

Dipentum (olsalazine sodium)

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

Ulcerative colitis (UC) is a chronic inflammatory bowel disease characterized by recurring episodes of inflammation limited to the mucosal layer of the colon. It commonly involves the rectum and may extend proximally in a contiguous pattern to affect part of or the entire colon. Symptoms include bloody diarrhea, abdominal pain, urgency, tenesmus, and extraintestinal manifestations. The clinical course is marked by exacerbations and remissions.

Treatment depends on the severity and extent of UC. Aminosalicylates (5-ASA) like mesalamine are first-line options for induction and maintenance of remission in mild-to-moderate UC. Corticosteroids may be used for induction of remission in moderate-to-severe disease but are not recommended for maintenance due to adverse effects. Immunomodulators (azathioprine, 6-mercaptopurine), biologics (infliximab, adalimumab, golimumab, vedolizumab, ustekinumab), and JAK inhibitors (tofacitinib) are options for moderate-to-severe UC.

Dipentum (olsalazine sodium) is an oral 5-ASA prodrug indicated for the maintenance of remission of UC in patients intolerant of sulfasalazine. It is enzymatically cleaved in the colon to release mesalamine, the therapeutically active moiety.

Definitions

"**Aminosalicylates**" are anti-inflammatory drugs that contain 5-aminosalicylic acid (5-ASA) and are used to treat inflammatory bowel disease. Examples include mesalamine, sulfasalazine, balsalazide and olsalazine.

"**Prodrug**" is an inactive compound that is converted into the active drug within the body.

"**Remission**" refers to the resolution of symptoms and endoscopic inflammation in ulcerative colitis.

"**Ulcerative colitis**" refers to a chronic inflammatory condition characterized by recurring episodes of inflammation of the mucosal layer of the colon.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Dipentum (olsalazine sodium)** medically necessary when **ALL** of the following criteria are met:

1. The medication is prescribed by or in consultation with a gastroenterologist; **AND**
2. The member is 18 years of age or older; **AND**
3. The member has a diagnosis of ulcerative colitis (UC); **AND**
4. The member is unable to use, or has tried and failed sulfasalazine.

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if the member has recent (within the last 6 months) documentation of positive clinical response as evidenced by at least **ONE** of the following:

1. Maintenance of remission (e.g. resolution of rectal bleeding, urgency, and diarrhea); **OR**

2. Improvement in signs and symptoms from baseline (e.g. reduction in rectal bleeding, urgency, diarrhea, abdominal pain); **OR**
3. Decreased requirement for corticosteroids to control symptoms.

Experimental or Investigational / Not Medically Necessary

Dipentum (olsalazine sodium) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- in combination with other 5-ASA products (e.g. mesalamine, sulfasalazine, balsalazide).
- in pediatric members under 18 years of age.

References

1. Dipentum (olsalazine sodium) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; July 2024.
2. 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 Apr;158(5):1450-1461. doi: 10.1053/j.gastro.2020.01.006. Epub 2020 Jan 13. PMID: 31945371; PMCID: PMC7175923.
3. 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 Feb;156(3):748-764. doi: 10.1053/j.gastro.2018.12.009. Epub 2018 Dec 18. PMID: 30576644; PMCID: PMC6858922.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019 Mar;114(3):384-413. doi: 10.14309/ajg.000000000000152. PMID: 30840605.

Clinical Guideline Revision / History Information

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