”.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Listed Lescol and Lescol XL in criteria and added a new drug, Ezallor Sprinkle.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Added new product, Roszet, and its branded generic to policy with relevant criteria and background information.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review

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06/14/2023 Medical Policy Implementation Committee approval. Added new product, Atorvaliq, to policy with relevant criteria.

06/06/2024 Medical Policy Committee review

06/12/2024 Medical Policy Implementation Committee approval. Added new product, generic pitavastatin, to policy with relevant criteria. Changed Livalo PA criteria to require trial of generic pitavastatin prior to brand.

Next Scheduled Review Date: 06/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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