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.
- Treatment of Cryptosporidium in children with HIV when used in combination with antiretroviral therapy (ART)

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. Per FDA labeling, 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 reconstituted suspension must be used within 7 days. Alinia for Oral Suspension is available as bottles of 60 mL.

The Centers for Disease Control and Prevention (CDC) website states on the basis of limited data nitazoxanide might be effective therapy in the treatment of human fascioliasis, and recommends the dosage regimen for adults is 500 mg twice a day for 7 days. This recommendation is based on an open label study where nitazoxanide appeared to be well-tolerated and effective when used in the treatment of human fascioliasis in adults (n=118) and children (n=7).

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. This recommendation is based on three studies. 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).

Per the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children, nitazoxanide, in addition to antiretroviral therapy (ART), can be considered for cryptosporidiosis in children with HIV (strong, moderate recommendation). The Guidelines for the

Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV state that other than ART, there is no consistently effective therapy to treat cryptosporidiosis in patients with HIV infection. However, the guidelines also state that the use of nitazoxanide should be considered in immunocompromised children with HIV infection (in conjunction with ART for immune restoration), given the seriousness of this infection in immunocompromised individuals and the potential benefit suggested in some studies. The duration of treatment in patients with HIV is uncertain.

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; April 2017.
- Centers for Disease Control. https://www.cdc.gov/parasites/fasciola/health_professionals/index.html. Accessed on April 28, 2020.
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- Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for th prevention and treatment of opportunistic infections in adults and adolescents with HIV: 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. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed on April 28, 2020.
- Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/oi_guidelines_pediatrics.pdf. Accessed on April 28, 2020.

*Some content reprinted from CVSHealth

POLICY HISTORY

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