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 Eligibility Criteria & New COVID-19 Therapeutic

2/16/2022

Background

COVID-19 therapeutics are important tools to decrease morbidity and mortality associated with COVID-19 disease. The purpose of this communication is to provide an update on changes to patient eligibility criteria for COVID-19 therapeutics and to inform clinicians of a newly approved COVID-19 therapeutic.

New COVID-19 Therapeutic: Bebtelovimab

On 2/11/22, the FDA granted an Emergency Use Authorization for a new COVID-19 therapeutic, Bebtelovimab. The medication is a monoclonal antibody and is authorized for the treatment of mild-to-moderate COVID-19 disease for patients aged 12+ and weighing ≥ 40kg. Bebtelovimab 175 mg is given intravenously over a 30 second infusion. An hour observation period is required after the infusion. This new therapeutic is anticipated to be available the week of February 21st, 2022.

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]

Patient Eligibility Criteria

Effective 2/16/2022, the Oral Antiviral and Monoclonal Antibody Screening Score (OMASS) tool will no longer be utilized in New Mexico. The tool is no longer necessary as current COVID-19 therapeutics inventory exceeds demand.

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.

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

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.
    - 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
    - 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]

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) for Select Age Groups and Comorbid Conditions
Attachment 3: COVID-19 Death Risk Ratio (RR) Increases as Number of Comorbid Conditions Increases

Given the projected limited supply of COVID-19 therapeutics for the next few months, clinicians should check the inventory status prior to treatment selection. 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/

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.

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	**1st Tier**
Remdesivir	87%	IV	Within 7 days	3 days (1-2 hr)	Patients ≥ 3.5kg Renal and hepatic considerations	**1st Tier**
Sotrovimab	85%	IV	Within 10 days	30 minutes	Patients age 12+ and ≥ 40kg	**2nd Tier** Reserve use for those whom: Paxlovid & Remdesivir are contraindicated or unavailable Outside treatment window for Paxlovid & Remdesivir
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.	**3rd Tier** Utilize when other treatment options 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	**3rd Tier** Utilize when other treatment options are contraindicated or unavailable

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

Please check cv.nmhealth.org for a list of current providers. Please send a referral or have the patient call ahead of time as appointments may be required and inventory status may change.

How do I prescribe oral therapeutics?

- Please check cv.nmhealth.org for a list of pharmacy locations. Community Walgreens #16544 will overnight medications to a patient's home or preferred pick-up location. Community is open Monday-Friday. Weekend orders after Friday at 4pm must be sent to a drive thru location.
- **Ask patients to go through the drive-thru to minimize exposure to pharmacy staff and customers.**
- Please include date of symptom onset. It helps the pharmacy staff ensure the patient receives the medication within the treatment window.

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

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

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NEW MEXICO DEPARTMENT OF HEALTH

Revised 2/2022

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

Is Patient:
- Hospitalized for COVID-19 **OR**
- Requiring O_2 **OR** an increase in baseline home O_2 due to COVID-19

No

Symptom onset within the past 5-7 days?

Yes

No

Symptom onset within the past 10 days?

Yes

Consider sotrovimab[4] 500 mg IV begun **ASAP within 10 days of symptom onset**

No

Yes

Treatment of symptoms, Management per NIH & CDC Guidelines

Does patient have severe renal impairment (eGFR <30mL/min) **OR** severe hepatic impairment (Child-Pugh Class C)

Yes

Consider sotrovimab[4] 500 mg IV begun **ASAP within 10 days of symptom onset**

If none of the other therapeutics are available or clinically appropriate for patient treatment within 7 days of symptom onset and patient is age 12 or greater and weighing at least 40 kg

Consider Bebtelovimab[7] 175 mg IV begun **ASAP within 7 days of symptom onset**

No

Consider one of the following therapeutics, if available:[1]

PAXLOVID[2] within **5 days of symptom onset**

eGFR ≥60 mL/min : 300 mg nirmatrelvir taken with 100 mg ritonavir twice daily for 5 days

eGFR ≥30-<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

sotrovimab[4] 500 mg IV begun **ASAP within 10 days of symptom onset**

OR

remdesivir[5] 200mg IV x 1 dose on Day 1, 100mg IV x 1 on Days 2-3 begun **ASAP within 7 days of symptom onset**

No

If none of the above therapeutics are available or clinically appropriate for patient treatment within 5 days of symptom onset and patient is **age 18 or greater**

Yes

No

Is possibility of pregnancy, if applicable, ruled out?

Yes

Consider molnupiravir[6] 800mg 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 **molnupiravir EUA[6]**

References:

[1] NIH's COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Non-hospitalized Patients With Mild to Moderate 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

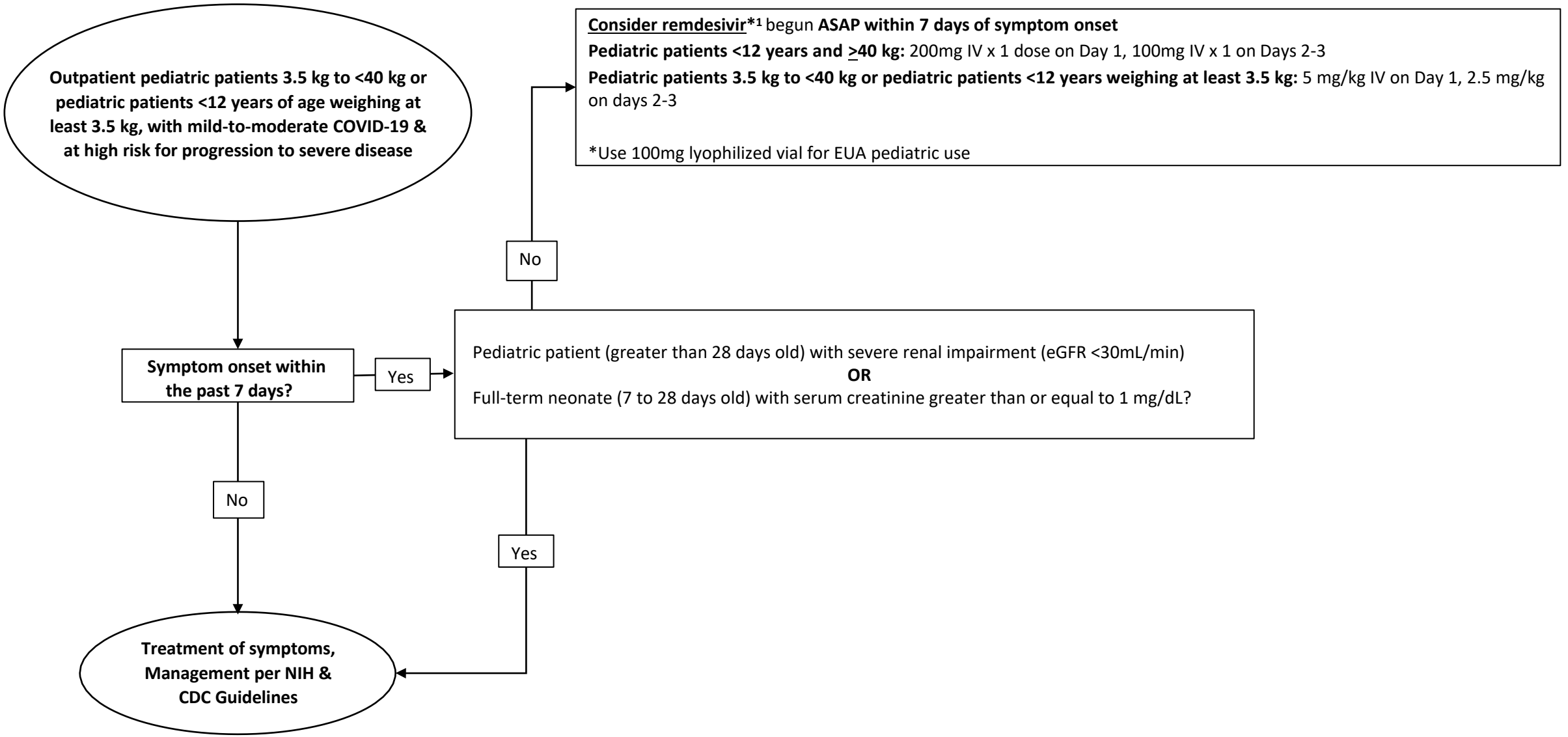
[3] NIH's COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/

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

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

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

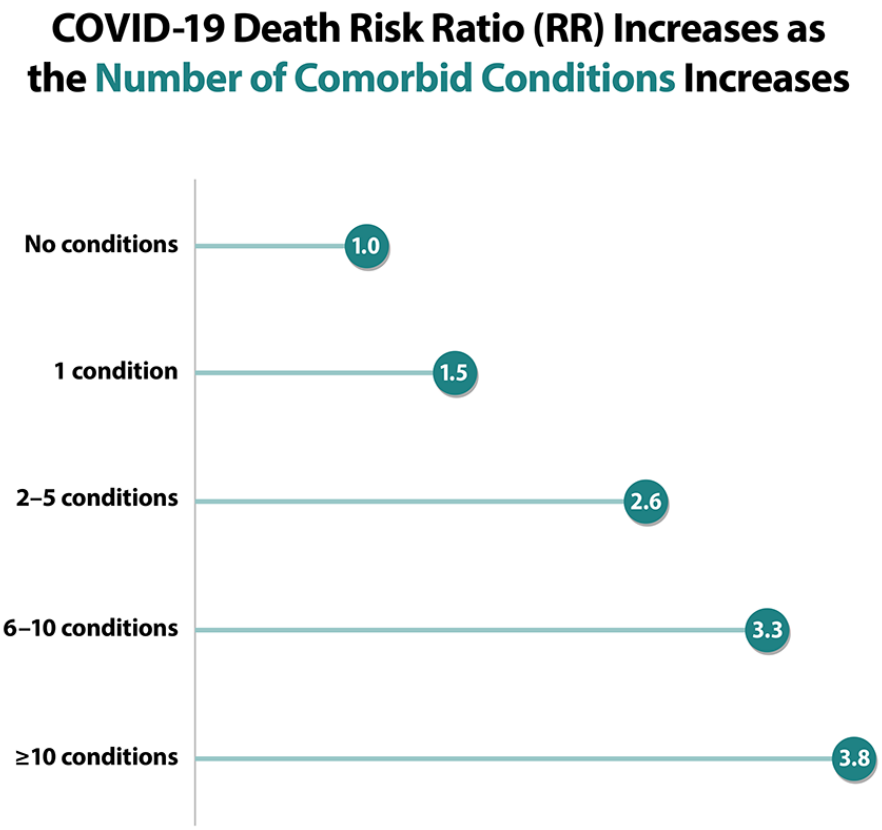
[6] Bebtelovimab EUA. https://www.fda.gov/media/156152/download



February 1, 2022

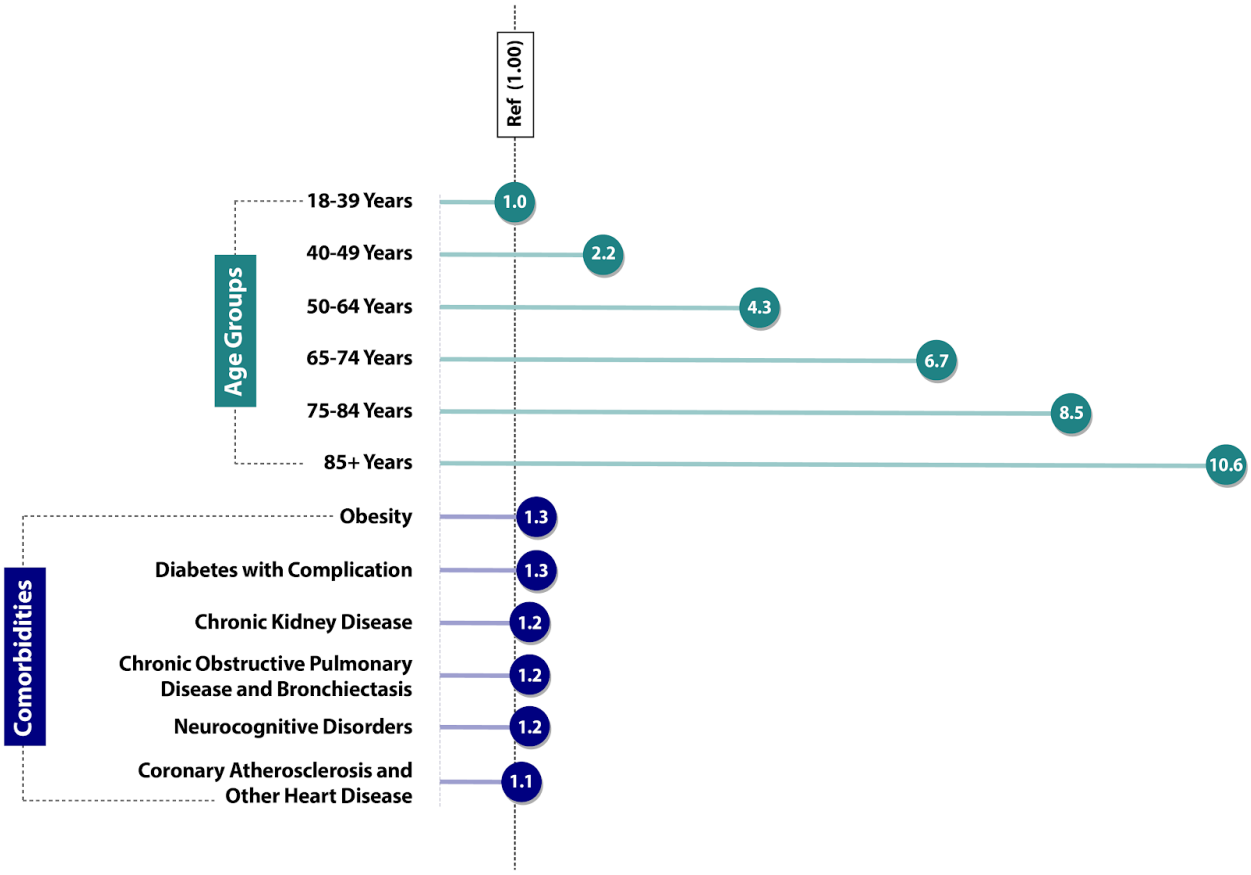
Reference:

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



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

COVID-19 Death Risk Ratio (RR) for Select Age Groups and Comorbid Conditions



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