

Antiparasitics : Antiprotozoal Agents – nitazoxanide (Alinia®)

Medical policy no. 16.40.00.60

Effective Date: July 1, 2019

Background:

Nitazoxanide is an antiprotozoal that is indicated for parasitic gastrointestinal infections. Parasitic infections can cause gastroenteritis, an inflammation of the gastrointestinal tract involving both the stomach and the small intestine. Symptoms include diarrhea, vomiting, and abdominal pain.

Medical necessity

Drug	Medical Necessity
nitazoxanide (Alinia®)	Nitazoxanide may be considered medically necessary for the treatment of infectious diarrhea caused by: <ol style="list-style-type: none"> 1. <i>Giardia lamblia</i>; OR 2. <i>Cryptosporidium parvum</i>

Clinical policy:

Clinical Criteria
<ol style="list-style-type: none"> 1. Patient has a diagnosis of infectious diarrhea caused by ONE of the following: <ol style="list-style-type: none"> a. <i>Giardia lamblia</i>; <ol style="list-style-type: none"> i. Patient has failed prior treatment with metronidazole for this episode (defined as no improvement or resolution of symptoms 5 days after completing regimen) or has contraindication to, intolerance to, or culture/sensitivity testing showing antibiotic resistance to metronidazole; OR b. <i>Cryptosporidium parvum</i>; <ol style="list-style-type: none"> i. Patients must not be immunodeficient or infected with HIV; AND 2. Maximum dose as follows: <ol style="list-style-type: none"> a. Patient greater than or equal to 1 year of age but less than 4 years of age <ol style="list-style-type: none"> i. Dose is less than or equal to 200 mg per day for 3 days b. Patient is greater than or equal to 4 years of age but less than 12 years of age <ol style="list-style-type: none"> i. Dose is less than or equal to 400 mg per day for 3 days c. Patient is greater than or equal to 12 years of age <ol style="list-style-type: none"> i. Dose is less than or equal to 1,000 mg per day for 3 days <p>If ALL criteria are met, the request will be approved for a 3-day supply.</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Nitazoxanide (Alinia®)	<p>≥ 1yo: ≤ 200mg/day x3 days</p> <p>≥ 4yo: ≤ 400mg/day x3 days</p> <p>≥ 12yo: ≤ 1000mg/day x3 days</p>

References

1. Alinia tablets and oral suspension (nitazoxanide) [prescribing information]. Tampa, FL: Romark Lc; April 2017.
2. HHS Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. September 2015. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed October 8, 2015
3. Available at: <http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-3-infectious-diseases-related-to-travel/amebiasis.htm>. Accessed January 24, 2017.
4. Giardia. Available at: <http://www.cdc.gov/parasites/giardia/index.html>. Accessed January 24, 2017.
5. BBB-Cryptosporidium parvum. Available at: <http://www.fda.gov/Food/FoodbornellnessContaminants/CausesOfIllnessBadBugBook/default.htm>. Accessed January 24, 2017.
6. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2016/the-pre-travel-consultation/travelers-diarrhea>. Accessed January 24, 2017.

History

Date	Action and Summary of Changes
05.03.2019	New Policy