Alinia (nitazoxanide) Post-Limit Prior Authorization Policy

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Alinia (nitazoxanide) Post-Limit Prior Authorization policy is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization and cost. Requests for Alinia (nitazoxanide) above the initial quantity limit and duration may be approved only when the member's medical condition justifies a longer treatment course as recommended by an infectious disease specialist.

FDA-Approved Indication

- Treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum.

Compendial Use

- Treatment of clostridioides difficile infection in adults.
- Treatment of human fascioliasis.

POLICY

Quantity Limit Exception Criteria

I. Additional quantities of Alinia (nitazoxanide) above the set quantity limit may be considered **medically necessary** when ONE of the following criteria are met:
   - The requested medication is being prescribed by an Infectious Disease Specialist
   - The requested medication is being prescribed in consultation with an Infectious Disease Specialist AND the member's medical condition justifies a longer treatment course as documented and supported by the infectious disease consult

Approval will be for 12 months.

Quantity Limits
Alinia Tablets: 20 tablets per 10-day treatment course.
Alinia Oral Suspension (100 mg/5mL): 540 mL (9 bottles) per 10-day treatment course.

Quantities above 20 tablets or 540 mL (9 bottles) per 10-day treatment course are allowed when the Quantity Limit Exception criteria is met.

CLINICAL RATIONALE

Alinia for Oral Suspension (patients 1 year of age and older) and Alinia Tablets (patients 12 years and older) are indicated for the treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum. Alinia for Oral Suspension and Alinia Tablets have not been shown to be effective for the treatment of diarrhea caused by Cryptosporidium parvum in HIV-infected or immunodeficient patients.

A single Alinia Tablet contains a greater amount of nitazoxanide than is recommended for pediatric dosing and should not be used in pediatric patients aged 11 years or younger. Alinia for Oral Suspension should be used for dosing nitazoxanide in pediatric patients. Safety and effectiveness of Alinia for Oral Suspension in pediatric patients less than one year of age have not been studied. The dosage of Alinia Oral Suspension (patients 1 year of age and older) is age dependent: 100 mg (5 mL) every 12 hours for three days for patients age 1-3 years, or 200 mg (10 mL) every 12 hours for three days for patients age 4-11 years. For patients age 12 years and older, the dosage of Alinia Tablets is 500 mg (1 tablet) every 12 hours for three days or 25 mL (500 mg) of Alinia Oral Suspension every 12 hours for 3 days.

The compendium states that evidence favors efficacy for Alinia used in the treatment of human fascioliasis. An open label study cites nitazoxanide appeared to be well-tolerated and effective when used in the treatment of human fascioliasis in adults (n=118) and children (n=7) .2 The Centers for Disease Control and Prevention (CDC) website states on the basis of limited data nitazoxanide might be effective therapy, and recommends the dosage regimen for adults is 500 mg twice a day for 7 days.

Also, the compendium states that evidence favors efficacy for Alinia in the treatment of adults with Clostridium difficile colitis. In a comparative double-blind trial, nitazoxanide was at least as effective as metronidazole in the treatment of patients (n=142) with Clostridium difficile colitis. In a multicenter, double-blind trial (n=49), noninferiority of nitazoxanide to vancomycin for the treatment of Clostridium difficile colitis was not established. Nitazoxanide demonstrated efficacy in patients with Clostridium difficile colitis who had failed oral metronidazole and/or vancomycin in an open-label trial (n=35). The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) guidelines for Clostridium difficile infection (CDI) in adults states that other potential options for treatment include alternative antimicrobial agents, such as nitazoxanide. The dosage of nitazoxanide indicated is 500 mg every 12 hours for 7 to 10 days.

Alinia is available as a 500mg tablet and as an oral suspension (100mg/5mL) in bottles of 60 mL. The reconstituted suspension must be used within 7 days. The initial limits are quantities sufficient for 10 days, taking into consideration available package sizes.

If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that quantity limits are exceeded and prior authorization is required.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.

- Code(s), if applicable

REFERENCES

- Alinia tablets and oral suspension (nitazoxanide) [prescribing information]. Tampa, FL: Romark LC; January 2022.
- Centers for Disease Control. https://www.cdc.gov/parasites/fasciola/health_professionals/index.html. Accessed on September 29, 2021.
- L Clifford McDonald, Dale N Gerding, Stuart Johnson, Johan S Bakken, Karen C Carroll, Susan E Coffin, Erik R Dubberke, Kevin W Garey, Carolyn V Gould, Ciaran Kelly, Vivian Loo, Julia Shaklee Sammons, Thomas J Sandora, Mark H Wilcox; Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 19 March 2018, Pages e1–48, https://doi.org/10.1093/cid/cix1085

*Some content reprinted from CVSHealth

POLICY HISTORY

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