Select Hydroxychloroquine Tablet Strengths

Policy # 00845
Original Effective Date: 08/14/2023
Current Effective Date: 08/14/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select hydroxychloroquine tablet strengths, including hydroxychloroquine 100 mg, 300 mg, and 400 mg, to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for select hydroxychloroquine tablet strengths, including hydroxychloroquine 100 mg, 300 mg, and 400 mg, will be considered when the following criteria are met:

- There is clinical evidence or patient history that suggests the use of generic hydroxychloroquine 200 mg tablets will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers select hydroxychloroquine strengths, including hydroxychloroquine 100 mg, 300 mg, and 400 mg, WITHOUT clinical evidence or patient history that suggests the use of generic hydroxychloroquine 200 mg will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

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Background/Overview

Hydroxychloroquine is an antimalarial and antirheumatic drug indicated for a number of medical conditions including, but not limited to, uncomplicated malaria, systemic lupus erythematosus, and rheumatoid arthritis, while also being used off-label for treatment of other various conditions. Though hydroxychloroquine has anti-inflammatory and immunomodulatory effects, its true mechanism of action is not fully known. Hydroxychloroquine 200 mg strength was initially introduced to the market under brand name Plaquenil®‡ and is now available as a generic formulation by many different manufacturers. However, no strength of hydroxychloroquine has been evaluated for efficacy as Plaquenil was approved before manufacturers were required by the FDA to prove effectiveness. For this reason, there is no clinical trial information mentioned in the package insert.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests the generic hydroxychloroquine 200 mg tablets will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using the hydroxychloroquine tablet strengths mentioned in this policy, which includes hydroxychloroquine 100 mg, 300 mg, and 400 mg, over the generic hydroxychloroquine 200 mg tablets.

References

1. Hydroxychloroquine sulfate [package insert]. Dr. Reddy's Laboratories Inc. Princeton, New Jersey. Updated December 2022.

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07/06/2023 Medical Policy Committee review
07/12/2023 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 07/2024

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.