BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

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

Policy # 00339
Original Effective Date: 01/09/2013
Current Effective Date: 11/20/2013

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.*

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), Vytorin®‡ (simvastatin/ezetimibe), and Caduet®‡ (atorvastatin/amlodipine) may be considered eligible for coverage when one of the patient selection criteria is 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:

- The patient has tried and failed one generic HMG-CoA reductase inhibitor (e.g. atorvastatin, lovastatin, pravastatin, fluvastatin, simvastatin); 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.

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 or for usage not included in the patient selection criteria to be **not medically necessary**.**

Background/Overview
HMG Co-A reductase inhibitors (statins) and statin combination drugs are used to treat lipid abnormalities.

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.

References
1. Express Scripts Statin Step Therapy Policy. 11/2012.

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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
Current Effective Date: 11/20/2013
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.
Next Scheduled Review Date: 11/2014

*****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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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
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.