NEW MEXICO Department of Health
Public Health Division

MICHELLE LUJAN GRISHAM
Governor

DAVID R. SCRASE, M.D.
Acting Cabinet Secretary

NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

COVID-19 Therapeutics Update: Patient Issuance of COVID-19 Therapeutic within Therapeutic Window

5/26/2022

Background

COVID-19 therapeutics are important tools to decrease morbidity and mortality associated with COVID-19 disease. The purpose of this communication is to remind prescribers of the importance of prescribing COVID therapeutics for high-risk individuals who meet eligibility criteria and that they are prescribed within the appropriate timeframe authorized within their respective EUAs.

COVID-19 Therapeutics:

Summary of Preferred Therapies

Tier 1

Paxlovid

- 88% reduction in hospitalizations and death
- **Must start therapy within 5 days of symptom onset – not indicated for asymptomatic infection**

Tier 2

Remdesivir

- 87% reduction in hospitalization and death
- **Must start therapy within 7 days of symptom onset - not indicated for asymptomatic infection**

Tier 3

Molnupiravir

- 30% reduction in hospitalizations and death
- **Must start therapy within 5 days of symptom onset - not indicated for asymptomatic infection**

Bebtelovimab

- In BLAZE-4, Bebtelovimab has been shown to improve symptoms in patients with mild-to-moderate COVID-19. Additionally, a reduction in SARS-CoV-2 viral load on Day 5 was observed relative to placebo, though the clinical significance of this is not known. The clinical trials were not powered or designed to determine differences in clinical outcomes. According to the FDA, it is reasonable to believe that Bebtelovimab may be effective for the treatment of patients with mild-to-moderate COVID-19 to reduce the risk of progression to hospitalization or death. Bebtelovimab retains activity against currently circulating variants.[1]
- **Must be taken within 7 days of symptom onset – not indicated for asymptomatic infection**

Paxlovid, molnupiravir and bebtelovimab are for non-hospitalized patients that do not require supplemental oxygen.

Treatment recommendations and efficacy can be seen at:

https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/

Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19 (hhs.gov)

Treatment Considerations
Paxlovid continues to be recommended for early-stage treatment of mild to moderate COVID-19 among persons at high risk for progression to severe disease.

Paxlovid does have significant drug-drug interactions. The following two tools can be utilized to review any potential drug interactions of Paxlovid against a patient's current medication list.

https://covid19-druginteractions.org/checker

Drug Interaction Checker | Pfizer Medical Information - US

- If an individual has significant drug-drug interactions with Paxlovid, Remdesivir is a highly effective alternative.
- Prescribers should utilize recommended therapies and advise against using therapies that are not approved by the FDA.
- Systemic corticosteroids are not recommended for patients who do not need supplemental oxygen
- Antibiotics are not recommended for treatment of COVID-19 without any clinical indications for their use.

Recommendations from the CDC are available at HAN Archive - 00463 | Health Alert Network (HAN) (cdc.gov)

Rebound COVID:
Per CDC guidance there is no evidence that additional treatment needs to be given for the small percentage of patients who get rebound COVID (recurrence of COVID symptoms 2 to 8 days after initial recovery). The reference can be found at COVID-19 Rebound After Paxlovid Treatment (cdc.gov)

Patient Eligibility Criteria
Providers should determine patient eligibility by reviewing each medication's individual FDA Emergency Use Authorization. The documents can be found on the FDA's Emergency Use Authorization Drugs and Non-Vaccine Biological Products webpage.

The state has provided a quick reference guide and treatment decision aid to assist providers in appropriate treatment selection. The state recommends prioritization of Tier 1 & 2 COVID-19 therapeutics for patients at risk of severe COVID-19 disease. The reference guide can be found at https://cv.nmhealth.org/wp-content/uploads/2022/05/22.04.04-COVID-Therapeutics-Quick-Reference-Guide-for-Prescribers-1.pdf

As a reminder, effective 2/16/2022 the use of the Oral Antiviral and Monoclonal Antibody Screening Score (OMASS) tool was discontinued in New Mexico.

Paxlovid Patient Eligibility Screening Checklist Tool
PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers (fda.gov)

Patients at Risk of Severe COVID-19 Disease

- Older adults are more likely to get severely ill from COVID-19. More than 81% of COVID-19 deaths occur in people over age 65. The number of deaths among people over age 65 is 80 times higher than the number of deaths among people aged 18-29.[2]
- The risk of severe COVID-19 increases as the number of underlying medical conditions increases in a person.
    - Some health conditions that increase risk include: Cancer, cerebrovascular disease, chronic kidney disease, chronic lung diseases, chronic liver diseases, cystic fibrosis, diabetes mellitus, down syndrome, heart conditions, HIV, Immunosuppressive

medications, mental health disorders, neurologic conditions, obesity/overweight, pregnancy and recent pregnancy, sickle cell disease, smoking (current and former), solid organ or blood stem cell transplantation, substance use disorders, thalassemia, and tuberculosis.[3]

- For a full list of health conditions that increase risk of severe COVID-19 disease, please visit https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html

Options for individuals to access COVID-19 therapeutics

Patients that cannot access their primary care provider or do not have a provider have the option to visit a provider who can assess and write a prescription for a COVID therapeutic via a Telehealth Visit or a Test to Treat Site. A positive COVID-19 result from any FDA approved COVID-19 diagnostic test including rapid antigen tests is acceptable. Confirmation with PCR is not necessary for the purpose of prescribing oral therapeutics.

Both of these options are available to folks who are in hard hit and high-risk areas with limited access to a health care provider. Providers that can provide this service in New Mexico can be found at https://cv.nmhealth.org/providers/treatment-evaluation/

Providers should confirm any positive COVID-19 test result with the presence of symptoms that support the positive test result. Oral therapeutics should be provided only to symptomatic patients.

Availability of COVID Therapeutics:

Information regarding participating locations, inventory status, and COVID-19 therapeutics can be found at: https://cv.nmhealth.org/providers/covid-19-oral-therapeutics-information-for-providers/ Availability of medications may change quickly – patients or providers should check with local pharmacies on availability.

Importance of Timely Treatment to Prevent Hospitalizations and Deaths from COVID

Treatment should be started within the indicated time frame after development of symptoms to be effective and prescribers should seek to remove all barriers to timely initiation of therapy. Failure to comply with this advisory or taking any action that would otherwise delay the dispensing of therapeutic medication within the time limits prescribed herein may result in referral to the Board of Pharmacy for possible disciplinary action

Resources for New Mexico Healthcare Systems and Providers

Attachment 1: COVID-19 Quick Reference Guide for Providers
Attachment 2: COVID-19 Death Risk Ratio (RR) Increases as Number of Comorbid Conditions Increases

Additional Information

For questions, please contact the New Mexico Department of Health COVID-19 Therapeutics Team at covid.thereaputics@state.nm.us

Information on the authorized products for the treatment of mild-to-moderate coronavirus and other authorized products for treatment or prevention of COVID 19 are available on FDA's Emergency Use Authorization Drugs and Non-Vaccine Biological Products webpage

New Mexico Health Alert Network:

To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page https://nm.readyop.com/fs/4cjZ/10b2 Please provide all information requested to begin receiving important health alerts and advisories.

1. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Bebtelovimab. https://www.fda.gov/media/156152/download
2. People With Certain Medical Conditions. CDC. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#MedicalConditionsAdults
3. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers. CDC. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

COVID THERAPEUTICS

Quick Reference for Prescribers

What therapeutic options are available for COVID positive patients?

Therapeutic	Reduction In hospitalization & death	Route	Treatment Initiation from Symptom Onset	Treatment Duration	Considerations	Preference
Paxlovid (Nirmatrelvir/ Ritonavir) 300mg/100mg po BID x 5days	88%	Oral	Within 5 days	5 days	Patients age 12+ and ≥ 40kg Multiple drug interactions Adjust dosing for renal impairment Not recommended in severe hepatic impairment	**Preferred - Tier 1**
Remdesivir	87%	IV	Within 7 days	3 days (1-2 hr)	Patients ≥ 3.5kg Renal and hepatic considerations	**Preferred - Tier 2**
Molnupiravir 200mg 4 tabs po BID x 5 days	30%	Oral	Within 5 days	5 days	Patients age 18+ Not recommended in pregnancy Contraceptive recommendations for males and females.	**Alternative - Tier 3** Utilize only when preferred therapies are contraindicated or unavailable.
Bebtelovimab	Clinical trial not powered or designed to determine difference in clinical outcomes	IV	Within 7 days	1 minute	Patients age 12+ and ≥ 40kg	**Alternative - Tier 3** Utilize only when preferred therapies are contraindicated or unavailable.

Where should I refer a patient for IV treatments (Remdesivir or Bebtelovimab)?

Check cv.nmheath.org/treatments for a list of providers. Send a referral. Appointments may be required.

How do I prescribe oral therapeutics?

- Please check cv.nmhealth.org/treatments for a list of pharmacy locations.
- **Ask patients to use the drive-thru.**
- Please include date of symptom onset. It helps ensure the patient receives the medication within the treatment window.

Where can I find up-to-date NIH treatment recommendations for non-hospitalized adults?

www.covid19treatmentguidelines.nih.gov

COVID-19 Drug Interaction tool:

https://www.covid19-druginteractions.org

NMDOH
NEW MEXICO DEPARTMENT OF HEALTH

QUESTIONS? EMAIL COVID.THERAPEUTICS@STATE.NM.US

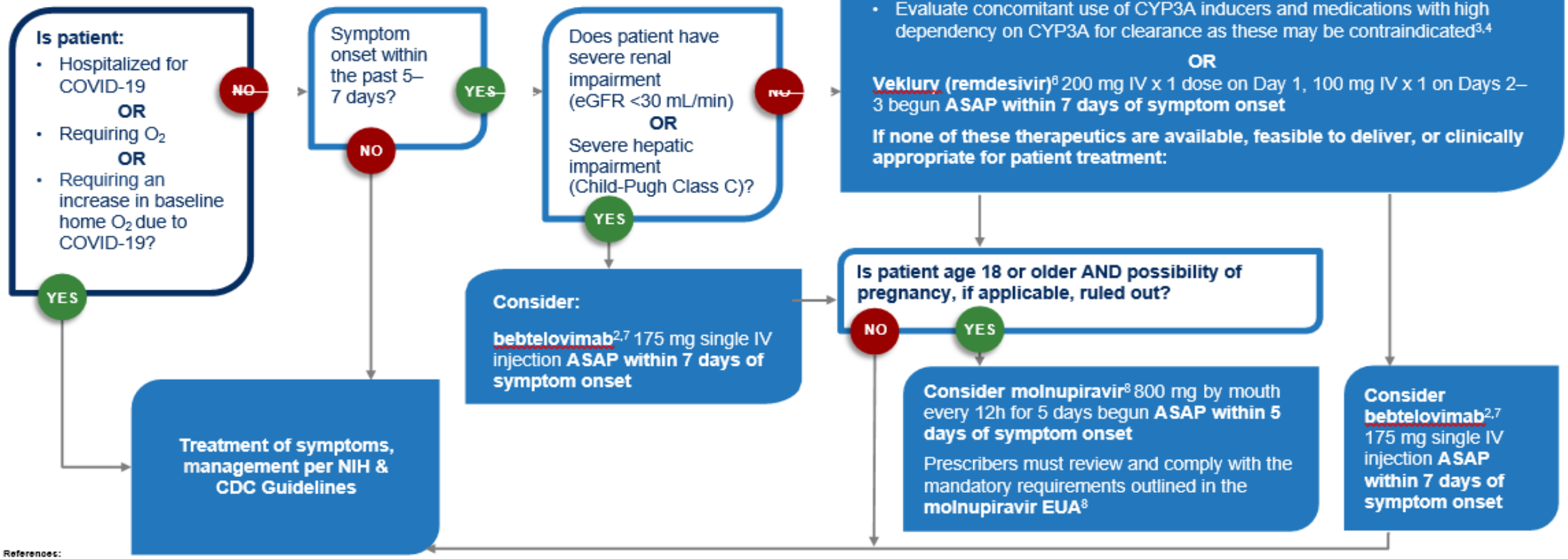
For more information, visit CV.NMHEALTH.ORG and click on the provider information tab

Revised 4/2022

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



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] NIH's COVID-19 Treatment Guidelines Statement on bebtelovimab https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-bebtelovimab/?utm_source=site&utm_medium=home&utm_campaign=highlights

[3] Paxlovid EUA. https://www.fda.gov/media/155050/download

[4] NIH's COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/

[5] Sotrovimab EUA. https://www.fda.gov/media/149534/download

[6] Veklury (remdesivir) Prescribing Information. https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf

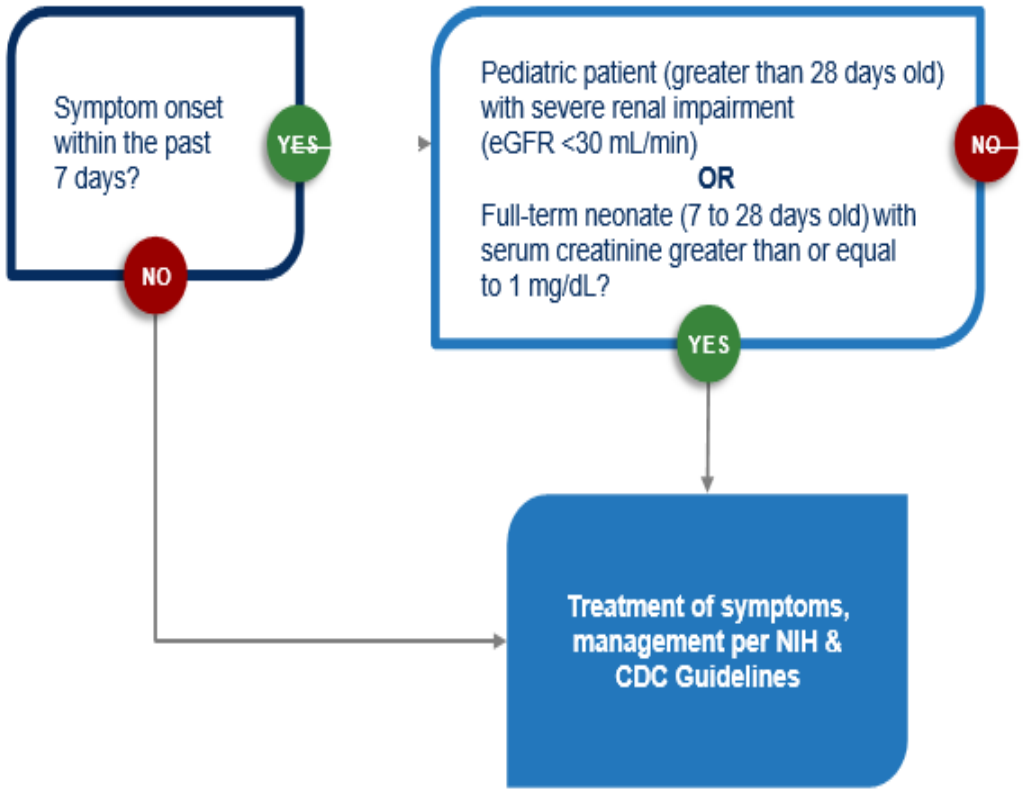
[7] Bebtelovimab EUA. https://www.fda.gov/media/156152/download

[8] Molnupiravir EUA. https://www.fda.gov/media/155054/download

Modified April 4, 2022 by NM Department of Health to reflect updated NIH Guidelines released April 1, 2022.

Clinical Decision Aid for Pediatric Patients

Outpatient **3.5 kg to less than 40 kg** or **younger than 12 years of age weighing at least 3.5 kg**, with mild to moderate COVID-19 and at high risk for progression to severe disease



Consider Veklury (remdesivir)*[1] begun ASAP within 7 days of symptom onset

Pediatric patients younger than 12 years and weighing 40 kg or greater: 200 mg IV x 1 dose on Day 1, 100 mg IV x 1 on Days 2–3

Pediatric patients 3.5 kg to less than 40 kg or pediatric patients younger than 12 years weighing at least 3.5 kg: 5 mg/kg IV on Day 1, 2.5 mg/kg on Days 2–3

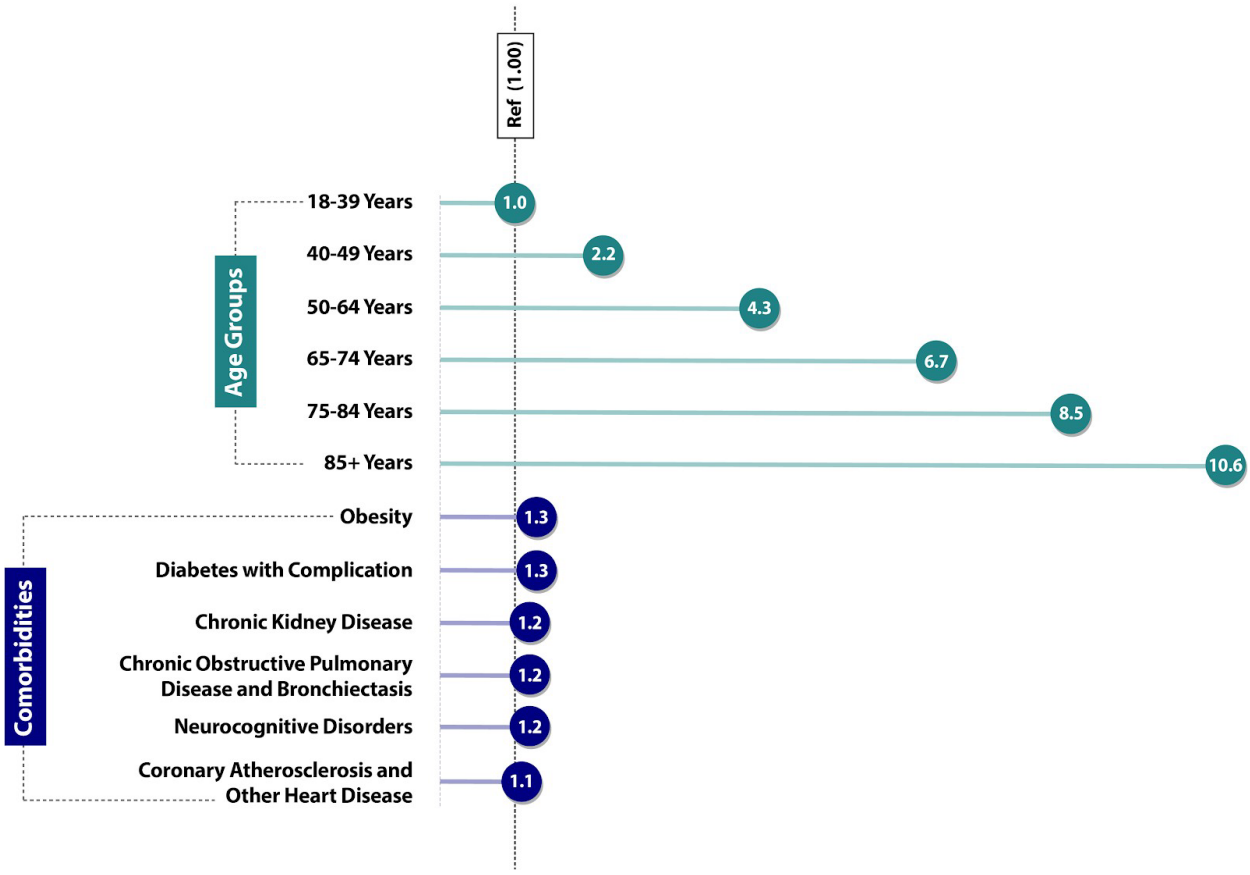
*Use 100 mg lyophilized vial for EUA pediatric use

Reference:

[1] Remdesivir EUA: https://www.fda.gov/media/137566/download.

ASPR

March 9, 2022



Source: Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. To learn more, visit the Preventing Chronic Disease article: https://www.cdc.gov/pcd/issues/2021/21_0123.htm