



Effective Date 1/1/2023
Next Review Date... 1/1/2024
Coverage Policy Number IP0467

Nitazoxanide for Individual and Family Plans

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for nitazoxanide tablets (Alinia®) for Individual and Family Plans.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Nitazoxamide (Alinia) is considered medically necessary when ALL of the following are met (1, 2, and 3):

1. For the treatment of ANY of the following infections documented by clinical findings and appropriate lab confirmation:
 - A. Amebiasis caused by *Entamoeba histolytica*.
 - B. Ascariasis caused by *Ascaris lumbricoides*.
 - C. Balantidiasis caused by *Balantidium coli*.
 - D. Blastocystis.
 - E. Cryptosporidiosis caused *Cryptosporidium parvum*.

- F. Giardiasis caused by *Giardia lamblia*.
- G. Fascioliasis caused by *Fasciola spp.*
- H. Hymenolepiasis caused by *Hymenolepis nana*.
- I. Isosporiasis (Cystoisosporiasis) caused by *Isospora belli (Cystoisospora belli)*.

2. Prescribed by or in consultation with an infectious disease or tropical disease specialist.
3. Individual meets the preferred covered alternative(s) criteria as indicated in the table below.

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Individual and Family Plan Non-Covered Products and Covered Alternative(s):

Non-Covered Product	Criteria
Alinia (nitazoxanide tablets)	The individual has tried nitazoxanide tablets [prior authorization required] (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration: up to 3 days
 Reauthorization approval duration: Not applicable

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Antiparasitic agents are used in the treatment of various parasitic infections. Drug selection, dose, and duration for treatment and/or prophylaxis are dependent upon the parasite. Nitazoxanide is an antiprotozoal indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*.¹

Off-label Uses^{2,3}

Nitazoxanide can also be used in treating other parasitic infections including Ascariasis, Amebiasis, Isosporiasis (Cystoisosporiasis), Balantidiasis, Blastocystis, Fascioliasis, and Hymenolepiasis.

Dosing¹

Nitazoxanide is supplied in 500 mg tablets (Alinia, generic) and 100 mg/5 mL oral suspension, reconstituted (Alinia brand only).

Nitazoxanide tablets (Alinia, generic) and Alinia suspension

Alinia oral suspension is indicated for patients ≥ 1 year of age, while nitazoxanide tablets are indicated for patients ≥ 12 years of age.¹ For patients 1 to 3 years of age, the recommended dose of Alinia suspension is 5 mL (100 mg) every 12 hours (Q12H). For patients 4 to 11 years of age, the recommended dose of Alinia suspension is 10 mL (200 mg) Q12H. For patients ≥ 12 years of age the recommended dose is 1 nitazoxanide tablet (Alinia, generic) [500 mg] Q12H or 25 mL (500 mg) of Alinia oral suspension Q12H. For all patients, the recommended duration of treatment is 3 days.

References

1. Alinia® (nitazoxamide) tablets and suspension [prescribing information]. Tampa, FL: Romark; January 2022.
2. Nitazoxamide. Drug Facts and Comparisons. Facts & Comparisons eAnswers. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed July 7, 2022. <http://online.factsandcomparisons.com>
3. Nitazoxanide. [AHFS Drug Information]. AHFS Clinical Drug Information. Bethesda, MD: American Society of Health-System Pharmacists, Inc. Updated June 3, 2019. Accessed July 7, 2022.

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