### UPMC LIFE CHANGING MEDICINE

Design and Implementation of a Weighted Lottery to Equitably Allocate Scarce Covid-19 Resources

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- UPMC established a system Covid Therapeutics Committee in April 2020
- 35 US-based hospitals
- No experimental therapies outside of a clinical trial
- Oversight for system trials (REMAP-CAP and homedesigned)





McCreary EK, et al. Learn Health Syst. 2022 Jan 27;6(3):e10304.



Draft version; May 28, 2020

### Model Hospital Policy for Fair Allocation of Scarce Medications to Treat COVID-19

#### Executive Summary

**Introduction**: The purpose of this document is to provide ethical guidance for the allocation of medications to treat COVID-19 in the event that need outstrips supply during the pandemic. These allocation recommendations should be implemented only if: 1) the supply of the medication is, or will soon be, insufficient to treat all patients, even after taking all appropriate steps to increase the supply; and 2) a regional authority has declared a public health emergency. This document describes 1) the creation of allocation teams to ensure consistent decision making and 2) allocation criteria for scarce medications to treat COVID-19.

**Ethical Framework:** This allocation framework is grounded in two public health ethical obligations: the duty to steward scarce resources to promote the public's health, and the duty to lessen the impact of social inequities on COVID-19 outcomes in disadvantaged communities. The development process included engagement with ethicists, community members, legal scholars, public health and disaster medicine experts, and diversity and inclusion experts.



## **Guiding Principles**

- To safeguard the public's health by allocating scarce treatments to maximize community benefit
- To lessen the impact of social inequities on COVID-19 outcomes in disadvantaged communities
- To ensure that no patient is refused access to treatment based on age, disability, religion, race, ethnicity, national origin, immigration status, gender, perceived quality of life, sexual orientation, or gender identity
- To ensure that all patients receive individualized assessments by clinicians based on the best available objective medical evidence

## Remdesivir Lottery – May 2020

- Anyone who meets clinical criteria is eligible
  - Setting clear inclusion/exclusion criteria based on highest level clinical evidence is crucial
- Weighted factors established by ethics + clinical committee
  - Remdesivir example May 2020
    - Essential worker (个 25%)
    - Area of deprivation index score 80-100 (↑ 25%)
    - End-of-life prognosis, defined as >50% chance of death within one year from underlying conditions ( $\downarrow$  50%)
    - Updated June 2020: pregnancy increased odds

White DB, McCreary EK, Chang CH, et al. A Multicenter Weighted Lottery to Equitably Allocate Scarce COVID-19 Therapeutics. Am J Respir Crit Care Med. 2022 Aug 15;206(4):503-506.



### **Remdesivir Allocation System**

#### Updated June 1:

This information is updated frequently during this evolving situation. Refer to Infonet for the latest information and communications.

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### **Remdesivir Lottery Daily Process**



### **Frequently Asked Questions**

## Q: My patient was not allocated remdesivir today. Can they be re-entered into the allocation system tomorrow?

A: At this time, patients will not be re-entered into the allocation system due to extremely limited supply. The allocation system takes into account eligible patients over a certain time frame (~2-3 weeks). If there is significant improvement in availability of drug, then the patient may be re-evaluated.

## Q: My patient declines his/her/their allocation and now wants to receive the drug. What do we do?

A: If a patient changes his/her/their mind prior to 1100 the next day, drug can be allocated. After that, they are no longer able to receive the allocation since the system will be run for the next day's group of patients.

### Lottery Team Responsibility

- Determine number of courses available of scarce medication
- Estimate number of eligible patients over designated time period for which drug is to be allocated
- Determine chances for each eligible "general population" patient to receive drug
- Apply weighted criteria
- Run lottery (with witness)

### Table 1. Weighted chances to receive treatment for each patient group

Group	Chances to receive treatment
General community chances	Number of available treatment courses/
	Number of eligible patients in the
	determined time period
Disadvantaged community member	(1 + 0.25) x (general community
	chances)
Essential worker	(1 + 0.25) x (general community
	chances)
Death likely within 1 year	$(1 - 0.5) \times (general community chances)$
Disadvantaged community member + Essential worker	(1 + 0.25 + 0.25) x (general community
	chances)
Disadvantaged community member + death likely within 1 year	(1 + 0.25 – 0.5) x (general community
	chances)
Essential worker + death likely within 1 year	(1 + 0.25 – 0.5) x (general community
	chances)

### Remdesivir Lottery May 2020 – July 2020

Eligible for Lottery Entry?	MRN	Address	Area Deprivation Score	Disadvantaged neighborhood?	Essential worker?	Poor near-term prognosis?	Lottery number (1- 1000)	To receive drug their lottery # must be less than this number)	Offer patient remdesivir?
1	10045670	1234 LOTTERY ST	3	No	No	No	420	879	yes
	12343078	FITT300KGH, FA 13223			NO		377	879	yes
1	565656565	5678 REMDESIVIR AVE PITTSBURGH, PA 15213	5	No	No	No			
1	778787878	910 MONOCLONAL WAY PITTSBURGH, PA, 15223	10	Yes	Yes (Bus Driver for hospital)	No	351	1001	yes



## **Communication Resources**

- Communication guidance for allocation team
- Responding to emotion
- Patient FAQ

Why can't my grandmother	This is a difficult time. We are trying to use resources in a way that is fair for everyone. Your grandmother was not selected by the lottery to receive Remdesivir. We are going to continue to
receive Remdesivir?	the lottery to receive Remdesivir. We are going to continue to use all other medical treatments that we think will help your loved one



You're treating us	I can't imagine the negative experiences you have had in the past with health care simply because of who you are. That is not fair, and I do not want people to be treated by the color of their skin.
differently because of the color of our skin.	The situation today is that there is not enough of the medicine. We are using guidelines that were developed by people in this community, including people of color, so that we can be fair. Race, ethnicity, disability, and age are not known by the team making the decisions.
It sounds like you are rationing.	What we are doing is trying to spread out our limited amount of medication in the best way possible. The state guidelines that we are following have been developed by groups outside of UPMC, including health care professionals, ethics experts, and lay people considering all options. I wish we had more.
You're playing God. You can't do that.	All hospitals are following the same rules given by the state on how to fairly choose who gets the limited supply of Remdesivir. A lottery is the fairest way to make sure everyone is treated by the same rules. I know that we don't have enough medicine. I wish we had more.



### **OPTIMISE C-19**

OPtimizing Treatment and Impact of Monocolonal antIbodies through Evaluation for COVID-19)



- Achieved FPI 21 days after study concept
- Ability to add/remove monoclonals in based on EUA status in days
  - >10,000 patients randomized since March 2021

### Regulatory

- Approved by
  - UPMC QI committee and University of Pittsburgh IRB
- Initial mAb rollout (Fall 2020)
  - UPMC offered mAbs under <u>therapeutic interchange policy</u>
    - Physician orders mAb (as generic referral order)
    - Pharmacy fills under therapeutic interchange
    - mAb availability overseen by Pharmacy and Therapeutics Committee
  - Patients provide verbal consent for any mAb treatment
  - Physicians provide and review EUA fact sheets for all available mAbs

### • OPTIMISE-C19 (March 2021)

- Provides therapeutic interchange via random allocation
- All else same

### OPTIMISE-C19 Outpatient Workflow

#### **Monoclonal Antibody Administration**

#### For Providers: Ordering Monoclonal Antibody Administration for Patients

If you are a non-UPMC provider and would like to order the Monoclonal Antibody Administration for a patient under your care, and unable to place orders in UPMC's electronic medical record, please:

- Download the paper order form
- Complete and fax the form to 412-802-6490

Your patients can learn more and see if they qualify for treatment by calling 866-804-5251.

- Generic referral order placed in Epic, Cerner, or paper
- Central operations team reviews all orders daily at 6am (7 days/week)
  - Screen for eligibility
  - Randomize and generate paper order
  - Place paper order in infusion center Teams folder
- Infusion centers call patients to schedule
  - \*\*COLLABORATION ACROSS CARE CENTERS\*\*
- Tracking/reporting in Microsoft Teams (patient status, ADRs)

CONSULT / REFERRAL	TO COVID MONOCLONAL ANTIBODY MEDICATION	]
Status: Norm	nal Standing Future	
Class: UPMC	HSNP	
Priority: Routin	ne ,O Routine STAT	
Reference 1. Bam Links:	Ianivimab Fact Sheet 2. Casirivimab and Imdevimab Fact Sheet	
Confirmed preferred	Cell phone number on file Home phone number on file Work phone number on file	
number:	Other (enter in comments)	
Reviewed FDA fact she	eet; patient/caregiver has agreed to receive drug: Yes	
Eligibility Criteria (sele	ct BMI >/= 35 Chronic kidney disease Diabetes Immunocompromised Age >/= 65	
all that apply):	□ Cardiovascular disease (age >/= 55) □ HTN (age >/= 55)	
	Chronic respiratory disease (age >/= 55) BMI >/= 85th percentile (age 12-17)	
	Sickle cell disease (age 12-17) Congenital/acquired heart disease (age 12-17)	
	Neurodevelopment disorder (age 12-17) Medical-related technological dependence (age 12-17)	
	Asthma or other respiratory disease (age 12-17) None - PATIENT NOT ELIGIBLE	
Obte of Symptom Ons	et (Fever, Cough, Sore throat, Malaise, Headache, Muscle pain, GI symptoms, or SOB w/ exertion):	
O Date of positive PCR T	est (see comments for last test recorded in Enick	
Contract province r and		
Is the patient pregnant or breastfeeding?	t yes no unknown	
O Does patient have a ne	ew or increasing oxygen requirement?	
	Yes No	
Preferred Infusion	Pittsburgh (South Side) Altoona (age 12 & up) Chautauqua East Hamot Jameson	
venter.	Passavant - Cranberry (Saturday only) Passavant - McCandless (age 12 & up) Pinnacle - Carlisle	
	Pinnacle - Hanover Pinnacle - Harrisburg (age 12 & up) Pinnacle - Lititz Pinnacle - York	
	Somerset (age 12 & up) Susquehanna - Wellsboro Susquehanna - Williamsport (age 12 & up)	



MC MAB Manager

Location List

#### File

Inventory Management Participant Management

#### UPM





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MAB Manager Clinical Analytic Apps

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Categories > Clinical Analytic Apps

QlikView Clinical Analytic Apps

Altoona ED		Drug Ramlaniuimah, L Etag
Altoona Outpatient		Drug barnanivimab + Etes
Bedford ED		
Chartwell		Drug Casirivimab + Imdevi
Chautauqua ED		
Chautauqua Outpatient		L
Childrens ED		Drug Sotrovimab
Childrens Outpatient		
Cole		
Cole Outpatient		
East ED		
East Outpatient		
Hamot ED		
Hamot Outpatient		
Horizon Greenville ED		
Horizon Shenango ED		
Inpatient		
Jameson ED		
Jameson Outpatient		
Lock Haven ED		
Magee ED		
Magee Outpatient		
McKeesport ED		
Mercy ED		
Mercy Outpatient		
Muncy ED		
Northwest ED		
Northwest Outpatient		
Observation Status		
Passavant Cranberry ED		
Passavant Cranberry Outpatient		
Passavant McCandless ED		
Passavant McCandless Outpatient		
Pinnacle Carlisle ED		
Pinnacle Carlisle Outpatient	~	Save Changes

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e			
Participant Info			
UPN			
Participant Name	TEST TEST		
Participant Gender	FEMALE		
Participant Race	White		
Participant DOB	Jan 23, 1978		
Participant Contact	123 FAKE ST PITTSBURGH PA 15213		
	Phone: 999-999-9999 Email: USER@DOMAIN.TLD		
Infusion Location	Presbyterian	~	
Result	Drug Bamlanivimab + Etesevimab	 	
	The second s		
Load Particip	ant Information EPIC		

### Extensive outreach to community members

- Patients
  - UPMC HealthPlan virtual town halls
  - Press conferences
  - Media
  - Vaccine clinics
  - Screening positive test results and direct-to-patient calls
  - Self-referral line
- Clinicians (internal education and promotion)
- Collaboration with local and state public health offices and other healthcare systems + community leaders
- Partnership with home infusion company
- Senior communities, behavioral health hospitals



McCreary EK, et al. The comparative effectiveness of COVID-19 monoclonal antibodies: A learning health system randomized clinical trial. Contemp Clin Trials. 2022 Aug;119:106822.

two years, 26,769 unique patients, and 27,108 infusions later the monoclonal antibody for treatment of COVID-19 program comes to an end today.

it is so sad this safe, effective therapy is not an option for now

thankful for where we've come and ready for the challenges ahead



McCreary EK. Our "Side Hustle". Clin Infect Dis. 2023 Oct 4:ciad543.

# Evusheld Lottery

- Weighted lottery process from 12/8/21 to 2/23/22
- 2x odds of allocation for patients from disadvantaged communities
  - Other weighted factors not practical
- All eligible patients gathered from data warehouse + manual EHR entry
  - >200,000 patients for 450 doses
- Grouped immunocompromised patients in 3 risk categories; lottery for group 1 (highest risk)
  - 10,834 patients

# **Evusheld Lottery**

- First notification of allocated doses from state DOH 12/21/21
- First patient injected 12/30/21
- Lottery repeated weekly with notification of allocations
- Lottery ended when supply > demand; all highest priority patients contacted



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# **Ethical Goals and Lottery Design**

#### Table 1. Ethical Goals and Corresponding Design Elements of the Weighted Lottery Process

Ethical goal	Design element of weighted lottery process				
Give all eligible individuals an opportunity	Proactively identify all eligible individuals via EHR searches, rather than requiring individuals to seek treatment				
to receive treatment	Prohibit exclusion criteria based on the presence of severe comorbidities or disabilities				
	Use a lottery mechanism that includes all eligible individuals				
	Establish multiple infusion centers across geographic regions to promote meaningful access				
	Provide transportation to/from infusion centers for individuals without access to an automobile				
	Arrange home injection of tixagevimab with cilgavimab for individuals who cannot leave home due to frailty or disability <sup>a</sup>				
Promote community benefit	Limit eligibility to high-risk individuals				
	Prohibit distribution of tixagevimab with cilgavimab outside the lottery mechanism <sup>b</sup>				
Mitigate health disparities in COVID-19	Give higher chances in the lottery to individuals from disadvantaged neighborhoods <sup>c</sup>				
outcomes	Provide information to individuals about tixagevimab with cilgavimab using language designed for individuals with lower health literacy				
	Locate infusion centers in or near disadvantaged neighborhoods				
	Provide tixagevimab with cilgavimab at no cost to individuals and provide financial counsel if a co-pay was charged for injection costs and posed a financial hardship <sup>d</sup>				



# **Key Strategies**

- All patients entered, not provider selected
- 22 infusion centers
- Transportation partnership or home infusion
- Patient-friendly communications for staff
- Free drug
- Centralized allocation team, blinded



Table 2. Comparison of Demographic Characteristics of the Overall Lottery Cohort With Individuals Allocated Tixagevimab With Cilgavimab in the Weighted Lottery and a Simulated Unweighted Lottery

		Allocated tixagevimab			
	Simulated unweighted lottery (n = 450) <sup>a</sup>		Received tixagevimab		
Variable	(N = 10834)	(n = 450)	Mean (SD)	% (SD)	(n = 125)
Age, mean (SD), y	62.9 (18.8)	63.2 (17.4)	62.9 (0.9)	62.9 (0.9)	64.2 (13.6)
Sex, No. (%)					
Female	5471 (50.5)	233 (51.8)	227.2 (10.5)	50.5 (2.3)	57 (45.6)
Male	5363 (49.5)	217 (48.2)	222.8 (10.5)	49.5 (2.3)	68 (54.4)
Race and ethnicity, No. (%)					
American Indian/Alaska Native/Hawaiian/ Pacific Islander	17 (0.2)	1 (0.2)	0.7 (0.8)	0.2 (0.2)	0
Asian	86 (0.8)	2 (0.4)	3.6 (1.9)	0.8 (0.4)	2 (1.6)
Black	767 (7.1)	41 (9.1)	31.9 (5.3)	7.1 (1.2)	3 (2.4)
White	9822 (90.7)	402 (89.3)	407.9 (6.1)	90.7 (1.4)	118 (94.4)
Not reported/unknown	142 (1.3)	4 (0.9)	5.9 (2.4)	1.3 (0.5)	2 (1.6)
ADI ≥80, No. (%) <sup>b</sup>	1800 (16.6)	131 (29.1)	74.8 (7.8)	16.6 (1.7)	36 (28.8)
Insurance status, No. (%)					
Commercial	6401 (59.1)	257 (57.1)	266.0 (10.3)	59.1 (2.3)	78 (62.4)
Medicare	2054 (19.0)	81 (18.0)	85.3 (8.2)	19.0 (1.8)	16 (12.8)
Medicaid	1082 (10.0)	54 (12.0)	44.9 (6.2)	10.0 (1.4)	11 (8.8)
Missing/unknown	1297 (11.9)	58 (12.9)	120.5 (9.2)	26.8 (2.0)	20 (16)

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McCreary EK, et al. JAMA Health Forum. 2023 Sep 1;4(9):e232774.

## Discussion

- This was possible
- Lottery structurally improved allocation
- Allocation does not equal receiving drug
- Association of lottery with underrepresented racial and ethnic groups other than Black was not evaluated due to small numbers
- Factors associated with not receiving drug need further explored



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### **Questions?**