



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Lialda™

Common Name: Mesalamine

PDL Category: GI – Inflammatory Bowel Agents

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Asacol	Preferred

Summary

Indications and Usage: Induction of remission in patients with active, mild to moderate ulcerative colitis

Mechanism of Action: Exact mechanism is not well understood; thought to reduce inflammation by blocking the production of cyclooxygenase and inhibition of prostaglandin production in the colon.

Dosage Forms: Tablets; 1.2gm

Recommended Dosage: 2.4 – 4.8mg once daily

Common Adverse Drug Reactions: Headache, flatulence

Contraindications: Previous hypersensitivity to any component of the product or salicylates

Manufacturer: Shire US Inc.

Analysis: Lialda™ is the first once-a-day oral formulation of mesalamine to be introduced to the market. Clinical studies show that 2.4gm and 4.8gm per day doses have similar efficacy. When compared to placebo, between 29.2 and 41.2% of patients were in remission after eight weeks of therapy with Lialda™. Although Lialda™ has not been directly compared to immediate release mesalamine, early data do not suggest Lialda™ to be clinically superior. Additionally, safety and efficacy of Lialda™ beyond eight weeks of therapy has not been established whereas the immediate release mesalamine product can be used for induction of remission and maintenance of remission in ulcerative colitis patients. Another oral mesalamine product appears on the Iowa Medicaid Preferred Drug List as a preferred product, which is more cost effective than Lialda™ and is also indicated for long term use.

IME Recommendation:

<input type="checkbox"/>	Preferred Drug	<input type="checkbox"/>	Recommended Drug
<input checked="" type="checkbox"/>	Non-Preferred Drug	<input type="checkbox"/>	Non-Recommended Drug
<input type="checkbox"/>	Preferred Drug with Conditions		