Clinical Policy: Gastrointestinal Agents: Ulcerative Colitis Agents

Reference Number: OH.PHAR.PPA.60
Effective Date: 01/01/2020
Last Review Date: N/A
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description:

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
APRISO® (mesalamine) BALSALAZIDE DISODIUM (generic of Colazal®) MESALAMINE DR (generic for Delzicol®) PENTASA® (mesalamine) SULFASALAZINE (generic of Azulfidine®) SULFASALAZINE EC (generic of Azulfidine Entab®)	DIPENTUM® (olsalazine) GIAZO® (balsalazide disodium) MESALAMINE DR (generic for Lialda®, Asacol HD®)

GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS AGENTS - RECTAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
MESALAMINE enema (generic of Rowasa® and SFRowasa®)	MESALAMINE (generic for Canasa® suppositories) MESALAMINE enema kit (generic for Rowasa® kit) UCERIS® foam (budesonide)

FDA Approved Indication(s)
Oral and rectal ulcerative colitis medications are indicated for the treatment of:

Proctitis
Ulcerative Colitis

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

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation®, that Dipentum, Giazo, Lialda, Asacol HD, Canasa, Rowasa Kit, and Uceris are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. FDA-Approved Indications (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug;

4. Documentation that there have been therapeutic failures to trials of no less than 30 days each of at least two medications that are preferred UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.

   NOTE: Ulcerative Colitis Agents are available in both oral (IR, ER) and rectal (enema, suppository) formulations. Members with mild or moderate disease may be treated with either rectal or oral agents.

Approval duration: 12 months.

II. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DR: Delayed Release
ER: Extended Release
FDA: Food and Drug Administration
IR: Immediate Release
PA: Prior Authorization

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 for all relevant lines of business and may require prior authorization.

*****See above tables for preferred alternatives***** *Dosing varies by drug product. See FDA approved dosing and administration*

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.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - 5-Aminosalicylates Hypersensitivity
  - GI Obstruction
  - Porphyria
  - Salicylate Hypersensitivity
  - Sulfonamide Hypersensitivity
  - Urinary Tract Obstruction

IV. **Dosage and Administration:** varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration

V. **Product Availability:** See package insert; clinical pharmacology or other appropriate clinical reference for product availability

VI. **References.** Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.