Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Livalo®

Common Name: Pitavastatin

PDL Category: Cholesterol- HMG CoA + Absorb Inhibitors

Comparable Products	Preferred Drug List Status
Lipitor®	**Preferred**
Pravastatin	**Preferred**
Simvastatin	**Preferred**

Summary

Indications and Usage: Treatment of 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).[1]

Mechanism of Action: Inhibits HMG-CoA reductase which results in inhibition of cholesterol synthesis in the liver.[1]

Dosage Forms: Tablets: 1mg, 2mg, & 4mg

Recommended Dosage: 1mg to 4mg once daily with or without food.
Moderate renal impairment (glomerular filtration rate 30 < 60 mL/min/1.73 m2) and end-stage renal disease on hemodialysis: Starting dose of 1 mg once daily and maximum dose of 2 mg once daily.[1]

Common Adverse Drug Reactions: Myalgia, back pain, diarrhea, constipation, pain in extremity. [1]

Contraindications: Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels. Women who are pregnant or may become pregnant. Nursing mothers. Co-administration with cyclosporine and Kaletra®. [1]

Manufacturer: Patheon, Inc.

Analysis: Livalo® is a new HMG-CoA reductase inhibitor indicated for the treatment of primary hyperlipidemia and mixed dyslipidemia. In the trials used to gain FDA approval, Livalo® was compared to atorvastatin (Lipitor®), pravastatin, and simvastatin. In a trial of patients with acute coronary syndrome, 4mg of pitavastatin reduced TC and LDL-C by 21.9% and 36.2% respectively compared to 21.9% and 35.8% with 20mg of atorvastatin. HDL-C was increased by 9.9% compared to 8.0% with atorvastatin. In a trial of patients with high cholesterol or dyslipidemia, 2mg of pitavastatin lowered LDL-C by 39% compared to 35% with 20mg of simvastatin. 4mg of pitavastatin and 40mg of simvastatin lowered LDL-C by 44% and 43%, respectively. Pitavastain 2mg significantly reduced TC, LDL-C, and triglycerides when compared to 10mg of pravastatin. Two (2) mg of pitavastain reduced triglycerides by 29.8% compared to 17.4% with 20mg of simvastain, not clinically significant. Pitavastatin has the potential for several clinically significant drug interactions and doses above 4mg increased the risk for severe myopathy. Preferred alternatives appear on the Preferred Drug List which have similar clinical efficacy, established safety records, and are more cost effective. Therefore, it is recommended that Livalo® be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation:

- ☐ Preferred Drug
- ☒ Non-Preferred Drug
- ☐ Preferred Drug with Conditions
- ☐ Recommended Drug
- ☐ Non-Recommended Drug

1. Livalo® [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc.; 2010.