

## DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

- POLICY:** Infectious Disease – Antiparasitic Agents Drug Quantity Management Policy – Per Days
- Albenza® (albendazole 200 mg tablets – Impax, generic)
  - Alinia® (nitazoxanide 500 mg tablets, 100 mg/5 ml suspension – Romark Laboratories, generic for 500 mg tablets only)
  - Arakoda™ (tafenoquine 100 mg tablets – Sixty Degrees)
  - Benznidazole 12.5 mg, 100 mg tablets – Exeltis
  - Coartem® (artemether/lumefantrine – 20 mg/120 mg tablets – Novartis)
  - Emverm™ (mebendazole 100 mg chewable tablets – Amedra)
  - Impavido® (miltefosine 50 mg capsules – Profounda)
  - Krintafel (tafenoquine 150 mg tablets – GlaxoSmithKline)
  - Lampit® (nifurtimox 30 mg, 120 mg tablets – Bayer HealthCare)
  - Malarone (atovaquone/proguanil – 62.5 mg/25 mg, 250 mg/100 mg tablets – GlaxoSmithKline, generic)
  - mefloquine 250 mg tablets (generic only)
  - moxidectin 2 mg tablets (Medicines Development for Global Health)
  - primaquine phosphate 26.3 mg tablets (generic only)
  - Qualaquin® (quinine sulfate 324 mg capsules – Sun Pharmaceutical, generic)
  - Stromectol® (ivermectin 3 mg tablets – Merck, generic)
  - Tindamax® (tinidazole 250 mg, 500 mg tablets – Mission Pharmacal, generic)

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### 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>1-16,19</sup>

| Medication                                | Indication(s)  |
|---|--|
| Albenza (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, suspension | <ul style="list-style-type: none"> <li>• Giardiasis caused by <i>Giardia lamblia</i></li> <li>• Cryptosporidiosis caused by <i>Cryptosporidium parvum</i></li> </ul>   |
| Arakoda (tafenoquine) tablets             | Malaria infections caused by <i>Plasmodium falciparum</i> or <i>Plasmodium vivax</i>   |
| Benznidazole tablets                      | Chagas disease (American trypanosomiasis) caused by <i>Trypanosoma cruzi</i>   |
| 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     | <ul style="list-style-type: none"> <li>• Enterobiasis caused by <i>Enterobius vermicularis</i> (pinworm)</li> <li>• Trichuriasis caused by <i>Trichuris trichiura</i> (whipworm)</li> <li>• Ascariasis caused by <i>Ascaris lumbricoides</i> (common roundworm)</li> <li>• Ancylostomiasis caused by <i>Ancylostoma duodenale</i> (common hookworm)</li> <li>• Necatoriasis caused by <i>Necator americanus</i> (American hookworm)</li> </ul> |

**Table 1 (continued). Drug-Specific Indications.**<sup>1-16,19</sup>

| Medication                              | Indication(s)   |
|---|---|
| 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> |
| Krintafel (tafenoquine) tablets         | Malaria infections caused by <i>Plasmodium vivax</i>  |
| Lampit (nifurtimox) tablets             | Chagas disease (American Trypanosomiasis), caused by <i>Trypanosoma cruzi</i>   |
| Malarone (atovaquone/proguanil) tablets | Malaria infections caused by <i>Plasmodium falciparum</i>   |
| Mefloquine tablets                      | Malaria infections caused by <i>Plasmodium falciparum</i> and <i>Plasmodium vivax</i>   |
| Moxidectin tablets                      | Onchocerciasis due to <i>Onchocerca volvulus</i>  |
| Primaquine phosphate tablets            | Malaria infections caused by <i>Plasmodium vivax</i>  |
| Qualaquin (quinine sulfate) capsules    | Malaria infections caused by <i>Plasmodium falciparum</i>   |
| Stromectol (ivermectin) tablets         | <ul style="list-style-type: none"> <li>• Strongyloidiasis caused by <i>Strongyloides stercoralis</i></li> <li>• Onchocerciasis caused by <i>Onchocerca volvulus</i></li> </ul>  |
| Tindamax (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>  |

## POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of 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 30 days.

**Automation:** None.

## Drug Quantity Limits.

<sup>1-19</sup>

| Medication   | Quantity Limit for 30 day period  |
|--|---|
| Albenza (albendazole) 200 mg tablets                     | 120 tablets   |
| Alinia (nitazoxanide) 500 mg tablets                     | 14 tablets  |
| Alinia (nitazoxanide) 100 mg/5 ml suspension             | 360 ml  |
| Arakoda (tafenoquine) 100 mg tablets.                    | 10 tablets<br>A quantity of 20 tablets is allowed in the previous 180 days without prior authorization.   |
| Benznidazole 12.5 mg tablets.                            | 360 tablets<br>A quantity of 720 tablets is allowed in the previous 180 days without prior authorization. |
| Benznidazole 100 mg tablets – for patients up to 150 kg. | 360 tablets<br>A quantity of 720 tablets is allowed in the previous 180 days without prior authorization. |
| Coartem (artemether/lumefantrine) 20 mg/120 mg tablets   | 24 tablets  |
| Emverm (mebendazole) 100 mg chewable tablets             | 6 tablets   |
| Impavido (miltefosine) 50 mg capsules                    | 84 capsules   |
| Krintafel (tafenoquine) 150 mg tablets                   | 2 tablets   |
| Lampit (nifurtimox) 30 mg tablets.                       | 360 tablets<br>A quantity of 720 tablets is allowed in the previous 180 days without prior authorization. |
| Lampit (nifurtimox) 120 mg tablets                       | 270 tablets<br>A quantity of 540 tablets is allowed in the previous 180 days without prior authorization  |
| Malarone (atovaquone/proguanil) 62.5 mg/25 mg tablets    | 90 tablets<br>A quantity of 180 tablets is allowed in the previous 180 days without prior authorization   |

**Drug Quantity Limits (continued).<sup>1-19</sup>**

| Medication   | Quantity Limit for 30 day period  |
|--|---|
| Malarone (atovaquone/proguanil) 250 mg/100 mg tablets            | 30 tablets<br>A quantity of 60 tablets is allowed in the previous 180 days without prior authorization              |
| Mefloquine 250 mg tablets  | 5 tablets<br>A quantity of 13 tablets is allowed in the previous 180 days without prior authorization               |
| Moxidectin 2 mg tablets  | 4 tablets   |
| Primaquine phosphate 26.3 mg tablets.                            | 60 tablets<br>A quantity of 120 tablets is allowed in the previous 180 days is allowed without prior authorization. |
| Qualaquin (quinine sulfate) 324 mg capsules                      | 42 capsules   |
| Stromectol (ivermectin) 3 mg tablets – for patients up to 100 kg | 14 tablets  |
| Tindamax (tinidazole) 250 mg tablets                             | 40 tablets  |
| Tindamax (tinidazole) 500 mg tablets                             | 20 tablets  |

**CRITERIA**

Albenza (albendazole) 200 mg tablets<sup>1</sup>

1. If the patient is diagnosed with Baylisascariasis caused by *Baylisascaris procyonis*, approve a quantity sufficient to treat at a dose of up to 37 mg/kg/day for 20 days.
2. If the patient is diagnosed with Clonorchiasis caused by *Clonorchis sinensis*, approve a quantity sufficient to treat at a dose of up to 10 mg/kg/day for 7 days.

Alinia (nitazoxanide) 500 mg tablets (generics) or 100 mg/5 ml suspension<sup>5</sup>

1. If the patient is immunocompromised (e.g., transplant patients, HIV patients) and is diagnosed with Cryptosporidiosis caused by *Cryptosporidium* species, approve a total quantity of up to 42 tablets or 1,080 ml of suspension.

Note: This will allow for the recommended treatment of 500 mg two times daily for 21 days.

Arakoda (tafenoquine) 100 mg tablets<sup>15,17</sup>

1. If the patient needs prophylaxis therapy for > 60 days or if the patient is initiating therapy, approve a quantity sufficient to allow up to two tablets daily for 3 days as a loading dose, then two tablets weekly during the stay in the endemic area and for 1 week after return from the endemic area.

Benznidazole 12.5 mg tablets<sup>2</sup>

1. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* since the last 60 day treatment, approve an additional supply of up to 720 tablets (360 tablets/30 days).

Benznidazole 100 mg tablets<sup>2</sup>

1. If the patient weighs > 150 kg, approve a quantity sufficient to treat at a dose of up to 8 mg/kg/day for 60 days.
2. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* since the last 60 day treatment, approve an additional supply of up to 720 tablets (360 tablets/30 days).

Coartem (artemether/lumefantrine) 20 mg/120 mg tablets<sup>8</sup>

No overrides.

Emverm (mebendazole) 100 mg chewable tablets<sup>4</sup>

1. If the patient is diagnosed with Capillariasis caused by *Capillaria philippinensis*, approve a total quantity of 80 tablets.  
Note: This will allow for the recommended treatment of 400 mg/day for 20 days.
2. If the patient is diagnosed with Trichinellosis caused by *Trichinella spiralis* and other *Trichinella* species, approve a total quantity of 195 tablets.  
Note: This will allow for the recommended treatment of 500 mg three times daily for 13 days.
3. If the patient is diagnosed with Toxocariasis or Visceral Larva Migrans, approve a total quantity of 40 tablets.  
Note: This will allow for the recommended treatment of 400 mg two times daily for 5 days.

Impavido (miltefosine) 50 mg capsules<sup>9</sup>

No overrides.

Krintafel (tafenoquine) 150 mg tablets<sup>16,17</sup>

No overrides.

Lampit (nifurtimox) 30 mg tablets<sup>19</sup>

1. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* since the last 60 day treatment, approve an additional supply of up to 720 tablets (360 tablets/30 days).

Lampit (nifurtimox) 120 mg tablets<sup>19</sup>

1. If the patient is diagnosed with a new episode of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* since the last 60 day treatment, approve an additional supply of up to 540 tablets (270 tablets/30 days).

Malarone (atovaquone/proguanil) 62.5 mg/25 mg tablets<sup>10,17</sup>

1. If the patient weighs  $\leq 40$  kg and needs prophylaxis therapy for  $> 60$  days, approve a quantity sufficient to allow up to three tablets daily for a period that includes 2 days before entering a malaria endemic area and continue daily during the stay in the endemic area and for 7 days after return.

Malarone (atovaquone/proguanil) 250 mg/100 mg tablets<sup>10,17</sup>

1. If the patient weighs  $> 40$  kg and needs prophylaxis therapy for  $> 60$  days, approve a quantity sufficient to allow up to one tablet daily for a period that includes 2 days before entering a malaria endemic area and continue daily during the stay in the endemic area and for 7 days after return.

Mefloquine 250 mg tablets<sup>11,17</sup>

1. If the patient needs prophylaxis therapy for  $> 60$  days, approve a quantity sufficient to allow one tablet weekly for a period that includes 3 weeks before entering a malaria endemic area and continue weekly during the stay in the endemic area and for 4 weeks after return.

Moxidectin 2 mg tablets<sup>14</sup>

No overrides.

Primaquine phosphate 26.3 mg tablets<sup>12</sup>

1. If the patient needs prophylaxis therapy for  $> 60$  days, approve a quantity sufficient to allow up to two tablets daily for a period that includes 2 days before entering a malaria endemic area and continue daily during the stay in the endemic area and for 7 days after return.

Qualaquin (quinine sulfate) 324 mg capsules<sup>13</sup>

No overrides.

Stromectol (ivermectin) 3 mg tablets<sup>3,18</sup>

1. If the patient is diagnosed with Trichuriasis caused by *Trichuris trichiura* (whipworm), approve a quantity sufficient to treat at a dose of 200 mcg/kg/day for 3 days.
2. If the patient is diagnosed with pediculosis, approve a quantity sufficient to treat at a dose of 200 mcg/kg/day for 3 days.
3. If the patient is diagnosed with scabies, approve a quantity sufficient to treat at a dose of 200 mcg/kg/day for 5 days.
4. If the patient is diagnosed with hyperinfection syndrome or disseminated strongyloidiasis, approve a quantity sufficient to treat at a dose of 200 mcg/kg/day until stool and/or sputum exams are negative for 2 weeks.
5. If the patient weighs > 100 kg, approve a quantity sufficient to treat at a dose of 200 mcg/kg/day for 2 days.

Tindamax (tinidazole) 250 mg, 500 mg tablets<sup>6</sup>

No overrides.

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