

### Clinical Pharmacy Program Guidelines for Alinia

Program	Prior Authorization
Medication	Alinia (nitazoxanide)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	1/2021

**1. Background:**

Alinia (nitazoxanide) oral suspension (patients 1 year of age and older) and tablets (patients 12 years and older) are indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*.

**2. Coverage Criteria:**

<p><b>A. <u>Diarrhea caused by <i>Giardia lamblia</i></u></b></p> <p>1. <b>Alinia</b> will be approved based on all of the following:</p> <p style="margin-left: 40px;">a. Diagnosis of giardiasis</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="margin-left: 40px;">b. History of failure, contraindication, or intolerance to metronidazole</p> <p><b>Authorization will be issued for 3 days.</b></p> <p><b>B. <u>Diarrhea caused by <i>Cryptosporidium parvum</i></u></b></p> <p>1. <b>Alinia</b> will be approved based on the following:</p> <p style="margin-left: 40px;">a. Diagnosis of cryptosporidiosis</p> <p><b>Authorization will be issued for 12 months.</b></p>
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**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Alinia [Package Insert]. Tampa, FL: Romark Laboratories L.C.; December 2019.
2. Centers for Disease Control and Prevention. Parasites- *Giardia*. Available at: <https://www.cdc.gov/parasites/giardia/treatment.html>. Accessed October 6, 2020.
3. Centers for Disease Control and Prevention. Parasites- *Cryptosporidium* (also known as "Crypto"). Available at: <https://www.cdc.gov/parasites/crypto/treatment.html>. Accessed October 6, 2020.

Program	Prior Authorization –Alinia (nitazoxanide)
<b>Change Control</b>	
Date	Change
12/2013	New guideline
12/2015	Annual review, no change
10/2016	Annual review, updated policy template
11/2017	Removed dosing table. Updated references.
11/2018	Modified criteria to remove immunocompetent requirement. Updated references.
11/2019	Changed authorization duration for cryptosporidiosis to 12 months for DX2RX. Updated references.
11/2020	Annual review. Added additional clinical rules section. Updated references.