

PREFERRED STEP THERAPY POLICY

- POLICY:** Inflammatory Bowel Preferred Step Therapy Policy
- Apriso[®] (mesalamine 0.375 g extended-release capsule – Salix, generics)
 - Asacol[®] HD (mesalamine 800 mg enteric-coated, delayed-release tablet – Warner Chilcott)
 - Azulfidine[®] (sulfasalazine 500 mg tablet – Pharmacia & Upjohn Companies, generics)
 - Azulfidine Entab[®] (sulfasalazine 500 mg enteric-coated, delayed-release tablet – Pharmacia & Upjohn Companies, generics)
 - Colazal[®] (balsalazide 750 mg capsule – Salix, generics)
 - Delzicol[®] (mesalamine 400 mg enteric-coated, delayed-release capsules – Warner Chilcott, generics)
 - Dipentum[®] (olsalazine 250 mg capsule – Alaven Pharmaceuticals)
 - Giazol[®] (balsalazide 1.1 g tablets – Salix)
 - Lialda[®] (mesalamine 1.2 g delayed-release tablet – Shire US, generics)
 - Mesalamine (800 mg delayed-release tablet – Zydus Pharmaceuticals)
 - Pentasa[®] (mesalamine 250 mg and 500 mg controlled-release capsule – Shire US)

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OVERVIEW

Various aminosalicylates are indicated for the treatment and/or remission maintenance of mild to moderate **ulcerative colitis**.¹⁻¹² Mesalamine may act by decreasing inflammation by blocking production of arachidonic acid in the colon. Oral mesalamine is absorbed in the small intestine, so many formulations have been developed to deliver the active agent to the site of inflammation in the colon. Some are pH-dependent systems and others are pH-independent. Sulfasalazine combines sulfapyridine (an antibiotic) with mesalamine in the same molecule.¹¹⁻¹² Thus, mesalamine is the active component of sulfasalazine for use in inflammatory bowel disease. The sulfapyridine component is thought to be responsible for many of the adverse events of sulfasalazine. Balsalazide is a prodrug of mesalamine.^{5,8} A daily dose of 6.75 g of balsalazide delivers 2.4 g of free 5-ASA to the colon.

Different formulations of mesalamine have been developed to deliver drug to the site of disease. All of the oral aminosalicylates are generally indicated for the treatment of mild-to-moderate UC; specific indications vary slightly among the agents. Refer to Table 1.

Table 1. Approved IBD Indications for Selected Mesalamine Products.¹⁻¹²

Brand (Generic)/ Site of Action	Approved Indication(s)
Apriso[®] (mesalamine extended-release capsule, 0.375 g)/ Terminal ileum, colon	Maintenance of remission of UC in patients ≥ 18 years.
Asacol[®] HD (mesalamine delayed-release tablet, 800 mg) mesalamine (800 mg delayed-release tablets)/ Distal ileum, colon	For the treatment of adults with moderately active UC.

Table 1 (continued). Approved IBD Indications for Selected Mesalamine Products.¹⁻¹²

Brand (Generic)/ Site of Action	Approved Indication(s)
Azulfidine [®] (sulfasalazine tablet, 500 mg)/ Colon	<ul style="list-style-type: none"> • Treatment of mild to moderate UC and as adjunctive therapy in severe UC. • For the prolongation of the remission period between acute attacks of UC. <p>*Safety and efficacy are not available for patients < 2 years of age. Dosing is available for patients ≥ 6 years of age.</p>
Azulfidine Entab [®] (sulfasalazine film enteric-coated, delayed-release tablet, 500 mg)/ Colon	<ul style="list-style-type: none"> • Treatment of mild to moderate UC, and as adjunctive therapy in severe UC. • For the prolongation of the remission period between acute attacks of UC. <p>Note: Particularly indicated in patients with UC who cannot take uncoated sulfasalazine tablets because of GI intolerance.</p> <p>*Safety and efficacy are not available for patients < 2 years of age. Dosing is available for patients ≥ 6 years of age.</p>
Colozal [®] (balsalazide disodium capsule, 750 mg)/ Colon	For the treatment of mild-to-moderate active UC in patients ≥ 5 years of age.
Delzicol [™] (mesalamine delayed-release capsules, 400 mg)/ Distal ileum, colon	<ul style="list-style-type: none"> • Treatment of mild to moderate active UC in patients ≥ 5 years of age. • Maintenance of remission of UC in adults.
Dipentum [®] (olsalazine capsule, 250 mg)/ Colon	For the maintenance of remission of UC in adults who are intolerant of sulfasalazine.
Giazo [®] (balsalazide disodium tablets, 1.1 g)/ Colon	For the treatment of mild-to-moderate active UC in <i>male</i> patients ≥ 18 years of age.
Lialda [®] (mesalamine delayed release tablet, 1.2 g) Terminal ileum, colon	Induction of remission in adults with active, mild to moderate UC and for maintenance of remission in adults with UC.
Pentasa [®] (mesalamine controlled-release capsule, 250 and 500 mg)/ Small bowel, colon	Induction of remission and treatment of adults with mild to moderate active UC.

IBD – Inflammatory bowel disease; UC – Ulcerative colitis; GI – Gastrointestinal.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Step 1: mesalamine 1.2 g delayed-release tablets (generic), mesalamine 0.375 g extended-release capsule (generic), mesalamine 400 mg delayed-release capsules (generic), Pentasa, balsalazide, sulfasalazine, sulfasalazine delayed release

Step 2: Apriso, Asacol HD, Azulfidine, Azulfidine Entab, Colozal, Delzicol, Dipentum, Giazo, Lialda

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Dipentum[®] capsules [prescribing information]. Smyrna, GA: UCB, Inc; October 2009.
2. Mesalamine delayed-release tablets [prescribing information]. Pennington, NJ: Zydus Pharmaceuticals; July 2016.
3. Pentasa[®] capsules [prescribing information]. Wayne, PA: Shire US, Inc.; October 2015.
4. Colazal[®] capsules [prescribing information]. Morrisville, NC: Salix Pharmaceuticals, Inc.; June 2016.
5. Lialda[®] delayed release tablets [prescribing information]. Wayne, PA: Shire US Inc; November 2015.
6. Apriso[®] capsules [prescribing information]. Morrisville, NC: Salix Pharmaceuticals, Inc; June 2016.
7. Giazol[®] tablets [prescribing information]. Morrisville, NC: Salix Pharmaceuticals, Inc.; June 2016.
8. Delzicol[®] capsules [prescribing information]. Rockaway, NJ: Warner Chilcott; March 2016.
9. Asacol[®] HD tablets [prescribing information]. Irvine, CA: Allergan; May 2016.
10. Azulfidine En-tabs[®] [prescribing information]. Kalamazoo, MI: Pharmacia & Upjohn Company; March 2014.
11. Azulfidine[®] tablets [prescribing information]. Kalamazoo, MI: Pharmacia & Upjohn Company; March 2014.
12. Mesalamine delayed-release capsules [prescribing information]. Peapack, NJ: Allergan/Greenstone LLC; July 2018.