STEP THERAPY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Mesalamine Oral Therapy
PAGE: 1 of 4	**REFERENCE NUMBER:** NH.PST.08
EFFECTIVE DATE: 11/11	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 11/11, 12/14, 12/15, 11/16, 12/16, 3/17
PRODUCT TYPE: All	**REVISED:** 11/12, 11/13, 12/14

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Mesalamine is thought to be the major therapeutically active part of the sulfasalazine molecule in the treatment of ulcerative colitis. Sulfasalazine is converted to equimolar amounts of sulfapyridine and mesalamine by bacterial action in the colon. The usual oral dose of sulfasalazine for active ulcerative colitis in adults is 3 to 4 g daily in divided doses, which provides 1.2 to 1.6 g of mesalamine to the colon.

Guideline Covers: Non-preferred mesalamine products

FDA Labeled Indications: For the induction of remission and the maintenance treatment of ulcerative colitis.

Centene Medical Policy Statements represent technical documents developed by the Medical Management Staff. Questions regarding interpretation of these policies for the purposes of benefit coverage should be directed to a Medical Management Staff person.

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Criteria for Approval:

A. Trail and failure of adherent use of one of the following medications: sulfasalazine, sulfasalazine EC, balsalazide, at maximal dosing for 3 consecutive months unless contraindicated **AND**
B. Trial and failure of adherent use of at least one PDL oral mesalamine formulation for 3 consecutive months at maximal dosing unless contraindicated. **OR**
C. Clinically unacceptable risk with a change in therapy to a preferred drug;
D. Request does not exceed the FDA approved dose limit.

Approval:

Initial Approval: 6 months
Continued Approval:12 months

Special Instructions

- Caution should be exercised when administering mesalamine to patients with impaired renal or hepatic function.
- Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported with mesalamine medications.
- Mesalamine has been associated with an acute intolerance syndrome that may be difficult to distinguish from a flare of inflammatory bowel disease. It has occurred in 3% of patients in clinical trials. If acute intolerance syndrome is suspected, the drug should be withdrawn.
- The safety and efficacy of mesalamine in children 18 years of age and younger have not been established

References:

1. Pentasa® prescribing information. Accessed October 2013. http://pi.shirecontent.com/PI/PDFs/Pentasa_USA_ENG.pdf

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2. Mesalamine Monograph. Clinical Pharmacology. Accessed on October 2013. http://clinicalpharmacology-ip.com
3. MacDermortt RP. Management of mild to moderate ulcerative colitis. Rutgeerts P. (Ed), Uptodate. Watham, MA. Accessed October 2013.
4. Peppercorn MA, Farell RJ. Management of severe ulcerative colitis. Rutgeerts P. (Ed), Uptodate. Watham, MA. Accessed October 2013.

Revision Log	
Revision	**Date**
Updated reference section to reflect current literature search.	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.	11/13
Modified FDA labeled indication to be applicable to all oral mesalamine formulation.	11/13
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	11/13
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	11/13
Added supporting references for the new criteria and updated previous references to reflect current literature search	11/13
Updated preferred/non-preferred language. Updated references	12/14
Added Clinically unacceptable risk with a change in	07/15

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therapy to a preferred drug	
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	12/15
Annual Review, No Changes	11/16
Annual Review, No changes	12/16
Annual Review, No Changes	03/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file