



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: mesalamine

Brand Name: Lialda

Medication Class: Gastrointestinal Agent; 5-Aminosalicylic Acid

FDA Approved Uses: induction of remission in patients with active, mild to moderate ulcerative colitis.

Available Dosage Forms: 1.2g tablets

Usual Dose: 2 to 4 tablets once daily with meals for 8 weeks

Duration of Therapy: 8 weeks

Approximate monthly cost (based on AWP 2007): \$273.60 for 2 tablets/day/month
\$547.20 for 4 tablets/day/month

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically documented mild to moderate ulcerative colitis.
- Must have had a gastrointestinal consult.
- Tried and failed/ intolerant to Asacol.
- Tried and failed /intolerant to Pentasa.
- If the patient has distal colitis they must have also tried and failed or intolerant to mesalamine enema.

Contraindications:

- Hypersensitivity to salicylates (including mesalamine) or to any components of Lialda.

Not Approved if:

- Does not meet the above stated criteria.
- Have any contraindications to the use of Lialda.

Special Considerations:

- One study included Asacol as a reference arm and remission rates were similar in Asacol and Lialda 2.4g qd and Lialda 4.8g qd treatment groups (32.6% vs 40.5% and 41.2% respectively). The difference in remission rates was not significantly significant.
- The efficacy of Lialda 1.2g tid was compared with mesalamine enema 4g qd in patients with active, mild to moderate, left sided ulcerative colitis. Remission rates were comparable.
- The differences in the various mesalamine formulations are not the results of differences in the pharmacology of the drug but the location of where the drug is released in the GI tract.



- Comparisons of other formulations of mesalamine

Brand Name		Target Site of Release	Approved indications	Cost/month
Asacol	Tablet	Terminal ileum and colon	-Induction of remission: active mild to moderate ulcerative colitis -Maintenance of remission of ulcerative colitis	400mg tablet 800mg po tid = \$240-\$270
Lialda	Tablet	Colon	-Induction of remission: active mild to moderate ulcerative colitis	1.2g tablet 2.4g po qd= \$262.80 4.8g po qd= \$525.60
Pentasa	Capsule	Duodenum, jejunum, ileum, and colon	-Induction of remission: active mild to moderate ulcerative colitis	250mg and 500mg capsule 1g po qid= \$386.68
Rowasa	Enema	Colon	-active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis.	4g/60ml bottle 4g pr qd= \$450 for generic

P&T Approval: _____ Date: _____