

Aminosalicylate

Commercial Pharmacy Benefit Drug Policy

Drug Details

USP Category: INFLAMMATORY BOWEL DISEASE AGENTS

Mechanism of Action: arachidonic acid inhibitor

Label Name	Quantity Limit
Apriso 0.375 GM CAP ER 24H	4 caps/day
Asacol HD 800 MG TAB DR	6 tabs/day
Canasa 1000 MG SUPPOS	1 suppository/day
Delzicol 400 MG CAP DR	6 caps/day
Dipentum 250 MG CAP	4 caps/day
Lialda 1.2 GM TAB DR	4 tabs/day
Mesalamine 1000 MG SUPPOS	1 suppository/day
Mesalamine 400 MG CAP DR	6 caps/day
Mesalamine 800 MG TAB DR	6 tabs/day
Mesalamine 800 MG TAB DR	6 tabs/day
Mesalamine ER 500 MG CAP ER	8 caps/day
Pentasa 250 MG CAP ER	4 caps/day
Pentasa 500 MG CAP ER	8 caps/day
SfRowasa 4 GM/60ML ENEMA	Quantity Limit May Apply

Condition(s) listed in policy (see coverage criteria for details)

- ULCERATIVE COLITIS (UC)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

The following condition(s) require Prior Authorization/Preservice:

ULCERATIVE COLITIS (UC)

1. Inadequate response, or intolerable side effect to one preferred alternative or contraindication to all preferred (e.g., balsalazide 750 mg (generic for Colazal), mesalamine 1200 mg (generic for Lialda), mesalamine er 375 mg (generic for Apriso)), and
2. Dose does not exceed FDA approved maximum.

Coverage Period:
one year

Additional Information

Table: Maximum Daily Dosing

Drug	Route	Maximum Daily Dose
Apriso	oral	1500 mg
Asacol HD	oral	2400 mg
Canasa	rectal	1000 mg
Colazal	oral	6750 mg
Delzicol	oral	2400 mg
Dipentum	oral	3000 mg
Lialda	oral	4800 mg
Pentasa	oral	4000 mg

- Ulcerative Colitis SEVERITY:
- Mild – Patients with mild clinical disease have ≤ 4 stools per day with or without small amounts of blood, no signs of systemic toxicity (eg, no tachycardia), and a normal C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR). Mild crampy abdominal pain, tenesmus, and periods of constipation are also common, but severe abdominal pain, profuse bleeding, fever, and weight loss are not part of the spectrum of mild disease.
- Moderate – Patients with moderate clinical disease may have frequent (four to six per day), loose, bloody stools, mild anemia not requiring blood transfusions (hemoglobin >10 g/dL), and abdominal pain that is not severe. Patients have no or minimal signs of systemic toxicity. Adequate nutrition is usually maintained, and weight loss is not associated with moderate clinical disease.
- Severe – Patients with a severe clinical disease typically have frequent, loose bloody stools (≥ 6 per day) with severe cramps and evidence of systemic toxicity as demonstrated by a fever (temperature $\geq 37.8^{\circ}\text{C}$), tachycardia (heart rate ≥ 90 beats per minute), anemia (hemoglobin <10 g/dL), and/or an elevated CRP or ESR. Patients may lose weight. The management of acute, severe UC is discussed separately.
- Ulcerative colitis may also be referred to by location or extent of colon involved.
 - Ulcerative proctitis – disease within 18 cm of the anal verge, distal to the rectosigmoid junction
 - Ulcerative proctosigmoiditis – disease limited to the rectum and sigmoid colon and not involving the descending colon

- Left-sided colitis – disease that extends beyond the sigmoid colon and as far proximally as the splenic flexure
- Extensive colitis – disease extending proximal to the splenic flexure

References

1. Asacol^(R) HD [package insert]. Medeva Pharma Suisse AG, 2009.
2. Canasa^(R) [package insert]. Allergan USA, Inc. (per FDA), Irvine, CA, 2016.
3. Delzicol^(R) [package insert]. Warner Chilcott (US), LLC. Rockaway, NJ, 2014.
4. Pentasa^(R) [package insert]. Shire US Inc. Lexington, MA, 2018.

Review History

Date of Last Annual Review: 1Q2024

Date of last revision: 01/31/2024

Changes from previous policy version:

- no clinical changes following annual review

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*