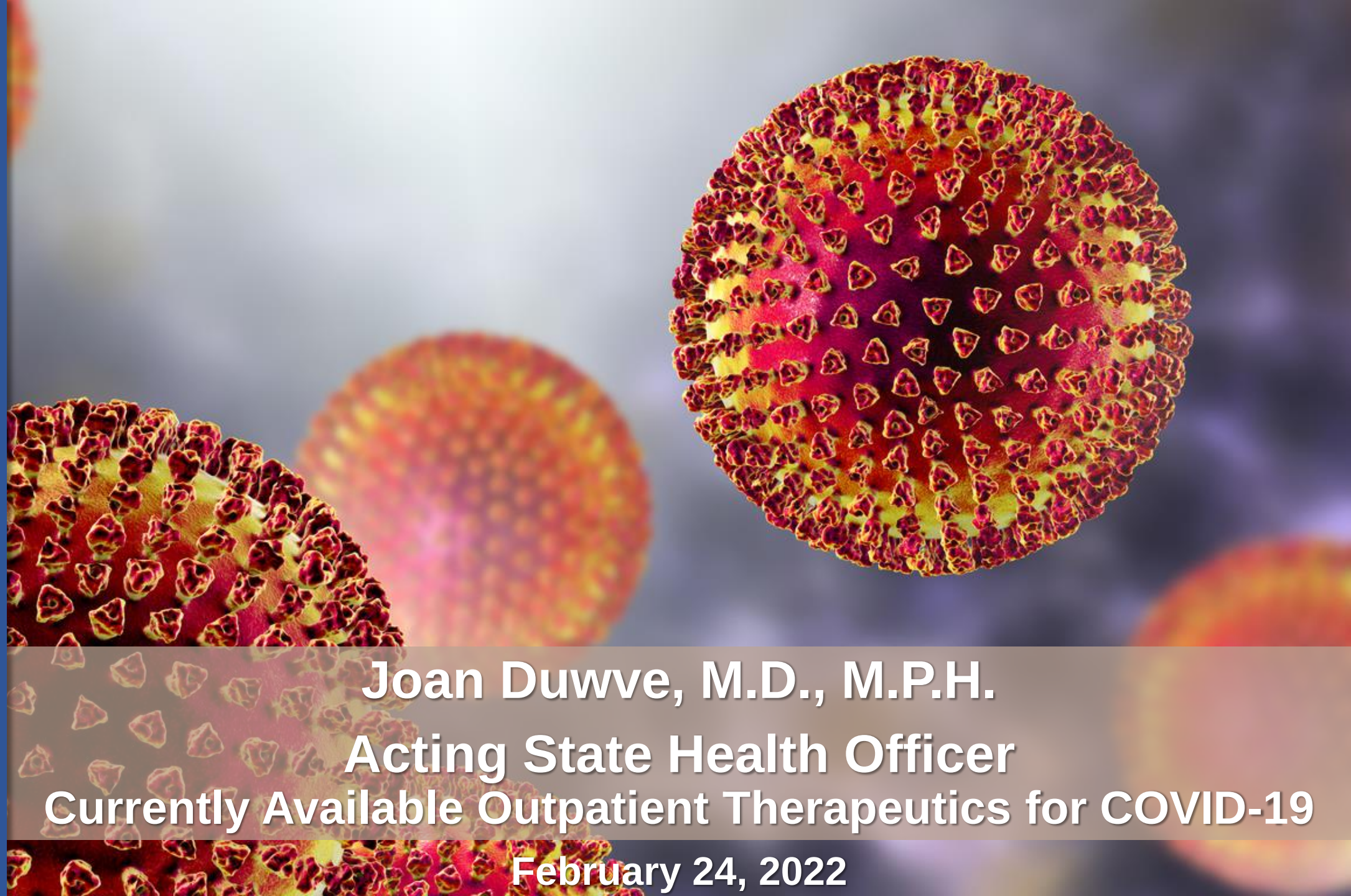


Kansas
Department of Health and Environment
Division of Public Health

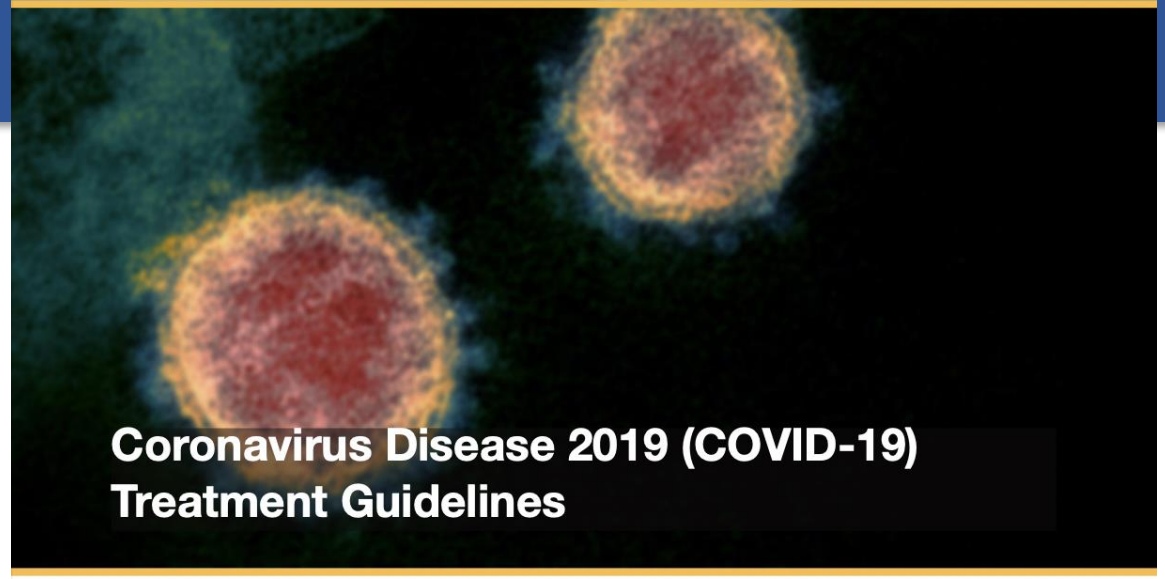
Joan Duwve, M.D., M.P.H.

Acting State Health Officer

Currently Available Outpatient Therapeutics for COVID-19

February 24, 2022

NIH | COVID-19 Treatment Guidelines



Coronavirus Disease 2019 (COVID-19) Treatment Guidelines

Credit NIAID-RML

How to Cite the COVID-19 Treatment Guidelines:

COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed [insert date].

The COVID-19 Treatment Guidelines Panel regularly updates the recommendations in these guidelines as new information on the management of COVID-19 becomes available. The most recent version of the guidelines can be found on the COVID-19 Treatment Guidelines website (https://www.covid19treatmentguidelines.nih.gov/).

Downloaded from https://www.covid19treatmentguidelines.nih.gov/ on 2/24/2022

With information added for Bebtelovimab from EUA documents and Eli Lilly website

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®** **Tixagevimab/Cilgavimab**	**PAXLOVID®** **Nirmatrelvir/Ritonavir**	**Molnupiravir**
Manufacturer	GlaxoSmithKline plc / Vir Biotechnology, Inc.	Eli Lilly and Company	AstraZeneca Pharmaceuticals LP's	Pfizer Inc.	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Date of First EUA1 Issuance	5/26/21	2/11/22	12/20/21	12/22/21	12/23/21
Mechanism of Action	Abs against spike protein; blocks viral entry	mAbs against spike protein; blocks viral entry	mAbs bind to non-overlapping regions of spike protein; blocks viral entry	Protease inhibitor cleaves viral proteins and halts viral replication/Boosting agent	Nucleoside analog inhibits viral replication by viral mutagenesis
Treatment Efficacy per Clinical Trials2	79% reduction in hospitalizations/deaths	Evidence of effectiveness	77% reduction in incidence of SARS-CoV-2 RT-PCR-positive symptomatic illness	88% reduction in hospitalizations/deaths	30% reduction in hospitalizations/deaths
Activity Against SARS-CoV-2 Variants	*Delta variant:* Active *Omicron variant:* likely active *Other variants:* See Section 15 of Sotrovimab Health Care Provider Fact Sheet	*Delta variant:* Active *Omicron variant:* Active against both the omicron variant and the BA.2 omicron subvariant.	*Delta variant*: Active *Omicron variant*: 12-30 fold reduced susceptibility	*Delta variant:* Active *Omicron variant:* Data pending *Other variants:* See Section 12.4 of PAXLOVID Health Care Provider Fact Sheet	*Delta variant:* Active *Omicron variant:* Data pending *Other variants:* See Section 12.4 of Molnupiravir Health Care Provider Fact Sheet

Overall Benefit-Risk Assessment and Limitations of [illegible] Supporting the Benefits of bebtelovimab[1]

- Based on the totality of scientific evidence available, including the available Phase 2 and pharmacokinetic data, along with the nonclinical viral neutralization data for Omicron and other variants of concern, 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.
- In addition, the mechanism of action for bebtelovimab is similar to other neutralizing SARS-CoV-2 monoclonal antibodies, including bamlanivimab and etesevimab, that have data from Phase 3 clinical trials showing a reduction in hospitalization or death in high risk patients infected with other SARS-CoV-2 variants.
- The safety profile of bebtelovimab is acceptable with monitorable risks and is comparable to other SARS-CoV-2 monoclonal antibodies, including bamlanivimab and etesevimab.
- Considered together, these data support that the known and potential benefits of treatment with bebtelovimab outweigh the known and potential risks 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.

1. FDA. EUA fact sheet of bebtelovimab. February 11, 2022.

See the Important Safety Information for bebtelovimab on slides 5-7.

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®**	**PAXLOVID®**	**Molnupiravir**
Authorized Use(s)	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19	Pre-Exposure Prophylaxis	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19
Eligible Populations	Adult and pediatric patients (at least 12 years of age and older weighing at least 40 kg) at high risk3 for progressing to severe COVID-19, including hospitalization or death	Adult and pediatric patients (12 years of age and older weighing at least 40 kg) at high-risk3for 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.	Adult and pediatric patients (12 years of age and older weighing at least 40 kg) with: 1. Moderate to severe immune compromise due to a medical condition or immunosuppressive medications or treatments AND may have inadequate response to vaccination3 OR 2. When vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction	Adults and pediatric patients (12 years of age and older weighing at least 40 kg) at high risk3 for progressing to severe COVID-19, including hospitalization or death	Adults at high risk3 for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
Prescribing Window	Treatment: Within 10 days of symptom onset	Treatment: Within 7 days of symptom onset	Not infected with COVID-19 and No known recent exposure to COVID-19	Treatment: Within 5 days of symptom onset	Treatment: Within 5 days of symptom onset
Testing Requirements	Treatment: Positive direct SARS-CoV-2 viral test	Treatment: Positive direct SARS-CoV-2 viral test	No Requirement	Treatment: Positive direct SARS-CoV-2 viral test	Treatment: Positive direct SARS-CoV-2 viral test

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®**	**PAXLOVID®**	**Molnupiravir**
Limitations of Authorized Use	Not authorized for: • Patients who are hospitalized due to COVID-19. • Patients who require oxygen therapy due to COVID-19 **OR** Require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non- COVID-19 related comorbidity).	Not authorized for: • Adults or pediatric patients who are hospitalized due to COVID-19, **OR** • Adults or pediatric patients who require oxygen therapy and/or respiratory support due to COVID-19, **OR** • Adults or pediatric patients who require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19(in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity).	Not authorized for: • For treatment of COVID-19, or • For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. • EVUSHELD should be administered at least two weeks after vaccination.	Not authorized for: • Patients requiring hospitalization due to severe or critical COVID- 19. • Pre-exposure or post-exposure prophylaxis for prevention of COVID-19. • Use for longer than 5 consecutive days.	Not authorized for: • Patients less than 18 years of age •Initiation in patients who are hospitalized due to COVID-19. •Use for longer than 5 consecutive days. •Pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®**	**PAXLOVID®**	**Molnupiravir**
Family Planning Considerations	None	None	None	• Ritonavir may reduce the efficacy of combined hormonal contraceptives. Patients should use an effective alternative contraceptive method or an additional barrier method of contraception.	•Not recommended for use during pregnancy because may cause fetal harm when given to pregnant individuals based on animal reproduction studies. •Authorized for use in pregnancy only if benefits would outweigh risks for the individual patient; documentation requirements apply. •Females of childbearing potential should be advised of potential risk to a fetus and should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. •Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®**	**PAXLOVID®**	**Molnupiravir**
Contraindications	Patients who have a history of anaphylaxis to Sotrovimab or to any of the excipients in the formulation	None	Individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD.	-Individuals with significant hypersensitivity reactions to any component of PAXLOVID. -Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. -Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.	None
Administration Route(s)	IV Infusion	IV Injection over >30 secs.	IM Injection X 2	Oral	Oral
Dosage	500 mg single infusion following dilution	Adults and pediatric patients (≥12 years of age and weighing at least 40 kg): 175 mg	150 mg of tixagevimab + 150 mg of cilgavimab Administered as two separate consecutive intramuscular injections.	300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) All tablets taken orally together twice daily for 5 days, with or without food The tablets should be swallowed whole and not chewed, broken, or crushed. For patients with renal impairment, see below.	800 mg po (four 200 mg capsules) every 12 hours for 5 days, with or without food.

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld**	**PAXLOVID®**	**Molnupiravir**
Dosage for Special Populations	**Pediatrics** - If eligible, no dosage adjustment **Pregnancy or Lactation** - No dosage adjustment **Renal** - No dosage adjustment **Hepatic** - Not specified	**Pediatrics**– if eligible no dosage adjustment **Pregnancy or Lactation** - No dosage adjustment **Renal** - No dosage adjustment **Hepatic** – No dosage adjustment with mild hepatic impairment	**Pediatrics**– if eligible no dosage adjustment **Pregnancy or Lactation** - No dosage adjustment **Renal** - No dosage adjustment **Geriatric** – No dosage adjustment **Hepatic** - Not specified	**Pediatrics:** • If eligible, no dosage adjustment **Pregnancy or Lactation** – No dosage adjustment **Renal**: • No dosage adjustment is needed in patients with mild renal impairment. •Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days. •**NOT recommended** in patients with severe renal impairment (eGFR <30 mL/min). **Hepatic:** •No dosage adjustment for mild or moderate hepatic impairment. • **NOT recommended** for use in patients with severe hepatic impairment.	**Pediatrics – NOT eligible**, as it may affect bone and cartilage growth. **Pregnancy or Lactation** – Not recommended for use during pregnancy. Breastfeeding not recommended during treatment or for 4 days after final dose. **Renal** - No dosage adjustment **Hepatic -** No dosage adjustment

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®**	**PAXLOVID®**	**Molnupiravir**
Post- Administration Observation Period	One hour	One hour	One hour	None	None
Adverse Events (from Clinical Trials)5	Infusion-related reactions (1%); One case of anaphylaxis *Other adverse events:* pyrexia, chills, dizziness, dyspnea, pruritus, rash *Clinical worsening vs. adverse events:* fever, hypoxia, increased respiratory difficulty, arrhythmia, fatigue, altered mental status	Infusion-related reactions (0.3%); No cases of anaphylaxis *Other adverse events (all <1%):* nausea, vomiting, pruritis, rash *Clinical worsening vs. adverse events:* fever, hypoxia, increased respiratory difficulty, arrhythmia, fatigue, altered mental status	No cases of anaphylaxis Other adverse events <1%: headache, fatigue, cough. Serious Adverse Events: Cardiovascular events in patients with cardiac risk factors 0.6% (vs. 0.2% placebo)	Adverse events (incidence ≥1% and ≥5 patient difference) dysgeusia (6%), diarrhea (3%), hypertension (1%), and myalgia (1%).	Adverse events (incidence ≥1%) Diarrhea (2%), nausea (1%), dizziness (1%)
Potential for Drug-Drug Interactions	Unlikely	Unlikely	Unlikely	**Moderate/High [see Fact Sheet Drug Interactions Section (7)]**	No drug interactions have been identified based on the limited available data
Potential for Patient Non- Compliance	Minimal	Minimal	Minimal	Moderate	Moderate
Cost to Patients for USG procured drug6	Medicare/Medicaid7: $0 Private insurers: $0	Medicare/Medicaid7: $0 Private insurers: $0	Medicare/Medicaid7: $0 Private insurers: $0	Medicare/Medicaid7: $0 Private insurers: $0	Medicare/Medicaid7: $0 Private insurers: $0

MONOCLONAL ANTIBODIES (mAbs)				ORAL ANTIVIRALS (AVs)	
Product	**Sotrovimab**	**Bebtelovimab**	**EvuSheld®**	**PAXLOVID®**	**Molnupiravir**
Provider Payment (Administration or dispensing fee)6, 8, 9, 10	Medicare: $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances6) Medicaid/Private insurers: Variable	*Medicare: $350 (most settings);* *$550 (beneficiary's home or residence, in certain circumstances6)* *Medicaid/Private insurers:* Variable	*Medicare*: $150 (most settings); $250 *(beneficiary's home or residence, in certain circumstances6)* *Medicaid/Private insurers*: Variable	Provider may bill applicable insurance or program for dispensing fees	Provider may bill applicable insurance or program for dispensing fees
Product Availability	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility
Other Considerations [May only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants licensed or authorized under state law to prescribe drugs in the therapeutic class to which it belongs	Infusion supplies; trained staff; IV access; immediate access to resuscitation meds; ability to activate EMS	Infusion supplies; trained staff; IV access; immediate access to resuscitation meds; ability to activate EMS Per EUA – administer with syringe extension set	Intramuscular injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder.	**Clinicians who are not experienced in prescribing ritonavir-boosted drugs should refer to resources such as the** EUA fact sheet for ritonavir-boosted nirmatrelvir (Paxlovid) **and the** Liverpool COVID-19 Drug Interactions website **for additional guidance**. Consultation with an expert (e.g., clinical pharmacist, HIV specialist, and/or the patient's specialist provider[s], if applicable) should also be considered.	Concerns about the potential effects of molnupiravir on SARS-CoV-2 mutation rates - Merck required to monitor as part of EUA
Product Websites	Sotrovimab website	Bebtelovimab website	EvuSheld website	PAXLOVID website	Molnupiravir website
Fact Sheets for Health Care Providers	Sotrovimab Health Care Provider Fact Sheet	Bebtelovimab Health Care Provider Fact Sheet	EvuSheld Health Care Provider Fact Sheet	PAXLOVID Health Care Provider Fact Sheet NIH Statement on Paxlovid Drug-Drug Interactions	Molnupiravir Health Care Provider Fact Sheet
Fact Sheets for Patients, Parents, and Caregivers (English)	Sotrovimab Patient Fact Sheet (English)	Bebtelovimab Patient Fact Sheet (English)	EvuSheld Patient Fact Sheet (English)	PAXLOVID Patient Fact Sheet (English)	Molnupiravir Patient Fact Sheet (English)
Fact Sheets for Patients, Parents, and Caregivers (Spanish)	Sotrovimab Patient Fact Sheet (Spanish)	Bebtelovimab Patient Fact Sheet (Spanish)		PAXLOVID Patient Fact Sheet (Spanish)	Molnupiravir Patient Fact Sheet (Spanish)

1 Emergency Use Authorization: The most recent EUAs, including updates and amendments, are available on the product websites.

2 For more details on clinical trial results, see Section 18 of each respective product's Fact Sheet for Health Care Providers.
3 See each product's Fact Sheet for Health Care Providers for additional details and criteria for identifying high risk patients/individuals. CDC also maintains a webpage listing underlying medical conditions associated with higher risk for severe COVID-19.

4 Individuals eligible for PEP include those who are not fully vaccinated (see CDC guidance) or who are not expected to mount an adequate immune response to vaccination (e.g., individuals with immunocompromising conditions including those taking immunosuppressive medications); AND have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC or who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes, prisons).

5 For more details on adverse events from clinical trials, see Section 6 of each respective product's Fact Sheet for Health Care Providers. For more details on clinical worsening after mAb administration, see Section 5.

6 For more details, see the CMS COVID-19 Monoclonal Antibodies Infographic and the CMS COVID-19 Monoclonal Antibodies Toolkit
7 For Medicaid beneficiaries, $0 cost-sharing for COVID-19 treatments is required only during the American Rescue Plan Act coverage period.

8 Some patients/individuals may be responsible for co-pays, deductibles, and/or other charges.
9 CMS billing codes, Medicare allowances, and effective dates for COVID-19 vaccines and monoclonal antibodies

10 For uninsured patients/individuals, healthcare providers can claim reimbursement, generally at Medicare rates, via the HRSA COVID-19 Uninsured Program for testing, treatment, and vaccine administration.

i 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 or receiving immunosuppressive treatment, in either the outpatient or inpatient setting. Fact Sheet for Healthcare Providers
ii VEKLURY® (Remdesivir) is an RNA-dependent RNA polymerase inhibitor that blocks replication of SARS-CoV-2. It is approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021; DOI: 10.1056/NEJMoa2116846)

Drug	EUA or FDA appr	Indications			Eligibility	Site		Limitations on Use	Administration Route	Risk Red.
		COVID Test^	When to Use (Sx onset)	Administration Criteria		Hosp	Outpt			
Bebtelovimab (Eli Lilly) mAb	EUA	+	w/in 7 days	Adults/adolescents with mild-moderate COVID-19 at high risk for progression to severe COVID-19, including hospitalization or death[1]	12 + years 40 + kg	No	YES	Not for use in people who are hospitalized or require oxygen therapy due to COVID-19	IV injection 175 mg IV injection over at least 30 seconds	?
***Sotrovamab (GSK) mAb**	EUA	+	w/in 10 days	Adults/adolescents who are at high risk for progression to severe COVID-19, including hospitalization or death[1]	12 + years 40 + kg	No	YES	Not for use in people who are hospitalized or require oxygen therapy due to COVID-19	IV infusion	79%
***EvuSheld (Astra Zeneca) mAb**	EUA	PrEP Test not required, but if tested, must be negative	No symptoms or No known exposures	1. Moderate to severe immune compromise due to a medical condition or immunosuppressive medications or treatments AND may have inadequate response to vaccination[2] **OR** 2. When vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction	12 + years 40 + kg	No	YES	Wait at least 2 weeks after COVID-19 vaccine administration to administer	IM injection X 2 (at 2 sites)	77%
***Molnupiravir (Merck) Antiviral**	EUA	+	w/in 5 days	Adults who are at high risk for progression to severe COVID-19, including hospitalization or death[1]	18 + years	No	YES	Mutagenic. Teratogenic in lab animals. Not recommended for use in pregnant women	PO (4 capsules bid X 5 days)	30%
***Paxlovid (Pfizer) Antiviral**	EUA	+	w/in 5 days	Adults who are at high risk for progression to severe COVID-19, including hospitalization or death[1]	18 +	No	YES	Significant and complex drug-drug interaction potential[3]	PO (2 tablets bid X 5 days)	88%
***Remdesivir (Gilead) Antiviral**	FDA appr	+	w/in 7 days	Adults/adolescents with mild-moderate COVID-19 at high risk for progression to severe COVID-19, including hospitalization or death[1]	12+ 40+ kg	YES	YES	Renal/hepatic function/PT before tx and as during tx. Don't use if eGFR <30 ml/min Administer in settings with immediate access to meds for severe infusion or allergic rxn and can activate EMS	IV x 3 days Day 1 =200mg Days 2-3 = 100mg	87%
	EUA	+	w/in 7 days	Pediatric patients with mild-moderate COVID-19 at high risk for progression to severe COVID-19, including hospitalization or death[1]	< 12 yrs. 3.5+ kgs	YES	YES		IV x 3 days Day 1 =5mg/kg Days 2-3 =2.5mg/kg	?

***Maintains activity against Omicron.**

^Direct SARS-CoV-2 viral testing (NAAT or antigen).

[1]People at high risk for progression to severe COVID-19

[2]For additional information please see CDC clinical considerations. Healthcare providers should consider the benefit-risk for an individual patient.

[3]Liverpool COVID-19 Drug Interactions website

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

No

Treatment of symptoms, Management per NIH & CDC Guidelines

Yes

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

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

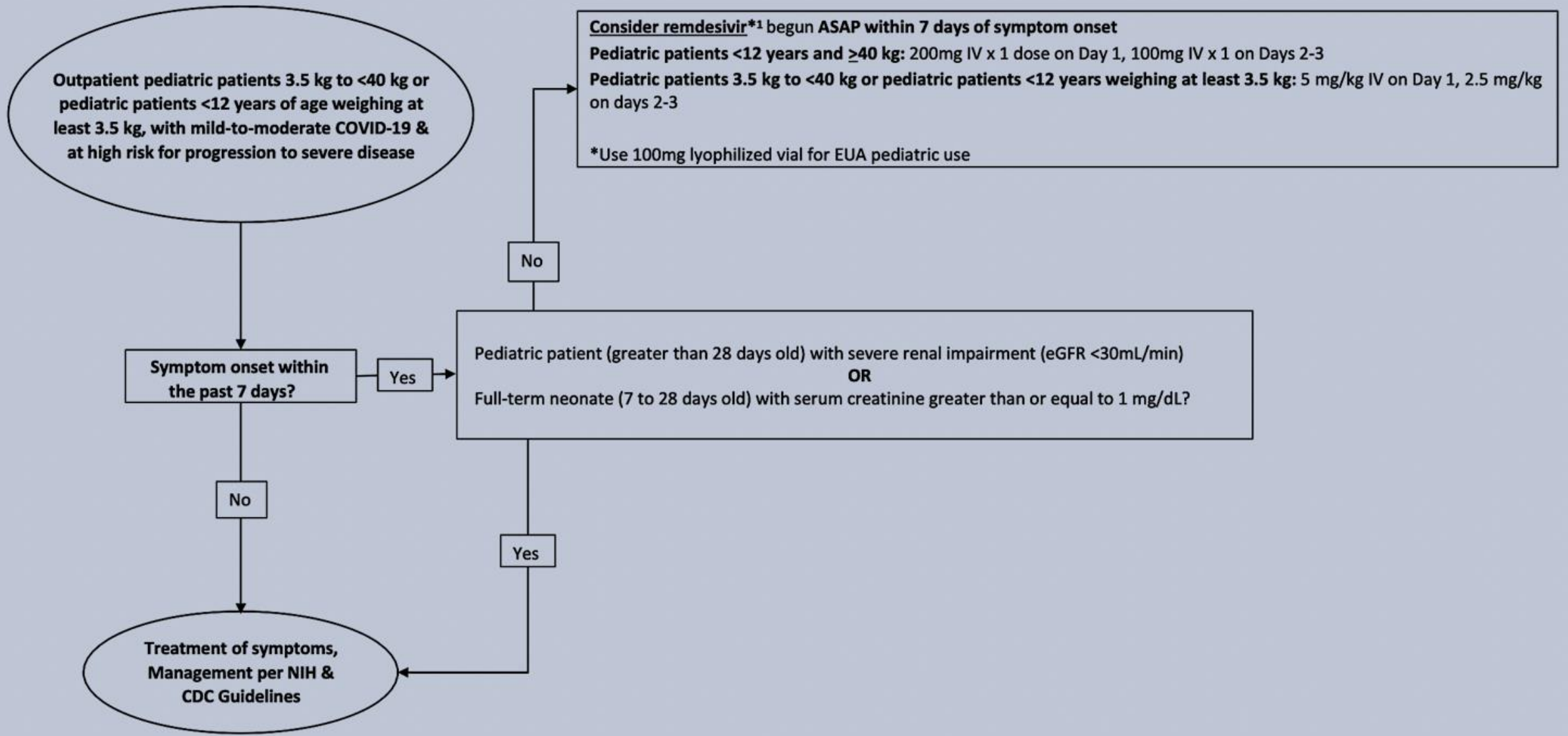
[3] NIH's COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/

[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

February 1, 2022



February 1, 2022

Reference:

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

NIH Outpatient COVID-19 Treatment Guidelines

Tier 1	**Immunocompromised** individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to underlying conditions, regardless of vaccine status; ***or*** **Unvaccinated** individuals at the highest risk of severe disease (anyone **aged ≥75 years** or anyone **aged ≥65 years with additional risk factors**).
Tier 2	**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**)
Tier 3	**Vaccinated** individuals at high risk of severe disease (anyone **aged ≥75 years** or anyone **aged ≥65 years with clinical risk factors**) **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.
Tier 4	**Vaccinated** individuals at risk of severe disease (anyone **aged ≥65 years** or anyone **aged <65 with clinical risk factors**) **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.

https://files.covid19treatmentguidelines.nih.gov/guidelines/section/section_163.pdf

NIH Guidance for Scarcity of Therapeutics

When it becomes necessary to triage patients for receipt of anti-SARS-CoV-2 therapies or preventive strategies, the Panel suggests prioritizing:

- **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** (see Immunocompromising Conditions below).
- Use of tixagevimab plus cilgavimab (**Evusheld) as pre-exposure prophylaxis (PrEP) for severely immunocompromised individuals** over moderately immunocompromised individuals (see Immunocompromising Conditions below)

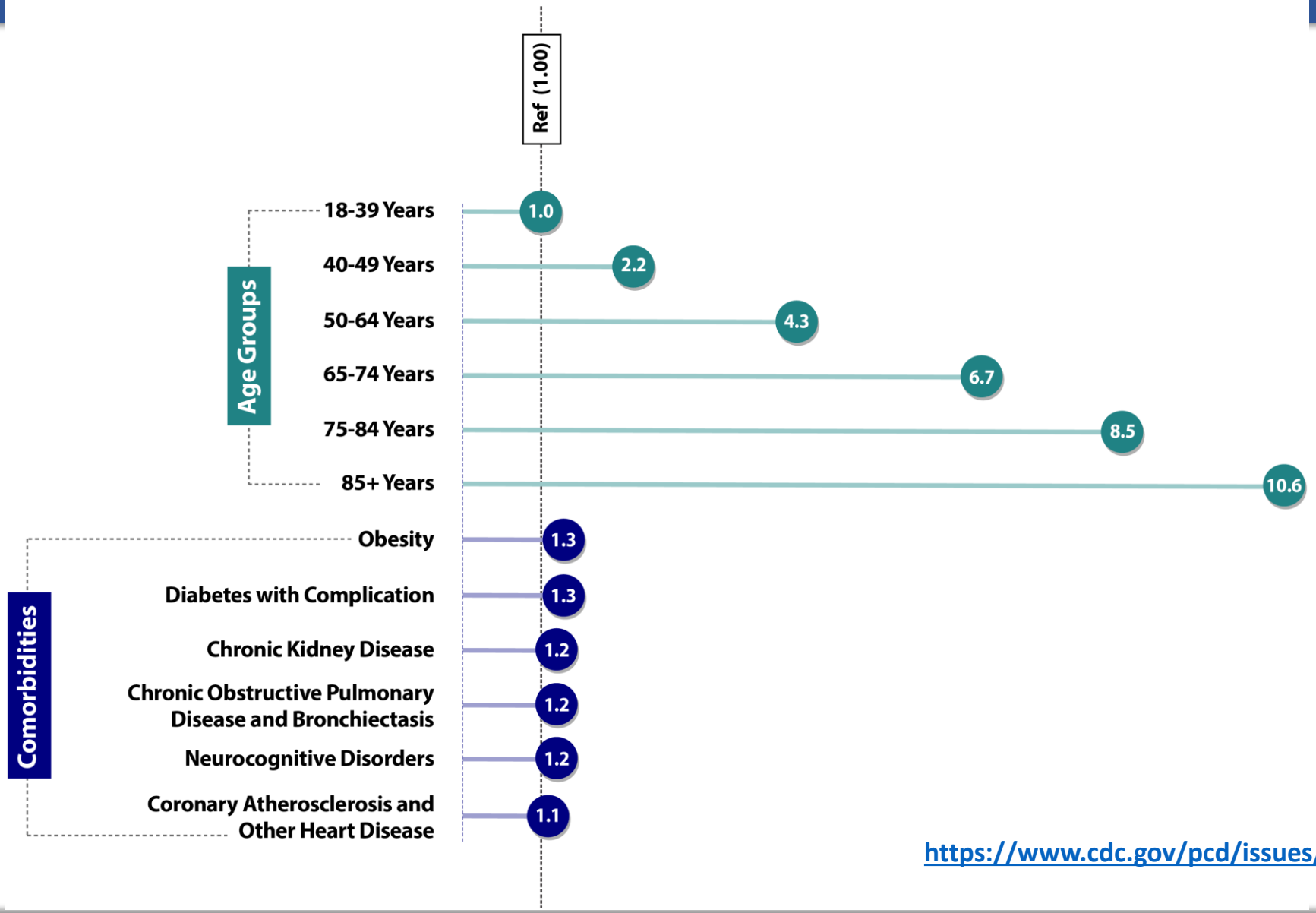
NIH Suggested Prioritization if Logistical Constraints or Supply Limitations

NIH Advisory Panel suggests prioritizing their use for those who are least likely to mount an adequate response to COVID-19 vaccination or SARS-CoV-2 infection and who are at risk for severe outcomes, including:

- Patients who are within 1 year of receiving B cell-depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
- Patients who are receiving Bruton tyrosine kinase inhibitors
- Chimeric antigen receptor T cell recipients
- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
- Patients with hematologic malignancies who are on active therapy
- Lung transplant recipients
- Patients who are within 1 year of receiving a solid organ transplant (other than a lung transplant)
- Solid organ transplant recipients with recent treatment for acute rejection with T cell- or B cell-depleting agents
- Patients with severe combined immunodeficiencies
- Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm^3

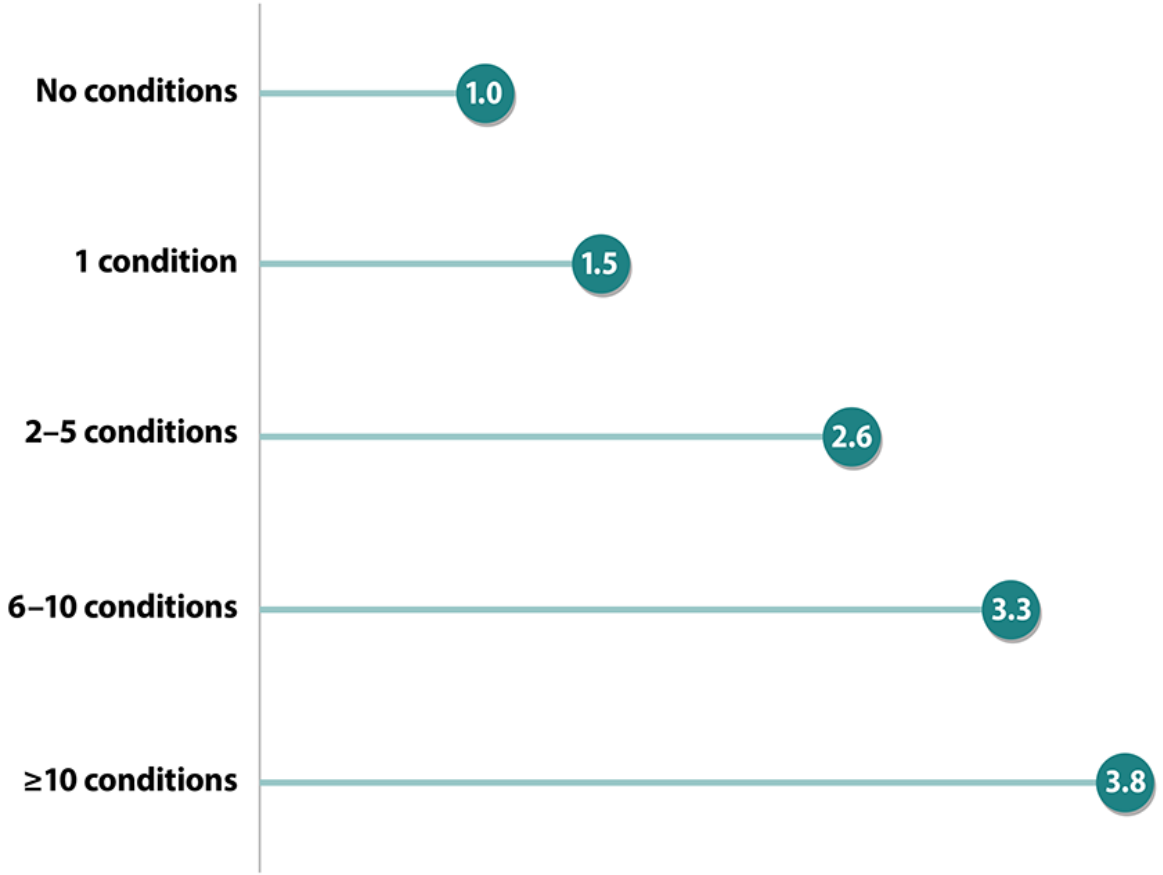
https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/

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



https://www.cdc.gov/pcd/issues/2021/21_0123.htm

COVID-19 Death Risk Ratio (RR) Increases as the Number of Comorbid Conditions Increases



https://www.cdc.gov/pcd/issues/2021/21_0123.htm

Links to References

- COVID-19 Vaccines for Moderately or Severely Immunocompromised People
- HHS/ASPR COVID-19 Therapeutics Webpage
- NIH Outpatient COVID-19 Treatment Guidelines
- HHS Combat Covid Website
- CDC webpage Underlying Medical Conditions Associated with High Risk for Severe COVID-19
- Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021
- Therapeutics Distribution Locations
- CMS Billing Guidance
- Medicare Payment for Remdesivir
- Medicare FFS Billing FAQs
- For Questions about Federal mAbs or AV program: COVID19Therapeutics@hhs.gov

THANK YOU!

Questions?

Joan.Duwve@ks.gov