

CA-ADAP Formulary Review: NITAZOXANIDE (ALINIA)

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CA-ADAP Formulary Review: AGENDA

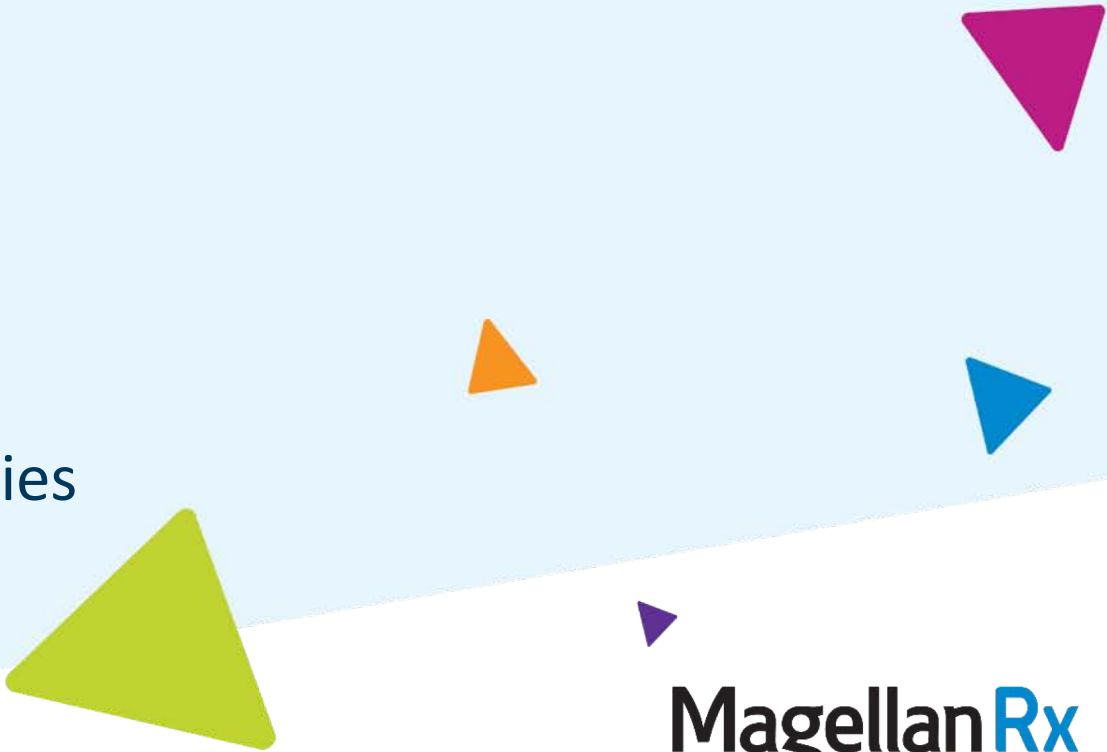
1 Disease Characteristics

2 Medications

3 Claims data

4 Other ADAP formularies

5 Recommendations





NITAZOXANIDE (ALINIA)

CRYPTOSPORIDIOSIS ('Crypto')



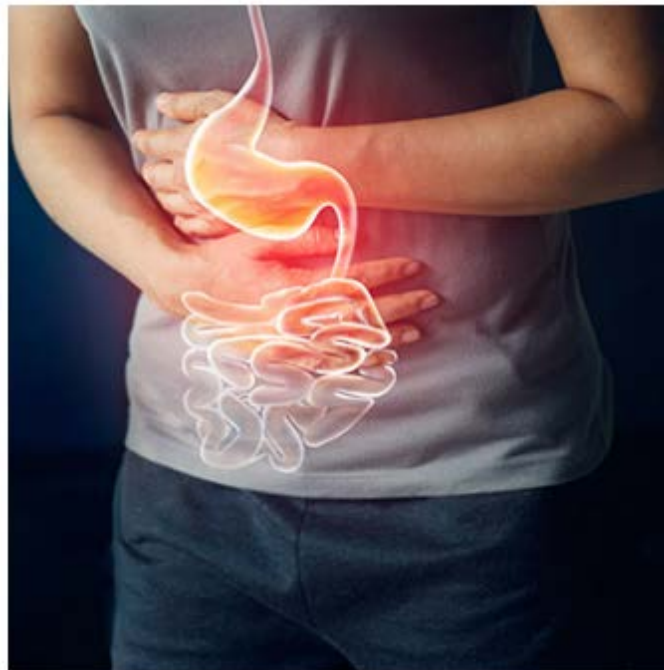
- Affects the small bowel mucosa
- Caused by the parasite *Cryptosporidium*
 - Outer shell allows it to survive outside the body for long periods of time
 - Makes it very tolerant to chlorine disinfection
- Diarrhea, vomiting, and weight loss are the most common symptoms
- Ingesting stool-tainted food or water is most common method of transmission
- Leading cause of waterborne disease among humans in the US



CRYPTO and PLWHIV



- <1 case per 1,000 person-years in US
- Can be serious, long-lasting, and sometimes fatal
- CD4+<200 more likely to cause severe symptoms and complications
- CD4+>200 may have no symptoms but still carry the parasite
 - Person-to-person transmission common, especially among MSM



TREATMENT of CRYPTOSPORIDIOSIS



- Most people w/**healthy immune systems** will recover without treatment
 - Drink fluids to avoid dehydration
 - Anti-diarrheal medicine may slow diarrhea
 - **Nitazoxanide** is approved for the treatment of diarrhea caused by *Cryptosporidium parvum* and *Giardia lamblia*
 - **Nitazoxanide is not indicated for use in HIV-infected or immunodeficient patients**
 - People w/HIV not taking ART should initiate ART to achieve immune restoration to CD4>100

Crypto Treatment: Nitazoxanide



- An antiprotozoal indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*
- Has not been shown to be effective in HIV-infected patients
- Oral suspension indicated for age 1+

Dosage 12 years and older	UNIQUE Denials Nov 2022 – Apr 2023	AZ	CT	FL	NY	TX	WA
500mg every 12 hours with food x 3 days	None	Y	-	-	-	-	-

Off-Label Recommendations



- Both drugs currently on ADAP formulary

Drug Name	Comments
CLARITHROMYCIN (BIAXIN)	<ul style="list-style-type: none">• Drug <i>may</i> have activity against <i>Cryptosporidium parvum</i>
PAROMOMYCIN (HUMATIN)	<ul style="list-style-type: none">• Drug <i>may</i> have activity against <i>Cryptosporidium parvum</i>• Has specific off-label dosing for PLWHIV

Formulary Management Recommendations:

NITAZOXANIDE



1

NITAZOXANIDE

Consider addition to the ADAP formulary.

References



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- Rossignol JF. Nitazoxanide in the treatment of acquired immune deficiency syndrome-related cryptosporidiosis: results of the United States compassionate use program in 365 patients. *Aliment Pharmacol Ther.* 2006 Sep 1;24(5):887-94. doi: 10.1111/j.1365-2036.2006.03033.x. PMID: 16918894.
- Rossignol JF, Hidalgo H, Feregrino M, Higuera F, Gomez WH, Romero JL, Padierna J, Geyne A, Ayers MS. A double-'blind' placebo-controlled study of nitazoxanide in the treatment of cryptosporidial diarrhoea in AIDS patients in Mexico. *Trans R Soc Trop Med Hyg.* 1998 Nov-Dec;92(6):663-6. doi: 10.1016/s0035-9203(98)90804-5. PMID: 10326116.

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