Clinical Policy: Nitazoxanide (Alinia)

Reference Number: HIM.PA.152
Effective Date: 12.01.20
Last Review Date: 11.21
Line of Business: HIM

Revision Log

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

Description

Nitazoxanide (Alinia®) is a synthetic antiprotozoal agent.

FDA Approved Indication(s)

Alinia is indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum.*

Limitation(s) of use: Alinia has not been shown to be effective for the treatment of diarrhea caused by *C. parvum* in HIV-infected or immunodeficient patients.

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 Alinia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cryptosporidiosis (must meet all)**:**

1. Diagnosis of infectious diarrhea caused *Cryptosporidium parvum;*
2. Age ≥ 1 year;
3. Member is not immunodeficient or infected with human immunodeficiency virus (HIV);
4. Request is for generic nitazoxanide tablets, unless contraindicated (e.g., contraindications to excipients), clinically significant adverse effects are experienced, or medical justification supports inability to swallow tablets;
5. Dose meets one of the following (a, b, or c):
   a. Age ≥ 1 year but < 4 years: dose does not exceed 200 mg (10 mL) per day for up to 3 days;
   b. Age ≥ 4 years but < 12 years: dose does not exceed 400 mg (20 mL) per day for up to 3 days;
   c. Age ≥ 12 years: dose does not exceed 1,000 mg (2 tablets or 25 mL) per day for up to 3 days.

Approval duration: 1 month

B. Giardiasis (must meet all)**:**

1. Diagnosis of infectious diarrhea caused by *Giardia lamblia;*

2. Age ≥ 1 year;
3. Failure of a 5-day course of metronidazole for this episode, unless contraindicated, clinically significant adverse effects are experienced, or culture/sensitivity testing showing antibiotic resistance to metronidazole;
4. Request is for generic nitazoxanide tablets, unless contraindicated (e.g., contraindications to excipients), clinically significant adverse effects are experienced, or medical justification supports inability to swallow tablets;
5. Dose meets one of the following (a, b, or c):
   a. Age ≥ 1 year, but < 4 years: dose does not exceed 200 mg (10 mL) per day for up to 3 days;
   b. Age ≥ 4 years, but < 12 years: dose does not exceed 400 mg (20 mL) per day for up to 3 days;
   c. Age ≥ 12 years: dose does not exceed 1000 mg (2 tablets or 25 mL) per day for up to 3 days.

Approval duration: 1 month

C. 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): HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Cryptosporidiosis and Giardiasis

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

A. 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): HIM.PA.154 for health insurance marketplace.

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: HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV: human immunodeficiency virus

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.

Drug Name	Dosing Regimen	Duration
Metronidazole (Flagyl®)	250 mg orally 3 times daily	5 days

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): Hypersensitivity
- Boxed warning(s): None reported

V. Dosage and Administration

Indication	Dosing Regimen	Duration
Cryptosporidiosis and Giardiasis	• Age 1-3 years: 5 mL oral suspension (100 mg) every 12 hours with food • Age 4-11 years: 10 mL oral suspension (200 mg) every 12 hours with food • 12 years and older: 1 tablet (500 mg) every 12 hours with food or 25 mL oral suspension (500 mg) every 12 hours with food	3 days

VI. Product Availability
- Tablets: 500 mg
- Oral Suspension: 100 mg/5 mL

VII. References
1. Alinia Prescribing Information. Tampa, FL: Romarck LC; July 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021497s001,021498s004lbl.pdf. Accessed August 11, 2021.
2. Centers for Disease Control and Prevention. Parasites – *Giardia.* Available at: https://www.cdc.gov/parasites/giardia/treatment.html. Accessed August 11, 2021.
3. Centers for Disease Control and Prevention. Parasites – *Cryptosporidium.* Available at: https://www.cdc.gov/parasites/crypto/treatment.html. Accessed August 11, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.08.20	11.20
4Q 2021 annual review: no significant changes; added that request should be for generic formulation for all indications; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.11.21	11.21

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.