Clinical Policy: Tafenoquine (Arakoda)
Reference Number: CP.PMN.178
Effective Date: 08.28.18
Last Review Date: 11.19
Line of Business: Commercial, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tafenoquine (Arakoda™) is an antimalarial.

FDA Approved Indication(s)
Arakoda is indicated for the prophylaxis of malaria in patients aged 18 years and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Arakoda is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Prophylaxis of Malaria (must meet all):
      1. Member is traveling to a malaria endemic area (see Appendix D);
      2. Age ≥ 18 years;
      3. Failure of one of the following, unless contraindicated, clinically significant adverse effects are experienced, or traveling to an area which has resistance to: atovaquone-proguanil, chloroquine, doxycycline, hydroxychloroquine, mefloquine, or primaquine;
      4. Dose does not exceed 200 mg (2 tablets) per day for 3 days, then once weekly starting 7 days after the last loading dose, then one-time terminal prophylaxis dose.

      Approval duration: 6 months or duration of travel in the malaria endemic area, whichever is less

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid.

II. Continued Therapy
   A. Prophylaxis of Malaria (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy as evidenced by absence of malarial infection;
3. If request is for a dose increase, new dose does not exceed 200 mg (2 tablets) once weekly, then one-time terminal prophylaxis dose.

Approval duration: up to 6 months or duration of travel in the malaria endemic area, whichever is less

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
P. vivax: Plasmodium vivax

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>atovaquone-proguanil</td>
<td><strong>Prophylaxis of malaria</strong></td>
<td>250 mg-100 mg/day; see</td>
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<tr>
<td>(Malarone™)</td>
<td>250 mg-100 mg atovaquone-proguanil</td>
<td>regimen</td>
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<tr>
<td></td>
<td>PO QD</td>
<td></td>
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<tr>
<td></td>
<td>Begin 1–2 days before travel to</td>
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<tr>
<td></td>
<td>malarias areas. Take daily at the</td>
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<tr>
<td></td>
<td>same time each day while in the</td>
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<tr>
<td></td>
<td>malarious area and for 7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>after leaving such areas.</td>
<td></td>
</tr>
<tr>
<td>chloroquine</td>
<td><strong>Prophylaxis of malaria</strong></td>
<td>500 mg/week; see regimen</td>
</tr>
<tr>
<td></td>
<td>500 mg PO once a week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Begin 1–2 weeks before travel to</td>
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</tr>
<tr>
<td></td>
<td>malarias areas. Take weekly on the</td>
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</tr>
<tr>
<td></td>
<td>same day of the week while in the</td>
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</tr>
<tr>
<td></td>
<td>malarious area and for 4 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>after leaving such area</td>
<td></td>
</tr>
<tr>
<td>Drug Name</td>
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</tbody>
</table>
| doxycycline (Oracea®, Acticlate®, Doryx®, Vibramycin®) | **Prophylaxis of malaria** 100 mg PO QD  
Begin 1–2 days before travel to malarious areas. Take daily at the same time each day while in the malarious area and for 4 weeks after leaving such areas. | 100 mg/day; see regimen |
| hydroxychloroquine (Plaquenil®) | **Prophylaxis of malaria** 400 mg PO once a week  
Begin 1–2 weeks before travel to malarious areas. Take weekly on the same day of the week while in the malarious area and for 4 weeks after leaving such areas. | 400 mg/week; see regimen |
| mefloquine                      | **Prophylaxis of malaria** 250 mg PO once a week  
Begin ≥ 2 weeks before travel to malarious areas. Take weekly on the same day of the week while in the malarious area and for 4 weeks after leaving such areas. | 250 mg/week; see regimen |
| primaquine*                     | **Prophylaxis of malaria** 52.6 mg PO QD  
Begin 1–2 days before travel to malarious areas. Take daily at the same time each day while in the malarious area and for 7 days after leaving such area. | 52.6 mg/day; see regimen |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

*Off-label

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - G6PD (glucose-6-phosphate dehydrogenase) deficiency or unknown G6PD status
  - Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown
  - Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of Krintafel/Arakoda

- Boxed warning(s): none reported
Appendix D: General Information

- The Centers for Disease Control and Prevention (CDC) presents country-specific information on malaria transmission and prophylaxis recommendations here: https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/yellow-fever-vaccine-and-malaria-prophylaxis-information-by-country. Updated information reflecting changes since publication can be found in the online version of this book (www.cdc.gov/yellowbook) and on the CDC Travelers’ Health website (www.cdc.gov/travel).

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Tafenoquine (Arakoda)</td>
<td>Loading dose: 200 mg PO QD for 3 days for each of the 3 days before travel to a malarious area</td>
<td>200 mg/dose</td>
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<td>Maintenance dose: 200 mg PO qweekly; start 7 days after the last loading dose while in the malarious area</td>
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<tr>
<td></td>
<td>Terminal prophylaxis: 200 mg PO once; give 7 days after the last maintenance dose in the week following exit from the malarious area</td>
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</tbody>
</table>

VI. Product Availability

Tablet: 100 mg

VII. References


Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.
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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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