MEDICATION POLICY:

Antimalarial - Chloroquines

Generic Name

Therapeutic Class or Brand Name: Chloroquines

Applicable Drugs (if Therapeutic Class): Generic chloroquine, generic hydroxychloroquine, Plaquenil®

GPI Code: 13000010, 13000020

Preferred: Generic Chloroquine, generic hydroxychloroquine

Non-preferred: Plaquenil

Date of Origin: 3/24/2020

Date Last Reviewed / Revised: 4/7/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when documented diagnosis of one of the following conditions I. through IV. AND meet criteria under applicable diagnosis)

I. Malaria and criteria A or B is met:

   A. Treatment of uncomplicated malaria due to P. falciparum, P. malariae, P. ovale, and P. vivax and acquired in geographic regions that have not reported chloroquine resistance.

   B. Prophylaxis of malaria in geographic areas where chloroquine resistance is not reported.

II. Gastrointestinal amebiasis

   A. Prescription is for chloroquine

III. Chronic discoid lupus erythematosus and systemic lupus erythematosus

   A. Minimum age requirement: 18 years old

   B. Prescription is for hydroxychloroquine

IV. Acute and chronic rheumatoid arthritis

   A. Minimum age requirement: 18 years of old

   B. Prescription is for hydroxychloroquine

EXCLUSION CRITERIA

- Known hypersensitivity to 4-aminoquinoline compounds.
- Patients with retinopathy of the eye.
- Hydroxychloroquine: Children below 6 years of age (200 mg tablets not adapted for weight <35 kg).
- Outpatient treatment of COVID-19
   1) On March 28, 2020 the Federal Drug Administration (FDA) issued an Emergency Use Authorization (EUA) allowing hydroxychloroquine and chloroquine product distribution from the Strategic National Stockpile (SNS) to States for doctors' use in treatment of

COVID-19 as appropriate. In order to mitigate the risks of using these products for unapproved use the following are EUA requirements:

- Treatment of adolescent and adult patients who weigh at least 50 kg and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.
- The following is documented in patient's medical records that the patient/caregiver has been:
  - Given the Fact Sheet for Patients and Parents/Caregivers, and
  - Informed of alternatives to receiving authorized chloroquine/hydroxychloroquine, and
  - Informed that chloroquine/hydroxychloroquine is an unapproved drug that is authorized for the unapproved use under this EUA.

2) Health care providers are directed to request chloroquine or hydroxychloroquine under the EUA by contacting their local or state health department.
3) The EUA requires that fact sheets providing important information about using chloroquine and hydroxychloroquine in treating COVID-19 be made available to health care providers and patients, including known risks and drug interactions.

OTHER CRITERIA

N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Chloroquine
  1) Acute malaria
     - 500 mg tablets: 5 tabs per 3-day treatment
     - 250 mg tablets: 10 tabs per 3-day
  2) Prophylaxis
     - 500 mg tablets: 6 tablets per 28 days
     - 250 mg tablets: 12 tablets per 28 days
  3) Amebiasis
     - 500 mg tablets: 25 tablets per 28 days
- Hydroxychloroquine
  1) Acute malaria
     - 200 mg tablets: 10 tablets per 28 days

2) Prophylaxis
   - 200 mg tablets: 12 tablets per 28 days
3) Rheumatoid arthritis
   - 200 mg tablets: 84 tablets per 28 days
4) Lupus
   - 200 mg tablets: 112 tablets per 28 days

APPROVAL LENGTH

- **Authorization:**
  - Acute malaria, malaria prophylaxis, and amebiasis is a 30-day authorization.
  - Rheumatoid arthritis and Lupus authorize for 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

N/A

REFERENCES

1. Chloroquine [Package Insert]. Bridgewater, NJ: Sanofi-Aventis 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/006002s044lbl.pdf
2. Hydroxychloroquine [Package Insert]. Morgantown, WV: Mylan Pharmaceuticals 6/2018. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ff0c9d83-6d86-4d22-939b-a838bffbcfd0.
3. https://www.cdc.gov/malaria/travelers/drugs.html . Accessed 3/24/20
4. Singh J et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Available at https://doi.org/10.1002/acr.22783
5. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics. Accessed 4/6/20
   a. Chloroquine Phosphate and hydroxychloroquine sulfate for treatment of COVID: Letter of Authorization. https://www.fda.gov/media/136534/download
   b. Chloroquine phosphate Factsheet for Healthcare Providers. https://www.fda.gov/media/136535/download
   c. Hydroxychloroquine sulfate Factsheet for Healthcare Providers. https://www.fda.gov/media/136537/download

d. Chloroquine phosphate factsheet for patients. https://www.fda.gov/media/136536/download

e. Hydroxychloroquine sulfate Factsheet for patients. https://www.fda.gov/media/136538/download

6. Medispan®

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
4/7/2020	1) **Added** "Outpatient treatment of COVID –19: 1) On March 28, 2020, the Federal Drug Administration (FDA) issued an Emergency Use Authorization (EUA)to allow hydroxychloroquine and chloroquine product distribution from the Strategic National Stockpile (SNS) to States for doctors' use in treatment of COVID-19 as appropriate. In order to mitigate the risks of using these products for unapproved use the following are EUA requirements: Treatment of adolescent and adult patients who weigh at least 50 kg and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible; the following is documented in patient's medical records that the patient/caregiver has been: given the Fact Sheet for Patients and Parents/Caregivers, and informed of alternatives to receiving authorized chloroquine/hydroxychloroquine, and informed that chloroquine/hydroxychloroquine is an unapproved drug that is authorized for the unapproved use under this EUA. 2) Health care providers are directed to request chloroquine or hydroxychloroquine under the EUA by contacting their local or state health department. 3) The EUA requires that fact sheets providing important information about using chloroquine and hydroxychloroquine in treating COVID-19 be made available to health care providers and patients, including known risks and drug interactions." **Under Exclusion Criteria.** 2) **Added "**5.)a. through e. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics. Accessed 4/6/20." **Under References.**
3/24/2020	1. New policy.