

Clinical Pharmacy Program Guidelines for Alinia

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| Program | Prior Authorization |
| Medication | Alinia (nitazoxanide) |
| Issue Date | 12/2013 |
| Pharmacy and Therapeutics Approval Date | 11/2017 |
| Effective Date | 1/2018 |

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:

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| <p>A. <u>Diarrhea caused by <i>Giardia lamblia</i></u></p> <p>1. Alinia 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;">-AND-</p> <p style="margin-left: 40px;">b. Patient is immunocompetent and is not infected with HIV</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 40px;">c. History of failure, contraindication, or intolerance to metronidazole</p> <p>Authorization will be issued for 3 days.</p> <p>B. <u>Diarrhea caused by <i>Cryptosporidium parvum</i></u></p> <p>1. Alinia will be approved based on all of the following:</p> <p style="margin-left: 40px;">a. Diagnosis of cryptosporidiosis</p> <p style="text-align: center;">-AND-</p> |
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b. Patient is immunocompetent and is not infected with HIV

Authorization will be issued for 3 days.

3. References:

1. Alinia [Prescribing Information]. Tampa, FL: Romark Pharmaceuticals; April 2017.
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.

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| Program | Prior Authorization –Alinia (nitazoxanide) |
| Change Control | |
| Date | Change |
| 12/2013 | New guideline |
| 12/2015 | Annual review, no change |

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| 10/2016 | Annual review, updated policy template |
| 11/2017 | Removed dosing table. Updated references. |