**FDA APPROVED INDICATIONS AND DOSAGE**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alinia®</strong> (nitazoxanide)</td>
<td>Treatment of diarrhea caused by <em>Giardia lamblia</em> or <em>Cryptosporidium parvum</em></td>
<td>Tablets should not be administered to pediatric patients 11 years of age or younger because a single tablet contains a greater amount of nitazoxanide than the recommended dosing in this pediatric age group.</td>
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<tr>
<td><strong>Tablet, suspension</strong></td>
<td></td>
<td><strong>Age</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1-3 years</strong></td>
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<tr>
<td></td>
<td></td>
<td><strong>4-11 years</strong></td>
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<td></td>
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<td><strong>12 years and older</strong></td>
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**CLINICAL RATIONALE**

IBM Micromedex lists the following non-FDA approved uses with a Class IIa Strength of Recommendation (treatment is generally considered to be useful, and is indicated in most cases) or higher:

- Infection by Fasciola in adults (IIa): Nitazoxanide appeared to be well tolerated and effective when used in the treatment of human fascioliasis, in an open-label study. Adult patients received an oral regimen of nitazoxanide 500 mg twice daily for 6 consecutive days.  
- General intestinal parasitism in adults and pediatrics (IIa): A 3-day course of nitazoxanide (NTZ) 500 mg twice daily was a safe and effective treatment for diarrhea associated with infection by the intestinal parasites *Giardia intestinalis*, *Entamoeba histolytica* or *Entamoeba dispar*. Results of a large field study in Egypt indicate that nitazoxanide is safe and effective for treating intestinal protozoan and helminthic infections. Patients took medication with food at 12-hour intervals over 3 days; those older than 12 years received 500 mg of nitazoxanide, children aged 4 to 11 years received 200 mg of drug, and children aged 1 to 3 years received 5 mL of a 100 mg per 5-mL suspension. Nitazoxanide and metronidazole have been similarly effective in treating symptomatic intestinal giardiasis in children.

**SAFETY**

Nitazoxanide has no black box warnings and has hypersensitivity as a contraindication.
REFERENCES
Alinia Quantity Limit

TARGET AGENT
Alinia® (nitazoxanide)

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity Limit per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alinia (nitazoxanide)</td>
<td>16400060000330</td>
<td>M, N, O, or Y</td>
<td>12 tablets</td>
</tr>
<tr>
<td>500 mg tablet</td>
<td>16400060001920</td>
<td>M, N, O, or Y</td>
<td>300 mL</td>
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</table>

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Quantities above the program quantity limit for the Target Agent will be approved when ALL of the following are met:

1. The patient has ONE of the following diagnoses:
   a. Diarrhea caused by Giardia lamblia or Cryptosporidium parvum
   OR
   b. Adult with Fasciola infection
   OR
   c. General intestinal parasitism

AND

2. ONE of the following:
   a. The patient has been re-infected AND requires an additional course of therapy
      AND ONE of the following:
      i. The requested quantity (dose) is less than or equal to the following:
         1. For diarrhea caused by Giardia lamblia or Cryptosporidium parvum, 3000 mg over 3 days
         OR
         2. For adults with Fasciola infection, 6000 mg over 6 days
         OR
         3. For general intestinal parasitism, 3000 mg over 3 days
      OR
      ii. The prescriber has provided information in support of therapy with a higher dose and/or duration for the requested indication
      OR
   b. The patient is seeking a higher dose and/or duration of therapy for the same infection AND the prescriber has provided information in support of therapy with a higher dose and/or duration for the requested indication

Length of Approval: up to 3 months