

QUANTITY LIMIT CRITERIA

BRAND NAME
(generic)

ALINIA
(nitazoxanide)

Status: CVS Caremark® Criteria

Type: Quantity Limit with Age Edit

POLICY

FDA-APPROVED INDICATIONS

Alinia for Oral Suspension (patients 1 year of age and older) and Alinia Tablets (patients 12 years and older) are indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*.

Limitations of Use

Alinia for Oral Suspension and Alinia Tablets have not been shown to be effective for the treatment of diarrhea caused by *Cryptosporidium parvum* in HIV-infected or immunodeficient patients.

Compendial Uses

Human fascioliasis (*Fasciola hepatica*)^{2,3}
Clostridium difficile colitis^{2,3}

LIMIT CRITERIA

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength

<u>Drug</u>	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>	<u>Age Edit</u>
Alinia 100 mg/5 mL Oral Suspension (nitazoxanide)	540 mL per 25 days	Does Not Apply*	1 year of age and older
Alinia 500 mg Tablets	20 tablets per 25 days	Does Not Apply*	12 years of age and older

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

* These drugs are for short-term acute use; therefore the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

REFERENCES

1. Alinia [package insert]. Tampa, FL: Romark Laboratories, L.C.; January 2022.
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3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/10/2024).
4. Centers for Disease Control. https://www.cdc.gov/parasites/fasciola/health_professionals/index.html#tx. Accessed January 10, 2024.
5. L Clifford McDonald, Dale N Gerding, Stuart Johnson, Johan S Bakken, Karen C Carroll, Susan E Coffin, Erik R Dubberke, Kevin W Garey, Carolyn V Gould, Ciaran Kelly, Vivian Loo, Julia Shaklee Sammons, Thomas J Sandora, Mark H Wilcox, Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), *Clinical Infectious Diseases*, Volume 66, Issue 7, 1 April 2018, Pages e1–e48, <https://doi.org/10.1093/cid/cix1085>. Accessed January 10, 2024.

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