Clinical Policy: Mesalamine Oral Therapy

Reference Number: CP.PST.08
Effective Date: 11/11
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Mesalamine is an aminosalicylate. The following mesalamine products require prior authorization: Apriso™, Asacol® HD, Pentasa®, and Delzicol®.

FDA Approved Indication(s)

Oral mesalamine is indicated for ulcerative colitis.

Limitation of use:

- Asacol HD: Safety and effectiveness of Asacol HD beyond 6 weeks have not been established.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that mesalamine (Apriso, Asacol HD, Pentasa) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy for Oral Mesalamine (must meet all)**:**

1. One of the following applies (a or b)
   a. Request for Delzicol: previous use of Lialda at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; **Generic Lialda is a preferred agent*
   b. Request for all other agents: must meet the following (i and ii):
      i. Previous use of 3 consecutive months of sulfasalazine, sulfasalazine EC, or balsalazide at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
      ii. Previous use of 3 consecutive months of two preferred oral mesalamine agents at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed FDA approved maximum recommended dose.

Approval duration: 12 months

II. Continued Therapy

A. Step Therapy for Oral Mesalamine (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose.

Approval duration: 12 months

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food & Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sulfasalazine, sulfasalazine EC (Azulfidine®)	1 g by mouth every 6 to 8 hours EC: 3 to 4 g by mouth every 8 hours	4 g/day
Balsalazide (Colazal®)	Three 750 mg capsules by mouth three times per day	6.75 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Apriso (mesalamine)	Four 0.375 g capsules daily	1.5 g/day
Asacol HD (mesalamine)	1600 mg three times a day	4.8 g/day
Lialda (mesalamine)	Two to four 1.2 g tablets daily	4.8 g/day
Pentasa (mesalamine)	1 g four times a day (total of 4 g daily)	4 g/day
Delzicol (mesalamine)	Two 400 mg capsules three times daily	2.4 g/day

V. Product Availability

Drug Name	Availability
Apriso (mesalamine)	0.375 mg extended-release capsule
Asacol HD (mesalamine)	800 mg delayed-release tablet
Lialda (mesalamine)	1.2 g delayed-release tablet
Pentasa (mesalamine)	250 mg, 500 mg controlled-release capsule
Delzicol (mesalamine)	Delayed-release capsules (containing four 100 mg tablets): 400 mg

VI. Workflow Document

N/A

VII. References

1. Kornbluth A and Sachar DB, "Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee," Am J Gastroenterol, 2010, 105(3):501-23.

2. Mottet C, Vader JP, Felley C, et al, "Appropriate Management of Special Situations in Crohn's Disease (Upper Gastro-Intestinal; Extra-Intestinal Manifestations; Drug Safety during Pregnancy and Breastfeeding): Results of a Multidisciplinary International Expert Panel-EPACT II," J Crohns Colitis, 2009, 3(4):257-63.
3. Mesalamine. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2015. Available athttp://www.clinicalpharmacology-ip.com. Accessed November 2017.
4. Asacol HD Prescribing Information. Irvine, CA: Allergan USA, Inc.; May 2016. Available at http://www.allergan.com. Accessed November 2017.
5. Apriso Prescribing Information. Raleigh, NC: Salix Pharmaceuticals, Inc., July 2009. Available at https://www.aprisorx.com. Accessed November 2017.
6. Lialda Prescribing Information. Lexington, MA: Shire US Inc., November 2015. Available at http://pi.shirecontent.com. Accessed November 2017.
7. Pentasa Prescribing Information. Lexington, MA: Shire US Inc.,October 2015. Available at https://www.pentasaus.com/. Accessed November 2017.
8. Delzicol Prescribing Information. Irvine, CA: Allergan USA, Inc. July 2017. Available at https://www.delzicol.com/. Accessed November 5, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
Updated reference section to reflect current literature search.	11.12	11.12
Deleted Asacol and added Delzicol from "Brand" because it has been discontinued by manufacturer and replaced with Delzicol. Added Apriso and Lialda to available brand and separated PDL and non PDL brands. Modified FDA labeled indication to be applicable to all oral mesalamine formulation. Deleted the criteria A and B because the relevant medication currently have no step therapy edit and changed it to request trial and failure of PDL ulcerative colitis agents. Updated approval criteria to initial approval period to 6 months and renewal to 12 months to allow monitoring for compliance during the initial 6 months of approval. Added supporting references for the new criteria and updated previous references to reflect current literature search.	11.13	11.13
Updated preferred/non-preferred language. Updated references	12.14	12.14
Guideline converted to new template Clarified that a PDL oral mesalamine must be used for 3 "consecutive" months Added that request must not exceed the FDA approve dose to criteria Reviewed and updated references	11.15	11.15
Converted to integrated template; Updated references.	09.16	11.16
Require failure of 2 PDL mesalamine products instead of only one mesalamine product Updated references	03.17	05.17

Reviews, Revisions, and Approvals	Date	Approval Date
Liadal removed from list of drug requiring PA based on addition of generic Lialda to formulary. Added criteria for Delzicol requiring a step through Lialda based on SDC decision.	11.01.17	
1Q18 annual review: - No significant changes. - References reviewed and updated.	11.05.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.