



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Infectious Disease – Antiparasitics Drug Quantity Management Policy – Per Days
- albendazole tablets – generic only
  - Alinia® (nitazoxanide tablets, suspension – Romark, generic for tablets only)
  - Arakoda™ (tafenoquine tablets – Sixty Degrees)
  - Benznidazole tablets – Exeltis
  - Coartem® (artemether/lumefantrine tablets – Novartis)
  - Emverm™ (mebendazole chewable tablets – Amedra)
  - Impavido® (miltefosine capsules – Profounda)
  - Krintafel (tafenoquine tablets – GlaxoSmithKline)
  - Lampit® (nifurtimox tablets – Bayer HealthCare)
  - Malarone and Malarone Pediatric (atovaquone/proguanil tablets – GlaxoSmithKline, generic)
  - mefloquine tablets – generic only
  - primaquine phosphate tablets – generic only
  - Qualaquin® (quinine sulfate capsules – Sun, generic)
  - Stromectol® (ivermectin tablets – Merck, generic)
  - tinidazole tablets – generic only

**REVIEW DATE:** 05/31/2023

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## **CIGNA NATIONAL FORMULARY COVERAGE:**

### **OVERVIEW**

The antiparasitic agents are used in the treatment of various parasitic infections. Drug selection, dose, and duration for treatment and/or prophylaxis are dependent upon the parasite. Table 1 provides drug-specific indications.

**Table 1. Antiparasitic Agents Indications.**<sup>1-6, 8-13, 15,16</sup>

Medication	Indication(s)
Albendazole tablets	<ul style="list-style-type: none"> <li>Hydatid Disease caused by <i>Echinococcus granulosus</i></li> <li>Neurocysticercosis caused by <i>Taenia solium</i></li> </ul>
Alinia (nitazoxanide tablets [generic], suspension)	Diarrhea caused by: <ul style="list-style-type: none"> <li><i>Giardia lamblia</i></li> <li><i>Cryptosporidium parvum</i></li> </ul>
Arakoda (tafenoquine tablets)	Prophylaxis of Malaria
Benznidazole tablets	Chagas disease (American trypanosomiasis) caused by <i>Trypanosoma cruzi</i> in patients 2 to 12 years of age.
Coartem (artemether/lumefantrine tablets)	<ul style="list-style-type: none"> <li>Malaria infections caused by <i>Plasmodium falciparum</i></li> </ul>
Emverm (mebendazole chewable tablets)	Gastrointestinal infections caused by: <ul style="list-style-type: none"> <li><i>Enterobius vermicularis</i> (pinworm)</li> <li><i>Trichuris trichiura</i> (whipworm)</li> <li><i>Ascaris lumbricoides</i> (common roundworm)</li> <li><i>Ancylostoma duodenale</i> (common hookworm)</li> <li><i>Necator americanus</i> (American hookworm)</li> </ul>
Impavido (miltefosine capsules)	<ul style="list-style-type: none"> <li>Visceral leishmaniasis caused by <i>Leishmania donovani</i></li> <li>Cutaneous leishmaniasis caused by <i>Leishmania braziliensis</i>, <i>Leishmania guyanensis</i>, <i>Leishmania panamensis</i></li> <li>Mucosal leishmaniasis caused by <i>Leishmania braziliensis</i></li> </ul>

**Table 1 (continued). Antiparasitic Agents Indications.**<sup>1-13, 15, 16</sup>

Medication	Indication(s)
Krintafel (tafenoquine tablets)	Radical cure of <i>Plasmodium vivax</i> malaria.
Lampit (nifurtimox tablets)	Chagas disease (American Trypanosomiasis), caused by <i>Trypanosoma cruzi</i> in patients < 18 years of age.
Malarone (atovaquone/proguanil tablets, generic)	<ul style="list-style-type: none"> <li>Prophylaxis of <i>Plasmodium falciparum</i> malaria</li> <li>Treatment of acute, uncomplicated <i>P. falciparum</i> malaria.</li> </ul>
Mefloquine tablets	<ul style="list-style-type: none"> <li>Treatment of acute, mild to moderate malaria caused by <i>Plasmodium falciparum</i> and <i>Plasmodium vivax</i>.</li> <li>Prophylaxis of <i>P. falciparum</i> or <i>P. vivax</i> malaria.</li> </ul>
Primaquine phosphate tablets	Radical cure (prevention of relapse) of malaria infections caused by <i>Plasmodium vivax</i> . The CDC also recognizes primaquine as prophylaxis of malaria for short-duration (not defined) travel to areas with principally <i>P. vivax</i> .
Qualaquin (quinine sulfate capsules, generic)	Treatment of uncomplicated malaria infections caused by <i>Plasmodium falciparum</i> .
Stromectol (ivermectin tablets, generic)	<ul style="list-style-type: none"> <li>Strongyloidiasis of the intestinal tract caused by <i>Strongyloides stercoralis</i></li> <li>Onchocerciasis caused by <i>Onchocerca volvulus</i></li> </ul>
tinidazole tablets	<ul style="list-style-type: none"> <li>Trichomoniasis caused by <i>Trichomonas vaginalis</i></li> <li>Giardiasis caused by <i>Giardia lamblia</i> or <i>Giardia duodenalis</i></li> <li>Amebiasis caused by <i>Entamoeba histolytica</i></li> <li>Bacterial vaginosis</li> </ul>

CDC – Centers for Disease Control and Prevention.

## Dosing

### Albendazole tablets

The dose of Albenza is based on the indication (Table 2).<sup>1</sup> Tablets may be crushed or chewed.

**Table 2. Albenza Dosing.**<sup>1</sup>

Indication	Patient Weight	Dose	Duration
Hydatid Disease	≥ 60 kg	400 mg BID	28-day cycle followed by a 14-day albendazole-free interval, for a total of 3 cycles
	< 60 kg	15 mg/kg/day given in divided doses twice daily (maximum total daily dose 800 mg)	
Neurocysticercosis	≥ 60 kg	400 mg BID	8 to 30 days
	< 60 kg	15 mg/kg/day given in divided doses twice daily (maximum total daily dose 800 mg)	

### Nitazoxanide tablets (Alinia, generic) and Alinia suspension

Alinia oral suspension is indicated for patients ≥ 1 year of age, while nitazoxanide tablets are indicated for patients ≥ 12 years of age.<sup>5</sup> For patients 1 to 3 years of age, the recommended dose of Alinia suspension is 5 mL (100 mg) every 12 hours (Q12H). For patients 4 to 11 years of age, the recommended dose of Alinia suspension is 10 mL (200 mg) Q12H. For patients ≥ 12 years of age the recommended dose is 500 mg Q12H, either as a nitazoxanide 500 mg tablet (Alinia, generic) or 25 mL (500 mg) of Alinia oral suspension. For all patients, the recommended duration of treatment is 3 days.

### Arakoda tablets

The recommended dosing for Arakoda is provided in Tables 3 and 4 below. Arakoda can be administered for up to 6 months of continuous dosing.<sup>15</sup>

**Table 3. Recommended Dosing for Arakoda.**<sup>15</sup>

Regimen	Timing	Dose
Loading	For each of the 3 days before travel to malarious area.	200 mg QD for 3 days.
Maintenance	While in malarious area.	200 mg QW started 7 days after the last loading dose.
Terminal prophylaxis	In the week following exit from malarious state,	200 mg taken one time, 7 days after the last maintenance dose.

QD – Once daily; QW – Once weekly.

### Benznidazole tablets

Benznidazole tablets are dosed by body weight (kg).<sup>2</sup> The recommended dose in pediatric patients (2 to 12 years of age), is 5 mg/kg/day to 8 mg/kg/day administered in two divided doses separated by approximately 12 hours, for a duration of 60 days. Although not indicated in adults, the Centers for Disease Control and Prevention (CDC) recognize some adults require treatment for Chagas disease and the dose is 5 mg/kg/day to 7 mg/kg/day in two divided doses for 60 days.<sup>23,24</sup>

**Table 5. Recommended Dosing of Benznidazole Tablets in Pediatric Patients 2 to 12 years of Age.**<sup>2</sup>

Body Weight Range	Dose	Number of 12.5 mg Tablets per Dose	Number of 100 mg Tablets	Duration and Frequency of Therapy
< 15 kg	50 mg	4 tablets	½ tablet	Administered twice daily approximately 12 hours apart for 60 days.
15 kg to < 20 kg	62.5 mg	5 tablets		
20 kg to < 30 kg	75 mg	6 tablets	¾ tablet	
30 kg to < 40 kg	100 mg		1 tablet	
40 kg to < 60 kg	150 mg		1 ½ tablets	
≥ 60 kg	200 mg		2 tablets	

### Coartem tablets

For all patients, a 3-day treatment schedule with a total of six doses is recommended.<sup>8</sup>

For adults (≥ 16 years of age) ≥ 35 kg the recommended dose is 4 tablets as an initial dose, then 4 tablets again after 8 hours, and then 4 tablets twice-daily (BID [morning and evening]) for the following 2 days (total course of 24 tablets).<sup>8</sup>

For pediatric patients weighing 5 kg to < 15 kg, the recommended dose is 1 tablet as an initial dose, 1 tablet again after 8 hours, and then 1 tablet BID (morning and evening) for the following 2 days (total course of 6 tablets). For pediatric patients weighing 15 kg to < 25 kg, the recommended dose is 2 tablets as an initial dose, then 2 tablets again after 8 hours and then 2 tablets BID (morning and evening) for the following 2 days (total course of 12 tablets). For pediatric patients weighing 25 kg to < 35 kg, the recommended dose is 3 tablets as an initial dose, then 3 tablets again after 8 hours and then 3 tablets BID (morning and evening) for the following 2 days (total course of 18 tablets). For pediatric patients weighing ≥ 35 kg, the recommended dose is 4 tablets as a single initial dose, then 4 tablets again after 8 hours, and then 4 tablets twice-daily (morning and evening) for the following 2 days (total course of 24 tablets).

For patients who are unable to swallow the tablets such as infants and children, the tablets may be crushed and mixed with a small amount of water (1 to 2 teaspoons) in a clean container for administration immediately prior to use.<sup>8</sup> In the event of vomiting within 1 to 2 hours after administration, a repeat dose should be taken. If the repeat dose is vomited, the patient should be given an alternative antimalarial for treatment.

### Emverm chewable tablets

The recommended dose for pinworm is 1 tablet one time.<sup>4</sup> For whipworm, roundworm, and hookworm, the recommended dose is 1 tablet BID (morning and evening) for 3 consecutive days. If the patient is not cured 3 weeks after treatment, a second course of treatment is advised.

### Impavido capsules

The recommended dose is 1 capsule (50 mg) BID for patients weighing 30 kg to 44 kg.<sup>9</sup> In patients weighing ≥ 45 kg the recommended dose is 1 capsule (50 mg) three times daily (TID). For all patients, the treatment duration is 28 days.

### Krintafel tablets

The recommended dose is a single, 300 mg dose administered (two 150-mg tablets taken together).<sup>16</sup> Tablets cannot be broken, crushed, or chewed. In the event of vomiting within 1 hour after dosing, a repeat dose should be given. Re-dosing should not be attempted more than once.

### Lampit tablets

The dose of Lampit is weight-based (Tables 6 and 7).<sup>16</sup> The recommended dose is taken TID for 60 days. The dose of Lampit is adjusted accordingly if body weight decreases during treatment. Tablets (30 mg and 120 mg tablets) are functionally scored and can be split into one-half (15 mg or 60 mg, respectively) at the scored lines by hand.

**Table 6. Total Daily Recommended Dose of Lampit Based on Body Weight.<sup>16</sup>**

Age	Body Weight Group	Total Daily Dose of Nifurtimox
Birth to < 18 years of age	≥ 41 kg	8 to 10 mg/kg
	< 41 kg	10 to 20 mg/kg

**Table 7. Individual Doses Based on Body Weight in Patients < 18 years of age.<sup>16</sup>**

Body Weight	Dose	Number of Lampit 30 mg Tablets/Day	Number of Lampit 120 mg Tablets/Day
2.5 kg to 4.5 kg	15 mg	1.5 tablets	--
4.6 kg to < 9 kg	30 mg	3 tablets	--
9 kg to < 13 kg	45 mg	4.5 tablets	--
13 kg to < 18 kg	60 mg	6 tablets	1.5 tablets
18 kg to < 22 kg	75 mg	7.5 tablets	--
22 kg to < 27 kg	90 mg	9 tablets	--
27 kg to < 35 kg	120 mg	12 tablets	3 tablets
35 kg to < 41 kg	180 mg	--	4.5 tablets
41 kg to < 51 kg	120 mg	--	3 tablets
51 kg to < 71 kg	180 mg	--	4.5 tablets
71 kg to < 91 kg	240 mg	--	6 tablets
≥ 91 kg	300 mg	--	7.5 tablets

### Atovaquone/proguanil tablets (Malarone, generic)

For the prevention of malaria, prophylactic therapy is started 1 or 2 days before entering a malaria endemic area and continued daily during the stay, and for 7 days after the return.<sup>10</sup> In adults, the dose is 1 tablet (250 mg/100 mg) per day. For pediatric patients, the dose is based on body weight (Table 8).

**Table 8. Dose for Prevention of Malaria in Pediatric Patients.<sup>10</sup>**

Body Weight	Total Daily Dose	Dose Regimen
10 to 20 kg	62.5 mg/25 mg	1 pediatric tablet QD
21 to 30 kg	125 mg/50 mg	2 pediatric tablets QD
31 to 40 kg	187.5 mg/75 mg	3 pediatric tablets QD
> 40 kg	250 mg/100 mg	1 adult strength tablet QD

QD – Once daily.

For the treatment of acute malaria, the recommended dose in adults is four tablets (adult strength) as a single daily dose (total daily dose 1 g atovaquone/400 mg

proguanil hydrochloride) for 3 consecutive days.<sup>10</sup> For pediatric patients, the dose is based on weight (Table 9); the duration of therapy is 3 consecutive days.

**Table 9. Dose for Treatment of Acute Malaria in Pediatric Patients.<sup>10</sup>**

<b>Weight</b>	<b>Total Daily Dose</b>	<b>Dose Regimen</b>
5 to 8 kg	125 mg/50 mg	2 pediatric tablets QD
9 to 10 kg	187.5 mg/75 mg	3 pediatric tablets QD
11 to 20 kg	250 mg/100 mg	1 adult strength tablet QD
21 to 30 kg	500 mg/200 mg	2 adult strength tablets QD
31 to 40 kg	750 mg/300 mg	3 adult strength tablets QD
> 40 kg	1 gram/400 mg	4 adult strength tablets QD

QD – Once daily.

For the prevention or treatment of malaria, in the event of vomiting within 1 hour after dosing, a repeat dose should be taken.<sup>10</sup>

#### Mefloquine tablets

For the treatment of malaria in adults, the recommended dose is 1,250 mg (5 tablets) as a single dose.<sup>11</sup> For the treatment of malaria in pediatric patients, the recommended dose is 20 to 25 mg/kg. The pediatric dose should not exceed the adult dose. Experience with mefloquine in pediatric patients weighing < 20 kg is limited. If a full-treatment course with mefloquine does not lead to improvement within 48 to 72 hours, mefloquine should not be used for retreatment. An alternative therapy should be used. Similarly, if previous prophylaxis with mefloquine has failed, mefloquine should not be used for curative treatment.

In pediatric patients, if a significant loss of drug product is observed or suspected because of vomiting, a second full dose of mefloquine should be administered to patients who vomit less than 30 minutes after receiving the drug.<sup>11</sup> If vomiting occurs 30 to 60 minutes after a dose, an additional half-dose should be given. If vomiting recurs, the patient should be monitored closely and alternative malaria treatment considered if improvement is not observed within a reasonable period of time.

For the prophylaxis of malaria in adults, the recommended dose is 250 mg (1 tablet) once weekly (QW).<sup>11</sup> In pediatric patients, the recommended dose for the prophylaxis of malaria is 5 mg/kg QW. In pediatric patients weighing > 45 kg, the dose is one 250 mg tablet QW, in pediatric patients weighing 30 to 45 kg the dose is three-quarters of a tablet QW, and in pediatric patients weighing 20 to 30 kg, the dose is one-half tablet QW. Prophylaxis should begin 1 week before arrival in an endemic area; the CDC cites prophylaxis can begin  $\geq$  2 weeks prior to arrival.<sup>28</sup> Subsequent weekly doses should be taken regularly, always on the same day of each week.<sup>11</sup> To reduce the risk of malaria after leaving an endemic area, prophylaxis must be continued for 4 additional weeks. In certain cases, such as when a traveler is taking other medication, it may be desirable to start prophylaxis 2 to 3 weeks prior to departure, in order to ensure that the combination of drugs is well tolerated. When prophylaxis with mefloquine fails, physicians should carefully evaluate which antimalarial to use for therapy.

#### Primaquine phosphate tablets

The FDA-approved dose for the radical cure of malaria is 1 tablet (26.3 mg) daily (QD) for 14 days.<sup>12</sup> Primaquine phosphate is recommended only following the termination of chloroquine phosphate suppressive therapy in an area where vivax malaria is endemic. The CDC recommends primaquine for its approved indication (radical cure) at a dose of 2 tablets (52.6 mg) daily for 14 days in adults or 0.8 mg/kg (not to exceed 52.6 mg/day) for 14 days.<sup>28</sup> The CDC also recommends primaquine for prophylaxis for short duration travel (duration not defined) to areas with principally *P. vivax*; the recommended dose is 52.6 mg daily (2 tablets) in adults and 0.8 mg/kg (not to exceed 52.6 mg) in pediatric patients started 1 to 2 days prior to travel, daily while in the malarious area, and daily for 7 days after return from travel.

Quinine sulfate capsules (Qualaquin, generic)

For treatment of uncomplicated malaria in adults, the recommended dose is 648 mg (2 capsules) every 8 hours (Q8H) for 7 days.<sup>13</sup> In patients with severe chronic renal impairment, the recommended dose is a loading dose of 648 mg (2 capsules) followed 12 hours later by maintenance doses of 324 mg (1 capsule) Q12H.

Ivermectin tablets (Stromectol, generic)

The recommended dose of Stromectol for the treatment of strongyloidiasis is a single oral dose designed to provide approximately 200 mcg/kg (Table 10).<sup>3</sup> The CDC also cites a two-dose regimen (200 mcg/kg/day for 2 days).<sup>18</sup>

**Table 10. Dosing for Ivermectin for Strongyloidiasis.<sup>3</sup>**

Body Weight	Single Oral Dose Number of 3 mg tablets
15 to 24 kg	1 tablet
25 to 35 kg	2 tablets
36 to 50 kg	3 tablets
51 to 65 kg	4 tablets
66 to 79 kg	5 tablets
≥ 80 kg	200 mcg/kg

The recommended dose for the treatment of onchocerciasis is a single oral dose designed to provide approximately 150 mcg/kg of body weight (Table 11).<sup>3</sup> In mass distribution campaigns in international treatment programs, the most commonly used dose interval is 12 months. For the treatment of individual patients, retreatment may be considered at intervals as short as 3 months.

**Table 11. Dosing for Stromectol for Onchocerciasis.<sup>3</sup>**

Body Weight	Single Oral Dose Number of 3 mg tablets
15 to 25 kg	1 tablet
26 to 44 kg	2 tablets
45 to 64 kg	3 tablets
65 to 84 kg	4 tablets
≥ 85 kg	150 mcg/kg

Tinidazole tablets

The recommended dose for trichomoniasis is 2 g as a single dose.<sup>6</sup> For the treatment of giardiasis in adults, the dose is 2 g as a single dose; in pediatric patients, the dose is 50 mg/kg (up to 2 g) as a single dose. For the treatment of intestinal amebiasis, the recommended dose in adults is a 2 g/day for 3 days. In pediatric patients the

recommended dose is 50 mg/kg/day (up to 2 g/day) for 3 days. For the treatment of amebic liver abscess, the recommended dose in adults is a 2 g/day for 3 to 5 days. In pediatric patients the recommended dose is 50 mg/kg/day (up to 2 g/day) for 3 to 5 days. There are limited pediatric data on durations of therapy exceeding 3 days, although a small number of children were treated for 5 days. For the treatment of bacterial vaginosis, the recommended dose in non-pregnant females is a 2 g/day for 2 days or a 1 g/day for 5 days. For those unable to swallow tablets, tinidazole tablets may be crushed in artificial cherry syrup; four 500 mg tablets can be pulverized and mixed with 10 mL of syrup (final volume of 30 mL).

## Availability

Medication	How Supplied
Albendazole tablets	200 mg tablets (bottles of 2 tablets)
Alinia (nitazoxamide tablets [generic], suspension)	500 mg tablets (bottles of 12 or 30 tablets; generic tablets are available in bottles of 6, 12, or 30 tablets) 100 mg/5 mL suspension (60 mL bottle)*
Arakoda (tafenoquine tablets)	100 mg tablets (1 box containing 16 tablets [8 tablets x 1 blister card, 2 blister cards per box])
Benznidazole tablets	12.5 mg tablets (bottles of 100 tablets) 100 mg tablets (bottles of 100 tablets) <u>Note:</u> 100 mg tablets are functionally scored and can be split into one-half (50 mg) or one-quarter (25 mg) to provide doses < 100 mg. 12.5 mg tablets and 100 mg can also be made into a slurry.
Coartem (artemether/lumefantrine tablets)	20 mg/120 mg tablets (bottles of 24 tablets)
Emverm (mebendazole chewable tablets)	100 mg chewable tablet (blister package of 1 tablet)
Impavido (miltefosine capsules)	50 mg capsules (1 carton containing 28 tablets [14 tablets x 1 blister card, 2 blister cards per box])
Krintafel (tafenoquine tablets)	150 mg tablets (unit dose bottle of 2 tablets)
Lampit (nifurtimox tablets)	30 mg tablets (bottles of 100 tablets) 120 mg tablets (bottles of 100 tablets)
Malarone Pediatric (atovaquone/proguanil tablets, generic)	62.5 mg/25 mg tablets (bottles of 100 tablets)
Malarone (atovaquone/proguanil tablets, generic)	250 mg/100 mg tablets (bottles of 100 tablets and unit dose pack of 24 tablets)
Mefloquine tablets	250 mg tablets (blister packs of 1, 10, or 25 tablets and bottles of 25 tablets)
Primaquine phosphate tablets	26.3 mg tablets (equivalent to 15 mg base) [bottles of 100 tablets]
Qualaquin (quinine sulfate capsules, generic)	324 mg capsules (bottles and blister packs of 30 capsules, blister packs of 20 capsules)
Stromectol (ivermectin tablets, generic)	3 mg tablet (blister card of 20 tablets)
tinidazole tablets	250 mg and 500 mg tablets (250 mg tablets in bottles of 20 and 40 tablets, 500 mg tablets in bottles of 12 and 20 tablets)

\* Reconstituted suspension can be stored for 7 days at room temperature, after which any unused portion must be discarded.



## POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of antiparasitic medications. If the Drug Quantity Management rule is not met for the requested product at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

### Drug Quantity Limits

Medication	Retail Maximum Quantity	Home Delivery Maximum Quantity
Albendazole 200 mg tablets	120 tablets per 30 days	360 tablets per 90 days
Alinia (nitazoxanide 500 mg tablets, generic)	12 tablets per 30 days	12 tablets per 30 days
Alinia (nitazoxanide 100 mg/5 ml suspension)	180 mL per 30 days	180 mL per 30 days
Arakoda (tafenoquine 100 mg tablets)	32 tablets per 180 days (maximum 16 tablets per dispensing)	32 tablets per 180 days (maximum 16 tablets per dispensing)
Benznidazole 12.5 mg tablets	720 tablets per 365 days (maximum of 360 tablets per dispensing)	720 tablets per 365 days (maximum of 360 tablets per dispensing)
Benznidazole 100 mg tablets (quantity provided is sufficient for a dose of 8 mg/kg/day for a patient weighing ≤ 150 kg. An exception is provided for patients weighing > 150 kg).	720 tablets per 365 days (maximum of 360 tablets per dispensing)	720 tablets per 365 days (maximum of 360 tablets per dispensing)
Coartem (artemether/lumefantrine 20 mg/120 mg tablets)	24 tablets per 30 days	72 tablets per 90 days
Emverm (mebendazole 100 mg chewable tablets)	6 tablets per 30 days	18 tablets per 90 days
Impavido (miltefosine 50 mg capsules)	84 capsules per 30 days	252 capsules per 90 days
Krintafel (tafenoquine 150 mg tablets)	2 tablets per 30 days	6 tablets per 90 days
Lampit (nifurtimox 30 mg tablets)	720 tablets per 180 days (maximum of 360 tablets per dispensing)	720 tablets per 180 days (maximum of 360 tablets per dispensing)
Lampit (nifurtimox 120 mg tablets)	540 tablets per 180 days (maximum of 270 tablets per dispensing)	540 tablets per 180 days (maximum of 270 tablets per dispensing)
Malarone Pediatric (atovaquone/proguanil 62.5 mg/25 mg tablets, generic)	180 tablets per 180 days (maximum of 90 tablets per dispensing)	180 tablets per 180 days (maximum of 90 tablets per dispensing)
Malarone (atovaquone/proguanil 250 mg/100 mg tablets, generic)	60 tablets per 180 days (maximum of 30 tablets per dispensing)	60 tablets per 180 days (maximum of 30 tablets per dispensing)
Mefloquine 250 mg tablets	13 tablets per 180 days (maximum 5 tablets per dispensing)	13 tablets per 180 days (maximum 5 tablets per dispensing)
Primaquine phosphate 26.3 mg tablets	120 tablets per 180 days	120 tablets per 180 days

Medication	Retail Maximum Quantity	Home Delivery Maximum Quantity
	(maximum 60 tablets per dispensing)	(maximum 60 tablets per dispensing)
Quaaluin (quinine sulfate 324 mg capsules, generic)	42 capsules per 30 days	126 capsules per 90 days
Stromectol (ivermectin 3 mg tablets, generic)	14 tablets per 30 days	42 tablets per 90 days
tinidazole 250 mg tablets	40 tablets per 30 days	120 tablets per 90 days
tinidazole 500 mg tablets	20 tablets per 30 days	60 tablets per 90 days

**Infectious Disease – Antiparasitics Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

### **CRITERIA**

#### Albendazole 200 mg tablets

1. If the request is for the treatment of Baylisascariasis, approve a one-time exception for a quantity sufficient to accommodate a dose of up to 50 mg/kg/day for up to 20 days at retail or home delivery.

Note: When suspicion of Baylisascariasis is high, immediate treatment with albendazole (25 to 50 mg/kg/day for 10 to 20 days) may be appropriate.<sup>20</sup>

2. If the request is for the treatment of Clonorchiasis, approve a one-time exception for a quantity sufficient to accommodate a dose of up to 10 mg/kg/day for 7 days at retail or home delivery.<sup>21</sup>

#### Nitazoxanide 500 mg tablets (Alinia, generic)

1. If the request is for the treatment of Cryptosporidiosis in an immunocompromised patient (e.g., transplant patients, patients with human immunodeficiency virus), approve a one-time exception for the requested quantity, not to exceed 56 tablets at retail or home delivery.

Note: This will allow for the recommended treatment of 500 mg to 1,000 mg two times daily for 14 days.<sup>22</sup>

#### Alinia 100 mg/5 mL suspension

1. If the request is for the treatment of Cryptosporidiosis in an immunocompromised patient (e.g., transplant patients, patients with human immunodeficiency virus), approve a one-time exception for the requested quantity, not to exceed 1,400 mL of suspension at retail or home delivery.

Note: This will allow for the recommended treatment of 500 mg to 1,000 mg two times daily for 14 days.<sup>22</sup>

#### Arakoda 100 mg tablets

1. If the patient needs prophylaxis for malaria for > 60 days, approve a one-time exception of a quantity sufficient to allow up to 2 tablets daily for 3 days prior to travel to the malaria endemic area (6 tablets), 2 tablets weekly during the stay in

the malaria endemic area (2 tablets/week), and 2 tablets taken one time 7 days after return (2 tablets) at retail or home delivery.

#### Benznidazole 12.5 mg tablets

1. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) since the last 60-day treatment, approve a one-time exception of up to 720 tablets as a 60-day supply at retail or home delivery.

#### Benznidazole 100 mg tablets

1. If the patient weighs > 150 kg, approve a one-time exception of a quantity sufficient to accommodate a dose of up to 8 mg/kg/day for 60 days at retail or home delivery.
2. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) since the last 60 day treatment, approve a one-time exception of up to 720 tablets as a 60 day supply at retail or home delivery.

#### Coartem 20 mg/120 mg tablets

No exceptions.

#### Emverm 100 mg chewable tablets

1. If the request is for the treatment of Capillariasis, approve a one-time exception of 80 tablets at retail or home delivery.  
Note: This will allow for the recommended treatment of 400 mg/day for 20 days.<sup>25</sup>
2. If the request is for the treatment of Trichinellosis, approve a one-time exception for the requested quantity, not to exceed 186 tablets at retail or home delivery.  
Note: This will allow for the recommended treatment of 200 mg to 400 mg three times daily for 3 days, then 400 mg to 500 mg three times daily for 10 days.<sup>26</sup>
3. If the request is for the treatment of Toxocariasis or Visceral Larva Migrants, approve a one-time exception of 20 tablets at retail or home delivery.  
Note: This will allow for the recommended treatment of 200 mg two times daily for 5 days.<sup>27</sup>

#### Impavido 50 mg capsules

No exceptions.

#### Krintafel 150 mg tablets

1. If the request is for a repeat dose in a patient who has vomited, approve a one-time exception of 2 tablets at retail or home delivery.

#### Lampit 30 mg tablets

1. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) since the last 60-day treatment, approve a one-time exception for the requested quantity, not to exceed 720 tablets as a 60-day supply at retail or home delivery.

#### Lampit 120 mg tablets

1. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) since the last 60-day treatment, approve a one-time exception

for the requested quantity, not to exceed 540 tablets as a 60-day supply at retail or home delivery.

Atovaquone/proguanil pediatric 62.5 mg/25 mg tablets (Malarone, generic)

1. If the patient weighs  $\leq$  40 kg and needs prophylaxis for malaria for > 60 days, approve a one-time exception of a quantity sufficient to allow up to 3 tablets daily for 2 days before entering a malaria endemic area (6 tablets), up to 3 tablets daily during the stay in the malaria endemic area (3 tablets/day), and 3 tablets daily for 7 days after return (21 tablets) at retail or home delivery.
2. If the request is for a repeat dose in a patient who has vomited, approve a one-time exception of up to 3 tablets at retail or home delivery.

Note: This allows for the maximum recommended daily dose for the prevention of malaria or for the treatment of acute malaria (3 tablets/day).

Atovaquone/proguanil 250 mg/100 mg tablets (Malarone, generic)

1. If the patient weighs > 40 kg and needs prophylaxis for malaria for > 60 days, approve a one-time exception of a quantity sufficient to allow up to 1 tablet daily for 2 days before entering a malaria endemic area (2 tablets), 1 tablet daily during the stay in the malaria endemic area (1 tablet/day), and 1 tablet daily for 7 days after return (7 tablets) at retail or home delivery.
2. If the request is for a repeat dose in a patient who has vomited, approve a one-time exception up to 4 tablets at retail or home delivery.

Note: This allows for the maximum recommended daily dose for the treatment of acute malaria (4 tablets per day).

Mefloquine 250 mg tablets

1. If the patient needs prophylaxis for malaria for > 60 days, approve a one-time exception of a quantity sufficient to allow 1 tablet weekly for 3 weeks before entering a malaria endemic area (3 tablets), 1 tablet weekly during the stay in the malaria endemic area (1 tablet/week), and 1 tablet weekly for 4 weeks after return (4 tablets) at retail or home delivery.
2. If the request is for a repeat dose in a patient who has vomited, approve a one-time exception of up to 5 tablets at retail or home delivery.

Note: This allows for the maximum recommended daily dose for the treatment of acute malaria (5 tablets per day).

Primaquine phosphate 26.3 mg tablets

1. If the patient needs prophylaxis for malaria for > 60 days, approve a one-time exception of a quantity sufficient to allow up to 2 tablets daily for 2 days before entering a malaria endemic area (4 tablets), 2 tablets daily during the stay in the malaria endemic area (2 tablets/day), and 2 tablets daily for 7 days after return (14 tablets) at retail or home delivery.

Quinine sulfate 324 mg capsules (Qualaquin, generic)

No exceptions.

Ivermectin 3 mg tablets (Stromectol, generic)

1. If the request is for the treatment of Trichuriasis caused by *Trichuris trichiura* (whipworm), approve a one-time exception of a quantity sufficient to accommodate a dose of 200 mcg/kg/day for 3 days at retail or home delivery.<sup>14</sup>
2. If the request is for pediculosis, approve a one-time exception of a quantity sufficient to accommodate a dose of up to 400 mcg/kg/day (1 dose) for two doses at retail or home delivery.  
Note: For the treatment of pediculosis, the CDC recommends ivermectin tablets be given in a single oral dose of 200 mcg/kg or 400 mcg/kg.<sup>17</sup> The dose may be repeated in 9 to 10 days.
3. If request is for the treatment of scabies, approve a one-time exception of a quantity sufficient to accommodate a dose of 200 mcg/kg/dose for up to 7 doses at retail or home delivery.  
Note: For classic scabies, the CDC recommends two doses of oral ivermectin (200 mcg/kg/dose) taken 1 week apart.<sup>7</sup> For crusted scabies, ivermectin 200 mcg/kg/dose should be taken in three doses (Days 1, 2, and 8), five doses (Days 1, 2, 8, 9, and 15), or seven doses (Days 1, 2, 8, 9, 15, 22, and 28).
4. If the request is for hyperinfection syndrome or disseminated strongyloidiasis, approve a one-time exception for a quantity sufficient to accommodate a dose of 200 mcg/kg/day until stool and/or sputum exams are negative for 2 weeks at retail or home delivery.<sup>18</sup>
5. If the patient weighs > 100 kg, approve a one-time exception of a quantity sufficient to accommodate a dose of 200 mcg/kg/day for 2 days at retail or home delivery.

#### Tinidazole 250 mg and 500 mg tablets

No exceptions.

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## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p><b>Moxidectin</b> was removed from the policy; the product is not available.</p> <p>Branded <b>Tindamax</b> was removed from the policy; the product is not available.</p> <p><b>Albendazole tablets (Albenza, generic):</b> For the treatment of Baylisacariasis, the one-time exception quantity was revised to accommodate a dose of up to 50 mg/kg/day (previously 37 mg/kg/day).</p> <p><b>Nitazoxamide tablets (Alinia, generic):</b> The maximum quantity per 30 days was changed to 12 tablets (previously 14 tablets); recommended dosing is up to 500 mg every 12 hours for 3 days (limit allows for two courses of treatment per 30 days). Exception criteria for immunocompromised patients</p>	05/18/2022

	<p>with Cryptosporidiosis was revised to approve up to 56 tablets per 30-day period (previously, 42 tablets per 30-day period).</p> <p><b>Alinia suspension:</b> Exception criteria for immunocompromised patients with Cryptosporidiosis was revised to approve up to 1,400 mL per 30-day period (previously, 1,080 mL per 30-day period).</p> <p><b>Arakoda tablets:</b> The maximum quantity was revised to 16 tablets/30 days (previously 10 tablets/30 days) and a total of 32 tablets/180 days (previously 20 tablets/180 days) to accommodate the loading dose (6 tablets), 1 month of maintenance (6 to 8 tablets), and the terminal dose (2 tablets). For patients needing prophylaxis therapy for &gt; 60 days, criteria were revised to add "prophylaxis for malaria" and to remove "or if the patient is initiating therapy".</p> <p><b>Emverm chewable tablets:</b> For the treatment of Trichinellosis exception criteria were revised to approve 186 tablets (previously 195 tablets). For Toxocariasis or Visceral Larva Migrants, exception criteria were revised to approve 20 tablets (previously 40 tablets).</p> <p><b>Krintafel:</b> One-time exception criteria were added for patients requesting a repeat dose after vomiting, 2 tablets are approved (previously, no exceptions were recommended).</p> <p><b>Atovaquone/proguanil pediatric (62.5 mg/25 mg) tablets (Malarone pediatric, generic):</b> For patients ≤ 40 kg needing prophylaxis for &gt; 60 days, criteria were revised to specify prophylaxis "for malaria". One-time exception criteria were added for patients requesting a repeat dose after vomiting, up to 3 tablets are approved.</p> <p><b>Atovaquone/proguanil (250 mg/100 mg) tablets (Malarone, generic):</b> For patients &gt; 40 kg needing prophylaxis for &gt; 60 days, criteria were revised to specify prophylaxis "for malaria". One-time exception criteria were added for patients requesting a repeat dose after vomiting, up to three tablets are approved.</p> <p><b>Mefloquine tablets:</b> For prophylaxis for &gt; 60 days, criteria were revised to specify prophylaxis "for malaria". One-time exception criteria were added for patients requesting a repeat dose after vomiting, up to five tablets are approved.</p> <p><b>Ivermectin tablets (Stromectol, generic):</b> For the treatment of pediculosis, the exception criteria were revised to approve a quantity sufficient to treat as a dose of up to 400 mcg/kg/day (one dose) for two doses (previously 200 mcg/kg/day for 3 days). For the treatment of scabies, exception criteria were revised to approve a quantity sufficient to accommodate a dose of 200 mcg/kg/dose for up to seven doses (previously a quantity sufficient to accommodate a dose of 200 mcg/kg/day for up to 5 days was approved).</p>	
Annual Revision	<p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p><b>Albedazole 200 mg tablets (Albenza, generic):</b> Brand Albenza removed from policy (obsolete for &gt; 3 years). Generics remain in policy.</p> <p><b>Alinia 100 mg/5 mL suspension):</b> Quantity limits changed to 180 mL per 30 days at retail or home delivery. Previously, quantity limits were 360 mL per 30 days at retail or 1,080 mL per 90 days at home delivery.</p>	05/31/2023

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