

mesalamine DR 800 mg (Asacol HD)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Inflammatory bowel disease (IBD) is characterized by chronic uncontrolled inflammation of the intestinal mucosa that can affect any part of the gastrointestinal (GI) tract. Ulcerative colitis (UC) and Crohn's disease (CD) are the primary forms of IBD.

- UC is characterized by recurring inflammation limited to the inner lining of the colon and may extend to the rectum.
- CD is characterized by relapsing, patchy inflammation in any part of the GI tract from the mouth to the anus. CD may involve the entire thickness of the bowel wall.

The appropriate treatment for IBD depends on the extent of disease, location of disease, disease severity (e.g. mild, moderate, or severe), and disease prognosis. Clinical disease severity is based on formal clinical disease activity index or scoring tools (e.g., Montreal Classification of Extent and Severity of Ulcerative Colitis, Mayo score, Lichtiger Index, Simple Clinical Colitis Activity Index). The goal of therapy includes treating the active disease to induce clinical remission, maintaining remission, and

prevent disease complications (e.g., stricture and fistula). Treatment options for UC and CD include non-biologic and biologic agents.

Aminosalicylates are a class of medications known to reduce inflammation in the GI tract and provide relief of symptoms such as diarrhea and abdominal pain. Examples of aminosalicylates include sulfasalazine, mesalamine, olsalazine, and balsalazide. Balsalazide, sulfasalazine, and olsalazine are converted to mesalamine in the gut. Certain mesalamine products are preferred (Table 1) by the Plan. Mesalamine is available in different preparations (Table 2) to ensure the drug reaches the affected areas of the intestine or colon.

Table 1: Mesalamine Formulary Status

Preferred	Non-formulary (NF) or Prior authorization (PA) Required
Mesalamine (Delzicol) 400 mg ER capsule Mesalamine (Lialda) 1200 mg ER tablet Mesalamine (Rowasa) 4 gram enema Mesalamine (Canasa) 1000 mg suppository	Mesalamine (Asacol HD) 800 mg ER tablet (PA) Mesalamine (Apriso) 0.375 gram ER capsule (NF) Mesalamine (Pentasa) 250 mg, 500 mg ER capsule (NF)

Table 2: Mesalamine Preparations and Indications for Use

Mesalamine Products	Formulation	Generic availability	FDA-Approved Indications and Usage
Apriso	0.375 gram ER capsule	Yes	APRISO is indicated for the maintenance of remission of ulcerative colitis in adults.
Asacol HD	800 mg ER tablet	Yes	Asacol HD is indicated for the treatment of moderately active ulcerative colitis in adults. Limitations of Use: Safety and effectiveness of Asacol HD beyond 6 weeks have not been established.
Canasa	1000 mg rectal suppository	Yes	CANASA is indicated in adults for the treatment of mildly to moderately active ulcerative proctitis.
Delzicol	400 mg ER capsule	Yes	DELZICOL is indicated for: <ul style="list-style-type: none"> the treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older. the maintenance of remission of ulcerative colitis in adults.
Lialda	1.2 gram ER tablet	Yes	LIALDA is indicated for the: <ul style="list-style-type: none"> induction and maintenance of remission in adult patients

			<p>with mildly to moderately active ulcerative colitis.</p> <ul style="list-style-type: none"> treatment of mildly to moderately active ulcerative colitis in pediatric patients weighing at least 24 kg.
Pentasa	250 mg, 500 mg ER capsule	No	PENTASA is indicated for the induction of remission and for the treatment of adult patients with mildly to moderately active ulcerative colitis
Rowasa	4 gram/60 mL rectal enema suspension	Yes	ROWASA® (mesalamine) Rectal Suspension Enema is indicated for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis in adults.
sfRowasa†	4 gram/60 mL rectal enema suspension	no	sfROWASA® (mesalamine) Rectal Suspension is indicated for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis or proctitis in adults.

† sfRowasa is a sulfite-free product

NOTE: The US Food and Drug Administration drug labeling for mesalamine products currently does not include uses for Crohn’s Disease (CD). Such therapies are considered off-label:

- extended-release oral preparations
 - for the management of active Crohn’s disease
 - to induce and maintain clinical remission in adults with mildly to moderately active disease
- rectal preparations, for the management of active Crohn’s disease

Definitions

“**Fistula**” is an abnormal connection or passageway between two body parts, typically between an organ or vessel and the body surface.

“**Stricture**” is a narrowing or constriction in the diameter of a bodily passage or orifice.

Medical Necessity Criteria for Authorization

The Plan considers **mesalamine DR 800mg (Asacol HD)** medically necessary when **BOTH** of the following criteria are met:

- The member has a documented diagnosis of moderately active ulcerative colitis; **AND**
- The member is unable to use, or has adequately tried and failed at least **TWO** preferred mesalamine products for a minimum **ONE** (1) month duration.

If the above prior authorization criteria are met, mesalamine DR 800mg (Asacol HD) will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

mesalamine DR 800mg (Asacol HD) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Apriso (mesalamine) extended-release capsules [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; November 2021.
2. Asacol (mesalamine) delayed-release tablets [prescribing information]. Madison, NJ: Allergan USA Inc; October 2020.
3. Canasa (mesalamine) rectal suppository [prescribing information]. Madison, NJ: Allergan USA Inc; November 2021.
4. Delzicol (mesalamine) [prescribing information]. Madison, NJ: Allergan USA Inc; November 2021.
5. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, Singh S; AGA Institute Clinical Guidelines Committee. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020;158(5):1450-1461. doi:10.1053/j.gastro.2020.01.006
6. Hanauer, S. B., Sandborn, W. J., Dallaire, C., Archambault, A., Yacyshyn, B., Yeh, C., & Smith-Hall, N. (2007). Delayed-release oral mesalamine 4.8 g/day (800 mg tablets) compared with 2.4 g/day (400 mg tablets) for the treatment of mildly to moderately active ulcerative colitis: the ASCEND I trial. *Canadian Journal of Gastroenterology*, 21(12), 827-834.
7. Ko CW, Singh S, Feuerstein JD, Falck-Ytter C, Falck-Ytter Y, Cross RK; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA clinical practice guidelines on the management of mild-to-moderate ulcerative colitis. *Gastroenterology*. 2019;156(3):748-764. doi:10.1053/j.gastro.2018.12.009
8. Kornbluth A, Sachar DB. Erratum: ulcerative colitis practice guidelines in adults: American College of Gastroenterology, practice parameters committee. *Am J Gastroenterol*. 2010; 105:501-23.
9. Lialda (mesalamine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; November 2021.
10. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517. doi:10.1038/ajg.2018.27
11. Pentasa (mesalamine) extended-release capsules [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; November 2021.
12. Rowasa (mesalamine) suspension [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; November 2021.
13. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413. doi:10.14309/ajg.000000000000152
14. Sandborn, W. J., Regula, J., Feagan, B. G., Belousova, E., Jojic, N., Lukas, M., ... & Hanauer, S. B. (2009). Delayed-release oral mesalamine 4.8 g/day (800-mg tablet) is effective for patients with moderately active ulcerative colitis. *Gastroenterology*, 137(6), 1934-1943.
15. sfRowasa (mesalamine) rectal suspension [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; November 2021.

16. Wang Y, Parker CE, Bhanji T et al. Oral 5-aminosalicylic acid for induction of remission in ulcerative colitis. Cochrane Database Syst Rev. 2016a; (4): CD000543.
17. Wang Y, Parker CE, Feagan BG et al. Oral 5-aminosalicylic acid for maintenance of remission in ulcerative colitis. Cochrane Database Syst Rev. 2016b; (5): CD000544.

Clinical Guideline Revision / History Information

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