

## State of California—Health and Human Services Agency California Department of Public Health



## Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19

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Many potential therapies for COVID-19 – both repurposed FDA approved drugs and new agents – are currently under investigation. When a medication is approved or authorized for emergency use to treat COVID-19, it is likely that initial demand will exceed supply. If this is a new medication, it is critical that some amount of the medication be reserved for additional trials to assess comparative effectiveness, additional indications, and optimal dosing strategies, as such research in the long run will save lives and decrease morbidity. With that said, the priority for a new effective treatment will be to improve the clinical outcomes of individual patients.

Hospitals may find themselves in a situation where they do not have adequate supply of a medication for all eligible inpatients with COVID-19. This situation will be challenging for patients and family members, clinicians, and hospital staff. The following recommendations are designed to help maximize transparent and fair allocation of scarce medications in a way that provides the greatest overall clinical benefit to patients with COVID-19, avoids bias, and mitigates healthcare disparities. This institutional guidance should be used along with the California SARS-CoV-2 Crisis Care Guidelines, and is intended to support and augment, not supersede, the clinical judgement of providers caring for COVID-19 patients.

- 1. <u>Establish a multidisciplinary evidence-based clinical prioritization committee</u>, including representatives from pharmacy, hospital medicine, critical care, nursing, administration, and if available, infectious disease and ethics. If appropriate, consider incorporating this work into existing hospital antimicrobial stewardship programs. The responsibilities of this committee would include:
  - a. Review emerging evidence on COVID-19 therapies. The following resources offer high-quality evidence summaries (check date of last update):
    - i. NIH COVID-19 Treatment Guidelines
       (https://www.covid19treatmentguidelines.nih.gov/)

- ii. Infectious Disease Society of America Guidelines on the Treatment and Management of Patients with COVID-19 (https://www.idsociety.org/practice-guideline/covid-19guideline-treatment-and-management/)
- b. Develop hospital guidelines on appropriate use of the drug (see below).
- c. Update those guidelines regularly according to best-available evidence and the severity of drug shortage.
- d. Communicate these guidelines to hospital leadership and appropriate clinical services and soliciting feedback.
- e. Track the hospital's supply and utilization patterns of the scarce medication.
- f. If needed, provide guidance on appropriate allocation of medication among hospitalized patients, with appropriate periodic review and appeals processes.
- 2. <u>Develop hospital guidelines for appropriate use of the scarce medication</u>. The committee preparing hospital guidelines should consider the following principles:
  - a. Appropriate use guidelines should adhere to the indications authorized by the FDA, with supplemental indications guided by new developments in the literature. The drug should be prioritized among patient groups that have been shown to benefit in randomized controlled trials (RCTs).
  - b. If the drug is approved for several indications, in critical shortage, the drug should be prioritized in settings where it has been shown to improve survival. The number of patients needed to treat (NNT) to save a life for different subgroups can be used to prioritize supply.
  - c. If supply of the drug is not adequate to treat all eligible patients, random allocation among patients can be considered (e.g., using a lottery system to select a certain proportion of patients who become eligible for the drug).
  - d. It is reasonable to give some priority to essential workers, who may have been repeatedly exposed to the virus or unable to physically distance at work. Protecting this workforce may help to

- maintain key healthcare and infrastructure functions as communities respond to the pandemic.
- e. No patient should be categorically excluded from receiving the drug on the basis of comorbidities, age, disability, race, sex, gender identity and sexual orientation, immigration status or perceived quality of life, which could be subject to bias. Reliance on unvalidated prognostic scores or perceived differences in likelihood of benefit to allocate the drug may be prone to bias and is not advisable.
- f. If the drug is in shortage for approved indications, compassionate use for patients in whom the drug has not been proven to have benefit should be carefully considered. Case-by-case exceptions to hospital guidelines may be prone to bias and may further reduce access to the drug among those with evidence-based indications.
- 3. If possible, incorporate prescribing criteria into the electronic medical record (e.g., requiring physicians to attest that the patient meets indications for the drug).
- 4. If feasible, designate a clinical pharmacist to review all orders for the scarce drug in real-time for appropriateness and consistency with hospital guidelines, and to refer cases that do not meet guidelines to the clinical prioritization committee for review.
- 5. Out-of-pocket costs for effective drugs for COVID-19 during a public health crisis should not be a barrier for patients. While this is a larger issue that requires alignment with policymakers and payers, hospitals should be proactive in developing policies to minimize cost sharing for patients.
- 6. Create regional partnerships to address institutional variation in access to medication. Depending on how a scarce medication is being procured or allocated, there may be a limited number of institutions in a given region with access to the medication. In this scenario, hospitals should work collectively to ensure access for patients across all hospitals. Where permitted, hospitals should establish mechanisms for sharing

medication with other regional facilities based on COVID-19 patient census. Alternately, hospitals can establish agreements and criteria for transferring and accepting patients who are most likely to benefit from medication.