ALAMEDA COUNTY HEALTH CARE SERVICES AGENCY
PUBLIC HEALTH DEPARTMENT

**Colleen Chawla,** Director
**Kimi Watkins-Tartt,** Director
**Erica Pan,** MD, MPH, Interim County Health Officer

Division of Communicable Disease Control and Prevention
1000 Broadway, Ste 500
Oakland, Ca 94607

**Nicholas Moss,** MD, MPH, Acting Director
Tel (510) 267-3250
Fax (510) 273-3744

# Alameda County Health Guidance
## Framework for Ethical Allocation of May 2020 Remdesivir Supply - Last Updated: 5/22/2020

**Situation:** The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product remdesivir (RDV) for treatment of COVID-19. Preliminary clinical trial results indicate that patients who received RDV had a 31% faster time to recovery than those who received placebo. Results also suggested a survival benefit, with a mortality rate of 8% for those who received RDV versus 11.6% for the placebo group.[i] Another potential benefit of RDV could include a reduced burden on hospital capacity by shortening length of patient stay. In May 2020, Alameda County began receiving limited quantities of RDV from CDPH to be allocated to health care facilities for treatment of patients hospitalized with severe disease.

This document aims to address ethical issues created by Alameda County's limited quantity of RDV and to establish a transparent and fair process for allocating the County's RDV supply. It details how allocation should occur at two levels: (1) allocation among health care facilities in Alameda County, and (2) allocation among patients within each health care facility.

Alameda County expects to continue to receive shipments that will hopefully increase the amount of RDV available for future allocation. The County should update guidance to address allocation of future quantities of the medication.

### ALLOCATION AMONG FACILITIES IN ALAMEDA COUNTY

- **STRATEGY FOR DISTRIBUTION THROUGHOUT THE COUNTY:** The California Department of Public Health (CDPH) recommends that until the number of patients who are eligible for RDV under the EUA no longer significantly outstrips the available supply, counties should randomly allocate among all acute care hospitals in the county that are treating COVID-19 patients. Counties should track the cumulative distribution of medication to each hospital.[ii] Distribution within Alameda County will be non-preferential based on hospital census of eligible patients at each facility.

- **OPERATIONALIZING DISTRIBUTION:** Within 24 hours of the county being informed of an RDV allocation shipment, the county will alert acute hospitals by email of the anticipated new supply of RDV. In certain instances (i.e. the county sends out a notification over the weekend), the county might also send out an alert over text message if hospitals have provided such contact information. Acute hospitals will be asked to report within 24 hours of notification how many patients they have currently who meet criteria for RDV distribution. Not every patient on mechanical ventilation or in the ICU will be eligible. When the doses arrive, the county will calculate how doses are available compared to the number of eligible patients. Hospitals will receive a number of doses proportional to their number of eligible patients, based on availability of RDV. For instance, if enough courses arrive to treat 50% of total eligible patients

County-wide, each hospital will receive doses representing 50% of the number of eligible patients they reported. The county anticipates a new allocation shipment approximately every two weeks.

- **ETHICAL VALUES:** ACDPH should continue to update guidance and procedures on RDV distribution to ensure a fair and consistent process as availability of RDV and expert guidance changes. ACDPH should work to create a framework that:[iii]
    - Protects the population's health by reducing mortality and serious morbidity;
    - Respects individuals and groups; and
    - Strives for fairness and protects against systematic unfairness and inequity.

**ACCOUNTABILITY**

- **IMPORTANCE OF DOCUMENTATION**: The county should create and maintain a documentation log including when the county receives RDV shipments and how much is received, which facilities receive allocations and how many, and rationale on distribution.

- **A COUNTY ADVISORY COMMITTEE AND PERSON TO CONTACT** should be designated to provide clarification, updates, take comments from health care facilities and providers, and help facilities resolve any questions related to the ethical distribution of RDV.

**Actions Requested of Health Care Facilities**

**ALLOCATION WITHIN INSTITUTIONS**

- **ALAMEDA COUNTY WILL ALLOCATE RDV IN 5-DAY TREATMENT DURATIONS** while supply remains extremely scarce. With regard to treatment duration, CDPH states, "clinical trial data have shown equivalent outcomes with 5 days of treatment compared with 10 days of treatment[iv] and better outcomes if treatment is started early (within 10 days of symptom onset).[v] Treating for 5 days and treating people with severe illness early could maximize the public health benefit of this medication."

  The FDA has a two-part recommendation based on clinical data, recommending a 5-day treatment course for patients not requiring invasive mechanical ventilation or ECMO and a 10-day treatment course for patients requiring invasive mechanical ventilation or ECMO.[vi]

  While supplies remain very limited, Alameda County will follow CDPH guidance. If a clinician feels their patient might benefit from a 10-day course, they should make a special request to their hospital's clinical prioritization team.

- **PATIENT CONSENT**: Health care providers must communicate information consistent with the FDA's "Fact Sheet for Patients and Parents/Caregivers" (and provide a copy) prior to the patient receiving remdesivir.[vii] If providing this information will delay the administration of remdesivir to a degree that would endanger the lives of patients, the information must be provided to the patients as soon as practicable after remdesivir is administered.[viii]

- **IF A PATIENT IS TRANSFERRED TO ANOTHER FACILITY WHILE RECEIVING RDV**, the remainder of the course should follow that patient.

- **UNUSED DOSES OF RDV**: Facilities may have more patients who are prioritized for access to RDV than available doses. Seven days after each distribution, the county will request hospitals to report on their RDV usage, any leftover drug, and any eligible patients for whom the hospital does not have adequate RDV supply. If appropriate, the county will facilitate reallocation between hospitals. Hospitals are currently permitted to facilitate the reallocation of RDV among themselves, but should inform the county of any reallocations.

**ACCOUNTABILITY**

- **A CLINICAL PRIORITIZATION TEAM** to make allocation decisions that is distinct from the clinicians providing direct care should be established to protect the integrity of the patient-provider relationship and to ensure that decisions are fair and consistent.[ix] A recommended framework for prioritization of patient access to RDV is provided below.

- **IMPORTANCE OF DOCUMENTATION:** Patients who receive RDV should have the order (including length of course) documented in the patient's record. Allocation decisions should be logged and recorded by facility to allow for transparency and retrospective review. This log should include which patients were eligible for RDV, which patients received the RDV allocation, and how randomization occurred.

- **IDENTIFY POINTS OF COMMUNICATION FOR ACDPH TO CONTACT** with information about 1) pending shipments and 2) number of patients currently being treated with RDV for any reason.

**RECOMMENDED FRAMEWORK FOR PRIORITIZATION OF PATIENTS:**

The following is based off guidance from infectious disease experts for the initial May 2020 allocation and was determined based on risk and likelihood of greatest benefit.[x]

- **PATIENTS RECEIVING HIGHEST PRIORITY FOR INITIAL ALLOCATION OF RDV**:
    - Patients with laboratory-confirmed COVID-19 (by RT-PCR testing on a respiratory specimen)
    - Not already on RDV (e.g., for clinical trials or compassionate use)
    - Mechanically ventilated for 5 days or less, or on ECMO, or on advanced respiratory support (high-flow nasal cannula; CPAP; BiPAP).
    - Patients should meet other clinical inclusion criteria as specified by the FDA EUA for RDV (GFR ≥30ml/min, ALT < 5 times upper limit of normal)

- **SECOND PRIORITY PATIENTS**: If facilities have met the needs of the highest priority group of patients, facilities should then allocate RDV based on the following criteria:
    - Patients with laboratory-confirmed COVID-19 (by RT-PCR testing on a respiratory specimen) who are not already on RDV (e.g., for clinical trials or compassionate use) and who have three of the four characteristics:
        - < 94% oxygen saturation on room air
        - Respiratory rate > 30
        - Lung infiltrates on imaging
        - Using supplemental oxygen

- **IN BOTH PRIORITY GROUPS**, in addition to prognosis of surviving current illness to hospital discharge, allocation decisions should consider whether the patient is imminently and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice). Given the scarcity of supply of RDV, patients in this group should not currently receive priority for access.

- **A RANDOMIZATION PROCESS SHOULD BE USED** when patients are otherwise of equal priority within a priority group of patients (i.e., there is no substantial difference in risk and likelihood of benefit) and there is not sufficient RDV for all patients in that group.

- **RACE AND ETHNICITY** have been demonstrated to have an impact on mortality from COVID-19.[xi, xii] Among COVID-19 deaths for which race and ethnicity data were available, identified death rates among Black/African American persons (92.3 deaths per 100,000 population) and Hispanic/Latino persons (74.3) that were substantially higher than that of white (45.2) or Asian (34.5) persons.[xiii] Issues of racial equity should be considered in the allocation of RDV among a hospital's patients. The county will work alongside hospitals to track and address issues of equity.

**SPECIAL INSTANCES IN ALLOCATION DECISION-MAKING[xiv]**

- **CHILDREN AND PREGNANT WOMEN** are currently eligible to receive RDV through compassionate use from Gilead and so should not be prioritized for the initial May 2020 allocations.

- **PATIENTS WHO ARE ALREADY RECEIVING RDV** (e.g., through clinical trials or compassionate use) will not be eligible to receive doses from this round of drug allocation.

- **ALLOCATION DECISIONS SHOULD NOT CONSIDER OR BE BASED UPON:[xv, xvi]**
    - Age as a criterion in and of itself (this does not limit consideration of a patient's age in clinical prognostication of likelihood to survive to hospital discharge);
    - Disability status or comorbid condition(s) as a criterion in and of itself (this does not limit consideration of a patient's physical condition in clinical prognostication of likelihood to survive to hospital discharge);
    - Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis), unless the patient is imminently and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice); and
    - First-come, first-served (should not distinguish between patients when treatment has not yet been started on equivalent patients).

**Local Health Department Contact Information**

**For questions about the clinical criteria:**
**Dr. Kathleen Clanon: Kathleen.Clanon@acgov.org or 510-612-5548**

**For questions about delivery details:**
**Med1@acgov.org**

**Additional Resources**

Fact Sheet for Health Care Providers: Emergency Use Authorization of Remdesivir (FDA)

Fact Sheet for Patients and Parents/Caregivers (FDA)COVID-19 Resource Center (Infectious Disease Society of America)

Remdesivir Distribution Fact Sheet (CDPH)

Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19 (CDPH)

Ethical Framework for May 2020 Distribution of Remdesivir in the COVID-19 Pandemic (Minnesota Department of Health)

Fair Allocation of Scarce Medical Resources in the Time of Covid-19 (New England Journal of Medicine)

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[i] https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19
[ii] https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CalliforniaRemdesivirDistributionFactSheet.pdf
[iii] https://www.health.state.mn.us/diseases/coronavirus/hcp/remdesivir.pdf
[iv] https://www.gilead.com/news-and-press/press-room/press-releases/2020/4/gilead-announces-results-from-phase-3-trial-of-investigational-antiviral-remdesivir-in-patients-with-severe-covid-19
[v] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext
[vi] https://www.fda.gov/media/137566/download
[vii] https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CalliforniaRemdesivirDistributionFactSheet.pdf
[viii] https://www.fda.gov/media/137566/download
[ix] https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CalliforniaRemdesivirDistributionFactSheet.pdf
[x] https://www.health.state.mn.us/diseases/coronavirus/hcp/remdesivir.pdf
[xi] https://jamanetwork.com/journals/jama/fullarticle/2764789
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[xiii] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html
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[xvi] https://www.nejm.org/doi/full/10.1056/NEJMsb2005114?query=featured_home#article_citing_articles