Alinia
Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

FDA APPROVED INDICATIONS[1]

Agent(s)	Indication(s)
Alinia® (nitazoxanide) Tablet* Suspension	Oral suspension (patients 1 year of age and older) and tablets (patients 12 years and older) indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* Limitations of Use: • Nitazoxanide has not been shown to be effective for the treatment of diarrhea caused by C. parvum in HIV-infected or immunodeficient patients

* – Generic equivalent available

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Infectious Diarrhea

Persistent watery diarrhea generally should not be treated in the absence of an identified cause. When persistent diarrhea is caused by infection, the most common etiologic agents are protozoal (including parasites such as *Giardia lamblia*, *Cryptosporidium* species, *Cyclospora cayetanensis*, and *Cystoisospora belli*) and are best managed with pathogen-specific therapy (rather than empiric therapy before the infection is diagnosed).(7)

Giardiasis is caused by the anaerobic protozoan parasite *Giardia duodenalis* (e.g., *G. lamblia* or *G. intestinalis*). Effective treatments include metronidazole, tinidazole, and nitazoxanide. Among the many protozoan parasites in the genus *Cryptosporidium*, the species *C. hominis* and *C. parvum* cause greater than 90% of human infections. Nitazoxanide is FDA approved as a treatment of cryptosporidiosis in immunocompetent patients.(8)

IBM Micromedex lists the following non-FDA approved uses with a Class IIa Strength of Recommendation (treatment is generally considered to be useful, and is indicated in most cases) or higher:

- Infection by *Fasciola* in adults (IIa)[2]
  - Nitazoxanide appeared to be well tolerated and effective when used in the treatment of human fascioliasis, in an open-label study. Adult patients received an oral regimen of nitazoxanide 500 mg twice daily for 6 consecutive days.[3]

- General intestinal parasitism in adults and pediatrics (IIa)[2]
    - A 3-day course of nitazoxanide (NTZ) 500 mg twice daily was a safe and effective treatment for diarrhea associated with infection by the intestinal parasites *Giardia intestinalis*, *Entamoeba histolytica*, or *Entamoeba dispar*.[4]
    - Results of a large field study in Egypt indicate that nitazoxanide is safe and effective for treating intestinal protozoan and helminthic infections. Patients took medication with food at 12-hour intervals over 3 days; those older than 12 years received 500 mg of nitazoxanide, children aged 4 to 11 years received 200 mg of drug, and children aged 1 to 3 years received 5 mL of a 100 mg per 5-mL suspension.[5]
    - Nitazoxanide and metronidazole have been similarly effective in treating symptomatic intestinal giardiasis in children.[6]

REFERENCES

1. Alinia prescribing information. Romark, L.C. January 2022.
2. IBM Micromedex. Alinia Non-FDA Uses. Last modified February 9, 2023.
3. Kabil SM, El Ashry E, Ashraf NK. An Open-Label Clinical Study of Nitazoxanide in the Treatment of Human Fascioliasis. *Curr Ther Res*. 2000;61(6):339-345.
4. Rossignol J-F, Ayoub A, Ayers MS. Treatment of Diarrhea caused by *Giardia intestinalis* and *Entamoeba histolytica* or *E. dispar*: A Randomized, Double-Blind, Placebo-Controlled Study of Nitazoxanide. *J Infect Dis*. 2001;184(3):381-384.
5. Abaza H, El-Zayadi AR, Kabil SM, Rizk H. Nitazoxanide in the Treatment of Patients with Intestinal Protozoan and Helminthic Infections: A Report on 546 Patients in Egypt. *Curr Ther Res Clin Exp*. 1998;59(2):116-121.
6. Ortiz JJ, Ayoub A, Gargala G, Chegne NL, Favennec L. Randomized Clinical Study of Nitazoxanide Compared to Metronidazole in the Treatment of Symptomatic Giardiasis in Children from Northern Peru. *Aliment Pharm Ther*. 2001;15(9):1409-15.
7. 2017 Infectious Diseases Society of America (IDSA) Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea. Clin Infec Dis. 2017 Dec;65:e45-e80.
8. 2020 Centers for Disease Control and Prevention (CDC) Yellow Book: Health Information for International Travel.

Alinia Quantity Limit

TARGET AGENT(S)
Alinia® (nitazoxanide)*
* – Generic equivalent available

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Alinia (nitazoxanide)			
500 mg tablet*	16400060000330	M, N, O, or Y	12 tablets/90 days
100 mg/5 mL suspension	16400060001920	M, N, O, or Y	300 mL/90 days

* – Generic equivalent available

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Quantities above the program quantity limit for the **Target Agent(s)** will be approved when ALL of the following are met:

1. The patient has ONE of the following diagnoses:
    A. Diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*
    OR
    B. Adult with *Fasciola* infection
    OR
    C. General intestinal parasitism

    AND
2. ONE of the following:
    A. The patient has been re-infected AND requires an additional course of therapy **AND** ONE of the following:
        i. The requested quantity (dose) is less than or equal to the following:
            a. For diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*, 3000 mg over 3 days
            OR
            b. For adults with *Fasciola* infection, 6000 mg over 6 days
            OR
            c. For general intestinal parasitism, 3000 mg over 3 days

        OR
        ii. The prescriber has provided information in support of therapy with a higher dose and/or duration for the requested indication

    OR
    B. The patient is seeking a higher dose and/or duration of therapy for the same infection **AND** the prescriber has provided information in support of therapy with a higher dose and/or duration for the requested indication

Length of Approval: up to 3 months