Pandemic COVID-19 Allocation Guidelines- Monoclonal Antibodies

These guidelines are meant to serve as general guidance to Sutter Health affiliates for the allocation of COVID-19 therapeutic medications when the demand is greater than the supply. Each Sutter Health affiliate should use the contents of this document for allocation decision making in conjunction with any available and applicable local public health department guidance regarding drug use and allocation.

BACKGROUND:

Several COVID-19 therapeutic medications are currently in nationwide allocation/severe shortage status. Supply situations are fluid, with often limited advance notice in changes in availability or sustainability of supply streams.

GOALS AND OBJECTIVES OF ALLOCATION GUIDELINES:

The purpose of this document is to describe procedures to be used to allocate scarce COVID-19 medications during a public health emergency in which demand exceeds supply. These guidelines align with Sutter Health’s Pandemic Triage Allocation Guidelines. The aim is to allow for the fair and ethical distribution of these medications.

The distribution of resources should consider ethically justifiable principles for resource allocation. Such allocation should be done at the macro level with protocols that address the issue using a decision-making framework to ensure a fair and just distribution process. A patient’s treating provider should not have to engage in the allocation of scarce resources at the bedside.

The primary goal of these guidelines is to try to save the most lives during the COVID-19 pandemic when there is a limited supply of medical resources. To accomplish this goal, patients for whom medications would most likely be beneficial based on existing evidence base are prioritized. For the purpose of these guidelines, survival is defined as a patient’s short-term likelihood of surviving the acute medical episode to hospital discharge. There should be no automatic exclusion criteria beyond a patient’s access to the drug through another source, a patient’s competent refusal, treatment considered to be medically non-beneficial for the intervention in question, patients who are likely to recover without treatment, and patients with a predictably low chance of survival despite treatment based on validated and recognized standards.

SCOPE:

These guidelines are intended only for circumstances when: i) COVID-19 patients meet criteria for medication use as per conditions outlined in the FDA EUA approval and, ii) Demand for medication exceeds the available supply.

IMPLEMENTATION:

These guidelines are intended to be implemented only when qualified COVID-19 patients who meet established use criteria exceed available supply. These guidelines should be implemented primarily in acute care hospital settings, but may also apply to the ambulatory setting for limited
resources such as COVID-19 vaccines, oral antiviral therapy (e.g. nirmatrelvir with ritonavir (Paxlovid™), molnupiravir), and tixagevimab with cilgavimab (Evusheld™) for pre-exposure prophylaxis (PREP). Since medication allocation will differ by site, each Sutter Health affiliate should use these guidelines in conjunction with any pertinent local public health department guidance. If a site’s allocation of an individual medication goes to the system instead of a single facility, the system will allocate supply proportionately to its facilities based on the number of prioritized patients in each facility. Efforts to increase medication supply and access should be made at both the hospital and system level.

ETHICAL CONSIDERATIONS AND JUSTIFICATION:

These guidelines take a multi-principled approach to allocating scarce medical resources that strive to try to **save the most lives, prioritize evidence-based decisions, and show compassion to non-recipients**. The ethical framework for these guidelines includes five components: duty to care, duty to steward resources, duty to plan, duty to implement distributive justice, and duty to provide transparency.

**Duty to Care:** A duty to care is a fundamental obligation of healthcare providers to patients. Health care providers work to care for and save the lives of as many patients as possible during a public health crisis. Doctors and other health care professionals should offer care at the bedside to individual patients, not to populations. An ethically sound allocation system must sustain this relationship between patient and provider. Physicians should not abandon patients in a just system of allocation. Patients who do not receive a scarce resource are still under their physician’s care and should be provided alternative forms of medical intervention and/or symptom management.

A public health emergency such as the COVID-19 pandemic, in the setting of severe resource scarcity, would impose strict limits on decision-making autonomy for patients and healthcare providers. Despite this, we must endeavor to respect our patients, when possible, in ways that also honor the duties of care and stewardship. For example, if a patient eligible for a COVID-19 medication expresses an informed wish to forgo the medication, that expression of treatment preference should be honored. In addition, provision of care that may be possible when the intended medication is not available should be emphasized.

**Duty to Steward Resources:** Healthcare providers should responsibly manage resources during a period of true scarcity. Providers should balance the effort to save the greatest possible number of lives with the obligation to care for each individual patient. In a public health crisis, where there is severe scarcity of resources, accommodating these two goals requires increasingly difficult decisions. An allocation system incorporates ethical decision-making processes so that the duty to steward resources and the limitations it may place on individual care is recognized as fair and acceptable under emergency circumstances.

**Duty to Plan:** An absence of a plan adds a burden to front-line healthcare providers who already bear a disproportionate burden in a public health emergency. Guidelines are essential to support healthcare staff’s commitment to patients, ethical practice, and to professionalism during a time of crisis.

**Duty to Implement Distributive Justice:** Justice means fairness; and, therefore, a just system of allocation ensures that decisions must be applied consistently to everyone. Applying an allocation system, such as a monoclonal antibody allocation protocol, uniformly (i.e., treating like
cases alike) helps the public recognize and accept that the allocation procedures are fair and ensures that vulnerable groups are not disproportionately affected.

**Duty to Provide Transparency**: Any just plan to allocate a scarce resource requires strong efforts to promote transparency by seeking broad input in the design of the plan and educating stakeholders.

To limit bias, allocation decisions should, as much as possible, be based on objective data and evidence-based research on predicting clinical outcomes.

**ALLOCATION DECISION MAKING:**

A patient’s attending physician conducts the patient’s clinical assessments and provides all relevant clinical data to the Clinical Prioritization Committee (CPC). The Clinical Prioritization Committee, utilized primarily in the hospital setting, makes the determination about a patient’s level of access to individual COVID-19 therapies. This process supports: (1) the ability of the attending physicians to care for their individual patients with resources available to them, (2) the Clinical Prioritization Committee’s ability to use real-time information in following the protocol, (3) the Clinical Prioritization Committee’s ability to make allocation decisions consistently across a group of patients reducing chances of bias, (4) the concept of role sequestration which enhances capacity for maintaining professionalism by helping to decrease burnout and stress for healthcare providers providing direct critical care during a public health crisis. The Clinical Prioritization Committee should only be provided clinically relevant data required by the allocation protocol.

**Clinical Prioritization Committee Composition**: Ideally, CPC should be a multidisciplinary group including Infectious Disease, Pharmacy, Hospital Medicine, Critical Care, Nursing, Administration, and Bioethics. At minimum, it should have a Hospital Physician, Infectious Disease Physician, and Pharmacist. CPC size can be based on staff availability. In no case should physicians involved in direct care of the patient be involved in the allocation process.

The CPC will use the provided allocation guidelines for making allocation decisions.

**MEDICATION ALLOCATION PROTOCOL**

This allocation protocol applies to all qualified COVID-19 patients undergoing assessment for access to COVID-19 medications where demand exceeds supply. The evaluation of inclusion and exclusion criteria is triggered by need for the medication by either an incoming patient or an inpatient who develops COVID-19.

All patients who are in need of COVID-19 therapeutic agents where demand exceeds supply are subject to this allocation protocol. Using clinical criteria, patients who are deemed most likely to benefit from the medication have an opportunity to receive the medication to maximize the number of survivors. (Survival definition: short-term likelihood of survival of the acute medical episode to hospital discharge; not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years later).)
STEP 1: Inclusion and Exclusion Criteria

1. Attending physician examines the patient for inclusion criteria (Table 1) and exclusion criteria (Table 2).

### INCLUSION CRITERIA (Table 1)

1. Treatment:
   a. Mild to Moderate Disease (symptomatic)
   b. Positive COVID-19 test since symptom onset
   c. Less than or equal to 5 calendar days since COVID-19 onset:
      i. Sotrovimab
      ii. Remdesivir in ambulatory patients
      iii. Nirmatrelvir/ritonavir (Paxlovid™) or molnupiravir
   d. At least one of the following:
      i. Immunocompromising conditions or immunosuppressive therapy
      ii. Diabetes
      iii. Chronic Lung Disease
      iv. Cardiac disease including hypertension
      v. BMI > 30
      vi. Age ≥ 65
      vii. Pregnancy (any gestational age), only if approved by OB

2. For PREP:
   a. Asymptomatic
   b. No known close contact exposure within last 10 calendar days
   c. Tixagevimab/cilgavimab (Evusheld™): Refer to Antibody Therapy Guidance for SH Tier System

### EXCLUSION CRITERIA (Table 2) - Patient is excluded if any of the following is present:

1. Treatment:
   a. Patient is seeking post-exposure prophylaxis and not early disease treatment
   b. Patient is receiving sotrovimab through alternative mechanisms, when available (e.g. active clinical trials, compassionate use availability, etc.)
   c. Hospitalization secondary to COVID-19
   d. Requires oxygen therapy or increase in baseline oxygen flow rate due to COVID-19
   e. Receipt of other COVID-19 EUA treatments within prior 90 days including convalescent plasma or IVIG

2. For PREP:
   a. Lack of vaccination unless due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine and/or COVID19 vaccine component.
2. If a patient has exclusion criteria and therefore does not have access to the medication, they are instead provided with alternative forms of medical intervention and/or symptom management (e.g., palliative care, comfort care). If they are stable to be discharged, they are discharged home.

**STEP 2: Discussion with Patient/Surrogate**

1. The Attending Physician should discuss the patient’s interest in receiving therapies not yet approved by the FDA as a therapeutic for COVID-19, but available under an EUA. If the patient is interested, they should be informed about the medication and the allocation decision making process using CPC. For patients who lack decision-making capacity, this discussion should happen with his/her surrogate decision maker. If the patient is unrepresented, the hospital’s Unrepresented Patient Policy should be utilized for this purpose unless there is evidence the patient previously refused to consent to unapproved therapies.

2. If the patient or surrogate is interested in being considered for the desired medication, the Attending Physician will provide the patient’s clinical data (inclusion and exclusion criteria) to the CPC to make the allocation decision.

3. If a patient who meets eligibility criteria is not interested in receiving the medication offered, alternative forms of medical intervention and/or symptom management will be provided.

**STEP 3: CPC Evaluation and Allocation Decision Making**

1. Attending physician will provide CPC with clinical data for patient (inclusion and exclusion criteria).

2. CPC will evaluate clinical information and make medication allocation decisions based on current hospital, clinic or infusion center supply, eligibility criteria, and number of patients undergoing evaluation for medication allocation.

3. The following **Treatment Priority Groups** should be used for allocation decision making. This is based on current clinical evidence of benefit.

<table>
<thead>
<tr>
<th>HIGHEST PRIORITY: IN NO PARTICULAR ORDER</th>
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<tr>
<td>a. Immunocompromised Patients</td>
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<tr>
<td>b. Age &gt; 65 years</td>
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<tr>
<td>c. BMI &gt; 30</td>
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<table>
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<tr>
<th>SECOND PRIORITY: IN NO PARTICULAR ORDER</th>
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<tr>
<td>a. Diabetes</td>
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<td>b. Chronic Lung Disease</td>
</tr>
<tr>
<td>c. Cardiac disease EXCLUDING ISOLATED HYPERTENSION</td>
</tr>
<tr>
<td>d. Pregnancy (any gestation age), only if approved by OB</td>
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4. In the hospital setting, if there are multiple patients in any priority group and the medication supply is not adequate to treat all eligible patients, random allocation using a lottery system (e.g. using a random number generator for conducting the lottery) will be utilized by CPC to make the allocation decision.

5. In order to maximize benefit of these scarce resources, no courses should be held in reserve for future use, particularly if there are current patients who qualify for receipt of the monoclonal antibody product.

6. Medication allocation decisions should not consider or be based upon: race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship/immigration status, or socioeconomic status; Ability to pay; Age as a criterion; 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 this illness); Predictions about long term prognosis; First-come, first-served; Judgments about “quality of life”; Judgments about “social value or worth”.

7. Unvalidated prognostic scores or perceived differences in likelihood of benefit to allocate the drug that are not supported by evidence-based medicine should not be utilized in making allocation decisions.

8. The allocation decision should be communicated to the patient’s Attending Physician. If the Attending Physician requires support to communicate the allocation decision to the patient/surrogate, the CPC should provide assistance.

**STEP 4: Discussion with Patient/Surrogate for Informed Consent**

If selected to receive the medication, the patient’s physician should seek informed consent from the patient to receive the treatment. The patient should be informed about the benefits and risks of the medication. If applicable, patients should be informed that the medication is not FDA-approved as a COVID-19 therapeutic, but is available under an Emergency Use Authorization for use in COVID-19. A patient who has decision-making capacity will need to provide informed consent for the medication. For patients who lack decision-making capacity, this discussion should happen with his/her surrogate decision maker. If the patient is unrepresented and no surrogate decision maker is available, the medication may be provided utilizing the hospital’s Unrepresented Patient Policy, in keeping with the best interests of the patient, unless the patient previously refused to consent to unapproved therapies.

**STEP 5: Assessments**

1. All patients should be allocated a course of one of the following medications as appropriate and pending availability:
   a. One time dose of sotrovimab for treatment
   b. Five-day course of nirmatrelvir/ritonavir (Paxlovid™) for treatment
   c. Five-day course of molnupiravir for treatment
   d. Five-day course of remdesivir for inpatient treatment
   e. Three-day course of remdesivir for ambulatory treatment
   f. One time dose of tixagevimab/cilgavimab (Evusheld™) for Pre-Exposure Prophylaxis
2. Once patients are selected to receive the therapy, they should not be denied therapy solely for purposes of reallocating to other patients who subsequently are identified

**DOCUMENTATION:**

1. Patients who receive allocated medications should have the order (including length of course) documented in the patient’s record.

2. Allocation decisions should be logged and recorded by the CPC to allow for transparency and retrospective review. This log should include all patients eligible for therapy, which patients received the medication allocation, and how randomization occurred. Each affiliate should utilize forms and tools for documentation of allocation request, patient comparison registry, pharmacy tracking tool, and allocation decisions.

**PATIENT TRANSFER:**

If a patient is transferred to another facility while receiving an allocated supply of medication, the remainder of the intended course of therapy should follow that patient.
Sutter Health has released guidelines for the allocation of scarce medications during the COVID-19 pandemic. The primary goal of these guidelines is to save as many lives as possible given the limited supply of medical resources. To accomplish this, use of scarce medications will be prioritized to patients who are most likely to benefit from the drug.

Are inter-facility transfers of scarce medications allowed?
Medication supply that is purchased by the hospitals can be transferred to another facility following the normal loan/borrow/sale regulations and polices. Medication provided by a government agency may be subject to interfacility transfer limitations except once a patient is initiated on a course of a scarce medication, the full allotment of medication to complete a recommended course of therapy must follow the patient. If a patient requires transfer during a course of therapy, the remaining allotment of medication for that patient must transfer with him/her to the receiving institution, following the procedures stated above.

What happens to the allocated medication supply when the patient is transferred to another facility?
Once the local Clinical Prioritization Committee (CPC) approves an allocation, sufficient supply to complete a recommended course of therapy is assigned to the patient. If a patient is transferred to another facility during the treatment course, the remaining supply must be transferred with the patient. Normal loan, borrow, and sale procedures should be followed.

Is patient consent required prior to the allocation process?
Providers should obtain patient consent prior to CPC evaluation. The patient consent must disclose both the existence of an allocation process, and that treatment may be contingent upon the results of the randomized allocation process. Patients must be notified if they are not selected to receive scarce medications via the randomized allocation.

Should a patient be started on a course of scarce medication if there is insufficient supply for treatment course?
A patient should not be started on a course of scarce medication if there is insufficient supply to complete the minimum recommended course of therapy.
Hospitals may attempt to secure additional supply from another facility if needed.

**What kind of documentation is needed after the Clinical Prioritization Committee (CPC) completes the randomization process to select patients to receive a scarce medication?**

Results of randomization processes via the CPC should be clearly documented in the patient’s medical record. This documentation should occur for ALL patients randomized in the allocation process, whether selected or not.

**What communication tools are available to provide to patients who were not selected to receive a scarce medication?**

The pharmacy team is working with Sutter Ethics Committee to develop a standard information sheet to provide to patients and family members.

**Is there guidance on an appeal process for patients who are not selected during randomization?**

An appeals process may vary, based upon additional drug availability. Ethical logic around appeals processes should consider the following possibilities:

1. If additional drug is not available, the randomization process will conclude. There is no new outcome possible without additional drug supply.
2. When additional drug becomes available, a new randomization process will commence for all eligible patients. This may include persons who were not selected in prior randomizations, but who are still eligible for therapy.
3. If a drug excess becomes available, such that drug supply exceeds the number of patients who are eligible for therapy, the randomization process should no longer occur, and drug should be supplied for all eligible patients.