



BRADLEY P. GILBERT, MD, MPP  
DIRECTOR

State of California—Health and Human Services Agency  
Department of Health Care Services



GAVIN NEWSOM  
GOVERNOR

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

### (Including 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. 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 March 28, 2020 the FDA issued a letter titled, “*Request for Emergency Use Authorization For Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease*”. The letter states that hydroxychloroquine sulfate and chloroquine phosphate have been granted Emergency Use Authorization (EUA) by the FDA for emergency use in **hospitalized** patients with COVID-19, according to the agency [emphasis added]. The EUA allows the US Biomedical Advanced Research and Development Authority (BARDA) to distribute donated hydroxychloroquine sulfate and chloroquine phosphate products to physicians. Physicians are then permitted to use these supplies of chloroquine and hydroxychloroquine from the Strategic National Stockpile (SNS) to treat adults and adolescents who weigh 50 kilograms or more and have been hospitalized and are unable to participate in a clinical trial. Additionally, DHCS is aware of concerns related to widespread shortages of FDA approved formulations of hydroxychloroquine and chloroquine. These shortages place Medi-Cal beneficiaries who are currently being treated with hydroxychloroquine and chloroquine for FDA-approved indications (Rheumatoid Arthritis, Malaria, and Lupus) at risk of potential disruption in their therapy.

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:
  - a. Established Clinical Trial
  - b. EUA process ( as described above)
4. Off- label use outside of clinical trials or the EUA must be approved through the TAR/SAR process. If the off-label request is for COVID 19 treatment, the requester will need to include “patient impacted by COVID-19” in the remarks section for a TAR, or the Freeform Message Text field for a SAR and also establish documented medical necessity for not adhering to FDA emergency use guidelines, particularly if treatment is to be provided outside of the hospital setting.