# Therapies for COVID-19 Update 4.13.2022

Michael McNulty

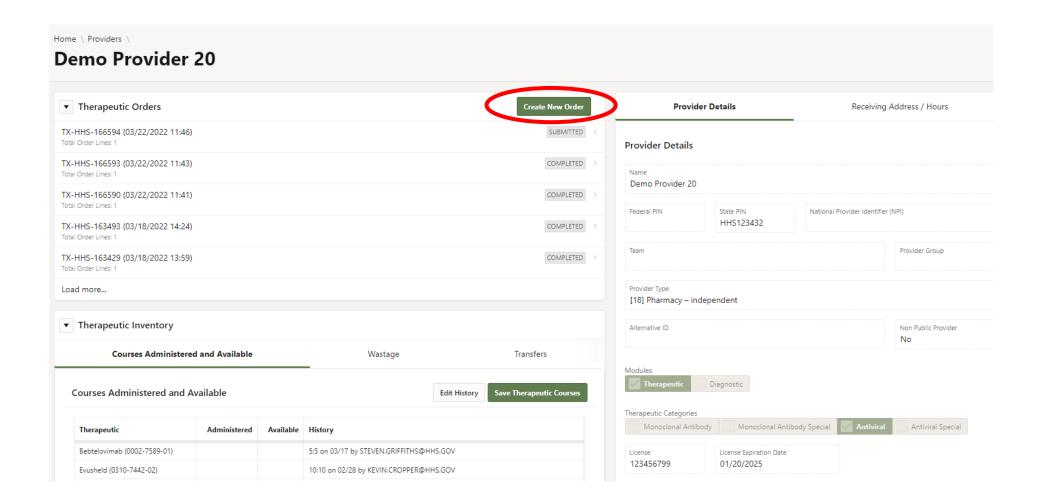
**Emergency Management Director** 

Kansas Department of Health and Environment

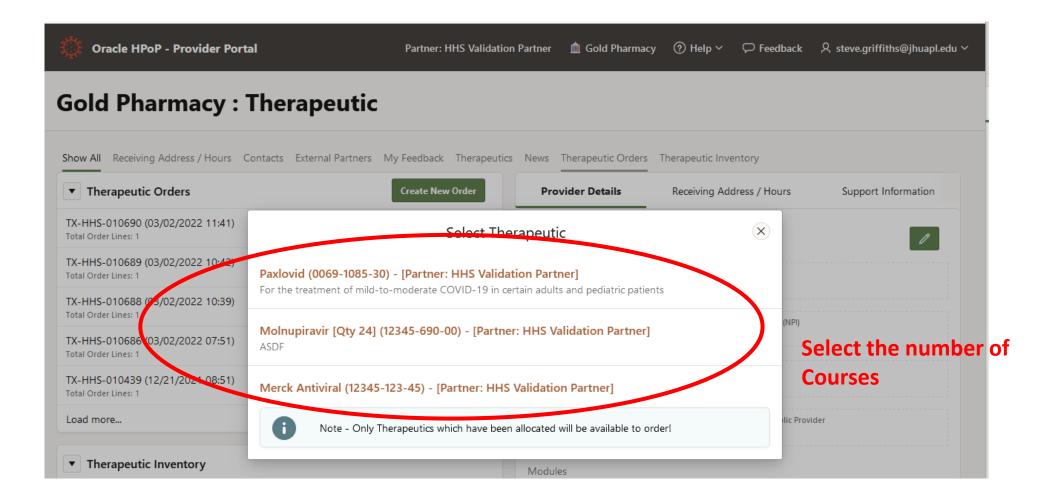
### **HPOP Direct Ordering Requests**

- HHS is moving to allow HPOP to be used for requesting therapeutics in addition to reporting use and inventory
- Direct Ordering Requests will be enabled in HPOP by April 18, 2022,
   9:00 a.m. CT
- Orders will validated by KDHE staff prior to actioning by HHS for distribution

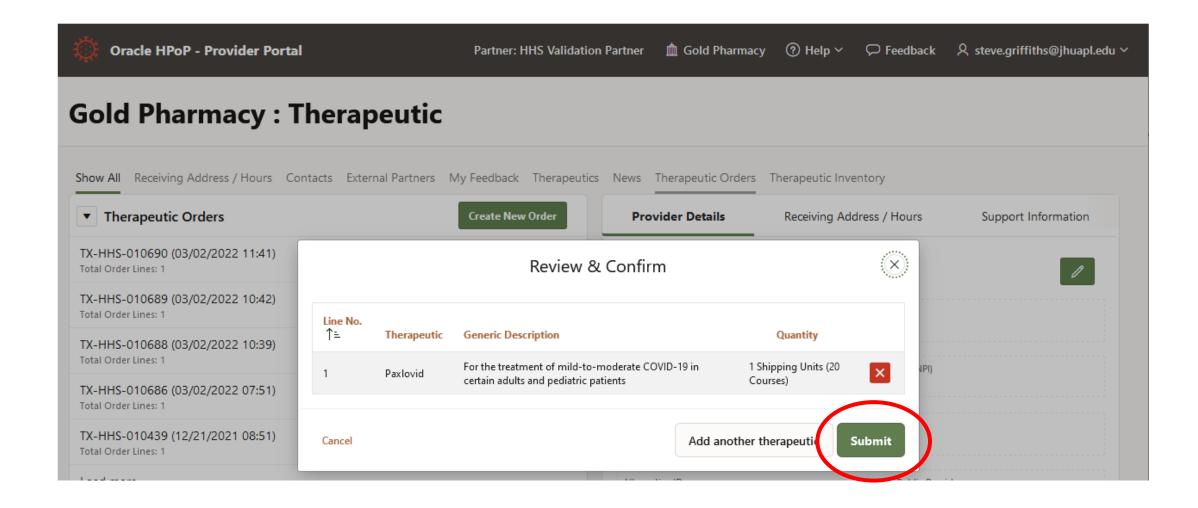
#### Create New Order button enabled



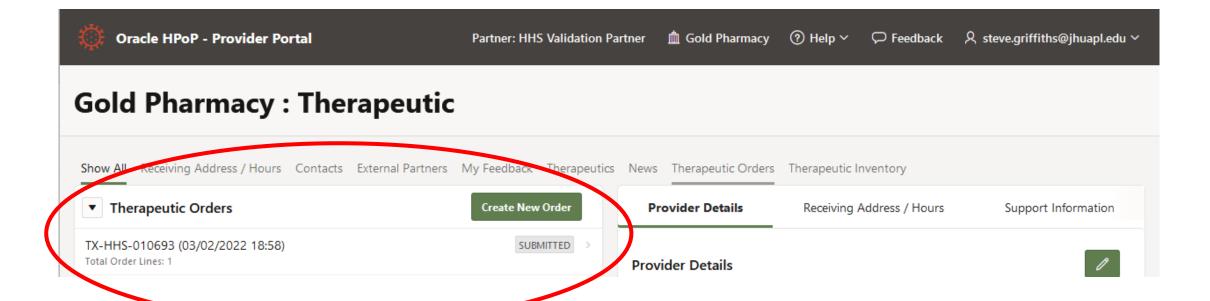
## Select Therapeutic



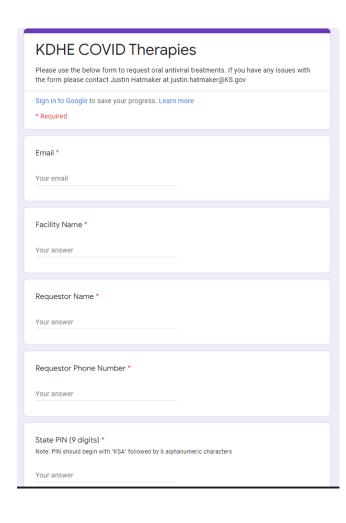
#### Submit the Order



# New order will appear



# Therapeutics Ordering (Until April 15)



- KDHE is accepting orders for all available therapeutics and will suspend allocating.
- Orders may be throttled based on availability
- Go to <a href="https://forms.gle/y66HCBTqsJNWqxYr6">https://forms.gle/y66HCBTqsJNWqxYr6</a>
- Enter all required information
  - Email
  - Facility Name
  - Requestor Name
  - Requestor Phone Number
  - HPOP State PIN (PIN is assigned to each facility)
  - Select the number of patient courses for the therapy requested
- Select Submit
- If there are any questions, the contact listed will be followed up with by KDHE staff

# Extended Expiry Dates on Sotrovimab/Paxlovid

Drug Name	Lot#	Extended Expiry Date
Sotrovimab	658W	08-2022
	XV6W, Y74D, JP9Y, 287F	10-2022
	287X, 432U, 433C, BX3T	11-2022
	9W8S,A39T	03-2023
	BD8F, BC9P, C86N, CC3D, CK9V, D74S	04-2023
	J23C, JJ7J, J67D	06-2023
	MJ8W, ME3Y, MJ8X, ME3Y, NM9X, NM6J, NX3P, PK8J	07-2023
	RM3K, S63E, R97L, S94Y, TE4L	08-2023
Paxlovid	FL4516, FL4517, FR7229	The initial 3 lots were extended from 7/31 to 10/31/22.
	FR9088	4th lot was extended from 8/31 to 11/30/22

#### HHS Product Return Guidance

- All therapeutic products are property of the USG and must be used in accordance with EUA guidance
- Sites of care cannot donate products to entities outside the U.S. of for use outside the U.S.
- Any returned product will be destroyed, as product integrity cannot be verified
- Non-expired product should not be destroyed. Returns only on damaged product or quality concerns
- HHS guidance is for facilities to retain product as these may be active against future variants
- Doses discarded on site (compromised vial, unused diluted vials, etc) should be recorded in HPOP
- FDA Shelf Life Extension for Therapeutics
  - Discussions between ASPR and FDA continue
  - Current information is available at <a href="https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#COVIDtherapeutics">https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#COVIDtherapeutics</a>
- For expired therapeutics
  - For REGEN-COV call 844-734-6643
  - For BAM/ETE call 800-821-0538

#### Sotrovimab Authorization Paused

- Results from in vitro assays used to assess susceptibility of viral variants to particular mAbs suggest that Sotrovimab is not fully active against BA.2 variant
- Centers for Disease Control and Prevention (CDC) estimated the proportion of COVID-19 cases caused by the Omicron BA.2 variant to be above 50% in all U.S. Department of Health and Human Services (HHS) regions
- Due to these data, use of sotrovimab is not authorized in any U.S. state or territory at this time.
- Accordingly and effective immediately, ASPR has paused sotrovimab distribution to all U.S. states and territories

### Currently Authorized Alternative Treatments

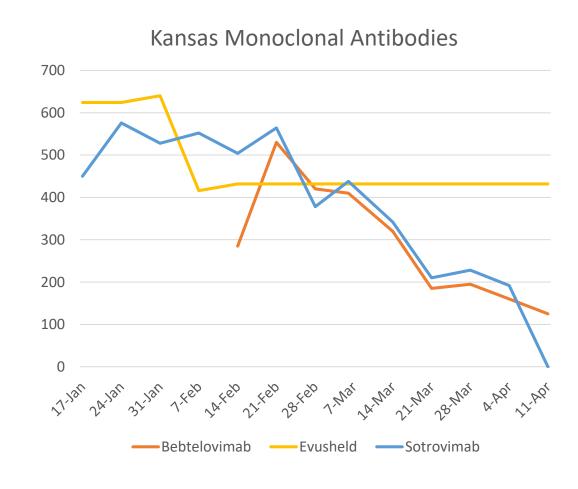
- Paxlovid (an oral antiviral treatment)
- Lagevrio (molnupiravir) (an alternative oral antiviral for patients for which Paxlovid is not appropriate or accessible)
- Bebtelovimab is an alternative monoclonal antibody therapy that is currently authorized and available for distribution
- Based on similar in vitro assay data currently available, these products are likely to retain activity against the BA.2 variant
- All treatment delivery sites can continue ordering Paxlovid, Lagevrio, and bebtelovimab from KDHE
- The FDA recommends that health care providers in all U.S. states and territories use alternative authorized therapy until further notice

#### **UPDATED - Evusheld EUA**

- April 1: Evusheld EUA updated to reflect dosage recommendation update to provide additional guidance for administration to patients who received only an initial dose of 300mg (150mg tixagevimab and 150mg cilgavimab)
- No changes to authorized dose for patient who received initial dose of 600mg (300mg tixagevimab and 300mg cilgavimab)
- Revised authorized dosage regimen is:
  - Individuals who received only the previously authorized initial dose of 300mg(150mg of tixagevimab and 150mg of cilgavimab) should receive an additional Evusheld dose as soon as possible. If a patient received their initial dose:
    - Less than 3 months ago, that patient should receive a dose of 300 mg (150mg of tixagevimab and 150mg of cilgavimab)
    - More than 3 months ago, that patient should receive a dose of 600mg (300mg tixagevimab and 300mg cilgavimab)

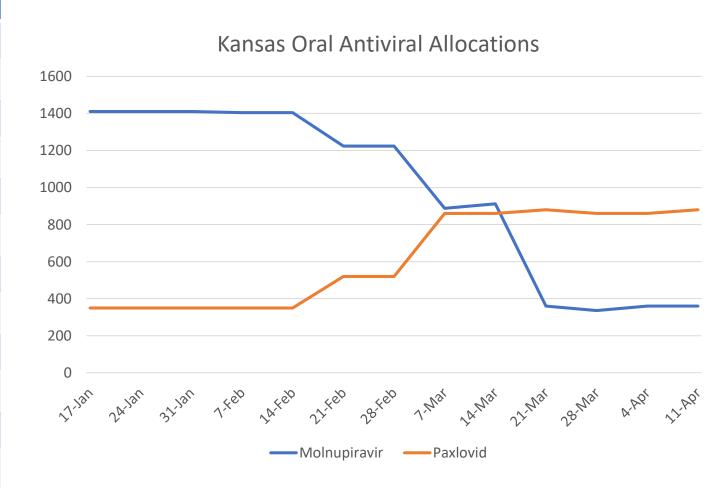
#### Kansas Monoclonal Antibody Allocations

WEEK	Bebtelovimab	Evusheld	Sotrovimab
24-Jan	0	624	576
31-Jan	0	640	528
7-Feb	0	416	552
14-Feb	285	432	504
21-Feb	530	432	564
28-Feb	420	432	378
6-Mar	410	432	438
14-Mar	320	432	342
21-Mar	185	432	210
28-Mar	195	432	228
4-Apr	160	432	192
11-Apr	125	432	0

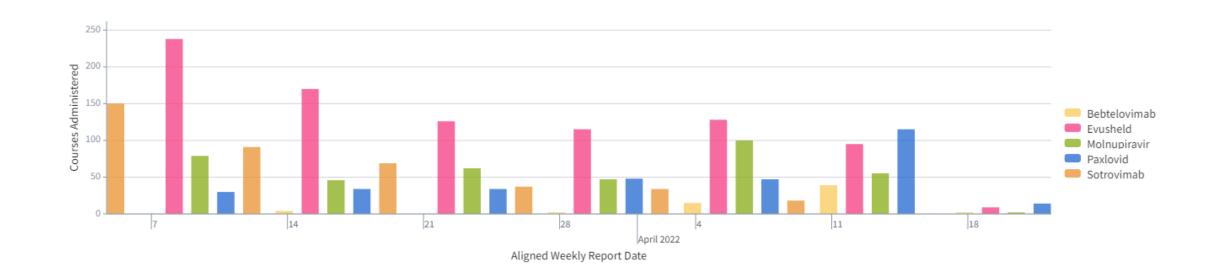


#### Kansas Oral Antiviral Allocations

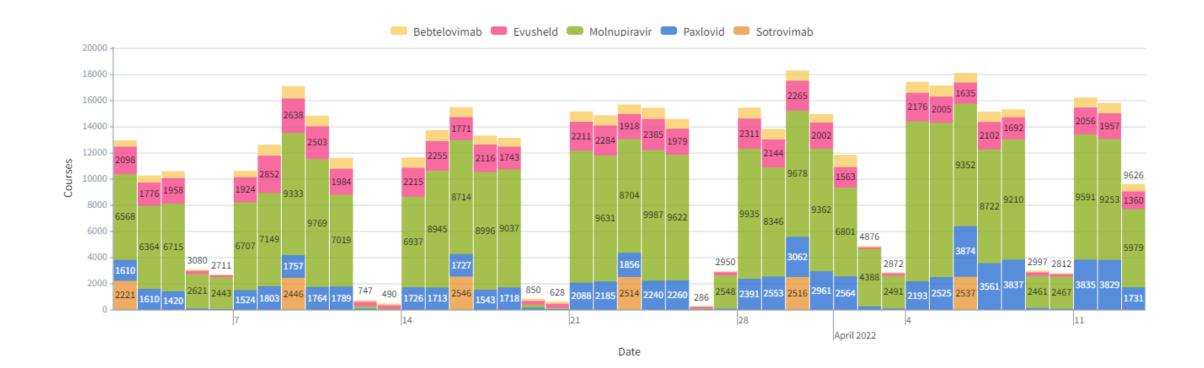
Date	Molnupiravir	Paxlovid
24-Jan	1410	350
31-Jan	1410	350
7-Feb	1404	350
14-Feb	1404	350
21-Feb	1224	520
28-Feb	1224	520
7-Mar	888	860
14-Mar	912	860
21-Mar	360	880
28-Mar	336	860
4-Apr	360	860
11-Apr	360	880



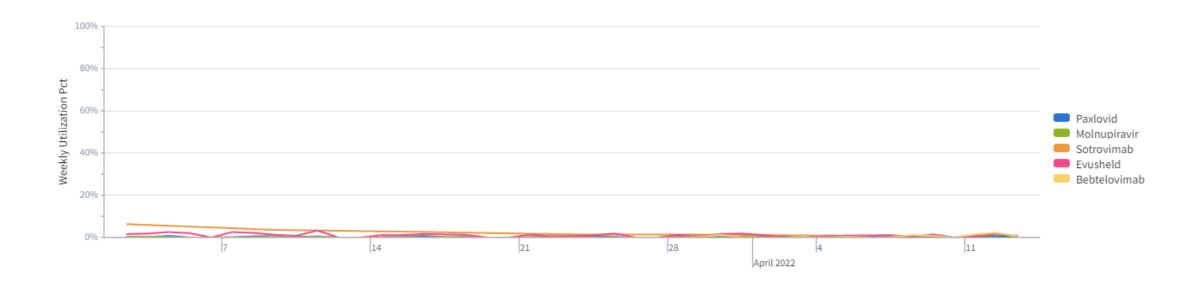
# Courses Used per Week (Wed – Tues)



# Inventory by Product by Date

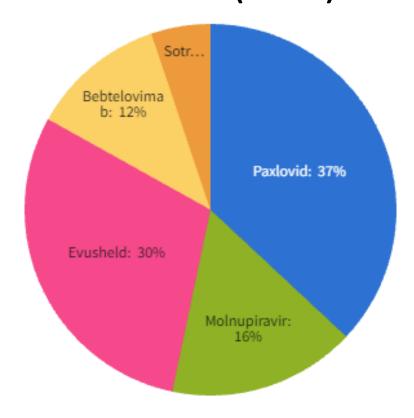


# % Utilization by Product

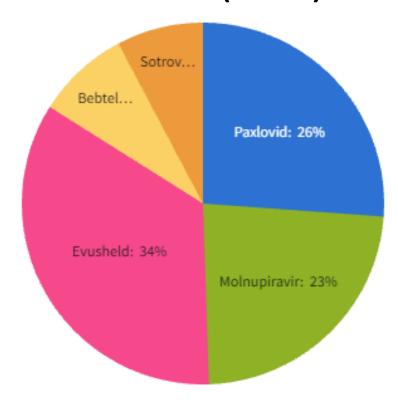


# Utilization by Product

#### Over the last 1 week (n=349)



#### Over the last 2 week (n=673)



#### Reporting Requirements

For Sotrovimab, bam/ete, REGEN-COV

Long Term Care / Skilled Nursing Facilities

NHSN

Hospitals / Hospital Pharmacies

HHSProtect/TeleTracking/
Health Departments

Non-hospital Facilities

HHS TeleTracking

Reporting required by 11:59 pm <u>each Wednesday</u>

For Evusheld, Paxlovid, Molnupiravir, Bebtelovimab

**HPOP** 

Reporting required by 11:59 pm daily

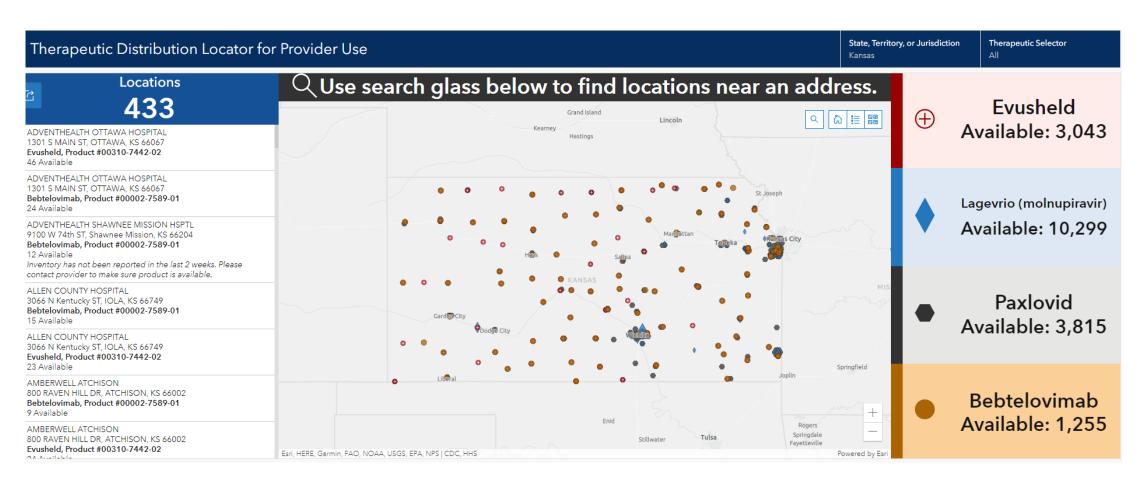
Sites administering/dispensing USG-purchased COVID-19 therapeutics must provide information on product utilization and stock on hand

Unclassified / For Public Distribution

## HHS Clinical Therapy Sessions

- Federal COVID-19 Response: COVID-19 Therapeutics Clinical Webinar
  - Every other Friday (11:00-12:00PM CT); Next Offering April 15
  - https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRF FtaWltejYzZz09
- Medical Professionals COVID-19 Roundtable
  - Every other Friday (11:00-12:00PM CT); Next Offering April 22
  - Email COVID19Therapeutics @hhs.gov if you'd like to join this session

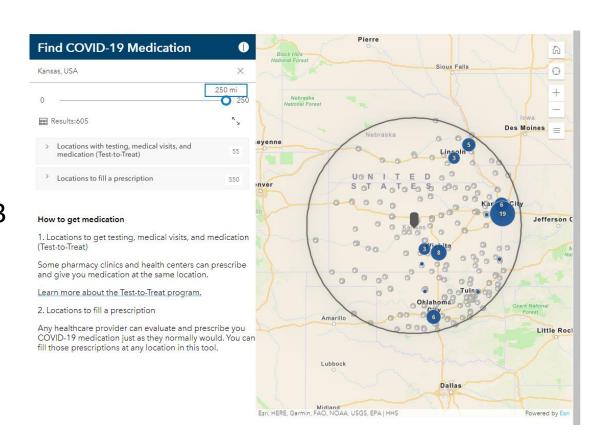
# Therapeutic Distribution Locator for Provider Use



https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

#### Test to Treat Locator

- New Test to Treat locator site launched Wed, 3/30
- https://covid-19-test-to-treat-locatordhhs.hub.arcgis.com/
- Identifies all Test to Treat program sites
- Call center also available: 1-800-232-0233 to get help in English, Spanish, and more than 150 other languages – 8am to midnight ET, 7 days a week
- Disability Information and access Line (DIAL) also available to specifically help those with disabilities access services. 1-888-677-1199. Monday-Friday from 9am to 8pm ET or DIAL@usaginganddisability.org



### Helpful Therapy Resources

- Side-by-Side Overview of Therapeutics Authorized or Approved for the Prevention of COVID-19 Infection or Treatment of Mild-Moderate COVID-19
  - https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/side-by-sideoverview.pdf
- Federal Response to COVID-19: Therapeutics Clinical Implementation Guide
  - <a href="https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/USG-COVID19-Tx-Playbook.pdf">https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/USG-COVID19-Tx-Playbook.pdf</a>
- COVID Therapeutics Decision Aid
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/ COVID-Therapeutics-Decision-Aid.pdf

## Therapies Questions

- If you have any questions related to monoclonal antibody distribution in Kansas, please contact Michael McNulty (<a href="mike.mcnulty@ks.gov">mike.mcnulty@ks.gov</a>)
- Issues with Logging into and using HPOP 833-748-1979 or cars helpdesk@cdc.gov