Mass General Brigham
Health Plan

Antimalarials
Arakoda (tafenoquine)
artesunate
Coartem (artemether/lumefantrine)
Daraprim (pyrimethamine)
Qualaquin (quinine)
Effective 9/1/23

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

No PA	Drugs that require PA
chloroquine phosphate tablet Malarone® # (atovaquone/proguanil) mefloquine Mepron® # (atovaquone) Plaquenil® # (hydroxychloroquine) ‡ primaquine	Arakoda® (tafenoquine) † artesunate Coartem® (artemether/lumefantrine) >24 units/year Daraprim® (pyrimethamine)* Qualaquin® (quinine)*

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
* A-rated generic available, both brand and A-rated generic require PA
† Agent does not participate in the federal rebate program. Please see the Non-FDA and Non-rebate products guideline for more information.
‡ Brand name does not participate in the federal rebate program. Please see the Non-FDA and Non-rebate products guideline for more information. A-rated generic has rebate and does not require PA.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization will be granted when all the following criteria has been met:

Arakoda® (tafenoquine)
ALL of the following:
1. Appropriate diagnosis of malaria prophylaxis
2. Appropriate dose and frequency
3. Member is ≥18 years of age
4. **ONE** of the following:
    a. Inadequate response, adverse reaction or contraindication to **ALL** alternative agents whose manufacturers participate in the federal rebate program (e.g., atovaquone-proguanil, mefloquine, doxycycline, chloroquine, and primaquine)*
    b. Clinical rationale for the use of a drug whose manufacturer does not participate in the federal rebate program

***** *Recommended prophylactic regimen depends on which malaria endemic area the member is traveling to. A list of recommended prophylactic agents by travel area is available at https://www.cdc.gov/malaria/travelers/country_table/a.html*

Artesunate
ALL of the following:
1. Appropriate diagnosis of malaria treatment
2. Appropriate dose and frequency

Daraprim® (pyrimethamine)
ALL of the following:
1. Appropriate diagnosis of malaria treatment or toxoplasmosis treatment
2. Appropriate dose and frequency
3. If the request is for BRAND NAME Daraprim® member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to generic pyrimethamine (as per the Brand Name guideline)

Qualaquin® (quinine)
ALL of the following:
1. Appropriate diagnosis of malaria treatment
2. Appropriate dose and duration
3. If the request is for BRAND NAME Qualaquin® member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to generic quinine (as per the Brand Name guideline)

Coartem® (artemether-lumefantrine) > 24 units/year
ALL of the following:
1. Appropriate diagnosis
2. Medical necessity for the requested agent above quantity limits

Continuation of Therapy

Reauthorization requires prescriber documentation of the following:

- **Malaria prophylaxis:** Medical necessity for continuation of therapy (e.g., extended travel, new travel to malaria endemic area)
- **Malaria treatment**: Reviewed on a case-by-case basis.
- **Toxoplasmosis**: Incomplete response or clinical or radiographic disease remaining. Secondary prophylaxis (at lower doses) is indicated in all patients who have completed initial therapy for toxoplasmosis –*See Appendix*

Limitations

1. Initial approvals will be granted for:
    a. Malaria prophylaxis: as requested depending on length of travel, up to 12 months
    b. Malaria treatment: 1 week
    c. Toxoplasmosis: 2 months
2. Reauthorizations will be granted for:
    a. Malaria prophylaxis: as requested depending on length of travel, up to 12 months
    b. Malaria treatment:
    c. Toxoplasmosis: 1 month
3. Dosing

Drug	Dosing
Arakoda®(tafenoquine) Tablet: 100 mg	Prevention of malaria in adults: 200 mg once daily for three days prior to travel to malarious area, 200 mg once weekly while in malarious area, starting seven days after the last dose of the loading regimen, and 200 mg as a single dose, seven days after the last dose of the maintenance regimen.
artesunate	Treatment of severe malaria in adults and pediatrics: 2.4 mg/kg at 0 hours, 12 hours, and 24 hours, and thereafter administered once daily until member is able to tolerate oral antimalarial therapy.
Coartem®(artemether/lumefantrine) Tablet: 20 mg/120 mg	Treatment of uncomplicated P. falciparum malaria in adults : **Age>16 years and wight ≥ 35 kg:** Four tablets as a single dose, four tablets after eight hours and then four tablets twice daily (morning and evening) for two days (total course of 24 tablets). **Children and adults weighing ≤ 35 kg**: *5 kg to less than 15 kg bodyweight:* One tablet as an initial dose, one tablet again after eight hours and then one tablet twice daily (morning and evening) for the following two days (total course of six tablets). *15 kg to less than 25 kg bodyweight:* Two tablets as an initial dose, two tablets again after eight hours and then two tablets twice daily (morning and evening) for the following two days (total course of 12 tablets).

	25 kg to less than 35 kg bodyweight: Three tablets as an initial dose, three tablets again after eight hours and then three tablets twice daily (morning and evening) for the following two days (total course of 18 tablets). *35 kg bodyweight and above:* Four tablets as a single initial dose, four tablets again after eighthours and then four tablets twice daily (morning and evening) for the following two days (total course of 24 tablets).
Daraprim®(pyrimethamine) Tablet: 25 mg	Treatment of toxoplasmosis: 50 mg or 75 mg daily (Per NIH guidelines, dosing is 50 mg daily for members <60 kg and 75 mg daily for members ≥60 kg) 200 mg daily for one day followed by 50 mg daily for members <60 kg or 75 mg daily for members ≥60 kg Treatment of malaria: 50 mg daily for two days Prophylaxis of malaria: 25 mg weekly
Qualaquin® (quinine) Capsule: 324 mg	Treatment of uncomplicated P. falciparum malaria in adults: 648 mg (two capsules) every eight hours for seven days

Appendix

Quinine for Leg Cramps

The following criteria may be used for the review of requests for the diagnosis of leg/muscle cramps.

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented of inadequate response, adverse reaction or contraindication to vitamin B complex
3. Paid claims or physician documented of inadequate response, adverse reaction **ONE** calcium channel blocker or contraindication to **ALL** calcium channel blockers
4. Paid claims or physician documented of inadequate response, adverse reaction to **ONE** of the following, or contraindication to **ALL** of the following:
    a. Diphenhydramine
    b. Gabapentin
    c. vitamin E
5. If the request is for BRAND NAME Qualaquin® member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to generic quinine (as per the Brand Name guideline)

If the criteria above are met, the request may be approved for **3 months**. Recertification may be approved for **6 months** upon submission of a positive response to therapy.

Pyrimethamine for Toxoplasmosis Prophylaxis

Primary prophylaxis
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dose and frequency (50 mg or 75 mg weekly may be used. Requests for 75 mg weekly should document a clinical rationale for use of the higher dose)
3. Inadequate response, adverse reaction or contraindication to trimethoprim-sulfamethoxazole
4. **ONE** of the following:
    a. CD-4 count is <200 cells/ mm^3
    b. Clinical rationale for prophylaxis (e.g. CD-4 count is ≥200 cells/ mm^3; however the prescriber documents that the member has not maintained this for at least three months)

Primary prophylaxis is indicated in toxoplasma-seropositive patients who have CD4 counts <100 cells/mm^3. Requests can be approved for **up to 3 months** until CD4 >200 cells/mm^3 for >3 months.

Primary prophylaxis should be discounted if CD4 >200 cells/mm3 for >3 months (unless CD4 falls to <200 cells/mm^3 during prophylaxis).

Secondary prophylaxis
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dose and frequency (25 mg or 50 mg daily may be used. Requests for 50 mg daily should document a clinical rationale for use of the higher dose)
3. **ONE** of the following:
    a. CD-4 count is <200 cells/mm^3
    b. Clinical rationale for prophylaxis (e.g., CD-4 count is ≥200 cells/mm^3; however the prescriber documents that the member has not maintained this for at least six months or member is symptomatic)

Secondary prophylaxis is indicated in all patients who have completed initial therapy for toxoplasmosis. Requests can be approved for **up to 6 months** until CD4 >200 cells/mm^3 for >6 months.

Secondary prophylaxis should be discounted if CD4 >200 cells/mm^3 for >6 months (unless member is symptomatic or CD4 falls to <200 cells/mm^3 during prophylaxis).

References

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Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL. Effective 4/1/23.
08/09/23 – Reviewed and updated for P&T. Admin update: benefit change to only PB for all drugs. Effective 9/1/23