

Clinical Policy Title:	tafenoquine
Policy Number:	RxA.345
Drug(s) Applied:	Arakoda™
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Tafenoquine (Arakoda™) is an antimalarial drug.

Tafenoquine is indicated for the prophylaxis of malaria in patients aged 18 years and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Tafenoquine (Arakoda™)	Prophylaxis of malaria	<p>Loading dose: 200 mg PO QD for 3 days for each of the 3 days before travel to a malarious area</p> <p>Maintenance dose: 200 mg PO once weekly; start 7 days after the last loading dose while in the malarious area</p> <p>Terminal prophylaxis: 200 mg PO one-time 7 days after the last maintenance dose in the week following exit from the malarious area</p>	200 mg/week

Dosage Forms

- Tablets: 100 mg

Clinical Policy

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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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 of age or older;
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

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Prophylaxis of Malaria (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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

Commercial: 6 months

Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

P. vivax: Plasmodium vivax

G6PD: glucose-6-phosphate dehydrogenase

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Atovaquone-proguanil (Malarone™)	<p>Prophylaxis of malaria 250 mg-100 mg atovaquone-proguanil PO QD</p> <p>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 areas.</p>	250 mg-100 mg/day; see regimen

chloroquine	<p>Prophylaxis of malaria 500 mg PO once a week</p> <p>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 area</p>	500 mg/week; see regimen
doxycycline (Oracea®, Acticlate®, Doryx®, Vibramycin®)	<p>Prophylaxis of malaria 100 mg PO QD</p> <p>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.</p>	100 mg/day; see regimen
hydroxychloroquine (Plaquenil®)	<p>Prophylaxis of malaria 400 mg PO once a week</p> <p>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.</p>	400 mg/week; see regimen
mefloquine	<p>Prophylaxis of malaria 250 mg PO once a week</p> <p>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.</p>	250 mg/week; see regimen
primaquine*	<p>Prophylaxis of malaria 52.6 mg PO QD</p> <p>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.</p>	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.
 - History of psychotic disorders or current psychotic symptoms.
 - Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of Arakoda™.
- Boxed warning(s):
 - None.

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/yellowfever-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).

References

1. Arakoda Prescribing Information. Washington, DC: Sixty Degrees Pharmaceuticals, LLC; August 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210607lbl.pdf. Accessed June 28, 2020.
2. The Centers for Disease Control and Prevention (CDC). Clinicians Treatment Guidelines for Malaria 2019. Available at <https://www.cdc.gov/malaria/resources/pdf/clinicalguidance.pdf>. Accessed June 28, 2020.
3. The World Health Organization (WHO). Guidelines for the Treatment of Malaria 2015, 3rd edition. Available at <https://www.ncbi.nlm.nih.gov/books/NBK294440/>. Accessed June 28, 2020.
4. FDA Briefing Document on Tafenoquine Tablet 150 mg. Meeting of the Antimicrobial Drugs Advisory Committee (AMDAC). July 12, 2018. Available at <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM612874.pdf>. Accessed June 28, 2020.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed June 28, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Dosing information updated. 2) Clinical policy (initial approval criteria) was updated. 3) Appendices updated. 4) References were updated.	06/28/2020	09/14/2020