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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td>nitazoxanide (Alinia®)</td>
<td>Nitazoxanide may be considered medically necessary for the treatment of infectious diarrhea caused by:</td>
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<tr>
<td></td>
<td>1. <em>Giardia lamblia</em>; <strong>OR</strong></td>
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<td>2. <em>Cryptosporidium parvum</em></td>
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Clinical policy:

**Clinical Criteria**

1. Patient has a diagnosis of infectious diarrhea caused by ONE of the following:
   a. *Giardia lamblia*;
      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. *Cryptosporidium parvum*;
      i. Patients must not be immunodeficient or infected with HIV; **AND**

2. Maximum dose as follows:
   a. Patient greater than or equal to 1 year of age but less than 4 years of age
      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
      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
      i. Dose is less than or equal to 1,000 mg per day for 3 days

If ALL criteria are met, the request will be approved for a 3-day supply.
Dosage and quantity limits

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

References

1. Alinia tablets and oral suspension (nitazoxanide) [prescribing information]. Tampa, FL: Romark Lc; April 2017.

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action and Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.03.2019</td>
<td>New Policy</td>
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