mesalamine DR 800 mg (Asacol HD)

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 or Prior authorization Required
Mesalamine (Delzicol) 400 mg DR capsule Mesalamine (Lialda) 1200 mg DR tablet Mesalamine (Rowasa) 4 gram rectal enema Mesalamine (Canasa) 1000 mg rectal suppository	Mesalamine (Asacol HD) 800 mg DR tablet (PA) Mesalamine (Apriso) 0.375 gram ER capsule (NF) Mesalamine (Pentasa) 250 mg, 500 mg ER capsule (NF)
DR, delayed release; ER, extended release; NF, non-formulary; PA, prior authorization	

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 DR 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 DR capsule	Yes	DELZICOL® is indicated for: ● the treatment of mildly to moderately active ulcerative colitis in those 5 years of age and older. ● the maintenance of remission of ulcerative colitis in adults.
Lialda	1.2 gram DR tablet	Yes	LIALDA® is indicated for the: ● induction and maintenance of remission in adults with mildly to moderately active ulcerative colitis. ● treatment of mildly to moderately active ulcerative colitis in pediatric individuals weighing at least 24 kg.
Pentasa	250 mg, 500 mg ER capsule	No (250 mg) Yes (500 mg)	PENTASA® is indicated for the induction of remission and for the treatment of adults with mildly to moderately active ulcerative colitis.
Rowasa	4 gram/60 mL rectal enema suspension	Yes	ROWASA® 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® 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:

1. The member has a documented diagnosis of mildly to moderately active ulcerative colitis; *AND*
2. 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 up to 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

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