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

Policy # 00339
Original Effective Date: 01/09/2013
Current Effective Date: 10/17/2018

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), Caduet®‡ (atorvastatin/amlodipine), FloLipid®‡ (simvastatin oral suspension), Zypitamag®‡ (pitavastatin), 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
- The requested drug is FloLipid AND
    - Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets; 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**.**

For Patients With "Prior Authorization" ONLY:
Based on review of the available data, the Company may consider Livalo (pitavastatin), Zypitamag (pitavastatin), Altoprev (lovastatin), and Crestor®‡ (rosuvastatin) to be **eligible for coverage** when the below patient selection criteria are met for the requested drug:

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Patient Selection Criteria
Coverage eligibility will be considered for Livalo (pitavastatin), Zypitamag (pitavastatin), FloLipid (simvastatin), Altoprev (lovastatin), 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.
- For Altoprev, Zypitamag, or Livalo 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 requests: Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets 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 Livalo (pitavastatin), Zypitamag (pitavastatin), FloLipid (simvastatin), Altoprev (lovastatin), or Crestor (rosuvastatin) when the patient selection criteria for the requested drug are not met to be **not medically necessary**.**

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), Vytorin (simvastatin/ezetimibe), Caduet (atorvastatin/amlodipine), and Altoprev (lovastatin) 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 and brand name HMG-CoA reductase inhibitor combination drugs when the following criteria are met for the requested drug:

- For Altoprev, Zypitamag, or Livalo 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 FloLipid requests: Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets AND patient is not currently taking any medication in tablet or capsule form.
- For ALL other requests: The 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 and brand name HMG-CoA reductase inhibitor combination drugs 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. The products that don't have a generic equivalent are Livalo, Zypitamag, FloLipid, 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). Crestor is the most recent brand in this class to gain a generic equivalent. 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.

Rationale/Source

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.

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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.
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”.

Next Scheduled Review Date: 10/2019

**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
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.

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.