Clinical Policy: Nitazoxanide (Alinia)

Reference Number: HIM.PA.152
Effective Date: 12.01.20
Last Review Date: 11.23
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. Member meets one of the following (a or b):
   a. Request for suspension: Age ≥ 1 year;
   b. Request for tablets: Age ≥ 12 years;
3. Member is not immunodeficient or infected with human immunodeficiency virus (HIV);
4. For members age ≥ 12 years, 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 does not exceed one of the following (a or b):
   a. Request for suspension and member meets one of the following (i, ii, or iii):
      i. Age ≥ 1 year and < 4 years: 200 mg (10 mL) per day for up to 3 days;
      ii. Age ≥ 4 years and < 12 years: 400 mg (20 mL) per day for up to 3 days;
      iii. Age ≥ 12 years: 1,000 mg (50 mL) per day for up to 3 days;
   b. Request for tablets: 1,000 mg (2 tablets) 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. Member meets one of the following (a or b):
   a. Request for suspension: Age ≥ 1 year;
   b. Request for tablets: Age ≥ 12 years;
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. For members age ≥ 12 years, 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 does not exceed one of the following (a or b):
   a. Request for suspension and member meets one of the following (i, ii, or iii):
      i. Age ≥ 1 year and < 4 years: 200 mg (10 mL) per day for up to 3 days;
      ii. Age ≥ 4 years and < 12 years: 400 mg (20 mL) per day for up to 3 days;
      iii. Age ≥ 12 years: 1,000 mg (50 mL) per day for up to 3 days;
   b. Request for tablets: 1,000 mg (2 tablets) per day for up to 3 days.

Approval duration: 1 month

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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®)	**Giardiasis** 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 Oral Suspension	• 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 • Age ≥ 12 years: 25 mL oral suspension (500 mg) every 12 hours with food	3 days
Cryptosporidiosis and Giardiasis Tablets	• 12 years and older: 1 tablet (500 mg) every 12 hours with food Nitazoxanide tablets should not be administered to pediatric patient 11 years of age or younger	3 days

VI. Product Availability

- Tablets: 500 mg
- Oral Suspension: 100 mg/5 mL

VII. References

1. Alinia Prescribing Information. Tampa, FL: Romarck LC; January 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021497s018,021498s019lbl.pdf. Accessed August 3, 2023.
2. Nitazoxanide Prescribing Information. Tampa, FL: Romarck LC; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021497s017lbl.pdf. Accessed August 3, 2023.
3. Centers for Disease Control and Prevention. Parasites – *Giardia.* Available at: https://www.cdc.gov/parasites/giardia/treatment.html. Accessed August 3, 2023.
4. Centers for Disease Control and Prevention. Parasites – *Cryptosporidium.* Available at: https://www.cdc.gov/parasites/crypto/treatment.html. Accessed August 3, 2023.

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
RT4: added FDA label clarification to limit age for oral tablets to 12 years or older; references reviewed and updated.	01.18.22	
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications.	06.20.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	08.03.23	11.23

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.