



## **Off-label and/or Investigational Drugs Used to Treat COVID 19 and/or Related Conditions**

### **(Including updated addendum for use of hydroxychloroquine sulfate and chloroquine phosphate)**

On March 23, 2020, DHCS received [approval of a federal waiver](#) allowing specific flexibilities related to the COVID-19 public health emergency. Further, on March 28, 2020 the Food and Drug Administration (FDA) issued [guidance](#) specific to the use of Chloroquine Phosphate and Hydroxychloroquine Sulfate. On June 15, 2020 the FDA issued additional guidance on the use of Chloroquine Phosphate and Hydroxychloroquin Sulfate. As a result, DHCS is issuing updated guidance relative to temporary flexibilities in dispensing/administration policies governing off-label and investigational use of medications used to treat COVID 19 under the Medi-Cal FFS pharmacy benefit. **This policy is temporary and remains in effect until further notice.**

### **Dispensing or administration of off-label and investigational use of medications**

According to the Centers for Disease Control and Prevention, there are no FDA-approved drugs specifically for the treatment of patients with COVID-19. At present, clinical management includes infection prevention and control measures and supportive care, including supplementary oxygen and mechanical ventilator support when indicated.

An array of drugs, approved for other indications as well as multiple investigational drugs, are being studied across the globe. Clinical use of these medications is subject to the professional judgment and interpretation of the practitioner due to the uniqueness of each medical facility's approach to the care of patients with COVID-19 and the needs of individual patients.

Due to the increasingly emergent nature of the impacts of COVID 19, effective immediately, DHCS will cover and reimburse off-label and/or investigational medications not yet having the required published documentation for use in COVID-19, as listed in Title 22, California Code of Regulations, sections 51303 and 51313. A Treatment Authorization Request (TAR) or Service Authorization Request (SAR) is not required.

## Authorization

- FDA-approved drugs being used off-label to treat COVID-19 must either:
  - 1) Be used as part of a clinical trial, registered on ClinicalTrials.gov, for treating COVID-19 (ClinicalTrials.gov Identifier must be documented in the medical record and be available for review upon request), or
  - 2) The treating physician must document in the medical record: evidence, indicating possible efficacy; the possible benefits and risks of the treatment for this patient; discussion of these potential benefits and risks with the patient or surrogate decision-maker; and consent of the patient or surrogate decision-maker to the off-label treatment. This documentation must be available for review upon request.
- Non-FDA-approved drugs must either:
  - 1) Be used as part of a clinical trial, registered on ClinicalTrials.gov, for treating COVID-19 (ClinicalTrials.gov Identifier must be documented in the medical record and be available for review upon request), or
  - 2) Be used in accordance with the FDA's Expanded Access pathway (sometimes called "compassionate use"), as documented on the FDA's website (<https://www.fda.gov/news-events/public-health-focus/expanded-access>) or other manufacturer provided "expanded access" programs. All the required documentation related to expanded access must be saved and available for review upon request.
- Prescriber is qualified, by merit of scope of practice/ clinical expertise, to treat COVID 19.
- Treatment may be initiated at the point in the disease deemed most appropriate by the treating medical practitioner(s). No TAR/SAR is required.

## Age

- All ages

## Billing

- Providers must utilize a paper claim process (CMS 1500 or UB04)
- Claims are to be submitted utilizing the local Healthcare Common Procedure Coding System (HCPCS) code **Z5999** and ICD-10-CM code U07.1 (2019-nCoV acute respiratory disease) for diagnosis related to the novel coronavirus (COVID-19).
- A TAR or SAR is not required for drugs or biologicals billed when the claim includes the statement "Patient impacted by COVID-19" in the remarks section for a TAR, and the *Freeform Message Text* field for a SAR.

- Providers are required to include the applicable HCPCS code and NDC for the billed drug(s) on the claim (if one is available).
- Provider reimbursement will be calculated based on the current reimbursement methodology used for the HCPCS code or NDC when billed by each provider type (physician, clinic, pharmacy).
- If the product is not a benefit of the Medi-Cal program, such as drugs not yet FDA approved for use in the United States, reimbursement may be based on a submitted invoice.
- Purchase invoice submitted by provider must show the shipment is to provider and that the date of invoice procurement is before date of service on claim.
- Claim may include shipping and handling as part of ingredient cost if documented in invoice(s), plus applicable dispensing/administration fees.

### **Addendum: Use of hydroxychloroquine sulfate and chloroquine phosphate**

On June 15, 2020, the US Food and Drug Administration (FDA) revoked its decision from March 28 allowing use of hydroxychloroquine and chloroquine to treat people hospitalized with COVID-19 under an emergency use authorization (EUA). Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA.

The FDA also warned that the use of hydroxychloroquine or chloroquine may have a potential drug interaction with the investigational antiviral drug remdesivir that limits its effectiveness against COVID-19 by possibly reducing its antiviral activity. This follows an April 24 release of a FDA Safety Communication which cautioned against use of the two agents outside of a hospital setting, citing an increase in outpatient prescriptions and "reports of serious heart rhythm problems."

Clinical trials will continue to evaluate the potential benefit of these drugs in treating or preventing COVID-19 even though the emergency use authorization is deemed no longer appropriate.

In light of the guidance issued by the FDA, and reports of drug shortages, effective immediately, the following utilization policy will apply to all claims for hydroxychloroquine sulfate and chloroquine phosphate:

1. Quantity Limits: In order to help insure that all beneficiaries who are currently being treated with Hydroxychloroquine and Chloroquine for medically accepted uses (Rheumatoid Arthritis, Malaria, Lupus) do not

experience a potential disruption in their therapy, Hydroxychloroquine will be limited to 120 tablets per prescription and Chloroquine will be limited to 60 tablets per prescription. This tablet restriction will allow for up to a 60-day supply for accepted uses.

2. If a beneficiary needs a larger quantity, it will be available only based upon medical necessity through the TAR/SAR process.
3. Beneficiaries requiring COVID 19 treatment with Hydroxychloroquine and Chloroquine should obtain the medication through an established Clinical Trial.
4. Off-label use of Hydroxychloroquine and Chloroquine outside of clinical trials must be approved through the traditional TAR/SAR process used for off-label use requests. A TAR/SAR must be submitted and approved prior to submission of an off-label claim for these two drugs. Authorization for unlabeled use of hydroxychloroquin/chloroquine shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:
  - (A) Reference to current medical literature.
  - (B) Consultation with provider organizations, academic and professional specialists.