



Update: Distribution and Administration of COVID-19 Therapeutics

JANUARY 5, 2022 (UPDATED)

Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

UNCLASSIFIED / FOR PUBLIC DISTRIBUTION

Agenda

- 1. Distribution and Utilization Overview**
- 2. This Week's Allocations**
- 3. Allocation Update: bam/ete, REGEN-COV**
- 4. COVID-19 Treatment Guidelines**
- 5. New Resource: Decision Guide**
- 6. Equity in Allocations**
- 7. Prevalence of Variants Nationally**
- 8. Reporting Requirements**
- 9. Weekly Stakeholder Engagements**
- 10. Helpful Information and Resources**
- 11. Frequently Asked Questions**
- 12. Discussion / Q&A**

Distribution and Utilization Summary

4.11M

Shipped through all Tx programs¹

12,298

Number of sites shipped to¹

2.62M

Total reported usage²

63.7%

% of distributed supply used³

1. Total for entire period 2. Total usage as reported since 12/29 3. Reported through date 12/29

Note: Number of sites, % of total stock on hand and total reported usage is updated weekly

Source: ABC Distribution reports, TeleTracking, State Reports

Update: Allocation of bam/ete and REGEN-COV

- Federal guidance updated Friday, Dec 31, 2021 - all states and territories can continue to order both bam/ete and REGEN-COV based on allocated amounts for clinically appropriate use
- A number of alternative therapeutics available, including oral and IV antivirals, that are effective against the Omicron variant
 - NOTE: NIH recommended IV Remdesivir for therapy consideration in outpatients
- If Delta variant represents significant proportion of infections in a region and other options are not available or are contraindicated, eligible patients can be offered bam/ete or REGEN-COV, with the understanding that these treatments would be ineffective if patients are infected with Omicron
 - Concern can be mitigated if virus-specific diagnostic testing¹ in a given patient indicates infection with the Omicron VOC is unlikely.
- Dec 30, 2021 [National Institutes of Health \(NIH\) clinical guidelines](#)

Assess local and CDC data; review NIH guidelines

About this Week's Allocations

- Approximately 200,000 (197,386) courses of COVID-19 therapeutics have been allocated to jurisdictions for the period of Jan 3-9, 2022:
 - Sotrovimab (GSK) – 48,498 courses
 - Evusheld (AstraZeneca) – 49,896 courses
 - Bam/Ete (Lilly) – 44,520 courses
 - REGEN-COV (Regeneron) – 54,472 courses
- Monoclonal antibodies now allocated on one-week cycles (for at least the next three weeks); next allocation Monday, Jan 10.
- During the one-week allocation cycles, Sotrovimab and Evusheld **WILL NOT** be swept at the end of each week – no Federal Pool for additional product requests
- Subsequent allocations will be added to product on hand to increase jurisdictional flexibility
- Oral antivirals on two-week allocation cycle; next allocation Monday, Jan 10

One-week cycle for mAbs; Two-week Cycle for Oral Antivirals

January Allocation Schedule

- For planning purposes only
- HHS assesses COVID-19 data on a daily basis and may adjust allocation schedule as required
- Jan 10:**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV
Molnupiravir, Paxlovid
- Jan 18**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV
- Jan 24**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV
Molnupiravir, Paxlovid
- Jan 31**
Evusheld, Sotrovimab, Bam/Ete, Regen-COV

Monday		Tuesday	
3		AZ – 50K	
		GSK – 50K	
ABC CLOSED		BAM-ETE – 45K	
		REGN – 55K	
10		AZ	
	MERCK	GSK	
	PFIZER	BAM-ETE	
		REGN	
17 – MLK HOLIDAY		18	AZ
			GSK
			BAM-ETE
			REGN
24		AZ	
	MERCK	GSK	
	PFIZER	BAM-ETE	
		REGN	
31		AZ	
		GSK	
		BAM-ETE	
		REGN	

COVID-19 Treatment Guidelines When There Are Logistical or Supply Constraints

- The purpose of this interim statement is to provide guidance on which individuals might receive the greatest benefit from anti-SARS-CoV-2 therapeutics for treatment or prevention
- Prioritization:
 - Treatment of COVID-19 over post-exposure prophylaxis (PEP) of SARS-CoV-2 infection
 - Treatment of COVID-19 in unvaccinated or incompletely vaccinated individuals with clinical risk factors for severe illness and vaccinated individuals who are not expected to mount an adequate immune response
 - Use of tixagevimab plus cilgavimab (Evusheld) as pre-exposure prophylaxis (PrEP) for severely immunocompromised individuals over moderately immunocompromised individuals

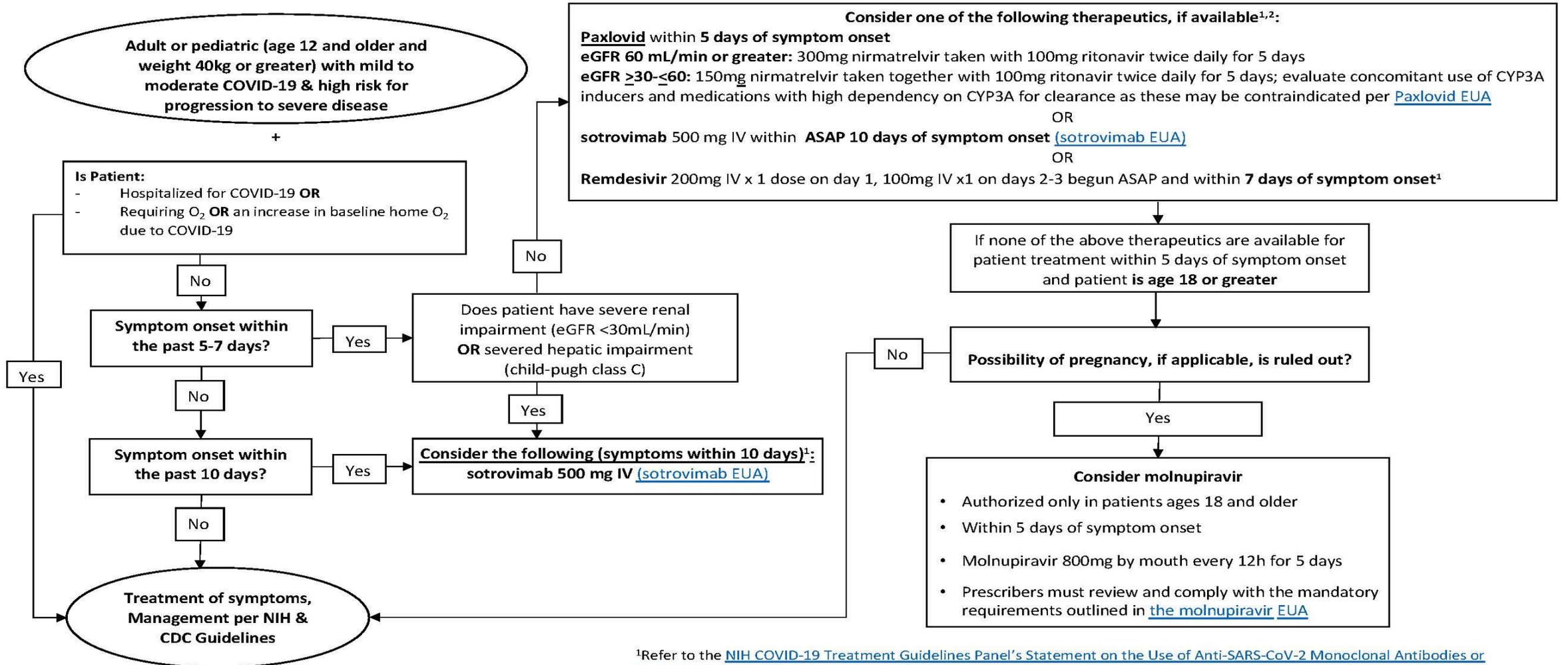
COVID-19 Treatment Guidelines When There Are Logistical or Supply Constraints

Tier	Risk Group
1	<p>Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); <i>or</i></p> <p>Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with additional risk factors).</p>
2	<p>Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥ 65 years or anyone aged < 65 years with clinical risk factors)</p>
3	<p>Vaccinated individuals at high risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with clinical risk factors)</p> <p>Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.</p>
4	<p>Vaccinated individuals at risk of severe disease (anyone aged ≥ 65 years or anyone aged < 65 with clinical risk factors)</p> <p>Note: Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.</p>

<https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/>

New Resource

COVID-19 Outpatient Therapeutics Decision Guide



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant¹

¹Refer to the [NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant](#); Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature ([Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients](#); DOI: 10.1056/NEJMoa2116846)

² COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting ([COVID-19 Convalescent Plasma EUA](#))

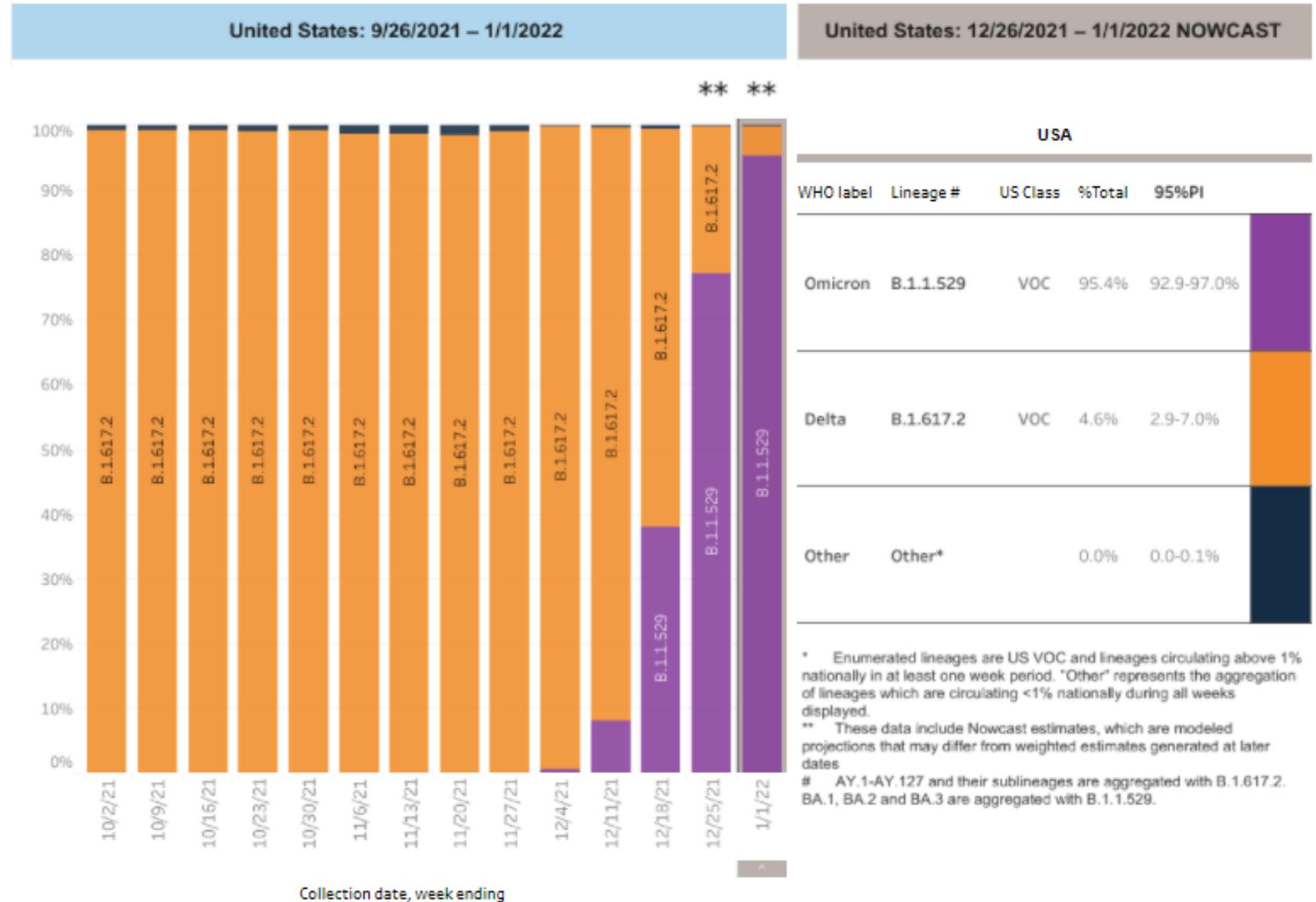
Equity Remains a Priority

- We urge jurisdictions to put equity at center of distribution plans
- HHS identifying about 200 HRSA-funded health centers across all 50 states to receive direct allocations of oral antiviral product
 - Separate from allocations to state and territorial health departments
- Will further help ensure oral antivirals are available to some of the most vulnerable communities and hard-hit populations across country
- We encourage jurisdictions to amplify where product is sent in their areas
 - Utilize provider communication networks
 - Post sites on health department websites
 - Partner with hospital associations for message amplification
 - Enlist support of public information officers

Equitable access to therapeutics is a shared responsibility

Prevalence of COVID-19 Variants Nationally

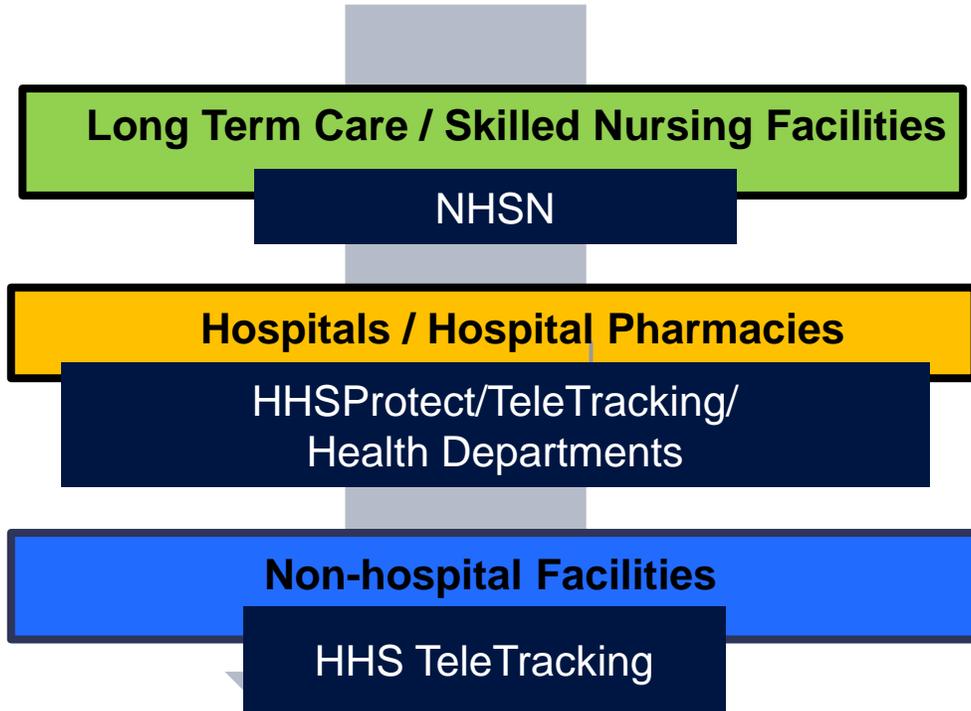
- HHS and CDC actively monitoring variant prevalence nationally
- Omicron prevalence is increasing



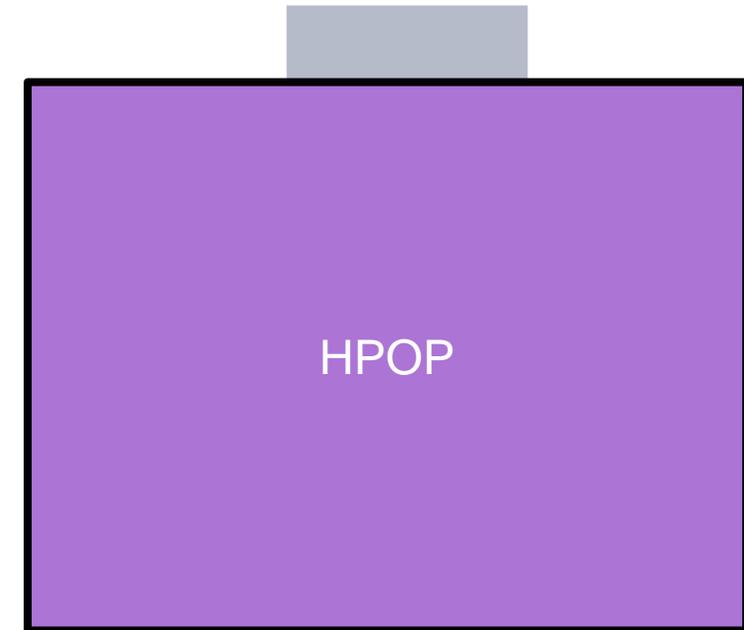
Reporting Requirements

For bam/ete, sotrovimab, REGEN-COV

For Evusheld, Paxlovid, Molnupiravir



**Reporting required
by 11:59 pm each Wednesday**



**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

Weekly Stakeholder Engagements

- **Office Call Sessions: HHS / ASPR Distribution and Administration of COVID-19 Therapeutics – open to all with equity in the process**
 - Tuesdays (2:00-2:30PM ET)
 - Thursdays (2:00-2:30PM ET)
- **Stakeholder Call: State and Territorial Health Officials**
 - Wednesdays (2:00-3:00PM ET)
- **Stakeholder Call: National Health Care and Medical Orgs and Associations**
 - Wednesdays (3:15-4:15PM ET)
- **Federal COVID-19 Response: Therapeutics 210 Webinar**
 - Every other Friday (12:00-1:00PM ET); Next session – *Jan 7*
 - Target audience: new administration sites, health officials

<https://hhsasproea.zoomgov.com/j/1617536991?pwd=NjFMcnJOUENuSFhtRFFtaWltZjYzZz09>

Please email COVID19Therapeutics@hhs.gov to request Zoom links for these calls

Helpful Information and Resources (I/II)

- **New!** [Outpatient Therapeutics Decision Guide](#)
- **Updated!** [Side-by-Side Overview of Outpatient mAb Therapies](#)
- **Recording of ASPR TRACIE webinar “[Monoclonals and More – Allocation and Distribution of Outpatient COVID-19 Therapeutics](#)”**
- [HHS Clinical Implementation Guide](#)
- **HHS Protect Therapeutics Dashboard**
<https://protect.hhs.gov/workspace/module/view/latest/ri.workshop.main.module.084a09b4-bcd0-4a6b-817a-90afb7a3cd1d>
- **HHS Therapeutics Homepage**
<https://www.phe.gov/COVIDTherapeutics>
- **COVID-19 Monoclonal Antibody Therapeutics Communications Toolkit** <https://www.phe.gov/mabs-toolkit>

Helpful Information and Resources (II/II)

- **REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers**
<https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/REGEN-COV-Subcutaneous-Injection-Instructions-for-Healthcare-Providers.aspx>
- **ASPR Regional Teams**
 - Consult [the ASPR Regional Team in your area](#) for questions regarding COVID-19 medical countermeasures
- **HRSA Uninsured Program [fact sheet](#)**
- **Increased CMS reimbursement rates for mAb administration: <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>**

Frequently Asked Questions (I/III)

Q1. Why did HHS transition from direct ordering to the state/territory-coordinated distribution system for COVID-19 mAbs?

The increased incidence of the Delta variant of SARS-CoV-2 caused a substantial surge in the utilization of monoclonal antibody (mAb) drugs, particularly in areas of the country with low vaccination rates. HHS is committed to helping ensure consistent availability of these critical drugs for current and future patients in all geographic areas of the country. As such, we updated the distribution process for mAbs to assure fairness and efficiency.

Q2. How do I reach my state/territorial health department point of contact?

If you do not know how to reach your health department POC, email HHS at COVID19Therapeutics@HHS.gov.

Q3. How are COVID-19 therapeutics distributed under the state/territory-coordinated distribution system?

The current process is a state/territory-coordinated distribution system similar to that used to distribute mAb product from November 2020 through February 2021.

HHS firmly believes a state and territory-coordinated distribution system will help maintain equitable distribution, both geographically and temporally, across the country - providing states and territories with consistent, fairly-distributed supply over the coming weeks.

Under this system, HHS determines the weekly amount of mAb product available to each state and territory. Subsequently, state and territorial health departments then determine which sites in their jurisdictions receive product and how much.



Contact COVID19Therapeutics@hhs.gov with any questions

Frequently Asked Questions (II/III)

Q4. Does HHS set aside distribution amounts for federal entities?

Yes; HHS determines separate distribution amounts for the Department of Health and Human Services, Department of Veterans Affairs, Department of Defense, Department of Homeland Security, Department of State, and select HHS HRSA-funded health centers

Q5. My distribution of mAbs was lost or destroyed in transit. Can it be replaced?

Yes! If your distribution of mAb products was lost or destroyed in transit, please contact HHS at COVID19Therapeutics@HHS.gov for assistance.

Q6. Will HHS transition back to the regular direct ordering process? If so, when?

HHS will continue to monitor product utilization rates, COVID-19 case burden, and overall availability of monoclonal antibody therapeutics to determine when we will shift back to the normal direct ordering process.

Q7. What is HPOP, and is it mandatory for state/territorial health departments to use this system?

HPOP is the Health Partner Ordering Portal - a therapeutics ordering portal which will eventually replace the Amerisource Bergen C-19 portal for therapeutics. All jurisdictional partners must use this system to order Evusheld, Paxlovid and Molnupiravir as well as satisfy the daily reporting requirements for these products. Health departments are encouraged to work through their ASPR RECs should they have questions

Q8. Is HHS still allocating the GSK sotrovimab product?

Yes; HHS continues to allocate GSK's sotrovimab monoclonal antibody. Allocation is currently on a one-week cadence. The next allocation of sotrovimab will be on Monday, Jan 10.

Q9. Is HHS still allocating bam/ete and REGEN-COV to jurisdictions?

Yes. In fact, HHS never paused allocation of bam/ete or REGEN-COV to any region. Currently, allocation of both products continues. Jurisdictions should keep in mind that bam/ete or REGEN-COV will not be effective in patients with the Omicron variant of COVID-19. Other treatment options do exist, and jurisdictions are encouraged to review NIH treatment guidelines. Please see slide 4 of this presentation.

Q10. Why is HHS still allocating COVID-19 therapeutics? Why are these products not available for purchase on the commercial market?

During this pandemic, it is imperative that COVID-19 therapeutics are accessible in a fair and equitable manner within communities across the country. It is for this reason that HHS oversees the distribution of COVID-19 therapeutics with equity and efficiency at the heart of allocation determinations.





ASPR

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

Thank you!