

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME*

(generic)

(chloroquine)

(hydroxychloroquine)

**Status: CVS Caremark Criteria
COVID19**

**Type: Quantity Limit; Post Limit Prior Authorization
3688-M**

Ref #

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

FDA-APPROVED INDICATIONS

Chloroquine

Chloroquine phosphate tablets are indicated for the:

- Treatment of uncomplicated malaria due to susceptible strains of *P. falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*.
- Prophylaxis of malaria in geographic areas where resistance to chloroquine is not present.
- Treatment of extraintestinal amebiasis.

Chloroquine phosphate tablets do not prevent relapses in patients with vivax or ovale malaria because it is not effective against exoerythrocytic forms of the parasites.

Limitations of Use in Malaria:

- Do not use chloroquine phosphate tablets for the treatment of complicated malaria (high-grade parasitemia and/or complications e.g., cerebral malaria or acute renal failure).
- Do not use chloroquine phosphate tablets for malaria prophylaxis in areas where chloroquine resistance occurs, Resistance to chloroquine phosphate tablets is widespread in *P. falciparum*, and is reported in *P. vivax*.
- Concomitant therapy with an 8-aminoquinoline drug is necessary for treatment of the hypnozoite liver stage forms of *P. vivax* and *P. ovale*.

Hydroxychloroquine

Malaria

Hydroxychloroquine Sulfate Tablets are indicated for the treatment of uncomplicated malaria due to *P. falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*.

Hydroxychloroquine Sulfate Tablets are indicated for the prophylaxis of malaria in geographic areas where chloroquine resistance is not reported.

Limitations of Use in Malaria:

- Hydroxychloroquine Sulfate Tablets are not recommended for the treatment of complicated malaria.
- Hydroxychloroquine Sulfate Tablets are not effective against chloroquine or hydroxychloroquine resistant strains of Plasmodium species.
- Hydroxychloroquine Sulfate Tablets are not recommended for the treatment of malaria acquired in geographic areas where chloroquine resistance occurs or when the Plasmodium species has not been identified. Hydroxychloroquine Sulfate Tablets are not recommended for malaria prophylaxis in geographic areas where chloroquine resistance occurs.
- Hydroxychloroquine Sulfate Tablets does not prevent relapses of *P. vivax* or *P. ovale* because it is not active against the hypnozoite forms of these parasites. For radical cure of *P. vivax* and *P. ovale* infections, concomitant therapy with an 8-aminoquinoline compound is necessary.

Prior to prescribing hydroxychloroquine sulfate tablets for the treatment or prophylaxis of malaria, consult the Centers for Disease Control and Prevention (CDC) Malaria website (<http://www.cdc.gov/malaria>).

Lupus Erythematosus

Hydroxychloroquine Sulfate Tablets are indicated for the treatment of chronic discoid lupus erythematosus and systemic lupus erythematosus in adults.

Rheumatoid Arthritis

Hydroxychloroquine Sulfate Tablets are indicated for the treatment of acute and chronic rheumatoid arthritis in adults.

Off Label Uses

Coronavirus disease 2019 (COVID-19)³

INITIAL STEP THERAPY*

**Include Rx and OTC products unless otherwise stated.*

Chloroquine

- If the patient has an ICD diagnosis code for an FDA-approved or compendial supported use outside of COVID-19, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.
- If the patient has filled a prescription for at least a 30 day supply of chloroquine within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.

If the patient does not meet the above initial step therapy criteria, then initial quantity limits will apply (see initial quantity limit chart below).

Hydroxychloroquine

- If the patient has an ICD diagnosis code for an FDA-approved or compendial supported use outside of COVID-19, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.
- If the patient has filled a prescription for at least a 30 day supply of hydroxychloroquine within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.

If the patient does not meet the above initial step therapy criteria, then initial quantity limits will apply (see initial quantity limit chart below).

INITIAL QUANTITY LIMIT**

<u>LIMIT CRITERIA</u>		
Drug	2 Month Limit*	3 Month Limit*
Chloroquine 250 mg	40 tablets / 50 days	Does Not Apply
Chloroquine 500 mg	20 tablets / 50 days	Does Not Apply
Hydroxychloroquine 200 mg	22 tablets / 50 days	Does Not Apply

**The duration of 50 days is used for a 60-day fill period.*

****If the patient is requesting more than the initial quantity limit supply, then the claim will reject with a message indicating that the patient can receive a quantity sufficient to treat COVID-19 and then prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.**

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is not being prescribed for the treatment of coronavirus disease 2019 (COVID-19)

[Note: Initial quantity limits allow for a sufficient quantity of the requested drug to treat coronavirus disease 2019 (COVID-19). A maximum of 40 tablets of chloroquine 250mg, 20 tablets of chloroquine 500mg, or 22 tablets of hydroxychloroquine is available without prior authorization.]

RATIONALE

Chloroquine:

- If the patient has an ICD diagnosis code for an FDA-approved or compendial supported use outside of COVID-19, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.
- If the patient has filled a prescription for at least a 30 day supply of chloroquine within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.

If the patient does not meet the above initial step therapy criteria, then initial quantity limits will apply. Chloroquine is available as 250 mg and 500 mg tablets. The dosing used for coronavirus disease 2019 (COVID-19) is 500 mg BID for 10 days.³ Therefore, the quantity limit is set at 40 tablets of the 250 mg strength and 20 tablets of the 500 mg strength.

Hydroxychloroquine:

- If the patient has an ICD diagnosis code for an FDA-approved or compendial supported use outside of COVID-19, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.
- If the patient has filled a prescription for at least a 30 day supply of hydroxychloroquine within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.

If the patient does not meet the above initial step therapy criteria, then initial quantity limits will apply. Hydroxychloroquine is available as 200 mg tablets. The dosing used for COVID-19 is 400 mg BID for 1 day, then 200 mg BID.³ Therefore, the quantity limit is set at 22 tablets.

If initial quantity limits are exceeded, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Since the initial quantity limits are sufficient to treat COVID-19, the post limit criteria will not approve additional quantities for this indication.

REFERENCES

1. Chloroquine [package insert]. Saddle Brook, NJ: Rising Pharmaceuticals, Inc.; February 2018.
2. Hydroxychloroquine [package insert]. Princeton, NJ: Dr. Reddy's Laboratories; May 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Elsevier Inc. Copyright 2020. <https://www.clinicalkey.com/pharmacology/>. Accessed March 2020.

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