What Clinicians Need to Know About Available Therapeutic Options for COVID-19

Clinician Outreach and Communication Activity (COCA) Call

Thursday, June 16, 2022

Free Continuing Education

- Free continuing education is offered for this webinar.
- Instructions on how to earn continuing education will be provided at the end of the call.

Continuing Education Disclaimer

- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies over the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.

- CDC, our planners, and presenters wish to disclose they have no financial relationship(s) with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients, except for Dr. Eric Daar who would like to disclose that he provides research support and is a consultant related to HIV for Gilead, Merck, and GSK/ViiV.

- All of the relevant financial relationships listed for these individuals have been mitigated.

- Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Farley's discussion of unapproved drug products currently authorized under EUA for treatment of COVID-19.

- CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Describe key points about COVID-19 rebound after use of Paxlovid.
2. Describe Paxlovid use, prescribing, and availability.
3. Discuss where to find more information about COVID-19 therapeutics and availability.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Today's Presenters

- **Pragna Patel, MD, MPH**
  Chief Medical Officer, COVID-19 Response
  Centers for Disease Control and Prevention

- **Eric Daar, MD**
  Chief, Division of HIV Medicine
  Harbor-UCLA Medical Center
  Clinical Guidelines Team
  National Institutes of Health

- **John Farley, MD, MPH**
  Director, Office of Infectious Diseases
  Office of New Drugs, Center for Drug Evaluation and Research
  U.S. Food and Drug Administration

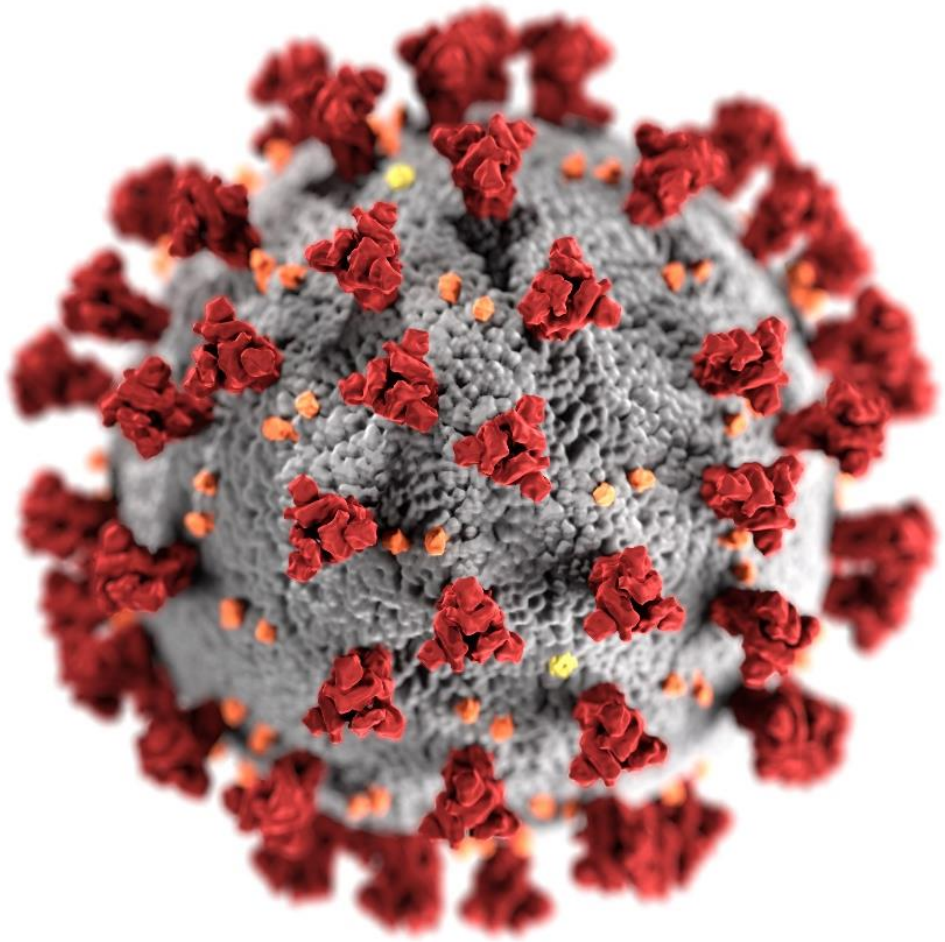
- **Meg Sullivan, MD, MPH, FAAP**
  Chief Medical Officer
  Office of the Assistant Secretary for Preparedness and Response
  U.S. Department of Health and Human Services

COVID-19 Surveillance Update

Pragna Patel, MD, MPH

Chief Medical Officer

COVID-19 Response

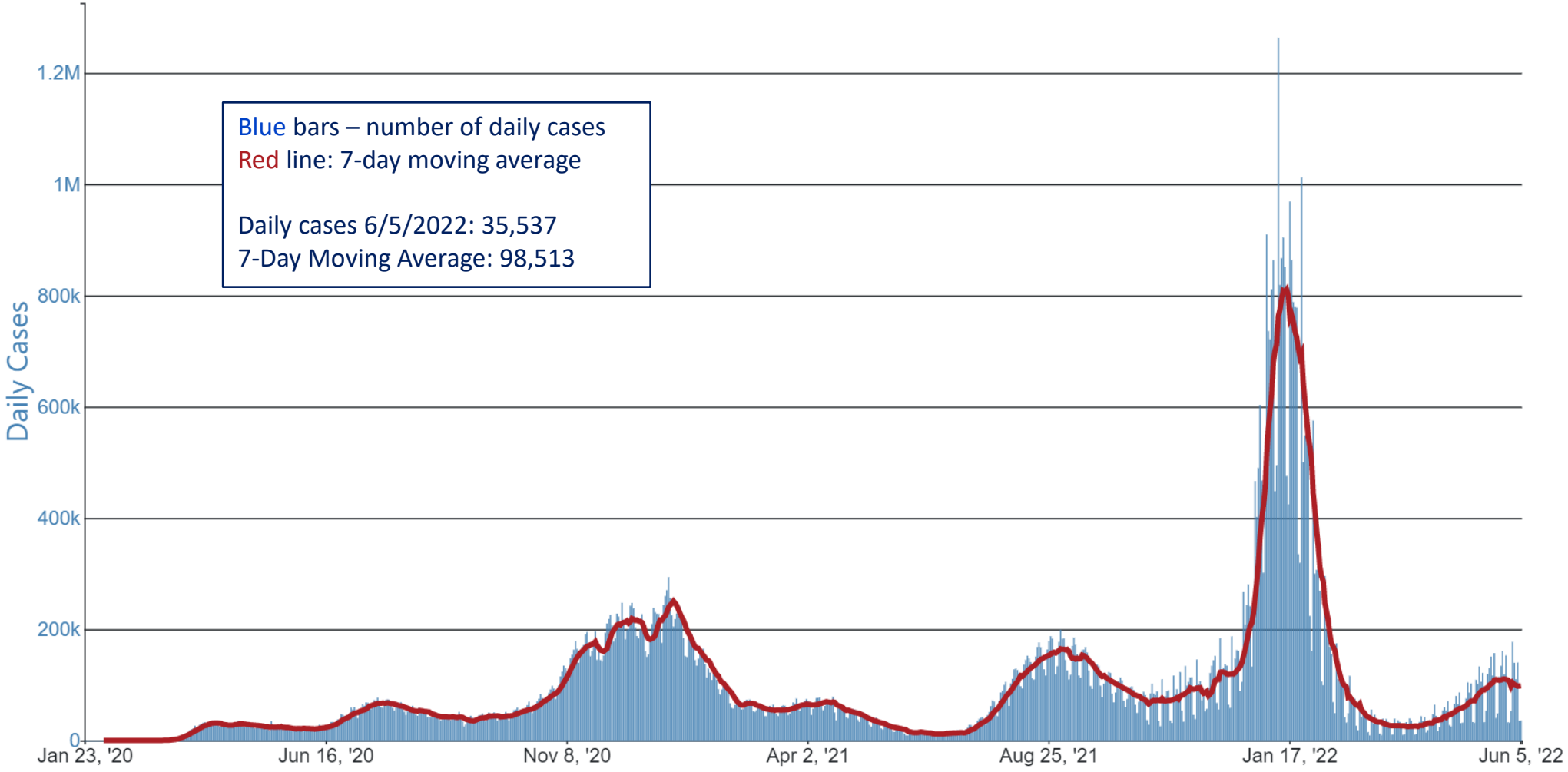


Clinician Outreach and Communication Activity Call

June 16, 2022

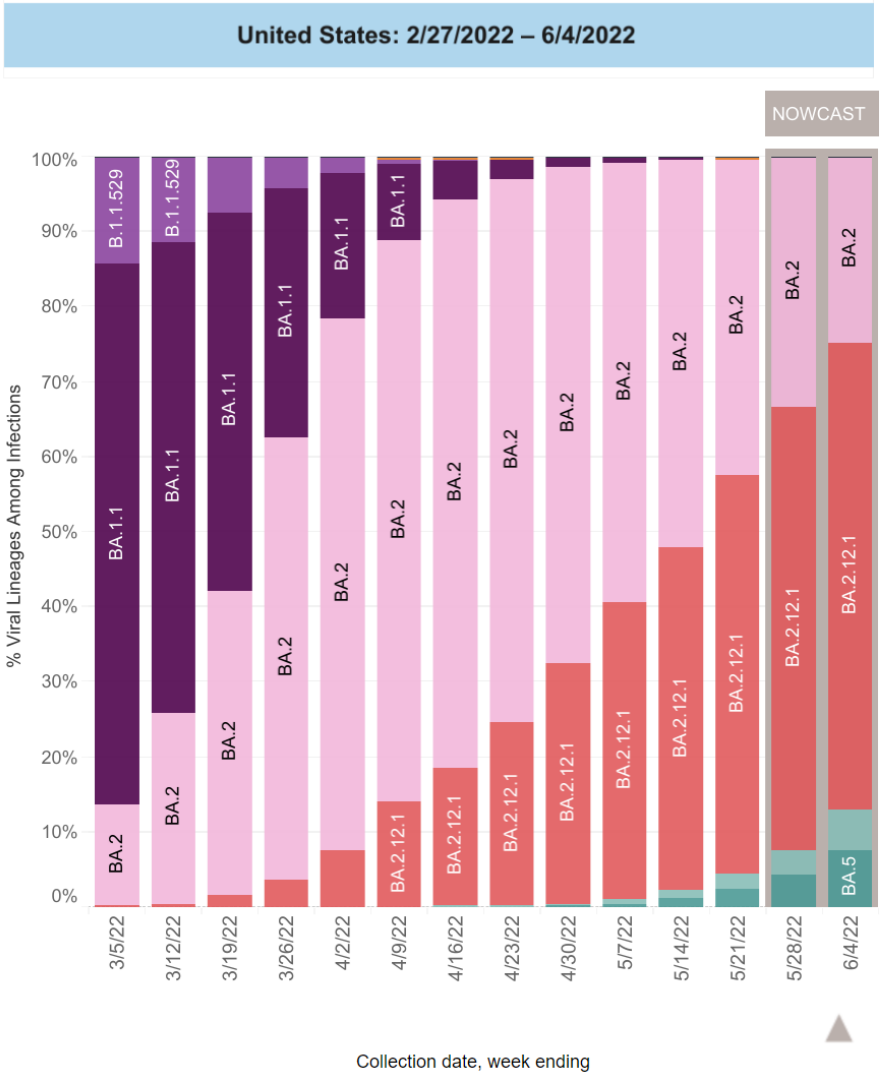
cdc.gov/coronavirus

Daily Trends in COVID-19 Cases in the United States



https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

Surveillance for Variants of Concern



United States: 5/29/2022 – 6/4/2022 NOWCAST

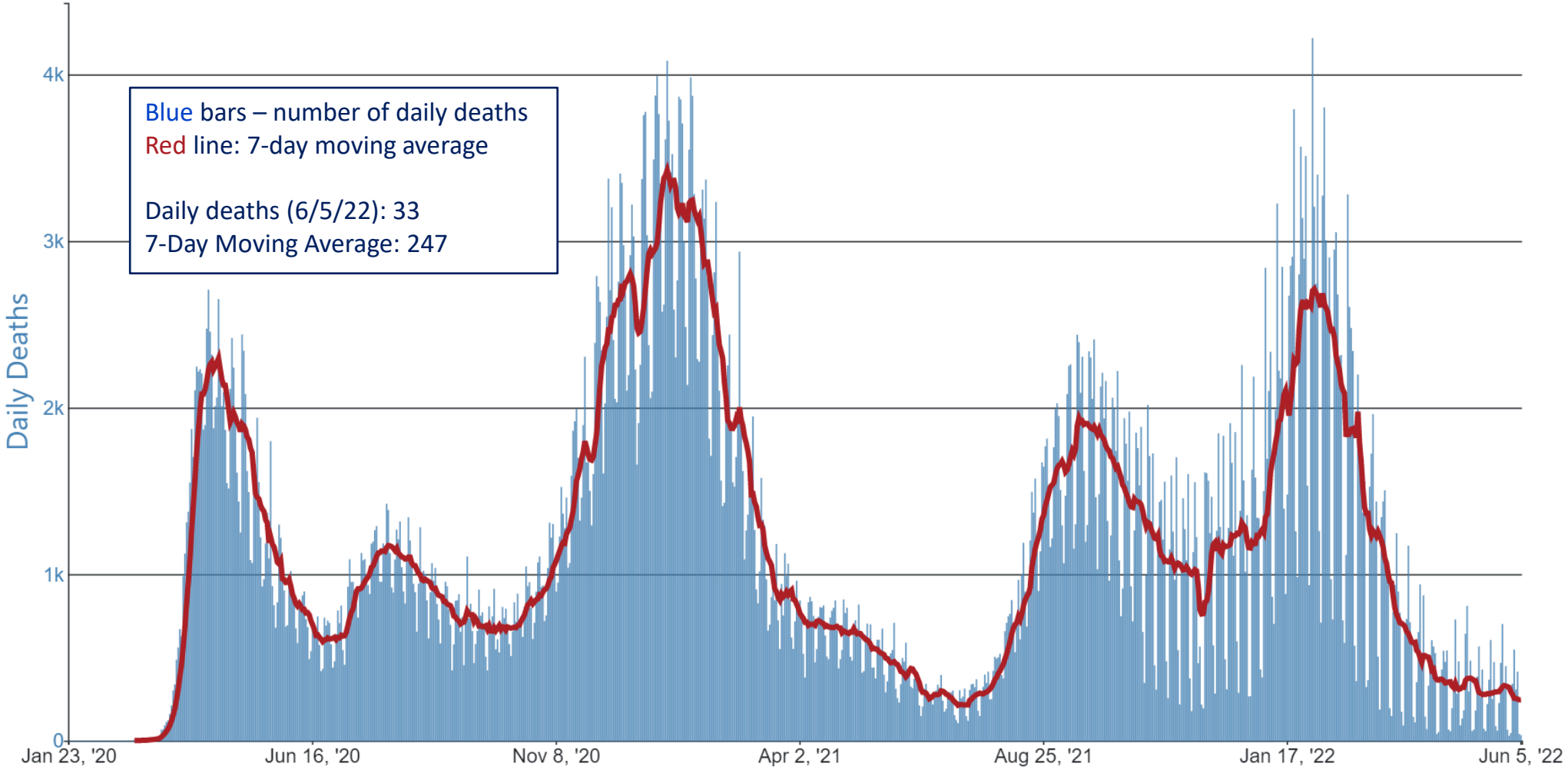
USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2.12.1	VOC	62.2%	58.5-65.7%
	BA.2	VOC	24.8%	22.4-27.3%
	BA.5	VOC	7.6%	5.6-10.1%
	BA.4	VOC	5.4%	3.8-7.5%
	BA.1.1	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.1%	0.0-0.1%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. For regional data, BA.1.1 and its sublineages are also aggregated with B.1.1.529, as they currently cannot be reliably called in each region. Except BA.2.12.1 and its sublineages, BA.2 sublineages are aggreagated with BA.2.

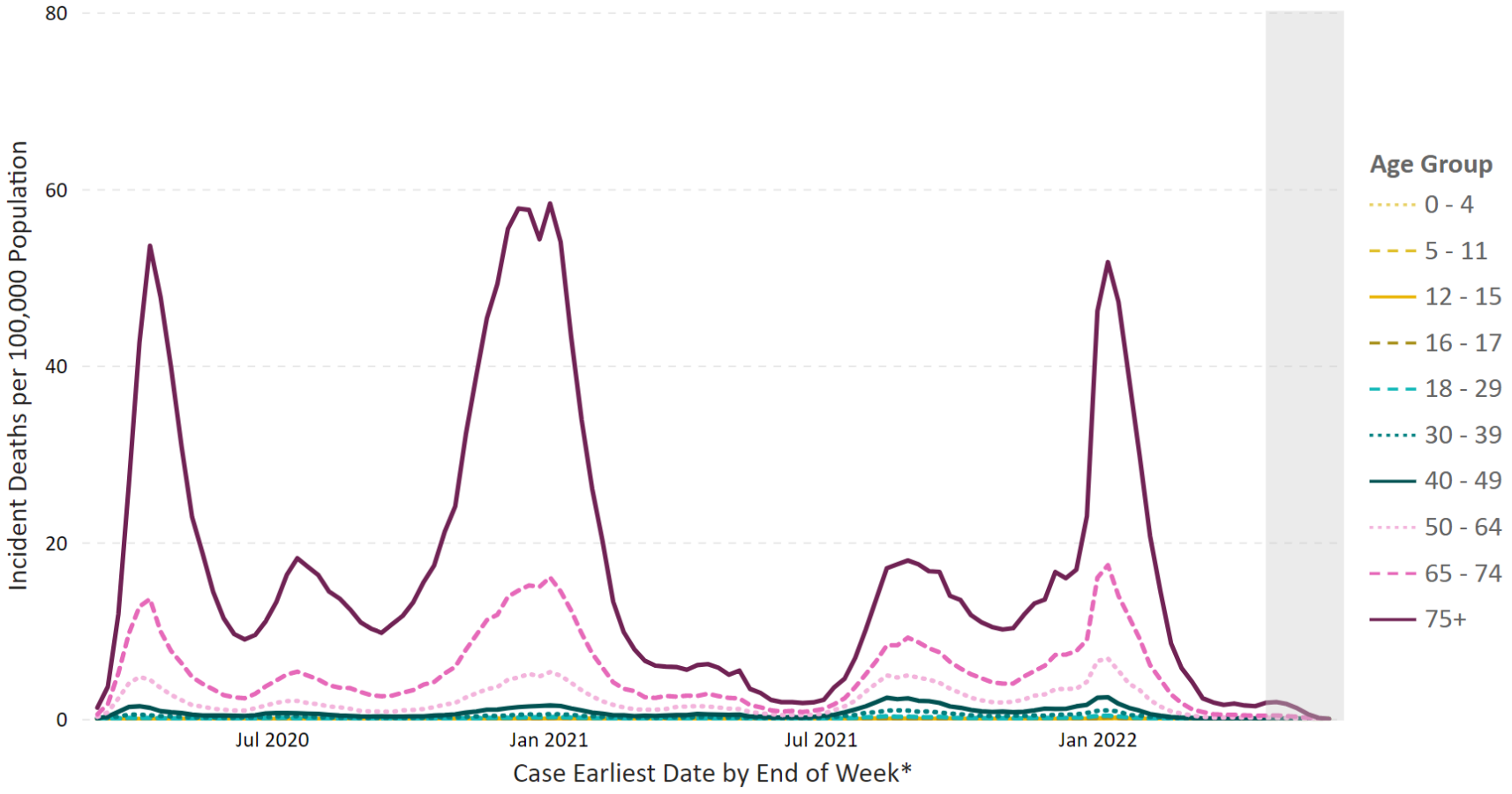
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Daily Trends in COVID-19 Deaths in the United States



https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths

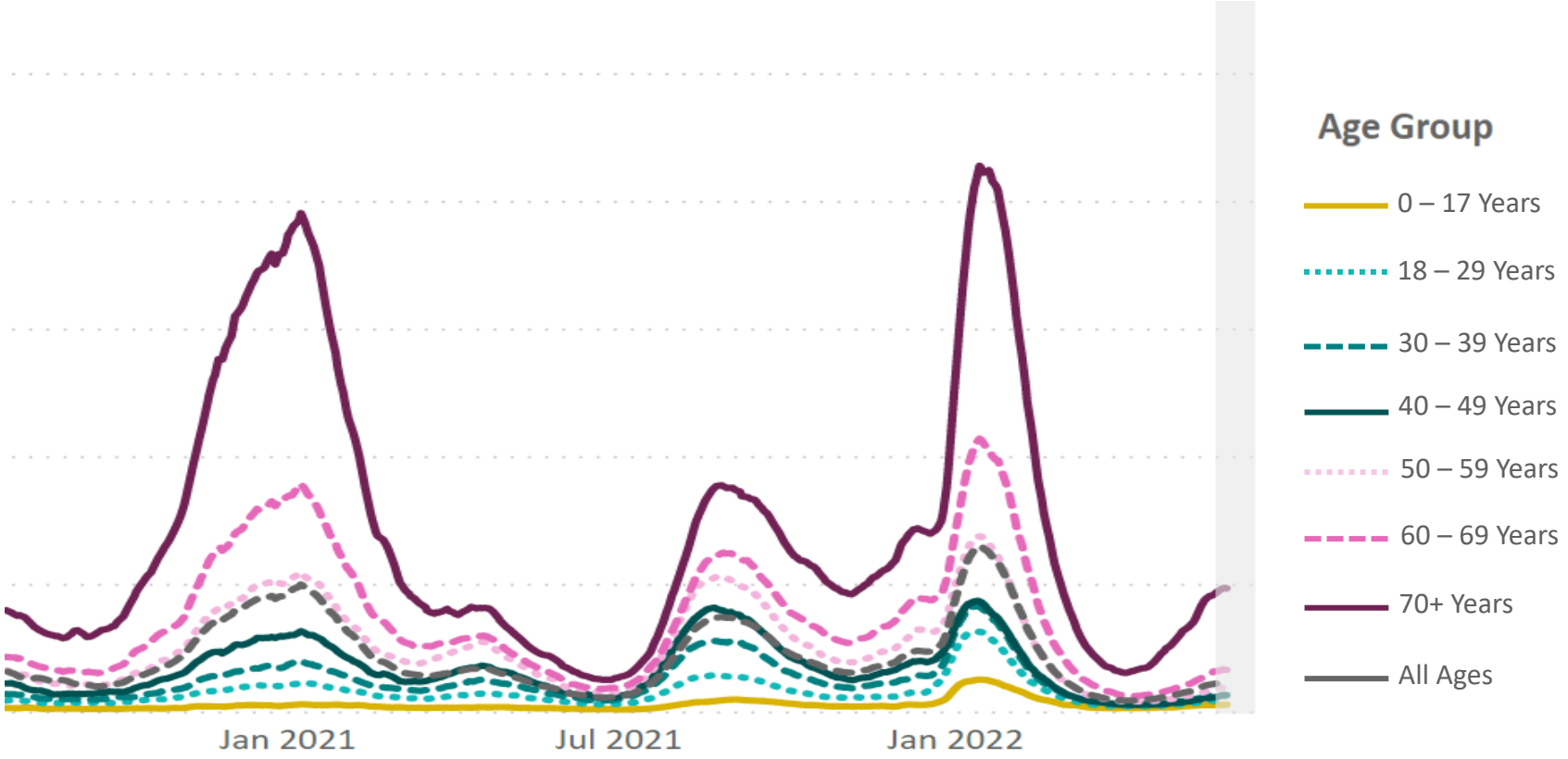
COVID-19 Weekly Deaths per 100,000 Population



Source: CDC COVID-19 Case Line-Level Data, 2019 US Census, HHS Protect; Visualization: Data, Analytics & Visualization Task Force and CDC CPR DEO Situational Awareness Public Health Science Team

https://covid.cdc.gov/covid-data-tracker/#demographicsovertime

New Admissions of Patients with Confirmed COVID-19



Last Updated: May 31, 2022

Unified Hospital Dataset, White House COVID-19 Team, Data Strategy and Execution Workgroup

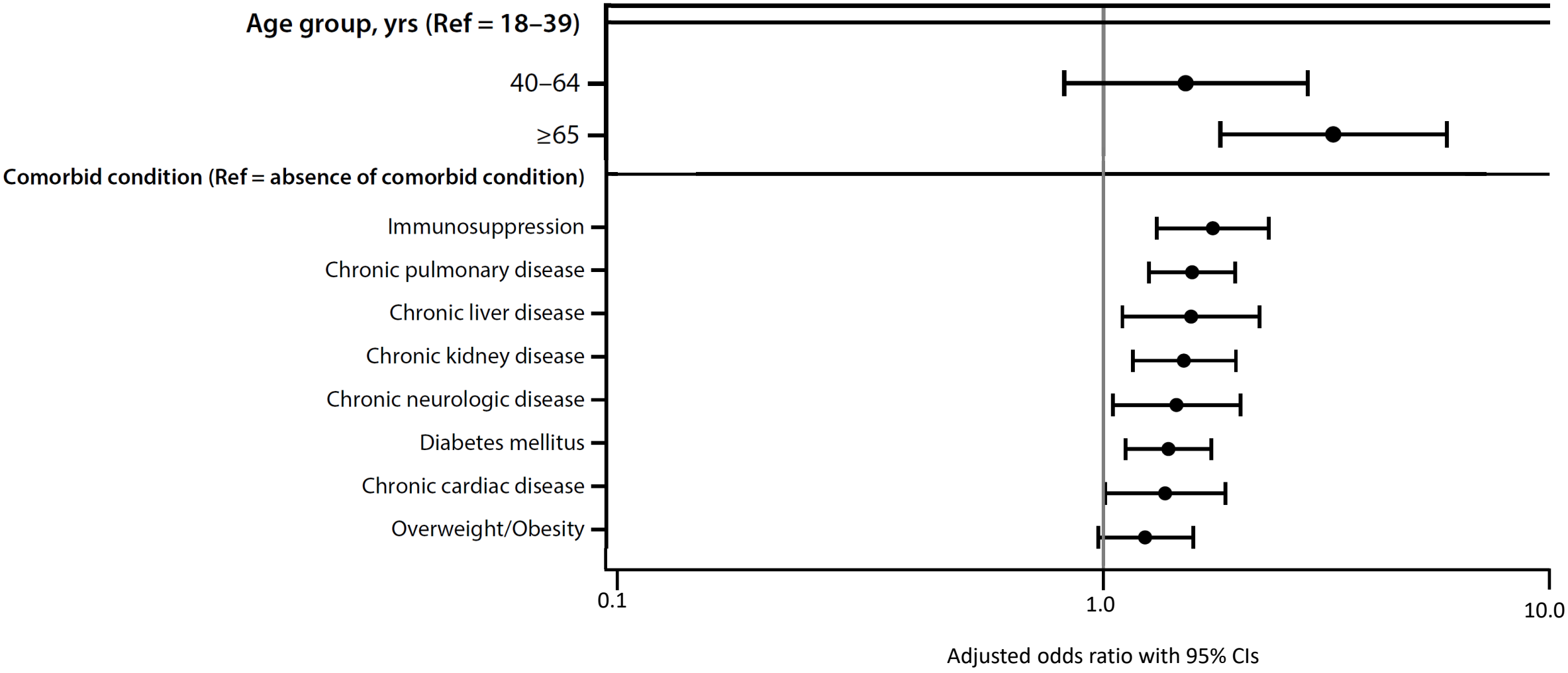
https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions

Risk for COVID-19 Infection, Hospitalization, and Death by Age Group

Rate compared to 18-29 years old	0-4 years old	5-17 years old	18-29 years old	30-39 years old	40-49 years old	50-64 years old	65-74 years old	75-84 years old	85+ years old
Cases	<1x	1x	Reference group	1x	1x	1x	1x	1x	1x
Hospitalization	1x	<1x	Reference group	2x	2x	3x	5x	8x	10x
Death	<1x	<1x	Reference group	4x	10x	25x	65x	140x	330x

https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html

Risk Factors for Severe COVID-19 Outcomes Among Persons Vaccinated with a Primary Series, December 2020–October 2021



Adapted from: Yek C, Warner S, Wiltz JL, et al. MMWR Morb Mortal Wkly Rep 2022;71:19-25. doi: http://dx.doi.org/10.15585/mmwr.mm7101a4

Healthcare Workers
Testing
Clinical Care
Quick Reference
Clinical Care Considerations
Ending Isolation
Specific Patient Types
Children
Underlying Medical Conditions
Pregnant People
Breastfeeding People
Family Planning Services

Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals

Updated Feb. 15, 2022 Languages Print

For the general public, see People with Certain Medical Conditions for an overview of medical conditions and resources. For information on the evidence used to update the list of underlying medical conditions, see the Science Brief.

On This Page

Purpose
Background
Summary of Conditions with Evidence
Actions Healthcare Professionals Can Take
Key Findings from One Large Cross-Sectional Study
More Information

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Self-knowledge Check

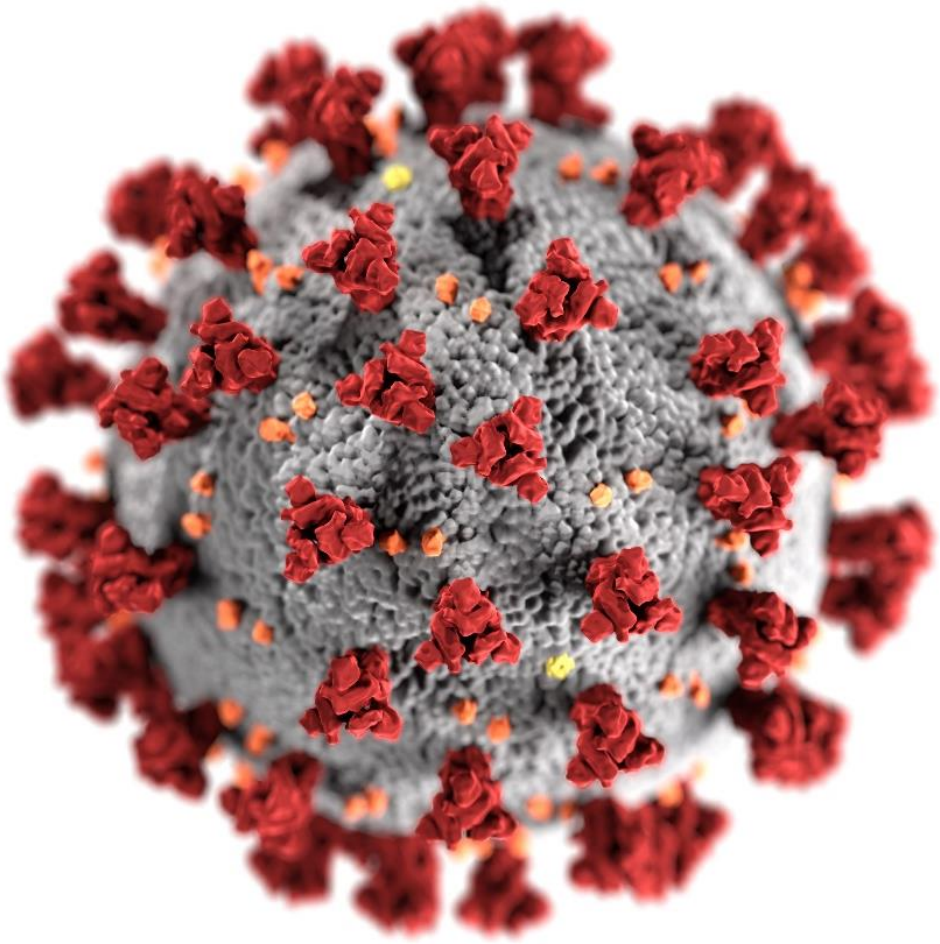
Which of the following individuals with SARS CoV-2 infection are at high risk for progression to severe disease?

A. 46-year-old obese person with diabetes and chronic obstructive pulmonary disease
B. 68-year-old women with mild arthritis but who remains very active
C. 82-year-old man with hypertension
D. A and C only
E. All of the above

Self-knowledge Check

The correct answer is E.

The reason for this is because increasing age is the most predominant risk factor for progression to severe disease with persons ≥ 65 years old being at highest risk compared with younger individuals. Therefore, patients B and C are at risk given their age alone. Multiple co-morbidities increase risk as well so patient A, although younger, is at risk given their history of chronic conditions, particularly lung disease and diabetes.



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Therapeutics for Treatment and Prevention of Patients at High Risk for Severe COVID-19

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Chief, Division of HIV Medicine
Harbor-UCLA Medical Center
Professor of Medicine
David Geffen School of Medicine
ACTIV-2 Vice Chair
Panel Member NIH COVID-19 Treatment Guidelines

Disclosures

- Research support and consultant for Gilead, Merck and GSK/ViiV (all for HIV products)

Coronavirus Disease 2019 (COVID-19) Treatment Guidelines

PATIENT DISPOSITION	PANEL'S RECOMMENDATIONS
Does Not Require Hospitalization or Supplemental Oxygen	All patents should be offered symptomatic management (AIII). For patients who are at high risk of progressing to severe COVID-19,[a] use 1 of the following treatment options: **Preferred Therapies** Listed in order of preference: • **Ritonavir-boasted nirmatrelvir (PaxlovId)[b,c] (AIa)** • **Remdeslvir[c,d] (BIa)** **Alternative Therapies** For use ONLY when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order: • **BebrelovImab[e] (CIII)** • **MolnupIrav1r[c,f] (CIIa)** The Panel **recommends against** the use of **dexamethasone[g]** or **other** systemic corticosteroids in the absence of another Indication **(AIII).**

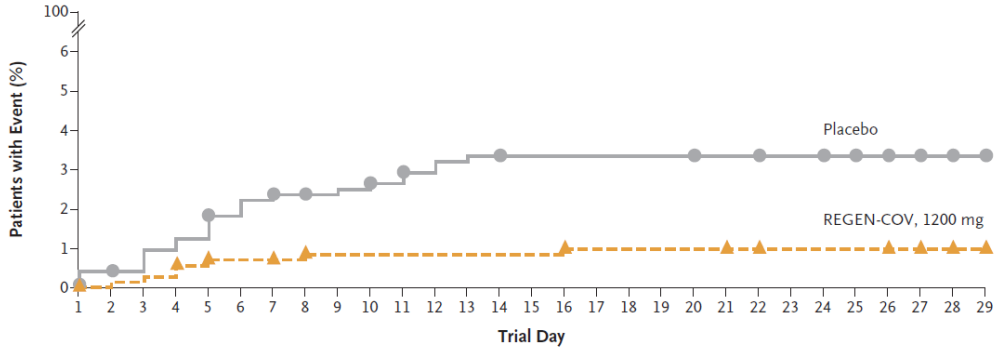
Ratings of Recommendations: A = Strong; B = Moderate; C = Weak
Ratings of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies II = Expert opinion

[a]CDC webpage for criteria of high risk; [b]Caution about drug-drug interactions; [c]If hospitalized , treatment course can be completed; [d]Remdesivir is 3 consecutive day infusion; [e]Bebtelovimab has in vitro activity but no clinical efficacy data; [f]Molnupiravir has lower efficacy than preferred options; [g]There is currently a lack of safety and efficacy data using glucocorticoids in non-hopstialized patients

REGEN-COV Antibody Combination and Outcomes in Outpatients with Covid-19

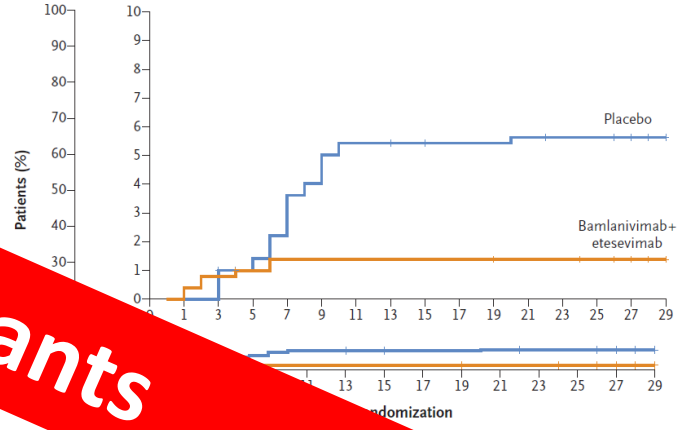
DOI: 10.1056/NEJMoa2108163

A Covid-19–Related Hospitalization or Death from Any Cause — Amended Phase 3 Trial



Bamlanivimab plus Etesevimab or Moderate Covid-19

DOI: 10.1056/NEJMoa2102685



Victim of Variants

JAMA | Original Investigation

Effect of Sotrovimab on Hospitalization or Death Among High-risk Patients With Mild to Moderate COVID-19

A Randomized Clinical Trial

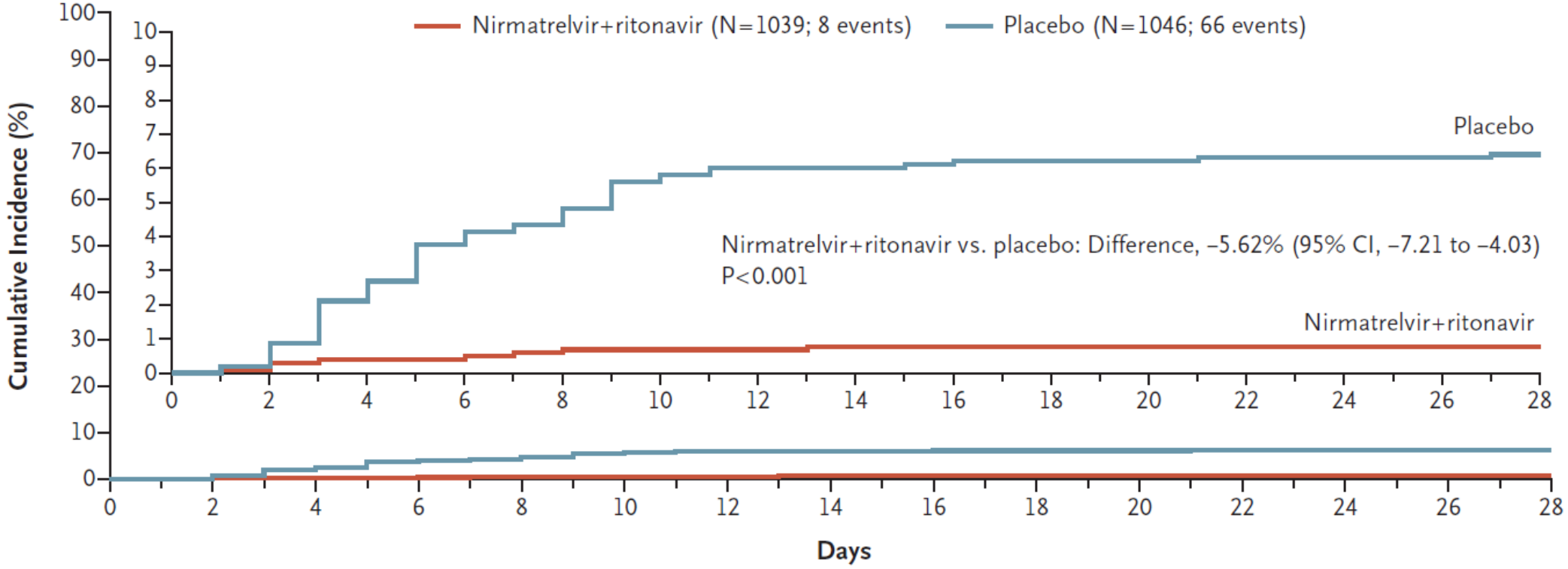
JAMA. 2022;327(13):1236-1246. doi:10.1001/jama.2022.2832

Table 2. Primary and Secondary Efficacy Outcomes for the As-Randomized Population[a]

	Sotrovimab (n = 528)	Placebo (n = 529)	Absolute difference (95% CI), %[b]	Adju (95% CI)	P value[c]
Primary efficacy outcome, No. (%)[d]					
All-cause hospitalization lasting >24 h for acute illness management or death due to any cause through 29 d	6 (1)	30 (6)	-4.53 (-6.70 to -2.37)	0.21 (0.09 to 0.50)[e]	<.001
Components of the primary outcome, No. (%)					
All-cause hospitalization lasting >24 h for acute illness management	6 (1)	29 (5)			
Death due to any cause	0	2 (<1)[f]			

Oral Nirmatrelvir for High-Risk, Nonhospitalized Adults with Covid-19

B **Covid-19–Related Hospitalization or Death from Any Cause through Day 28 among Patients Treated ≤5 Days after Symptom Onset**



No. at Risk

NMV-r	1039	1034	1023	1013	1007	1004	1002	1000	997	995	993	993	993	993	992
Placebo	1046	1042	1015	990	977	963	959	959	955	953	951	948	948	948	945

DOI: 10.1056/NEJMoa2118542

Nirmatrelvir plus Ritonavir Drug-Drug Interactions

https://covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-/paxlovid-drug-drug-interactions/

https://covid19-druginteractions.org/checker

Nirmatrelvir plus Ritonavir Interactions

Medications Without Clinically Relevant Interactions

These commonly prescribed medications may be co-administered without dose adjustment and without increased monitoring. This list is not inclusive of all noninteracting medications within each drug category.

Acid reducing agents
- Famotidine
- Omeprazole
- Pantoprazole

Allergy medications
- Cetirizine
- Diphenhydramine
- Loratadine

Anti-infective agents
- Azithromycin
- Hydroxychloroquine

Diabetes medications
- Empagliflozin
- Insulin
- Metformin
- Pioglitazone

Immunosuppressants
- Methotrexate
- Mycophenolate
- Prednisone

Lipid-modifying agents
- Ezetimibe

Pain medications
- Acetaminophen
- Aspirin
- Codeine
- Ibuprofen
- Naproxen

Respiratory medications
- Corticosteroids (inhaled)
- Formoterol
- Montelukast

Adjust Concomitant Medication Dose and Monitor for Adverse Effects.

Consult the Liverpool COVID-19 Drug Interactions website or the Ontario COVID-19 Science Advisory Table for specific dosing recommendations. If the dose of the concomitant medication cannot be adjusted. withhold the medication (if clinically appropriate) or use an alternative concomitant medication or COVID-19 therapy.

Temporarily Withhold Concomitant Medication, If Clinically Appropriate

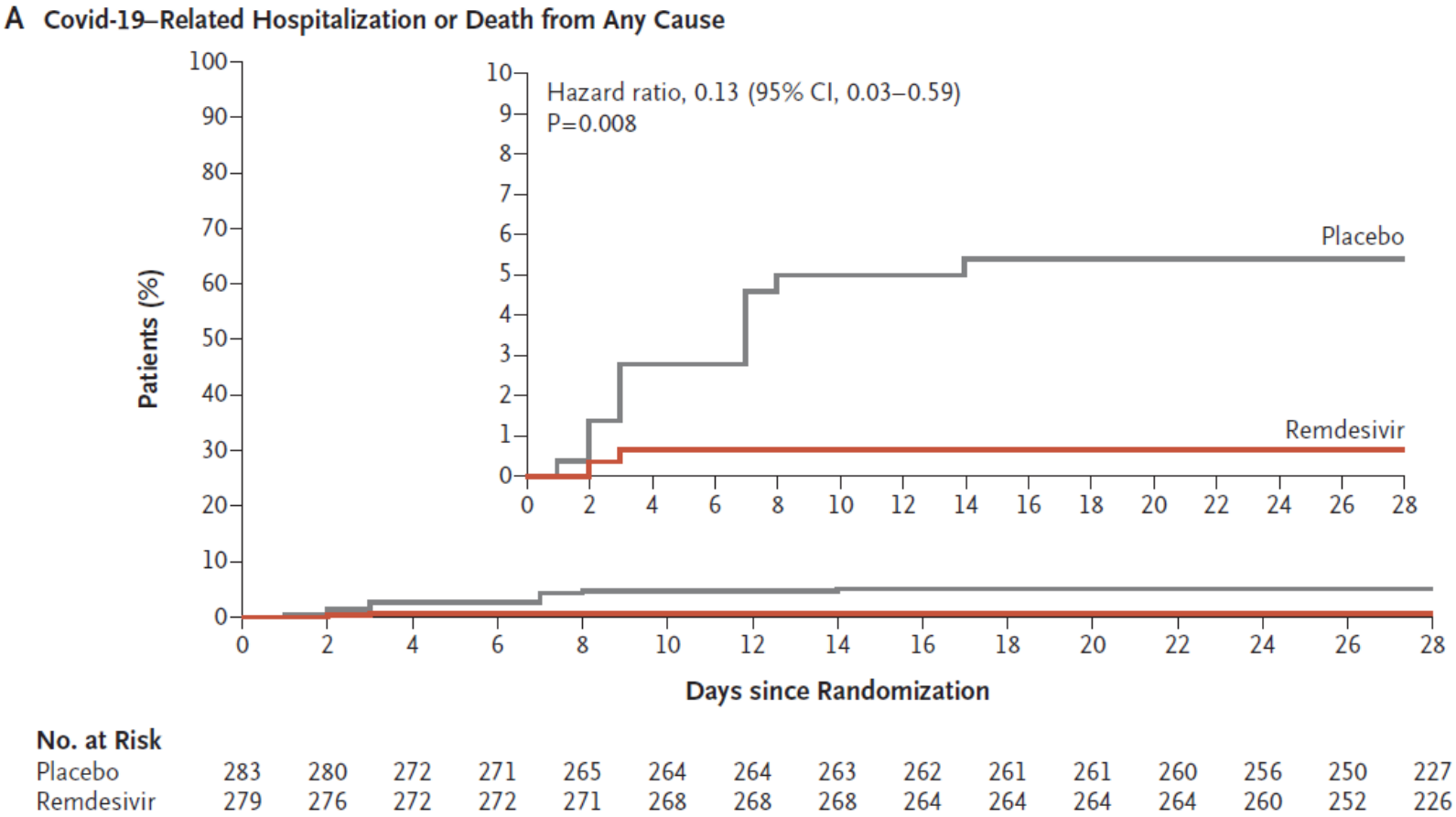
With hold these medications ions during ritonavir-boosted nirmatrelvir treatment and for at least 2-3 days after treatment completion. They may need to be withheld for longer if the patient 1s elderly or the medication has a long half- life. If withholding is not clinically appropriate, use an alternative concomitant medication or COVID-19 therapy.

Prescribe Alternative COVID-19 Therapy.

For these medications. management strategies are not possible or feasible, or the risks outweigh the potential benefits.

Early Remdesivir to Prevent Progression to Severe COVID-19 in Outpatients

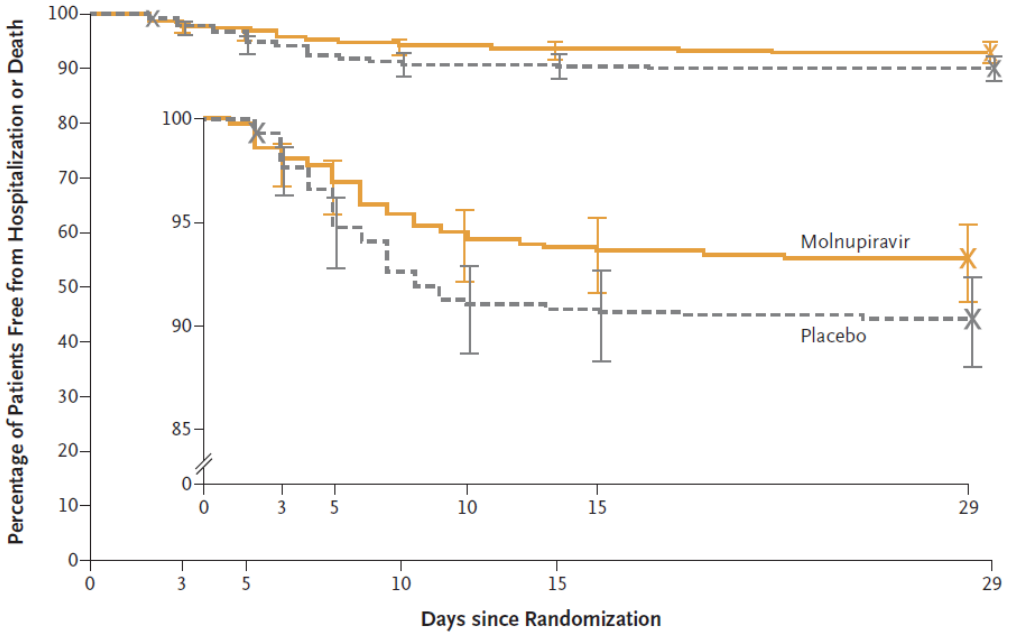
R.L. Gottlieb, C.E. Vaca, R. Paredes,J. Mera, B.J. Webb, G. Perez, G. Oguchi, P. Ryan, B.U. Nielsen, M. Brown, A. Hidalgo, Y. Sachdeva, S. Mittal, 0. Osiyemi, J. Skarbinski, K.Juneja, R.H. Hyland, A. Osinusi, S. Chen, G. Camus, M. Abdelghany, S. Davies, N. Behenna-Renton, F. Duff, F.M. Marty,* M.J. Katz, A.A. Ginde, S.M. Brown, J.T. Schiffer, and J.A. Hill, for the GS-US-540-9012 (PINETREE) Investigators†



DOI: 10.1056/NEJMoa2116846

Molnupiravir for Oral Treatment of COVID-19 in Nonhospitalized Patients

A. Jayk Bernal, M.M. Gomes da Silva, D.B. Musungaie, E. Kovalchuk, A. Gonzalez, V. Delos Reyes, A. Martin-Quiros, Y. Caraco, A. Williams-Diaz, M.L. Brown, J. Du, A. Pedley, C. Assaid, J. Strizki, J.A. Grobler, H.H. Shamsuddin, R. Tipping, H. Wan, A. Paschke, J.R. Butterton, M.G.Johnson, and C. De Anda, for the MOVe-OUT Study Group*



No. at Risk						
Molnupiravir	709	699	693	670	665	661
Placebo	699	693	674	637	634	631
No. of Events						
Molnupiravir	10	6	23	5	4	0
Placebo	5	19	37	3	3	0

N Engl J Med 2022;386:509-20.
DOI: 10.1056/NEJMoa2116044

FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR BEBTELOVIMAB

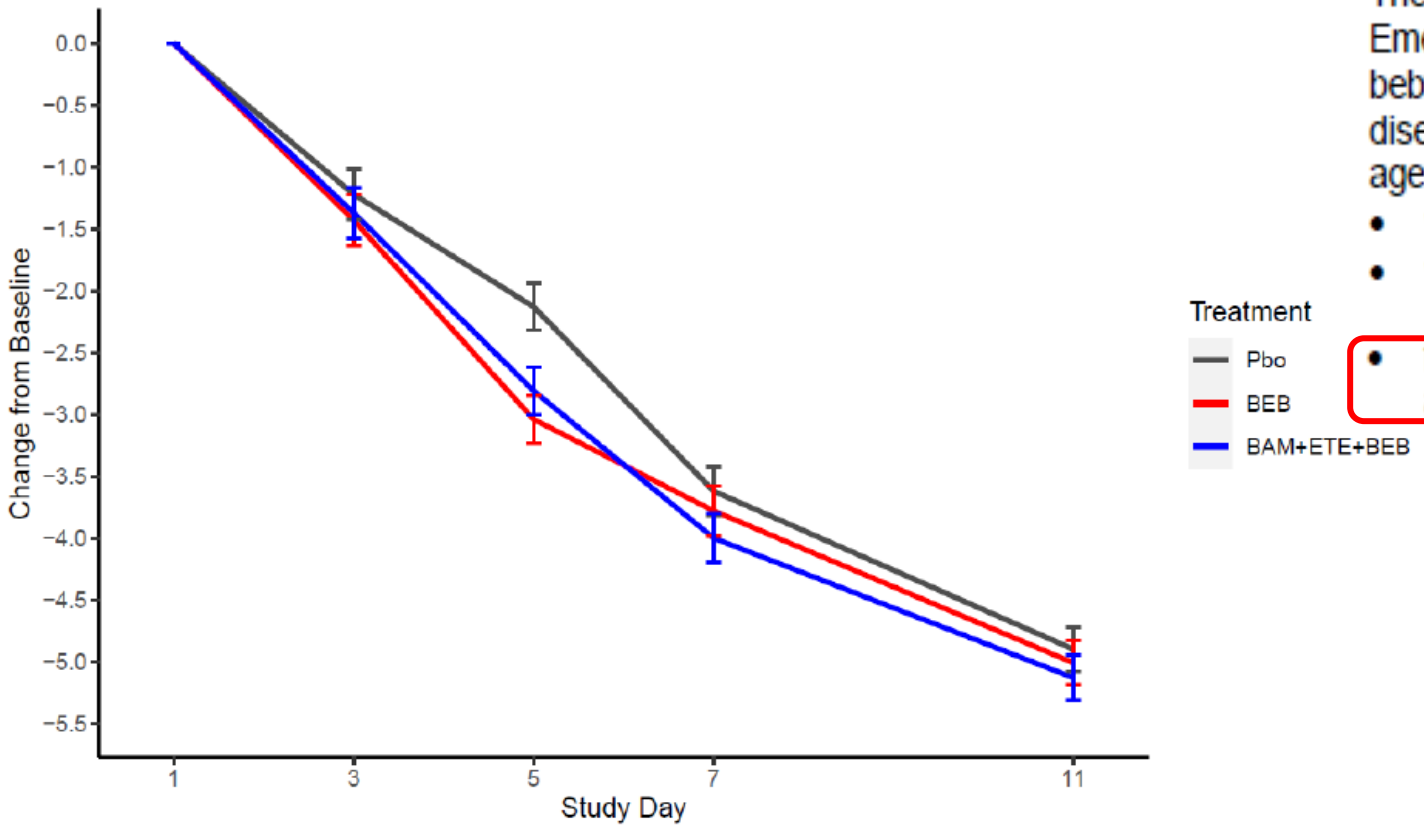


Figure 1: SARS-CoV-2 Viral Load Change from Baseline (Mean ± SE) by Visit from the Placebo-Controlled Portion of BLAZE-4 in Low Risk Adults (700 mg bamlanivimab, 1,400 mg etesevimab, 175 mg bebtelovimab together and 175 mg bebtelovimab alone).

----------EMERGENCY USE AUTHORIZATION----------

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg):

- with positive results of direct SARS-CoV-2 viral testing, **and**
- who are at high risk for progression to severe COVID-19, including hospitalization or death, **and**
- for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

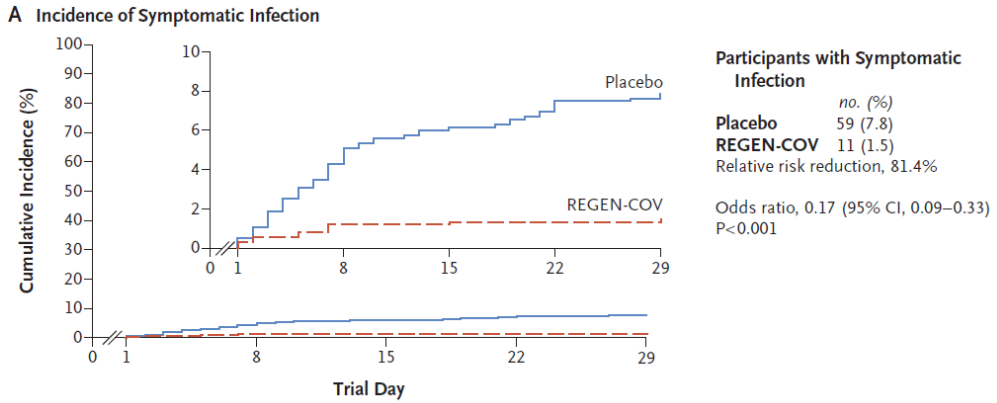
Drug	Dosing	Duration	Time from Symptom Onset	Specific issues
Nirmatrelvir (N) + ritonavir (RTV)	eGFR ≥60mL/min: N 300 mg with RTV 100 gm po bid eGFR ≥30 to <60 mL/min Nirmatrelvir 150 mg with RTV 100 mg po bid	5 days	≤5 days	• DDIs • Not recommended with Child-Pugh Class C
Remdesivir (RDV)	RDV 200 mg IV F/B 100 mg IV daily	Day 1 Day 2, 3	≤ 7 days	• Infusion over 30-120 min • Infusions over 3 consecutive days
Bebtelovimab (BEB)	BEB 175 mg IV	Day 1	≤ 7 days	• Administer ≥30 seconds • No clinical endpoint data
Molnupiravir (MOL)	MOL 800 mg po bid	5 days	≤5 days	• Potentially less efficacious than other options • Safety concerns

Prevention

Sub utan EN-COV Antibody
Combination t Covid-19

IMoa2109682

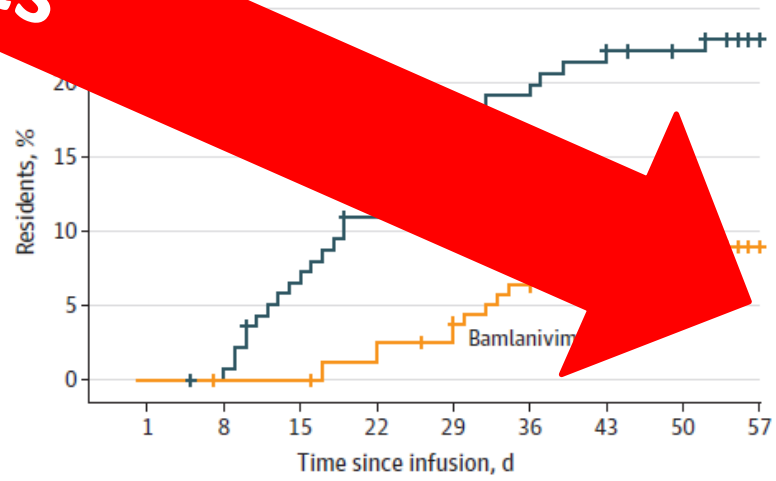
Victim of Variants



JAMA | Original Investigation

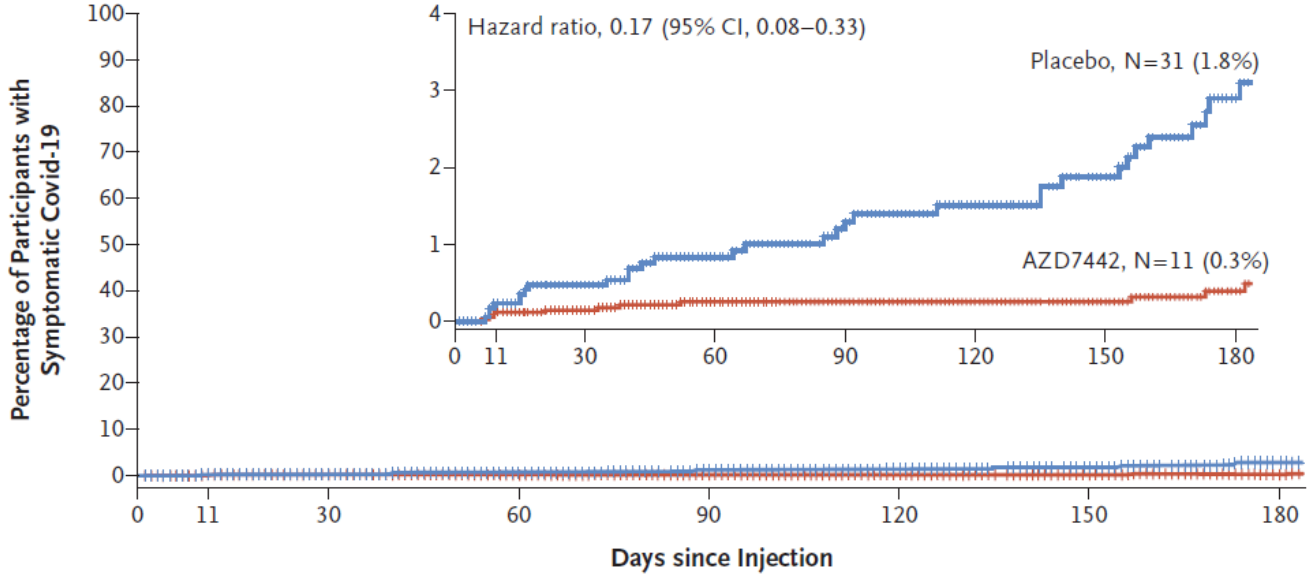
Effect of Bamlanivimab vs Placebo on Incidence of COVID-19 Among Residents and Staff of Skilled Nursing and Assisted Living Facilities
A Randomized Clinical Trial

JAMA. doi:10.1001/jama.2021.8828



Intramuscular AZD7442 (Tixagevimab-Cilgavimab) for Prevention of COVID-19

M.J. Levin, A. Ustianowski, S. De Wit, O. Launay, M. Avila, A. Templeton, Y. Yuan, S. Seegobin, A. Ellery, D.J. Levinson, P. Ambery, R.H. Arends, R. Beavon, K. Dey, P. Garbes, E.J. Kelly, G.C.K.W. Koh, K.A. Near, K.W. Padilla, K. Psachoulia, A. Sharbaugh, K. Streicher, M.N. Pangalos, and M.T. Esser, for the PROVENT Study Group*



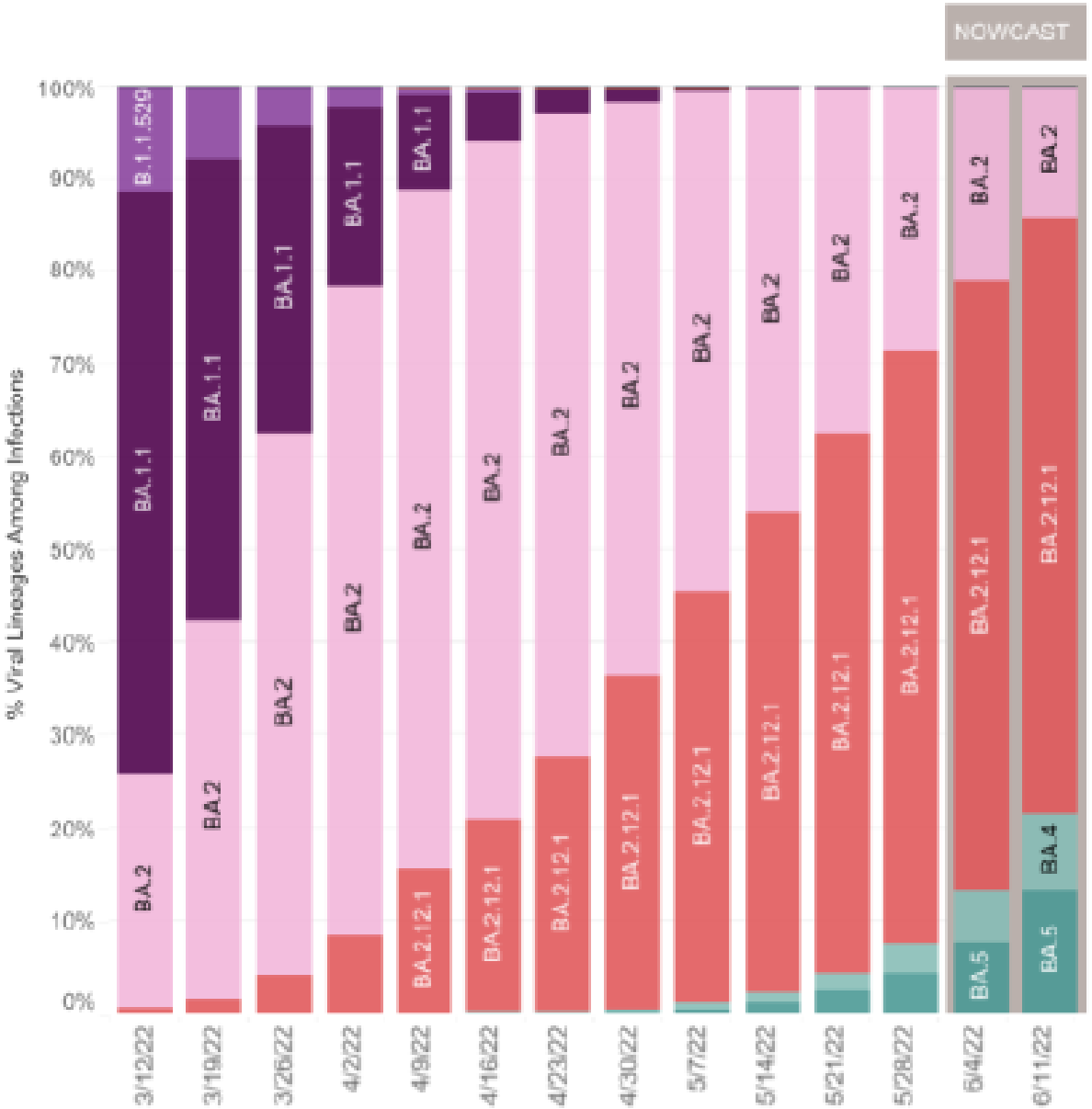
No. at Risk								
Placebo	1731	1680	1483	1177	991	856	774	472
AZD7442	3441	3323	2957	2393	2054	1815	1667	1044

DOI: 10.1056/NEJMoa2116620

Emergency Use Authorization for Tixagevimab with Cilgavimab (Dec 2021)

- Not to be used as substitute for COVID-19 vaccine
- For PrEP in age ≥12 yrs and weighing ≥40 kg who do not have SARS-CoV-2 infection, who have not been recently exposed to infected individuals, **AND**
  - Are moderately to severely immunocompromised and may have an inadequate immune response to COviD-19 vaccination, **OR**
  - Are not able to be fully vaccinated due to history of severe adverse reactions to COVID-19 vaccine or any of its components 2021
- Dose: 150 mg/150 mg consecutive IM injections
- Can repeat in 6 months if ongoing risk

United States: 3/6/2022 – 6/11/2022



United States: 6/5/2022 – 6/11/2022 NOWCAST

USA

WHO label	Lineage #	US Class	% Total	95%PI
Omicron	BA.2.12.1	VOC	64.2%	59.9-68.3%
	BA.2	VOC	14.2%	12.7-15.9%
	BA.5	VOC	13.3%	10.0-17.4%
	BA.4	VOC	8.3%	6.3-10.7%
	BA.1.1	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.1%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

\# AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. For regional data, BA.1.1 and its sublineages are also aggregated with B.1.1.529, as they currently cannot be reliably called in each region. Except BA.2.12.1 and its sublineages, BA.2 sublineages are aggregated with BA.2. BA.5.1 is aggregated with BA.5.

Pseudotyped and authentic SARS-CoV-2 neutralization data for variants

Linage with spike protein substitution	Country 1st Identified	WHO Nomenclature	Key Substitutions Tested	Fold Reduction in Susceptibility* (Pseudotyped VLPs†)	Fold Reduction in Susceptibility* (Authentic virus‡)
BA.1	Botswana	Omicron (BA.1)	G339D+S371L+S373P+S375F+K417N+N440K+G446S+S477N+T478K+E484A+Q493R+G496S+Q489R+N501Y+Y505H	132- to 183-fold#	12- to 30-fold
BA.1.1	Multiple country origin	Omicron (BA.1.1) [+R346K]	G339D*346K+S371L+S373P+S375F+ K417N+N440K+G446S+S477N+T478K+E484A+Q493R+G496S+Q489R+N501Y+Y505H	424-fold	176-fold
BA.2	Multiple country origin	Omicron (BA.2)	G339D+S371F+S373P+S375F+T376A+D405N+R408S+K417N+N440K+S477N+T478K+E484A+Q493R+Q498R+N501Y+Y505H+H655Y+N679K+P681H+N764K	No Change§	5.4-fold

Range of reduced potency †VLP, Pseudotype virus like particles ‡Authentic SARS-CoV-2 § <5-fold reduction in susceptibility #EC_{50} value=1.13-1.83 nM

Emergency Use Authorization for Tixagevimab with Cilgavimab (April 2022)

- For PrEP in age ≥12 yrs and weighing ≥40 kg who do not have SARS-CoV-2 infection, who have not been recently exposed to infected individuals, **AND**
  - Are moderately to severely immunocompromised and may have an inadequate immune response to COviD-19 vaccination, **OR**
  - Are not able to be fully vaccinated due to history of severe adverse reactions to COVID-19 vaccine or any of its components 2021
- **Dose: 300 mg/300 mg consecutive IM injections**
  - **Previously dosed with 150/150 mg ≤3 months prior, repeat 150/150 mg dose ASAP; >3 months 300/300 mg dose ASAP**
  - **No authorization for repeat dosing**

Self-knowledge Check

Which of the following individuals would be appropriate for administration of tixagevimab with cilgavimab for pre-exposure prophylaxis of SARS-CoV-2 infection?

A. A COVID-19 vaccinated person with history of solid organ transplant
B. An asymptomatic person recently exposed to someone with COVID-19
C. A person who was not fully vaccinated for COVID-19 because of documented adverse events to available vaccinations
D. A and B only
E. A and C only
F. All of the Above

Self-knowledge Check

The correct answer is E.

The reason for this is because administration of tixagevimab with cilgavimab for pre-exposure prophylaxis is for those who do not have SARS-CoV-2 infection and who were not recently exposed to an infected person. In addition, such individuals must be immunocompromised, and therefore at risk for not responding to COVID-19 vaccination, or not able to be fully vaccinated due to history of severe adverse reactions to available vaccines. Therefore, a vaccinated person with history of solid organ transplant (A) and someone unable to be fully vaccinated due to adverse events (C) would be appropriate. In contrast, someone with recent exposure to SARS-CoV-2-infected individual (B) would not be appropriate for treatment until it is certain that they were not infected at time of exposure.

Thank You!!

U.S. FOOD & DRUG ADMINISTRATION

Therapeutics Update -

Treatment of Non-Hospitalized Patients with Mild-Moderate COVID-19 at High Risk of Disease Progression

John Farley, MD, MPH
Director, Office of Infectious Diseases
Office of New Drugs,
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Treatment of Non-Hospitalized Patients with Mild-Moderate COVID-19 at High Risk of Disease Progression

- A number of therapeutics are authorized or approved for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
- Primary care physicians can play a key role utilizing these therapeutics to help reduce the risk of hospitalization or death in high-risk patients with mild-moderate COVID-19.

Direct SARS-CoV-2 Viral Testing

- Two types of diagnostic tests:
  - Molecular tests, such as PCR tests, that detect the virus's genetic material
  - Rapid antigen diagnostic tests that detect specific proteins from the virus
- Patients in the authorized population who report a positive home test result from a rapid antigen diagnostic test to their provider are eligible for the therapeutic.
- A positive PCR also meets the requirement.
- Confirmation of a positive home rapid antigen diagnostic test with additional testing, such as a PCR, is not required.

Risk Factors for Disease Progression

- Our intention is to encourage health care providers to make an appropriate benefit risk decision for their individual patient.
- CDC web page resource for information on medical conditions and factors associated with increased risk of progression to severe COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html
- Patients in the authorized population with a risk factor for progression to severe COVID-19 are eligible even if they are fully vaccinated and/or up to date on their COVID-19 vaccines.
- Patients do not have to have more than one risk factor to be considered high risk.

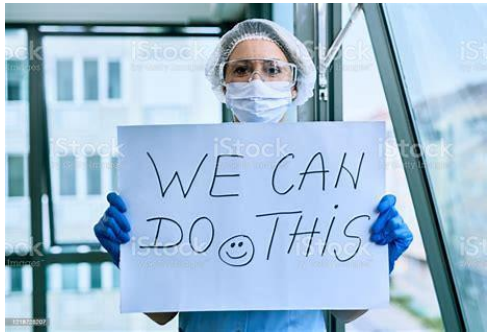
Paxlovid

Paxlovid contains Nirmatrelvir (a SARS-CoV-2 main protease inhibitor (aka Mpro, 3CLpro, or nsp5)) and Ritonavir (a strong CYP3A inhibitor included as a pharmacokinetic enhancer to increase nirmatrelvir plasma levels)

- Regulatory Status: Emergency Use Authorization
- Age Range: adults and pediatric patients (12 years of age and weighing at least 40 kg)
- Dosing: (standard) two 150 mg tablets (300 mg) nirmatrelvir with one 100 mg tablet ritonavir orally bid x 5 days (without regard to food)

Paxlovid

- Timing: as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset
- Special Consideration – Renal Impairment: For patients with moderate renal impairment (eGFR ≥30 to <60 mL/min), the dosage of Paxlovid is 150 mg nirmatrelvir and 100 mg ritonavir for 5 days (special packaging now available). Not recommended for patients with severe renal impairment (eGFR <30 mL/min).
- Special Consideration – Hepatic Impairment: Not recommended for patients with Child-Pugh Class C.
- Special Consideration – Potential Drug Interactions



Paxlovid

- Potential to affect other drugs (ritonavir is a strong CYP3A inhibitor) and for other drugs to affect Paxlovid (components are CYP3A substrates)
- Drug Interaction Resources for Providers:
  - EUA Webpage https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
    - Fact Sheet for Health Care Providers, Checklist, and more
  - NIH COVID-19 Treatment Guidelines

https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-/

  - University of Liverpool COVID-19 Drug Interactions

https://www.covid19-druginteractions.org/checker

Veklury

Veklury (remdesivir) is a nucleotide analog RNA polymerase inhibitor

- Regulatory Status: Approved Drug
- Age Range: adults and pediatric patients (28 days and older and weighing at least 3 kg)
- Dosing (non-hospitalized): a single loading dose on Day 1 (200 mg or 5 mg/kg) followed by once-daily maintenance doses on Days 2 and 3 (100 mg or 2.5 mg/kg) by intravenous infusion

Veklury

- <u>Timing:</u> as soon as possible after COVID-19 diagnosis and within 7 days of symptom onset
- <u>Special Consideration – Renal Impairment:</u> Not recommended in patients with eGFR less than 30 mL/min
- <u>Special Consideration – Hypersensitivity Reactions:</u> Monitor patients during infusion and for at least one hour after infusion is complete.
- <u>Special Consideration - Chloroquine:</u> Potential antagonistic effect of chloroquine on antiviral activity of Veklury

Bebtelovimab

Bebtelovimab is a human IgG1 monoclonal antibody targeting the SARS-CoV-2 spike protein.

- Regulatory Status: Emergency Use Authorization limited to patients for whom alternative COVID-19 treatment options are not accessible or clinically appropriate
- Age Range: adults and pediatric patients (12 years of age and older and weighing at least 40 kg)
- Dosing: 175 mg administered as a single intravenous injection over at least 30 seconds

Bebtelovimab

- Timing: as soon as possible after COVID-19 diagnosis and within 7 days of symptom onset
- Special Consideration – Hypersensitivity Reactions: Monitor patients during infusion and for at least one hour after infusion is complete.
- Special Consideration - Variants: Based on authentic virus and/or pseudotyped virus like-particle neutralization data, no reduction in susceptibility to BA.1.1, BA.2, and BA.2.12.1.

Lagevrio

Lagevrio (molnupiravir) is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis.

- Regulatory Status: Emergency Use Authorization limited to patients for whom alternative COVID-19 treatment options are not accessible or clinically appropriate
- Age Range: Not authorized for use in patients less than 18 years of age
- Dosing: 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food

Lagrevio

- Timing: as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset
- Special Consideration – Embryo-Fetal Toxicity: Not recommended for use during pregnancy
- Special Consideration – Bone and Cartilage Toxicity: Not authorized for use in patients less than 18 years age because it may affect bone and cartilage growth
- Special Consideration – Contraception: Females for duration of treatment and 4 days after the last dose. Males during treatment and 3 months after the last dose (Risk beyond 3 months unknown; nonclinical studies not yet completed)

COVID-19 Rebound

- Recent case reports document that some patients with normal immune response who have completed a 5-day course of Paxlovid for laboratory-confirmed infection and have recovered can experience recurrent illness 2 to 8 days later, including patients who have been vaccinated and/or boosted.
  - Both the recurrence of illness and positive test results improved or resolved without additional antiviral treatment.

COVID-19 Rebound

- In the Paxlovid clinical trial supporting the EUA (EPIC-HR), a small number of participants had one or more positive SARS-CoV-2 RT-PCR test results after testing negative, or an increase in the amount of SARS-CoV-2 detected by PCR, after completing their treatment course (NP swab samples). This finding was observed in persons randomized to Paxlovid and in persons randomized to placebo.
  - There was no increased occurrence of hospitalization or death, and there was no evidence that the rebound in detectable viral RNA was the result of SARS-CoV-2 resistance to Paxlovid.

COVID-19 Rebound

- There is currently no evidence that additional treatment for COVID-19 is needed for COVID-19 rebound.
- These reports do not change the conclusions from the Paxlovid clinical trial which demonstrated a marked reduction in hospitalization and death.
- Electronic Health Record based data analyses may more fully characterize incidence and risk of disease progression associated with COVID-19 rebound. However, prospective data are likely needed to fully understand pathophysiology and association with drug treatment.

CDC Health Advisory: https://emergency.cdc.gov/han/2022/han00467.asp

Evusheld
Pre-Exposure Prophylaxis

Tixagevimab co-packaged with cilgavimab – human IgG1 monoclonal antibodies, SARS-CoV-2 spike protein attachment inhibitors

- Regulatory Status: Emergency Use Authorization
- Age Range: adults and pediatric patients (12 years of age and older and weighing at least 40 kg)
- Dosing (Initial): 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections

Evusheld
Pre-Exposure Prophylaxis

Authorized for the pre-exposure prophylaxis of COVID-19 in adults and certain pediatric individuals who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 <u>and</u>

- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination <u>or</u>
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s)

Self-knowledge Check

A one-year-old male weighing 9.6 kg is post bone marrow transplant for a severe combined immune deficiency. He developed rhinorrhea and a cough one day ago and tests positive on a home rapid antigen test for SARS-CoV-2. His physical exam is unremarkable and oxygen saturation by oximetry is measured at 98%. Which of the following authorized or approved therapeutics would be appropriate?

A. Paxlovid
B. Veklury
C. Bebtelovimab
D. Lagevrio

Self-knowledge Check

The correct answer is B (Veklury).

The reason for this is because Veklury (remdesivir) is approved for adults and pediatric patients (28 days and older and weighing at least 3 kg). Paxlovid and bebtelovimab are authorized for adults and pediatric patients (12 years of age and weighing at least 40 kg). Lagevrio is not authorized for use in patients less than 18 years of age.

FDA U.S. FOOD & DRUG ADMINISTRATION

ASPR Office of the Assistant Secretary for Preparedness & Response

Update:
COVID-19 Therapeutics

Meg Sullivan, MD, MPH
Chief Medical Officer
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
June 16, 2022

Unclassified/FOUO

Update: COVID-19 Therapeutics

Overview

1. Distribution and Utilization Overview
2. Efforts to increase Access and Utilization
3. Test to Treat Program
4. Utilization Challenges
5. Equity in Allocations
6. Weekly Stakeholder Engagement Opportunities
7. Helpful Information and Resources

Current COVID-19 Therapeutics: Distribution

- The COVID-19 therapeutics program has been actively distributing products at no cost since November 2020
- Monoclonal antibody treatment availability has fluctuated based on circulating variants; bebtelovimab is currently the only monoclonal antibody available for treatment
- Evusheld (pre-exposure prophylaxis) and oral antivirals for treatment (Paxlovid, Lagevrio) have been distributed since December 2021
- Thresholds are set each week* for central partners (states, territories, federal entities, federal retail pharmacy partners)
  - Central partners further apportion supply throughout their networks

*Evusheld thresholds are on a monthly cadence

Current COVID-19 Therapeutics: Distribution and Utilization

Distribution and Utilization Summary

11.4M	Shipped through all therapeutics programs [1]
44,461	Active Providers[2]
5.2M	Total reported usage [1]
46%	% of distributed supply used

1. All data is current as of 5/31 2. Includes active providers for all active products. Source: ABC Distribution reports, State Reports, Tiberius.

Current COVID-19 Therapeutics: Utilization

Utilization Summary of Currently Distributed Products

- December 17, 2021 – June 5, 2022
- Based on 94% of sites reporting as of June 5, 2022
- Product specific national administration data for the above timeframe
- State and territorial specific data now publicly available and updated weekly
- https://aspr.hhs.gov/COVID-19/Therapeutics/orders/Pages/default.aspx

Total for all open distribution channels		
Therapeutic (currently in use)	Courses Ordered	Courses Administered
Paxlovid[1]	3,082,484	1,155,419
Lagevrio	1,995,847	289,260
Bebtelovimab	433,176	148,899
Evusheld (300mg doses)	722,257	301,233

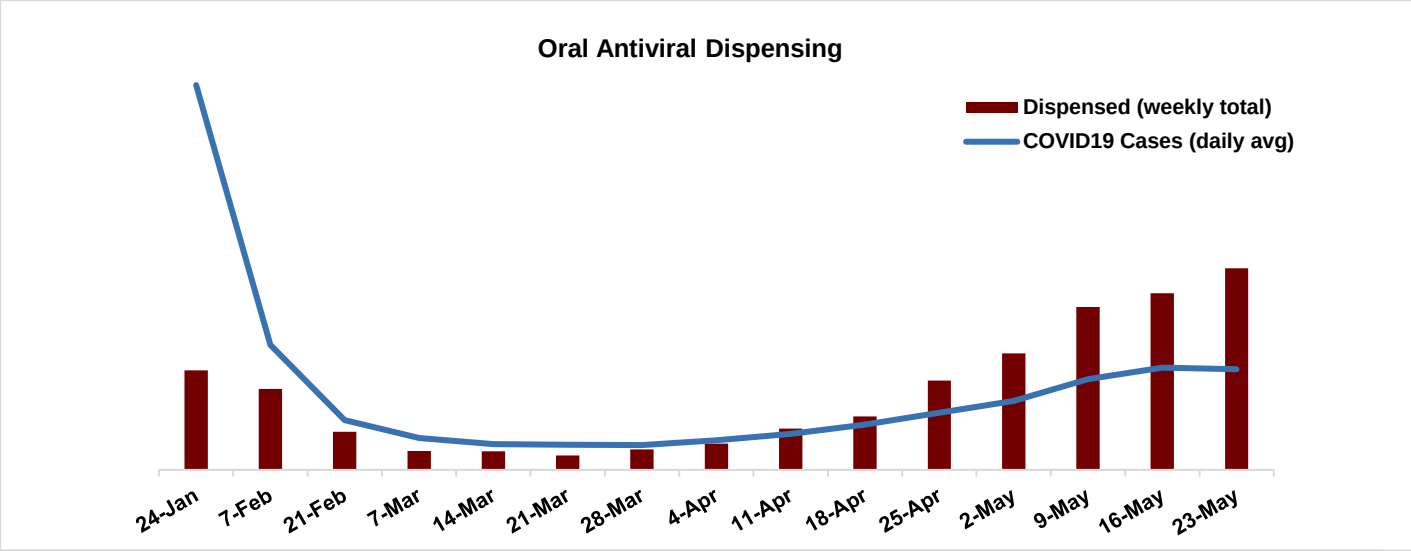
[1]Paxlovid + renal Paxlovid

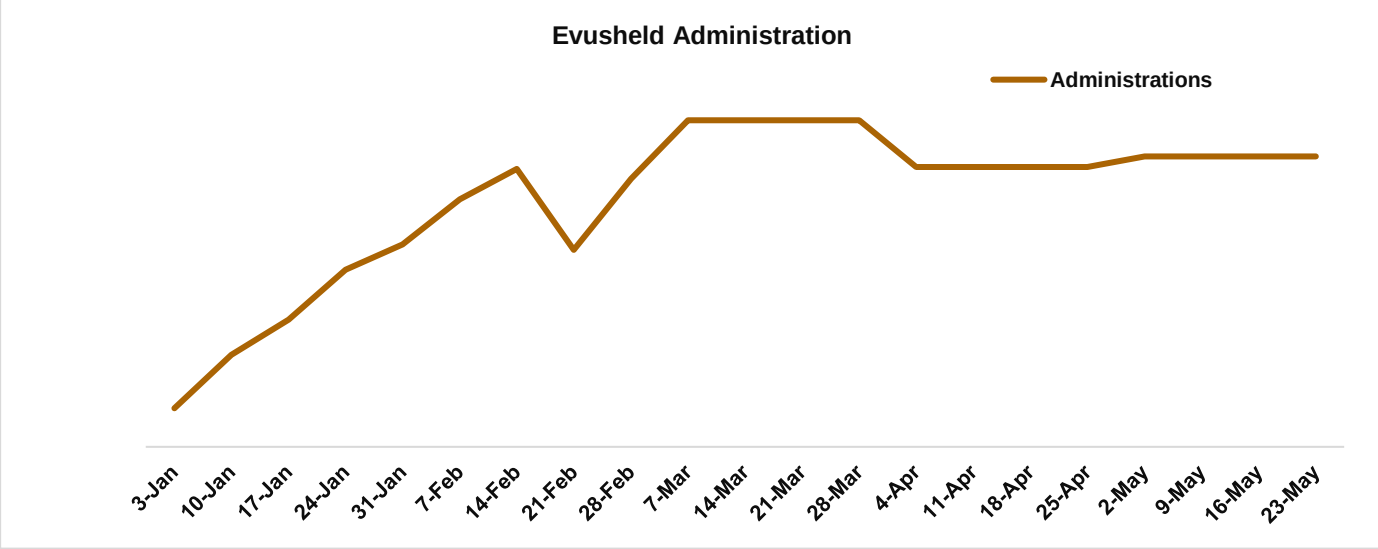
Current COVID-19 Therapeutics: Utilization

- Oral antiviral (Paxlovid, Lagevrio) use has increased substantially in past month (>300% increase in use)
- Outreach and operational efforts are ongoing to increase use, with focus on prioritized populations

- Bebtelovimab use has increased with rising cases (data not shown); serves as alternative for patients for whom other authorized or approved treatments are not recommended

- Evusheld use continues to be lower than expected
- Outreach and operational efforts ongoing to increase use, with focus on eligible populations



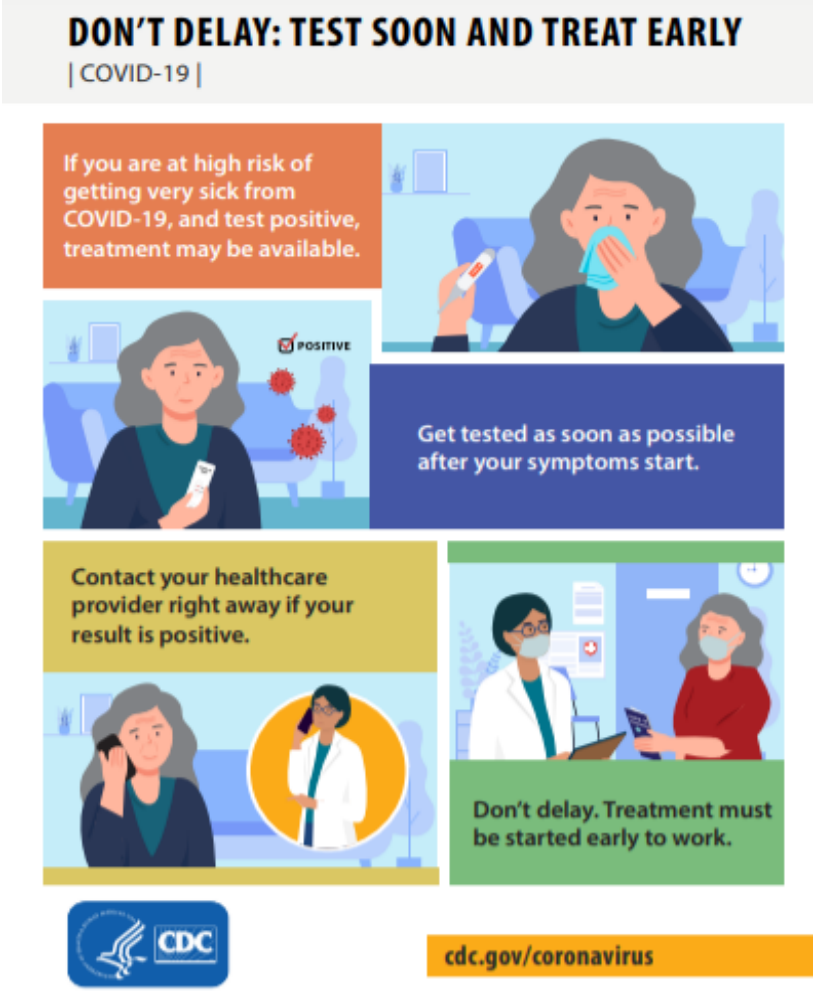


Federal Efforts to Increase Access and Awareness

- Oral antivirals are not currently supply constrained; this increases breadth of patients that can be offered treatment
- Increased the number of places oral antivirals are available
  - Currently available at more than 35,000 locations nationwide
  - Pharmacies in the federal retail pharmacy therapeutics partner program—tens of thousands of pharmacy locations nationwide—can order free oral antiviral treatments directly from the federal government.
  - Test to Treat Initiative
- Supporting medical providers with more guidance and tools to understand and prescribe treatments
  - Recurring webinars, CME opportunities, stakeholder engagement
  - Enhanced provider guidance and tools
- Communicating to the American people that safe, effective treatments are widely available

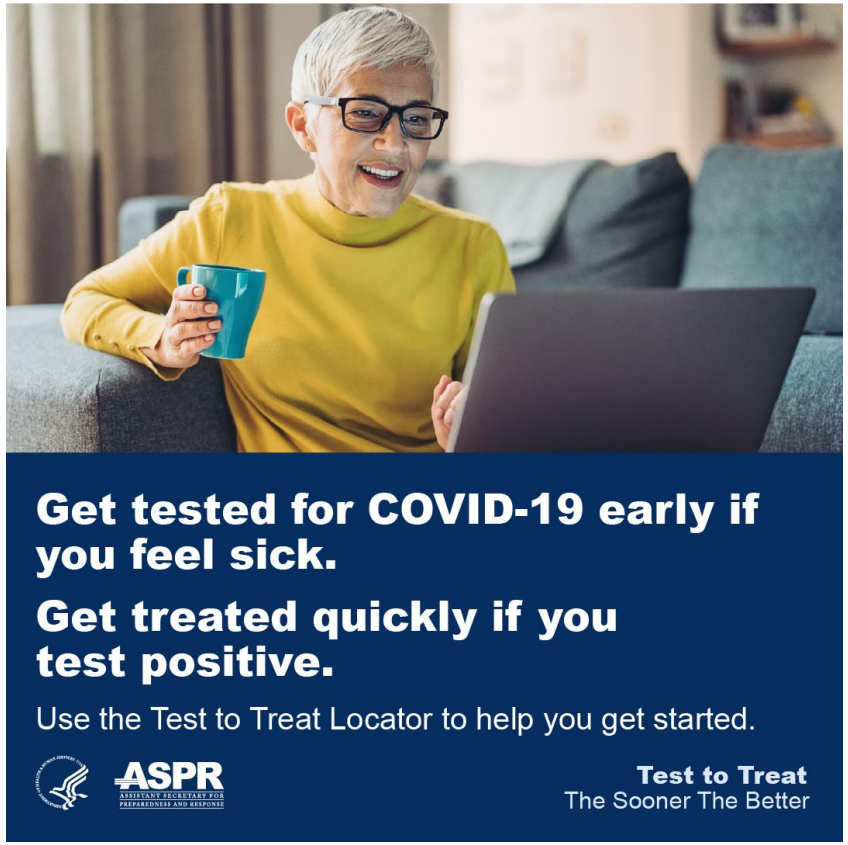
Test to Treat: About the Program

- Overall goal of Test to Treat program is to increase access to COVID-19 oral therapeutics, **particularly for individuals who don't have ready access to a health care provider**
- COVID-19 treatments delivered as part of Test to Treat Program (Paxlovid and Lagevrio) must be taken within 5 days of initial COVID-19 symptoms.
  - Helps close gap between positive COVID-19 test and receiving treatment for those eligible
- Builds upon existing distribution of oral antivirals we are already making available at no cost to thousands of locations nationwide.
- More than 2500 Test to Treat sites across country; more than 40,000 total locations with oral antivirals
- An individual's healthcare providers remain the first option for care; Test to Treat sites are one additional access point.



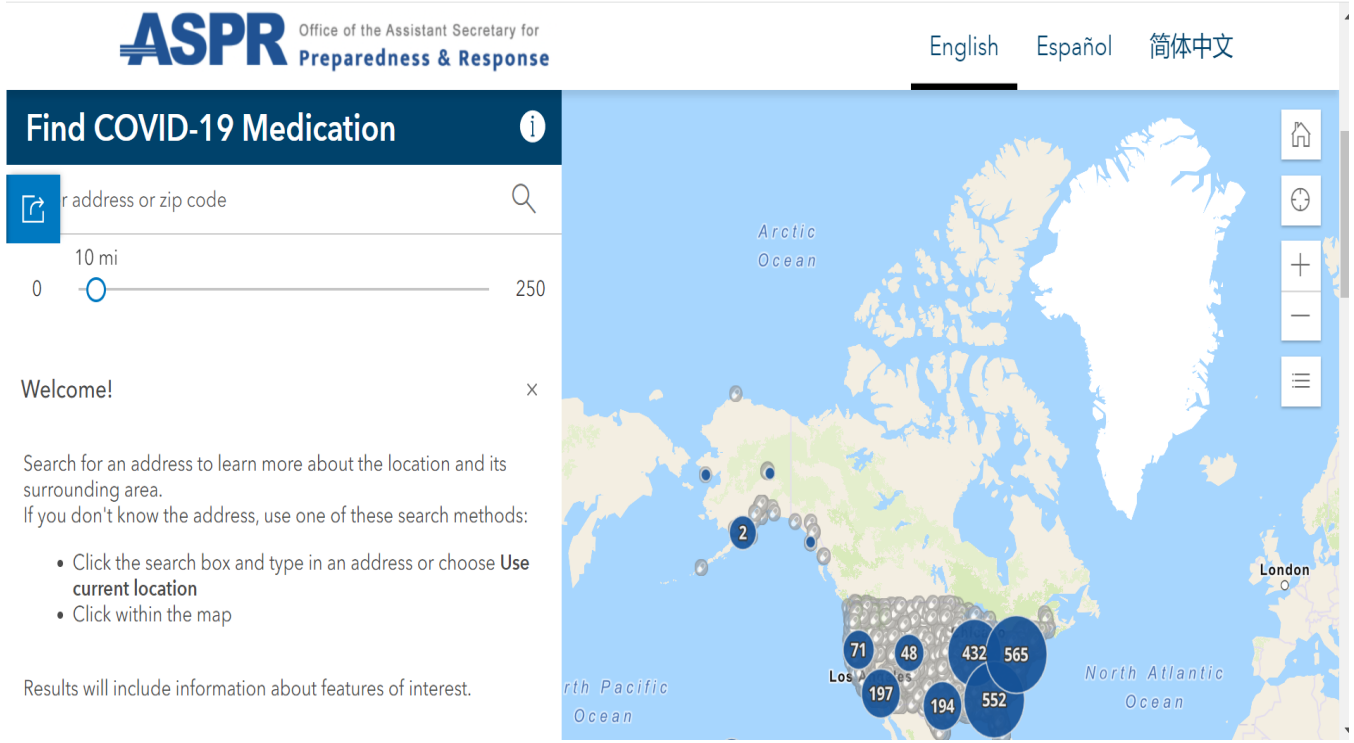
Test to Treat: Considerations for Site Selection

- Provide/offer comprehensive end-to-end test and treat services to support seamless patient experience:
  - COVID-19 testing on-site (or evaluation of at-home or other testing)
  - Linkage to a clinical evaluation by licensed health care provider after positive result to provide prescription when appropriate (on-site or via telemedicine)
  - Co-located or affiliated pharmacy able to readily dispense medication to eligible patients
- Provide services to all individuals, regardless of insurance status
- Accept new patients for priority same-day or next-day visit for COVID-19 services



Test to Treat Locator

- Test to Treat site locator launched 3/30/22
- Identifies all Test to Treat program sites and all sites to fill an existing prescription
  - Increasing visibility of telehealth options on locator
- Call center also available: 1-800-232-0233 (TTY 1-888-720-7489) to get help in English, Spanish, and more than 150 other languages – 8am to 12 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 9 am to 8:00 pm ET or email DIAL@usaginganddisability.org



https://covid-19-test-to-treat-locator-dhhs.hub.arcgis.com/

Test to Treat: Federally Supported Sites

- **ASPR and FEMA partnering with State, Tribal, and Territorial (STT) governments** to establish federally-supported Test to Treat sites
- **Effort builds upon existing Test to Treat network** by focusing on reaching hard-hit and high-risk communities and ensuring equitable access to lifesaving COVID-19 treatments
- **STT partners work directly with appropriate ASPR and FEMA Regional Emergency Coordinators** to request federal support for new Test to Treat sites
- Type of Federal support available through this effort:
  - **Testing**
    - Depending on STT need, the Federal government can deploy testing supplies to support an existing community-based testing site or reopen a former community-based testing site
  - **Providers**
    - STT partners can be fully reimbursed for all provider services at federally-supported Test-to-Treat sites through FEMA's Federal Public Assistance program
    - Federal partners may deploy limited resources on a site-specific basis, as needed
  - **Pharmacy Services**
    - HHS can provide technical assistance, logistical support, access to new/additional drug supply

Challenges: Therapeutics Utilization

- Inequities persist in the use of these therapeutics:
  - Inconsistent awareness of the therapies and comfort level for prescribing among providers
  - Unequal community access to the therapies
  - Inequities in technology use to support therapeutic uptake (telemedicine)—often due to resource constraints

- Heightening the challenge: fall and winter are only a few months away

- We need ongoing and new innovative approaches to address and overcome these challenges.

Equity Remains a Shared Responsibility

- States/Territories urged to put equity at center of distribution plans; consider allocating to sites that help increase product access within communities that have been socially/economically marginalized and to priority populations

- HRSA expanding Health Center COVID-19 Therapeutics Program (HCCT) to all HRSA-supported Health Centers with pharmacy capacity, in support of the Biden-Harris Administration's Test to Treat Initiative
  - Over 1,000 health centers were invited, and those that enroll will be able to order from the HRSA oral antiviral therapeutics allocation
  - This program supplements state/jurisdictional oral antiviral allocations and aims to ensure equitable access by providing an additional supply directly to HRSA-supported health centers
  - Health centers that enroll and place at least one order will be labeled as a Test to Treat site on ASPR's Test to Treat site locator
  - Up-to-date list of HRSA HCCT Program participants located here

- States/Territories encouraged to amplify where product is sent in their areas
  - Utilize provider communication networks
  - Post receiving sites on state and local health department websites
  - Partner with hospital associations for message amplification
  - Enlist support of public information officers

Upcoming Stakeholder Meetings

- **Federal COVID-19 Therapeutics Weekly Clinical Rounds**
  - Every Friday (12:00-1:00PM ET); Next Session – June 17
- **Stakeholder Meeting: Federal Retail Pharmacy Therapeutics Program (FRPTP) Participants**
  - Every Tuesday (12:00-12:30PM ET); Next Session – June 21
- **Stakeholder Meeting: State/Territorial Health Officials + Nat'l Heath Care & Med Orgs/Associations**
  - Wednesdays (2:00-3:00PM ET); Next Session – June 22
- **Office Call Session: HHS/ASPR Distribution and Administration of COVID-19 Therapeutics**
  - Wednesdays (3:15-4:15PM ET); Next Session – June 22
- **Office Call Session: Health Partner Ordering Portal (HPOP)**
  - Every other Thursday (4:00-5:00PM ET); Next Session – June 23

Weekly Engagement Opportunities with Federal Team
Questions? Email: COVID19Therapeutics@hhs.gov

Resources

Helpful Information and Resources

- FDA Paxlovid Patient Eligibility Screening Checklist for Providers
- HHS Therapeutics Homepage
- Product Expiration Date Extensions
- Test to Treat Initiative webpage and Fact Sheet
- Test to Treat Site Locator and Digital Tool Kit
- General Therapeutics Locator
- HHS Clinical Implementation Guide
- Outpatient Therapeutics Decision Aid
- Side-by-Side Overview of Outpatient Therapeutics
- Paxlovid Potential Drug-Drug Interactions Resource (Pfizer)
- ASPR Regional Emergency Coordinators
- CMS reimbursement information for mAbs
- CMS reimbursement information for oral antivirals

Latest COVID-19 Therapeutics Updates Found at aspr.hhs.gov

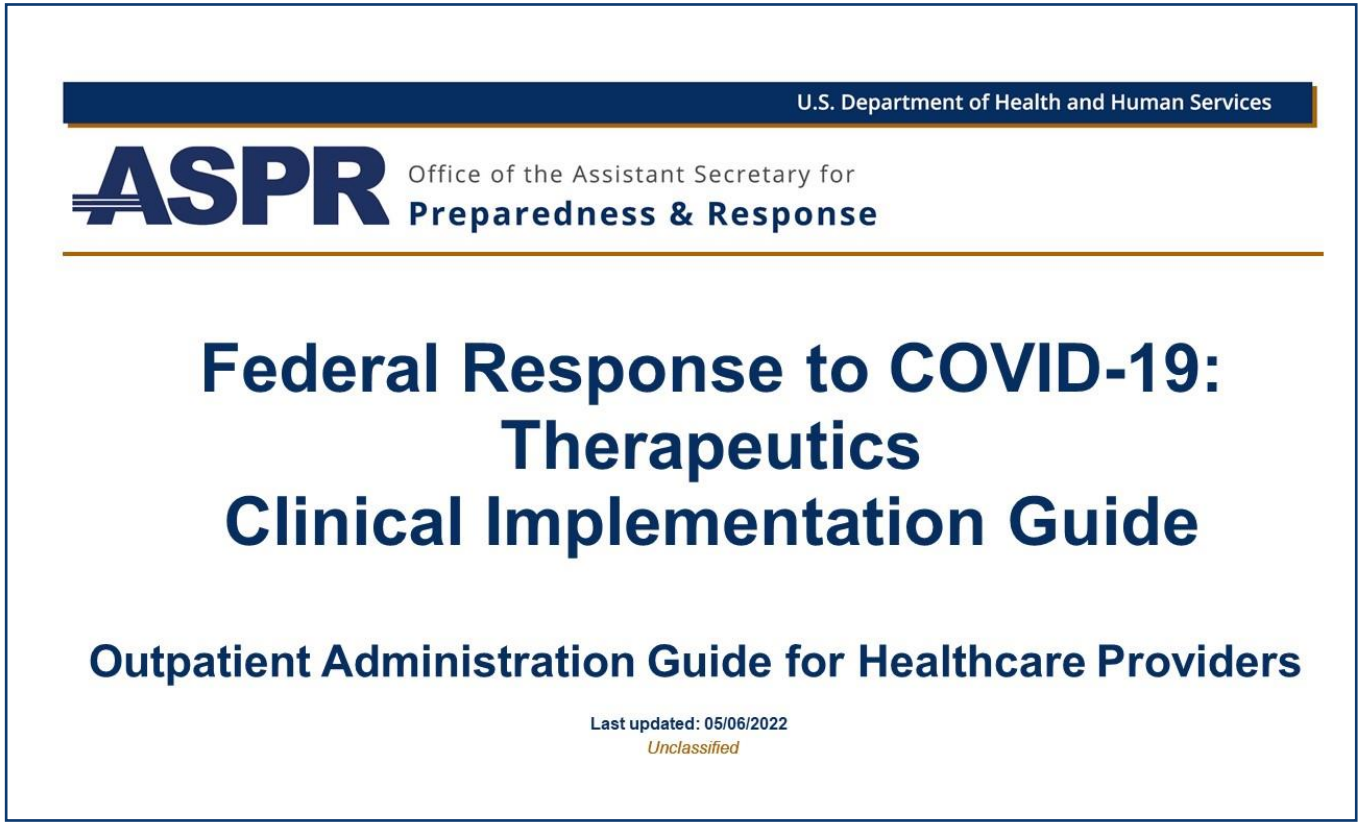
Related Resources: Paxlovid

Additional Paxlovid Prescribing Resources

- University of Liverpool COVID-19 Drug Interactions: https://covid19-druginteractions.org/checker
- FDA PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers: https://www.fda.gov/media/158165/download
- Pfizer Drug Interaction Checker: https://www.pfizermedicalinformation.com/en-us/drug-interaction-checker?product=PAXLOVID%E2%84%A2+%7C+nirmatrelvir+tablets%3B+ritonavir+tablets&product2=Alfuzosin
- NIH COVID-19 Treatment Guidelines - Ritonavir-Boosted Nirmatrelvir (Paxlovid): https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-/
- CDC/IDSA COVID-19 Clinician Call: All About Paxlovid; Plus Variants Update: https://www.idsociety.org/multimedia/clinician-calls/cdcidsa-covid-19-clinician-call-all-about-paxlovid-plus-variants-update/

COVID-19 Therapeutics Clinical Implementation Guide

- The ***Clinical Implementation Guide*** summarizes key information on COVID-19 outpatient therapeutics and aims to support health care providers' understanding of these therapies and how to implement administration.
- The *Clinical Implementation Guide* is updated regularly following changes to COVID-19 therapeutics' Emergency Use Authorizations (EUAs); however, there may be a gap in publishing updated versions. As such, it is important for health care providers to stay abreast of the latest changes to EUAs and their impact on the distribution and administration of COVID-19 therapeutics. See the latest information on all FDA products under EUA.


U.S. Department of Health and Human Services

ASPR Office of the Assistant Secretary for Preparedness & Response

Federal Response to COVID-19: Therapeutics Clinical Implementation Guide

Outpatient Administration Guide for Healthcare Providers

Last updated: 05/06/2022

Unclassified

COVID-19 Outpatient Therapeutics

Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease

Is patient:

- Hospitalized for COVID-19

OR

- Requiring O_2

OR

- Requiring an increase in baseline home O_2 due to COVID-19?

NO → Symptom onset within the past 5–7 days?

YES → Consider one of the following therapeutics, if available, feasible, and clinically appropriate[1]:

Paxlovid[2] within 5 days of symptom onset If patient does not have severe renal impairment (eGFR <30mL/min OR severe hepatic impairment (Child-Pugh Class C)

- **eGFR ≥ 60 mL/min:** 300 mg nirmatrelvir taken with 100 mg ritonavir twice daily for 5 days
- **eGFR ≥ 30 to < 60:** 150 mg nirmatrelvir taken together with 100 mg ritonavir twice daily for 5 days
- Evaluate concomitant use of CYP3A inducers and medications with high dependency on CYP3A for clearance as these may be contraindicated[2,3]

OR

Veklury (remdesivir)[4] 200 mg IV x 1 dose on Day 1, 100 mg IV x 1 on Days 2–3 begun **ASAP within 7 days of symptom onset**

YES → Treatment of symptoms, management per NIH & CDC Guidelines

NO → Treatment of symptoms, management per NIH & CDC Guidelines

If Paxlovid and Veklury (remdesivir) are not available, feasible or clinically appropriate consider one of the following therapeutics:

bebtelovimab[5] ASAP within 7 days of symptom onset
175 mg single IV injection

OR

Lagevrio (molnupiravir)[6] if patient age 18 or older AND possibility of pregnancy, if applicable, ruled out:

800 mg by mouth every 12h for 5 days begun **ASAP within 5 days of symptom onset**

Prescribers must review and comply with the mandatory requirements outlined in the **Lagevrio (molnupiravir) EUA[6]**

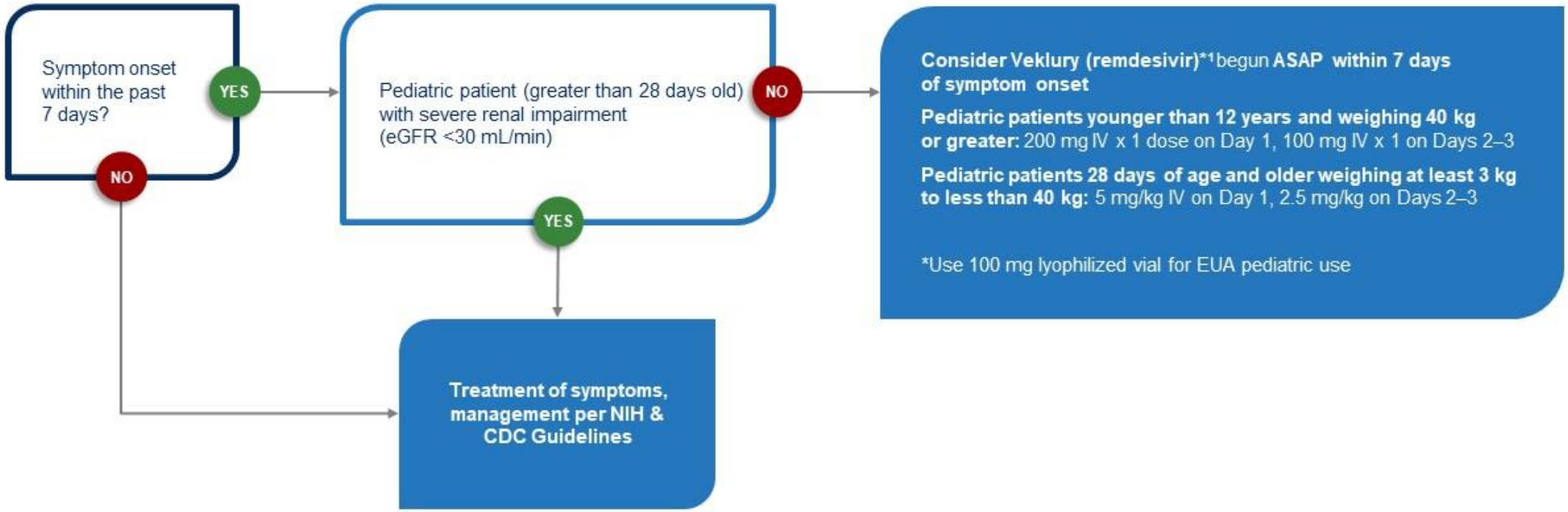
References:

[1] NIH's COVID-19 Treatment Guidelines Therapeutic Management of Nonhospitalized Adults With COVID-19. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/
[2] Paxlovid EUA. https://www.fda.gov/media/155050/download
[3] NIH's COVID-19 Treatment Guidelines Panel. Ritonavir-Boosted Nirmatrelvir (Paxlovid). https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-/
[4] Veklury (remdesivir) Prescribing Information. https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf
[5] Bebtelovimab EUA. https://www.fda.gov/media/156152/download
[6] Lagevrio EUA. https://www.fda.gov/media/155054/download

COVID-19 Outpatient Therapeutics

Clinical Decision Aid for Pediatric Patients

Outpatient 28 days of age and older weighing at least 3 kg to less than 40 kg, with mild to moderate COVID-19 and at high risk for progression to severe disease



Reference:
[1] Veklury Prescribing Information: https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf

Self-knowledge Check

Based on current supply, COVID-19 therapeutics should be considered for any COVID-19+ patient who meets which of the following criteria

A. No additional criteria needed
B. Has mild to moderate symptoms and are within 5-7 days of symptom onset
C. Has one or more risk factors for severe COVID.
D. Due to current supply constraints, COVID-19 therapeutics should be considered only for individuals who are severely immunocompromised.
E. B and C only

Self-knowledge Check

The correct answer is E.

The reason for this is because…

- Oral antivirals are **not** currently supply constrained
- Clinicians should consider COVID-19 treatment in non-hospitalized patients who meet all of the following:
  - Test positive for SARS-CoV-2
  - Have symptoms consistent with mild-to-moderate COVID-19
  - Are within 5-7 days of symptom onset
  - Have one or more risk factors for severe COVID-19

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- **When:** A few hours after the live call ends*
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