Pharmacy Policy Bulletin

Title: Pitavastatin calcium (Livalo™)

Policy #: Rx.01.72

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

Pitavastatin (Livalo) is indicated for patients with primary hyperlipidemia and mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).

The use of Pitavastatin (Livalo) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Pitavastatin (Livalo) competitively inhibits HMG-CoA reductase, which is a rate-determining enzyme involved with biosynthesis of cholesterol, in a manner of competition with the substrate so that it inhibits cholesterol synthesis in the liver. As a result, the expression of LDL-receptors followed by the uptake of low-density lipoprotein cholesterol (LDL-C) from blood to liver is accelerated and then the plasma total cholesterol (TC) decreases. Further, the sustained inhibition of cholesterol synthesis in the liver decreases levels of very low density lipoprotein.

Policy:

Pitavastatin (Livalo) is approved when the following inclusion criteria is met:

- Documentation of a trial and failure or contraindication/intolerance/allergy to two of the following agents:
  - A lovastatin containing product
  - A pravastatin containing product
  - A simvastatin containing product
  - An atorvastatin (Lipitor) containing product
  - Rosuvastatin calcium (Crestor)

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Livalo (Pitavastatin) [package insert]. Cincinnati, OH: Kowa Pharmaceuticals America, Inc.; July 2009.

Pitavastatin (Livalo). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed December 30, 2011.

Pitavastatin (Livalo). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed December 30, 2011.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Livalo	Pitavastatin

Cross References:

Policy Version Number:	1.00
P&T Approval Date:	November 10, 2011
Policy Effective Date:	February 01, 2012
Next Required Review Date:	November 10, 2012