

## 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 (the feeling of needing to pass stool despite the bowels being empty), and extraintestinal manifestations (outside of the intestines). 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 (e.g., infliximab [Remicade], adalimumab [Humira], golimumab [Simponi], vedolizumab [Entyvio], ustekinumab [Stelara]), and JAK inhibitors (e.g., tofacitinib [Xeljanz]) are commonly prescribed for moderate-to-severe UC.

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

therapeutically active moiety. While the exact mechanism by which Dipentum (olsalazine sodium) exerts its effects is unknown, it is thought to have topical anti-inflammatory properties.

### 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 up to 12-months.

### Medical Necessity Criteria for Reauthorization

The Plan considers Dipentum (olsalazine sodium) medically necessary when ONE (1) of the following criteria are met (within the last 6 months):

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.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.

### 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).  
Dipentum (olsalazine sodium), balsalazide and sulfasalazine are metabolized into mesalamine in the colon, and Dipentum (olsalazine sodium) is intended for those who are intolerant to sulfasalazine. Thus, concomitant use of Dipentum (olsalazine sodium) with any of these agents would not be clinically appropriate, due to duplicative therapy. Those who are sensitive to mesalamine or sulfasalazine may demonstrate cross-reactivity to balsalazide, and use of this agent in someone who is intolerant to sulfasalazine may not be clinically appropriate.
- In pediatric members under 18 years of age. Safety and effectiveness of Dipentum (olsalazine sodium) has not been established in those under the age of 18 years.

### References

1. Ananthakrishnan AN, Nguyen GC, Bernstein CN. AGA Clinical Practice Update on Management of Inflammatory Bowel Disease in Elderly Patients: Expert Review. *Gastroenterology*. 2021 Jan;160(1):445-451. doi: 10.1053/j.gastro.2020.08.060. Epub 2020 Oct 1.
2. Dipentum (olsalazine sodium) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; July 2024.
3. 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.
4. Ireland A, Mason CH, Jewell DP. Controlled trial comparing olsalazine and sulphasalazine for the maintenance treatment of ulcerative colitis. *Gut*. 1988 Jun;29(6):835-7. doi: 10.1136/gut.29.6.835.
5. 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.
6. Murray A, Nguyen TM, Parker CE, Feagan BG, MacDonald JK. Oral 5-aminosalicylic acid for induction of remission in ulcerative colitis. *Cochrane Database Syst Rev*. 2020 Aug 12;8(8):CD000543. doi: 10.1002/14651858.CD000543.pub5.
7. Murray A, Nguyen TM, Parker CE, Feagan BG, MacDonald JK. Oral 5-aminosalicylic acid for maintenance of remission in ulcerative colitis. *Cochrane Database Syst Rev*. 2020 Aug 28;8(8):CD000544. doi: 10.1002/14651858.CD000544.pub5.
8. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment. *J Crohns Colitis*. 2022 Jan 28;16(1):2-17. doi: 10.1093/ecco-jcc/jjab178.
9. 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.
10. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343. doi: 10.1053/j.gastro.2024.10.001.

#### Clinical Guideline Revision / History Information

Original Date: 09/18/2024

Reviewed/Revised: 12/01/2025