

### Clinical Pharmacy Program Guideline for Alinia

Program	Prior Authorization
Medication	Alinia (nitazoxanide)
Pharmacy & Therapeutics Approval Date	10/2016
Effective Date	1/2017

**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*. Alinia oral suspension and tablets have not been shown to be superior to placebo for the treatment of diarrhea caused by *Cryptosporidium parvum* in HIV-infected or immunodeficient patients.

**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> <ul style="list-style-type: none"> <li>a. Diagnosis of giardiasis</li> <li style="text-align: center;"><b>-AND-</b></li> <li>b. Patient is immunocompetent and is not infected with HIV</li> <li style="text-align: center;"><b>-AND-</b></li> <li>c. History of failure, contraindication, or intolerance to metronidazole</li> </ul> <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 all of the following:</p> <ul style="list-style-type: none"> <li>a. Diagnosis of cryptosporidiosis</li> <li style="text-align: center;"><b>-AND-</b></li> <li>b. Patient is immunocompetent and is not infected with HIV</li> </ul> <p><b>Authorization will be issued for 3 days.</b></p>
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Drug Name	Description
Alinia [1] - Diarrhea caused by Giardia lamblia or Cryptosporidium parvum	(1) 1-3 years: 5mL of Alinia for Oral Suspension (100mg nitazoxanide) every 12 hours with food for 3 days; (2) 4-11 years: 10mL of Alinia for Oral Suspension (200mg nitazoxanide) every 12 hours with food for 3 days; (3) greater than or equal to 12 years: 1 Alinia Tablet (500 mg nitazoxanide) every 12 hours with food or 25 mL of Alinia for Oral Suspension (500 mg nitazoxanide) every 12 hours with food for 3 days

**3. References:**

1. Alinia [Prescribing Information]. Tampa, FL: Romark Pharmaceuticals; October 2007.
2. Rossignol J, Ayoub A, Ayers M. Treatment of diarrhea caused by Cryptosporidium parvum: a prospective randomized, double-blind, placebo-controlled study of nitazoxanide. J Infect Dis. 2001;184:103-106.
3. Ortiz J, Ayoub A, Gargala G, Chegne N, Favennec L. Randomized clinical study of nitazoxanide compared to metronidazole in the treatment of symptomatic giardiasis in children from Northern Peru. Aliment Pharmacol Ther. 2001;15:1409-1415.
4. Centers for Disease Control and Prevention, Division of Parasitic Diseases. Laboratory Identification of Parasitic Diseases of Public Health Concern: Giardiasis 2009. Available at: <http://www.dpd.cdc.gov/dpdx/HTML/Giardiasis.htm>. Accessed January 5, 2011.
5. Centers for Disease Control and Prevention, Division of Parasitic Diseases. Laboratory Identification of Parasitic Diseases of Public Health Concern: Cryptosporidiosis 2009. Available at: <http://www.dpd.cdc.gov/dpdx/HTML/Cryptosporidiosis.htm>. Accessed January 5, 2011.
6. Guerrant R, Van Gilder T, Steiner T, et al. Practice guidelines for the management of infectious diarrhea. Clin Infect Dis. 2001;32:331-50.
7. The Medical Letter. Drugs for Parasitic Infections. The Medical Letter 2004 August;(1189):1-12.

Program	Prior Authorization –Alinia (nitazoxanide)
<b>Change Control</b>	
Date	Change
Dec 2013	New guideline
Dec 2015	Annual review, no change
Oct 2016	Annual review, updated policy template