Clinical Policy: Nitazoxanide (Alinia)

Reference Number: HIM.PA.152
Effective Date: 12.01.20
Last Review Date: 11.26
Line of Business: HIM/ICHRA

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 meets one of the following (a or b):
   a. Member is not immunodeficient;
   b. If member has human immunodeficiency virus (HIV) infection, member is currently on antiretroviral therapy;
4. For members age ≥ 12 years, member must use 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 and member meets one of the following (i or ii):
      i. 1,000 mg (2 tablets) per day for up to 3 days;

ii. For immunocompromised patients: 1000 mg (2 tablets) per day for up to 14 days (*off-label; see Appendix D)*.

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;*
   ** For Illinois HIM requests, the step therapy requirement above does not apply as of 1/1/2026 per IL HB 5395*
4. For members age ≥ 12 years, member must use 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/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; 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/ICHRA.

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/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA; 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/ICHRA.

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/ICHRA 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** • Adults: 250 mg PO TID or 500 mg PO BID • Pediatrics (age ≥ 28 days): 15 mg/kg/day PO in 3 divided doses (maximum 250 mg per dose)	5 to 7 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

Appendix D: General Information

- Off-label dosing requests for Cryptosporidiosis
  - The CDC, National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America (IDSA) recommends nitazoxanide 500 mg to 1,000 mg BID for 14 days for the treatment of Cryptosporidiosis in an immunocompromised patients.

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

- Tablet: 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 July 10, 2026.
2. Nitazoxanide Prescribing Information. Tampa, FL: Romarck LC; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021497s017lbl.pdf. Accessed July 10, 2026.
3. Centers for Disease Control and Prevention. Parasites - Clinical care of crypto. Available at: https://www.cdc.gov/cryptosporidium/hcp/clinical-care/index.html. Updated June 25, 2025. Accessed August 25, 2026.
4. Guidelines for the prevention and treatment of opportunistic Infections in Adults and Adolescents With HIV – Cryptosporidiosis. Reviewed January 10, 2024. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf. Accessed August 25, 2026.
5. Centers for Disease Control and Prevention. Parasites – Treatment of *Giardia* infection. Available at: https://www.cdc.gov/giardia/treatment/. Updated January 30, 2025. Accessed July 25, 2026.
6. Centers for Disease Control and Prevention. CDC Yellow Book 2024 – Giardiasis. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/giardiasis. Accessed August 25, 2026.

7. Guidelines for the prevention and treatment of opportunistic infections in children with and exposed to HIV – Giardiasis. Reviewed August 29, 2019. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-oi/guidelines-pediatric-oi.pdf. Accessed August 25, 2026.
8. Shane AL, Mody RK, Crump JA, et al. 2017 IDSA clinical practice guidelines for the diagnosis and management of infectious diarrhea. Clinical Infectious Diseases 2017;65(12):e45-e80.
9. La Hoz, RM. Intestinal parasites including Cryptosporidium, Cyclospora, Giardia, and Microsporidia, Entamoeba histolytica, Strongyloides, Schistosomiasis, and Echinococcus: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin. Transplant. 2019, 33, e13618.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
4Q 2024 annual review: for all indications, clarified that member must use generic formulation if age ≥ 12 years; for cryptosporidiosis, revised requirement for members with HIV infection to currently use antiretroviral therapy per HIV guidelines; references reviewed and updated.	07.25.24	11.24
4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	07.09.25	11.25
4Q 2026 annual review: added ICHRA line of business; added option for extended off-label dosing requests for the treatment of cryptosporidiosis in an immunocompromised patient per IDSA/CDC/NIH guidelines; references reviewed and updated.	07.10.26	11.26

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.

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