

## Clinical Policy: Balsalazide (Giazo)

Reference Number: CP.CPA.36

Effective Date: 11.16.16

Last Review Date: 08.19

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Balsalazide (Giazo®) is a locally acting aminosalicylate.

### FDA Approved Indication(s)

Giazo is indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older.

Limitation(s) of use:

- Effectiveness in female patients was not demonstrated in clinical trials.
- Safety and effectiveness of Giazo beyond 8 weeks have not been established.

### 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 health plans affiliated with Centene Corporation® that Giazo is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Ulcerative Colitis (must meet all):

1. Diagnosis of ulcerative colitis;
2. Failure of balsalazide at up to maximally indicated doses, unless clinically significant adverse effects are experienced;
3. Dose does not exceed 6.6 g (6 tablets) per day.

##### Approval duration: Length of Benefit

##### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

#### II. Continued Therapy

##### A. Ulcerative Colitis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 6.6 g (6 tablets) per day.

**Approval duration: Length of Benefit**

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less); or**
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** 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 policies – CP.CPA.09 for commercial or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and 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 for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
balsalazide (Colazal®)	Three 750 mg capsules PO TID for up to 12 weeks	6.75 g per 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.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- With adjustment for multiplicity, statistically significant differences were seen in the male patients for clinical remission (35% with Giazo vs. 13% for placebo) and for mucosal healing (52% with Giazo vs. 20% for placebo). Effectiveness of Giazo was not demonstrated in the female subpopulation in the clinical trial.

**V. Dosage and Administration**

<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Ulcerative colitis	Three 1.1 g tablets PO BID (6.6 g/day) with or without food for up to 8 weeks	6.6 g/day

**VI. Product Availability**

Tablets: 1.1 g

## VII. References

1. Giazo Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; June 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed>. Accessed May 28, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed April 20, 2018.
3. Kornbluth A, Sachar DB, MACG and the Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, practice parameters committee. Am J Gastroenterol 2010; 105: 501-523.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	01.10.17	8.17
3Q 2018 annual review: no significant; references reviewed and updated.	04.20.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.28.19	08.19

### **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.

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