# COVID-19 Vaccines & Therapies (Clinician Info Session)

**Isaac Benowitz, MD**
State Epidemiologist
Maine Center for Disease Control and Prevention

**DRAFT**

*June 14, 2022*

STATE OF MAINE
Department of
Health and Human Services

# Next webinar: Tuesday, July 12, at 12pm

**COVID-19 Vaccines & Therapies (Maine CDC Clinician Info Sessions)**
*Please join us to learn more about COVID-19 in Maine and current vaccines and therapies*
(2nd Tuesday of the month from 12–1pm)

https://mainestate.zoom.us/j/83384535429
Meeting ID: 833 8453 5429

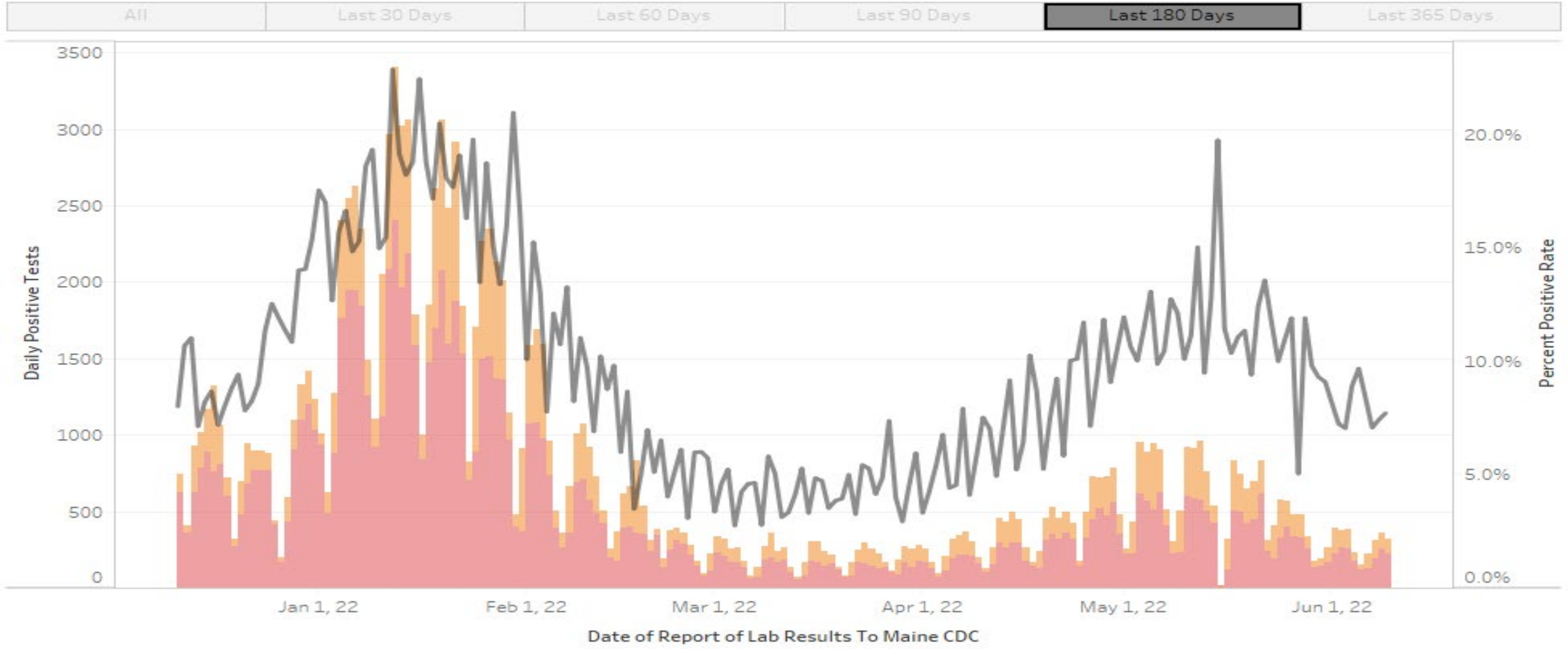
*One tap mobile*
- +13017158592,,83384535429# US (Washington DC)
- +13126266799,,83384535429# US (Chicago)

*Dial by your location*
- +1 301 715 8592 US (Washington DC)
- +1 312 626 6799 US (Chicago)
- +1 646 876 9923 US (New York)
- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)
- +1 408 638 0968 US (San Jose)
- Meeting ID: 833 8453 5429

Find your local number: https://mainestate.zoom.us/u/keev9ZGoew

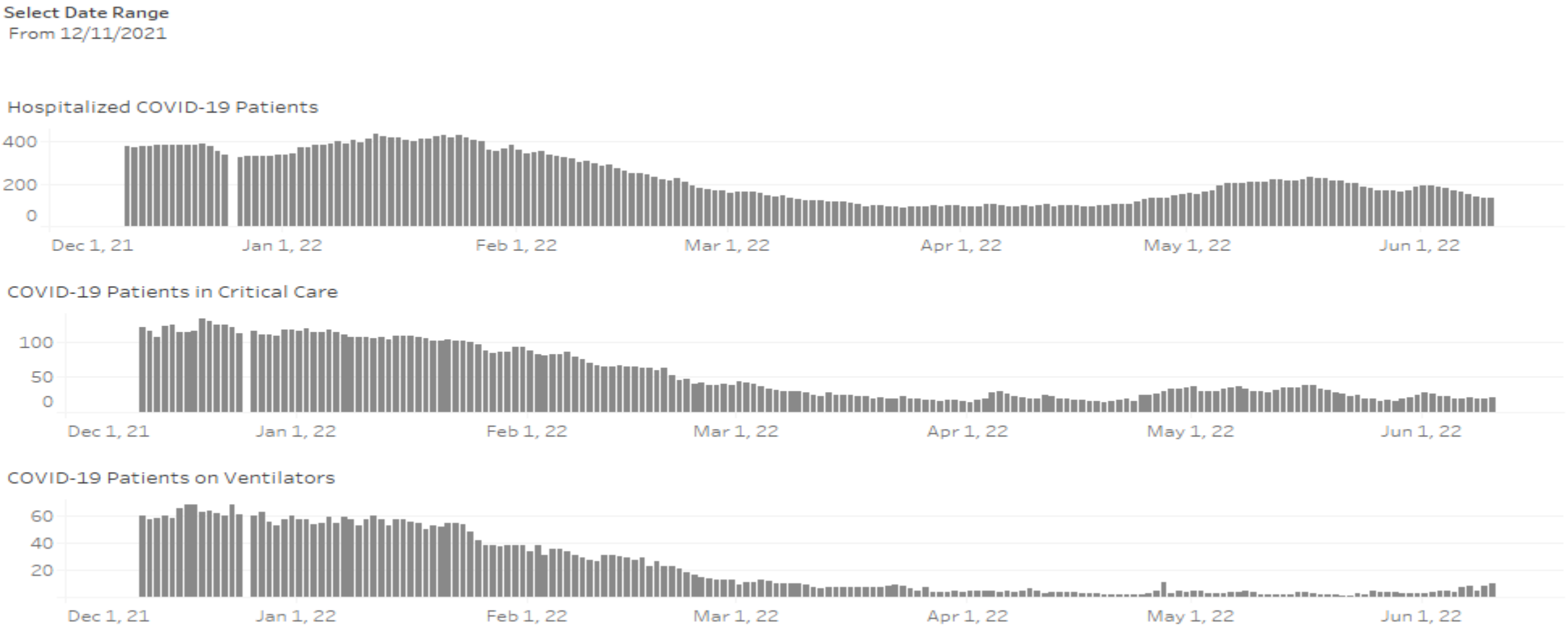
# COVID-19 in Maine, Hospitalizations, and Deaths

# COVID-19 lab results, Maine, past 6 months



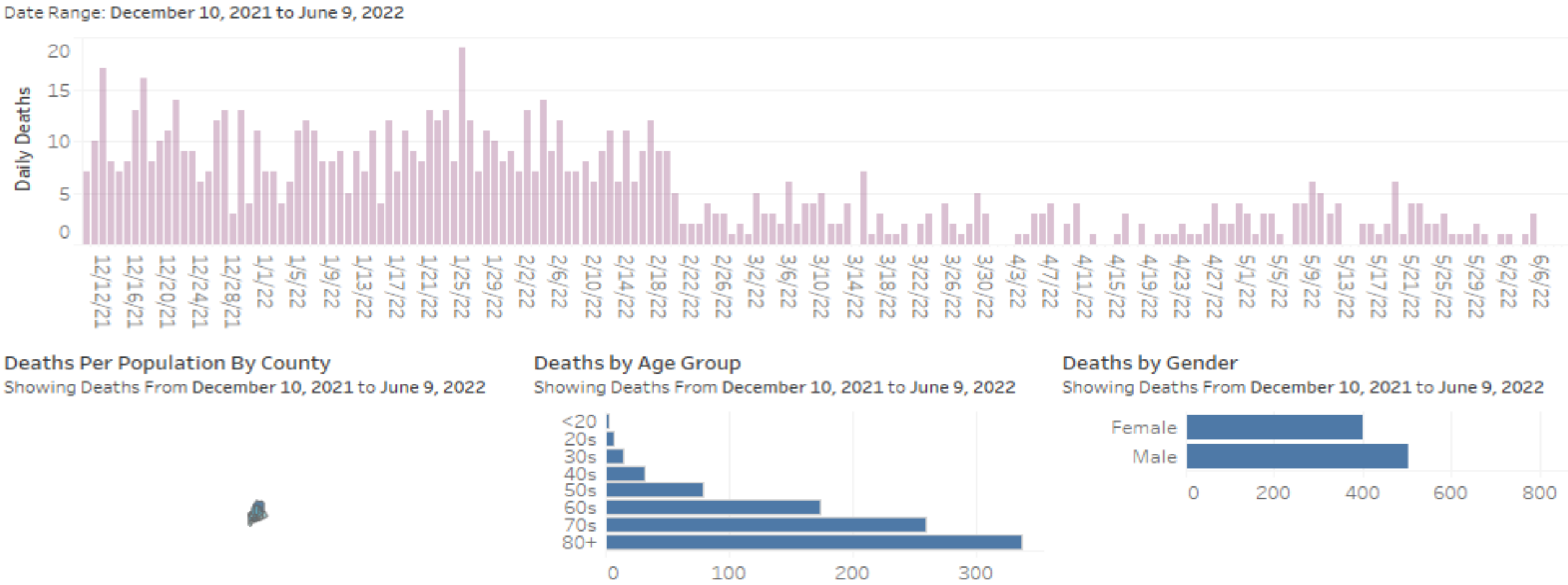

Maine CDC: COVID-19: Maine Data (https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml)

# COVID-19 hospitalizations, Maine, past 6 months




Maine CDC: COVID-19: Maine Data (https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml)

# COVID-19 deaths, Maine, past 6 months







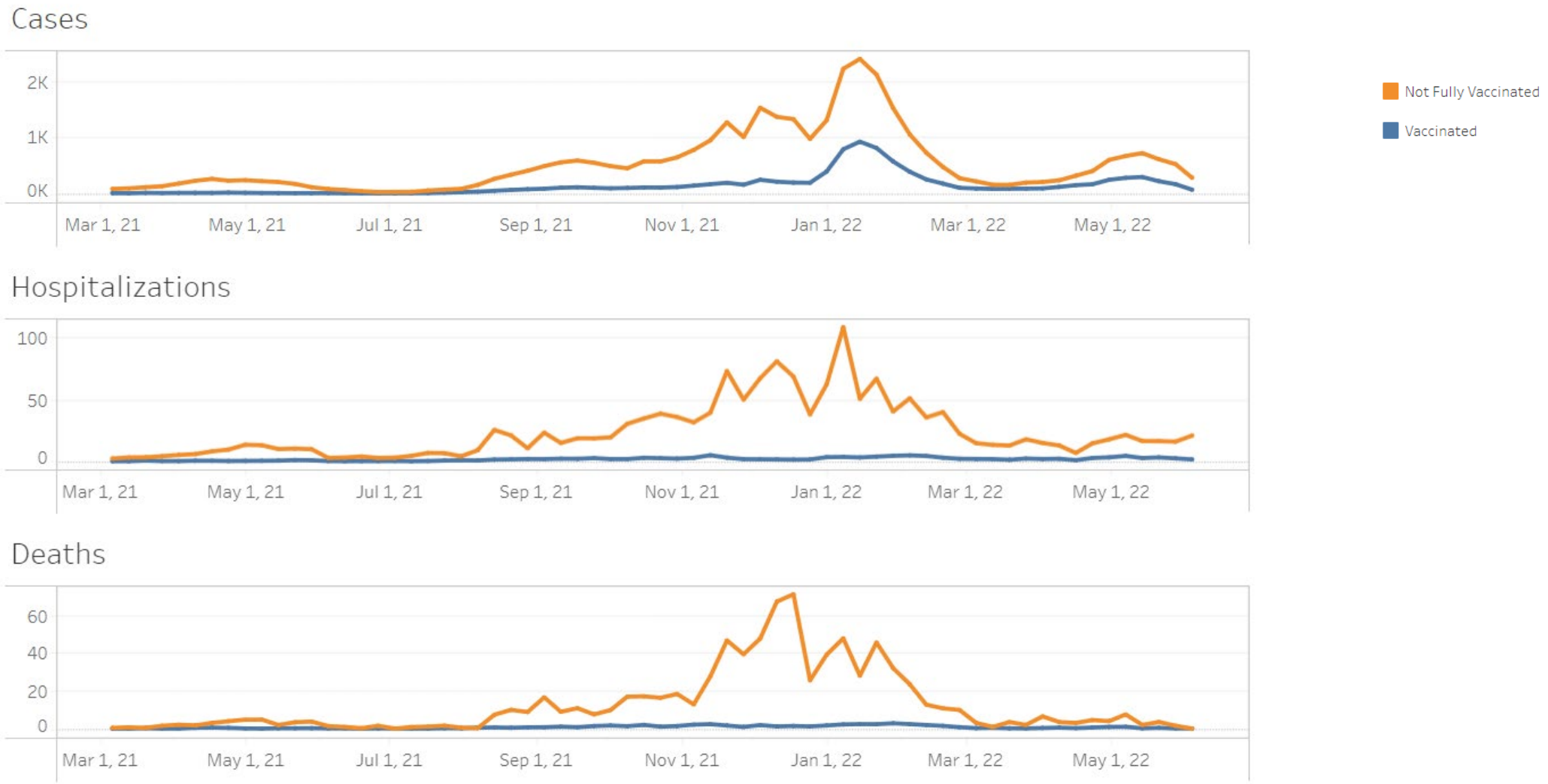






Maine CDC: COVID-19: Maine Data (https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml)

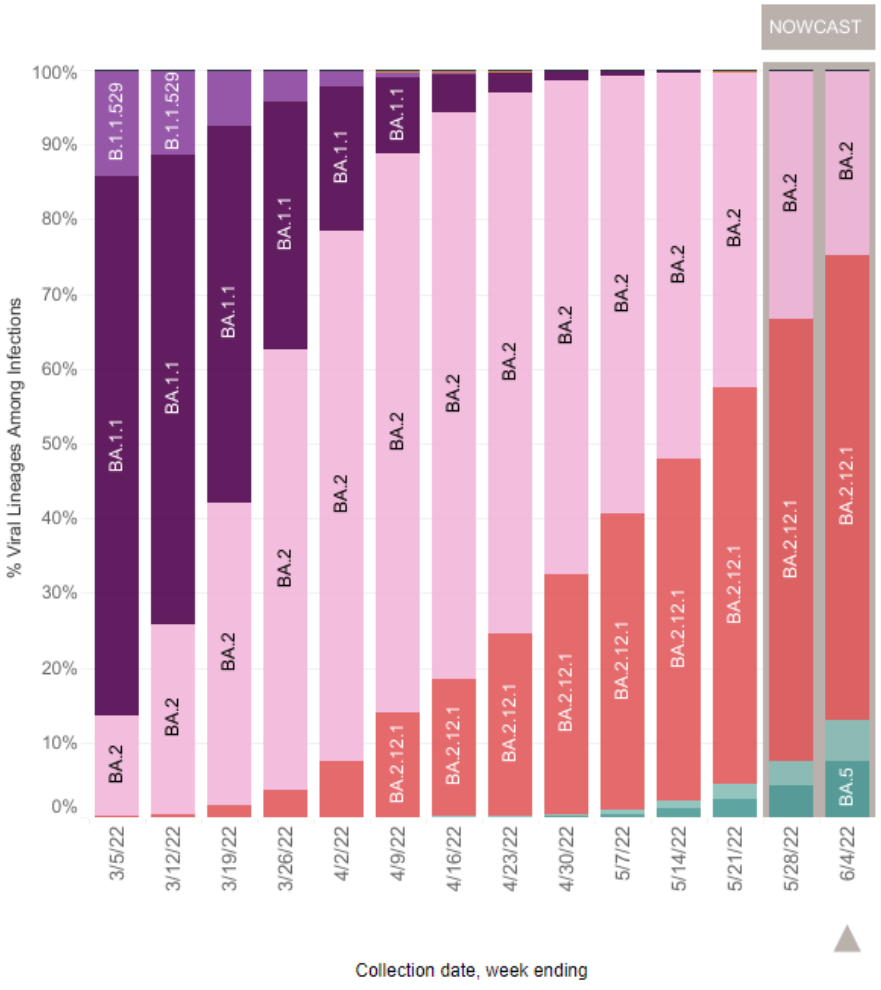
# COVID-19 Breakthrough Cases, Hospitalizations, and Deaths



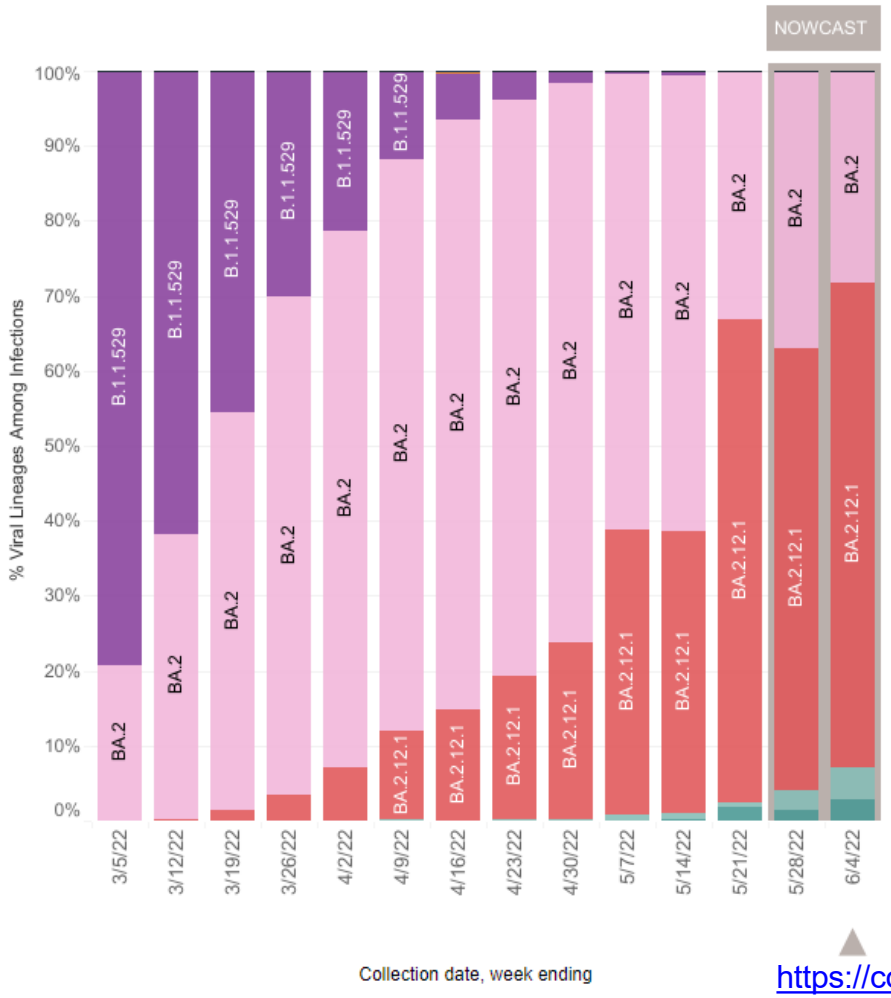

Maine CDC: COVID-19: Maine Data (https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/data.shtml)

# Prevalence of COVID-19 Variants Nationally & HHS Region 1

**United States: 2/27/2022 – 6/4/2022**




**HHS Region 1: 2/27/2022 – 6/4/2022**




**HHS Region 1: 5/29/2022 – 6/4/2022 NOWCAST**

**Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont**

| WHO label | Lineage # | US Class | %Total | 95%PI |
|---|---|---|---|---|
| Omicron | BA.2.12.1 | VOC | 64.5% | 54.6-73.4% |
| | BA.2 | VOC | 28.3% | 20.6-37.5% |
| | BA.4 | VOC | 4.4% | 2.6-7.1% |
| | BA.5 | VOC | 2.8% | 1.3-5.7% |
| | 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% |

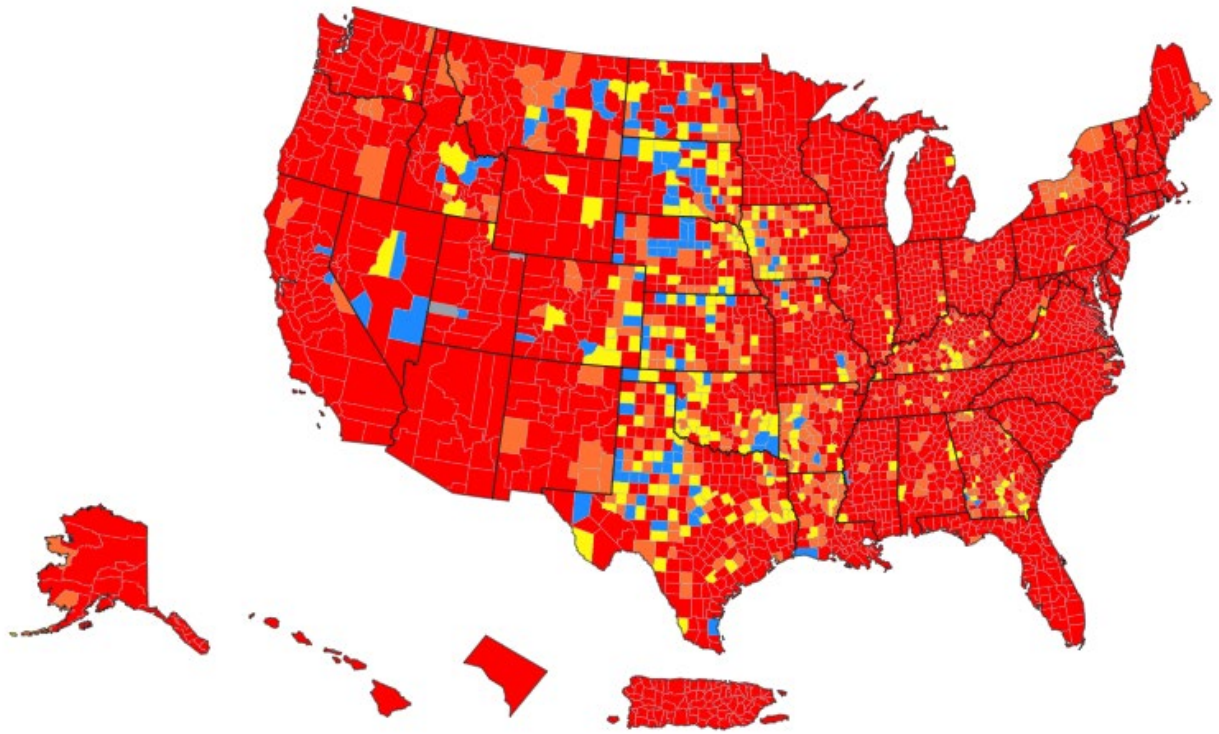
* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ 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 aggreagated with BA.2.

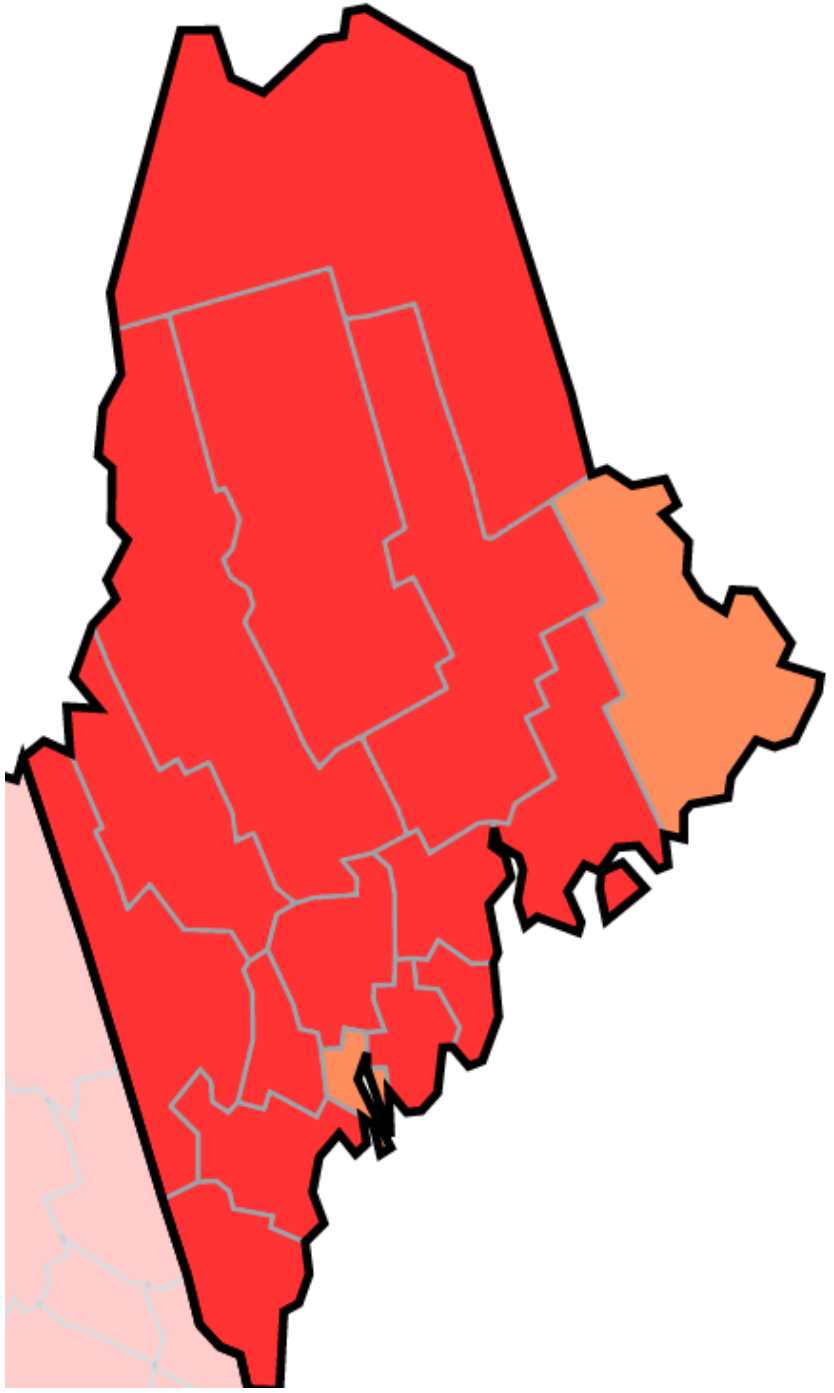
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

# Community Transmission

Community Transmission in US by County

| | Total | Percent | % Change |
|---|---|---|---|
| High | 2541 | 78.86% | 9.34% |
| Substantial | 346 | 10.74% | – 3.66% |
| Moderate | 224 | 6.95% | – 4.03% |
| Low | 109 | 3.38% | – 1.64% |



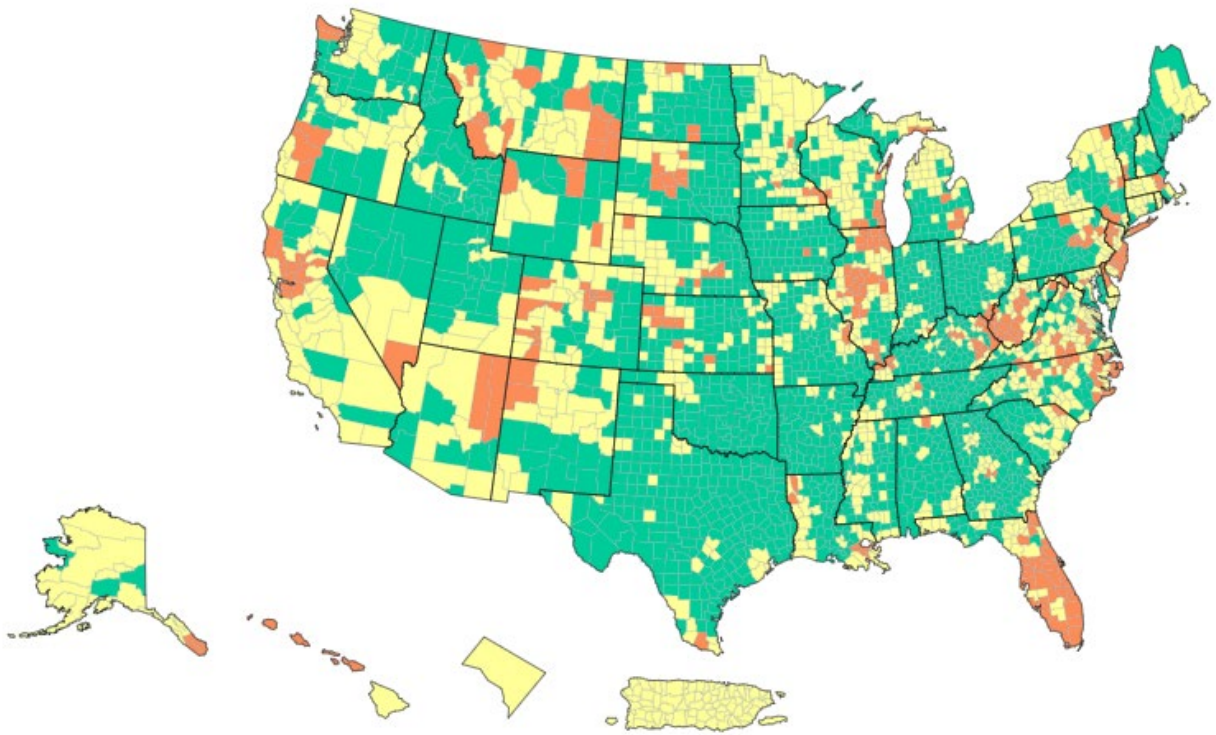


High Substantial Moderate Low No Data

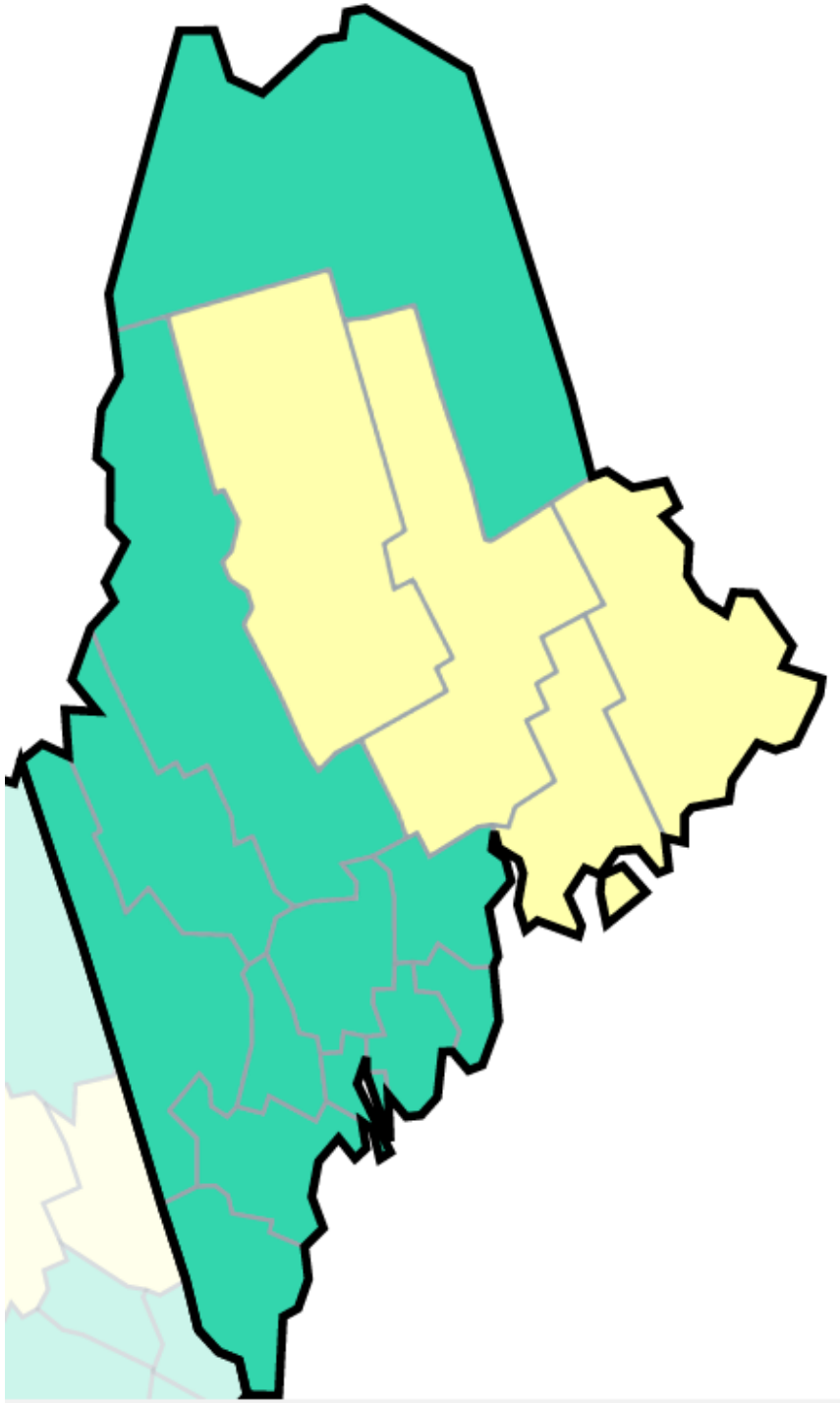
# Community Levels

COVID-19 Community Levels in US by County

| | Total | Percent | % Change |
|---|---|---|---|
| High | 314 | 9.74% | 2.26% |
| Medium | 1056 | 32.75% | 9.93% |
| Low | 1854 | 57.51% | – 12.19% |



Low Medium High No Data



# COVID-19 Vaccines and Pre-exposure Prophylaxis

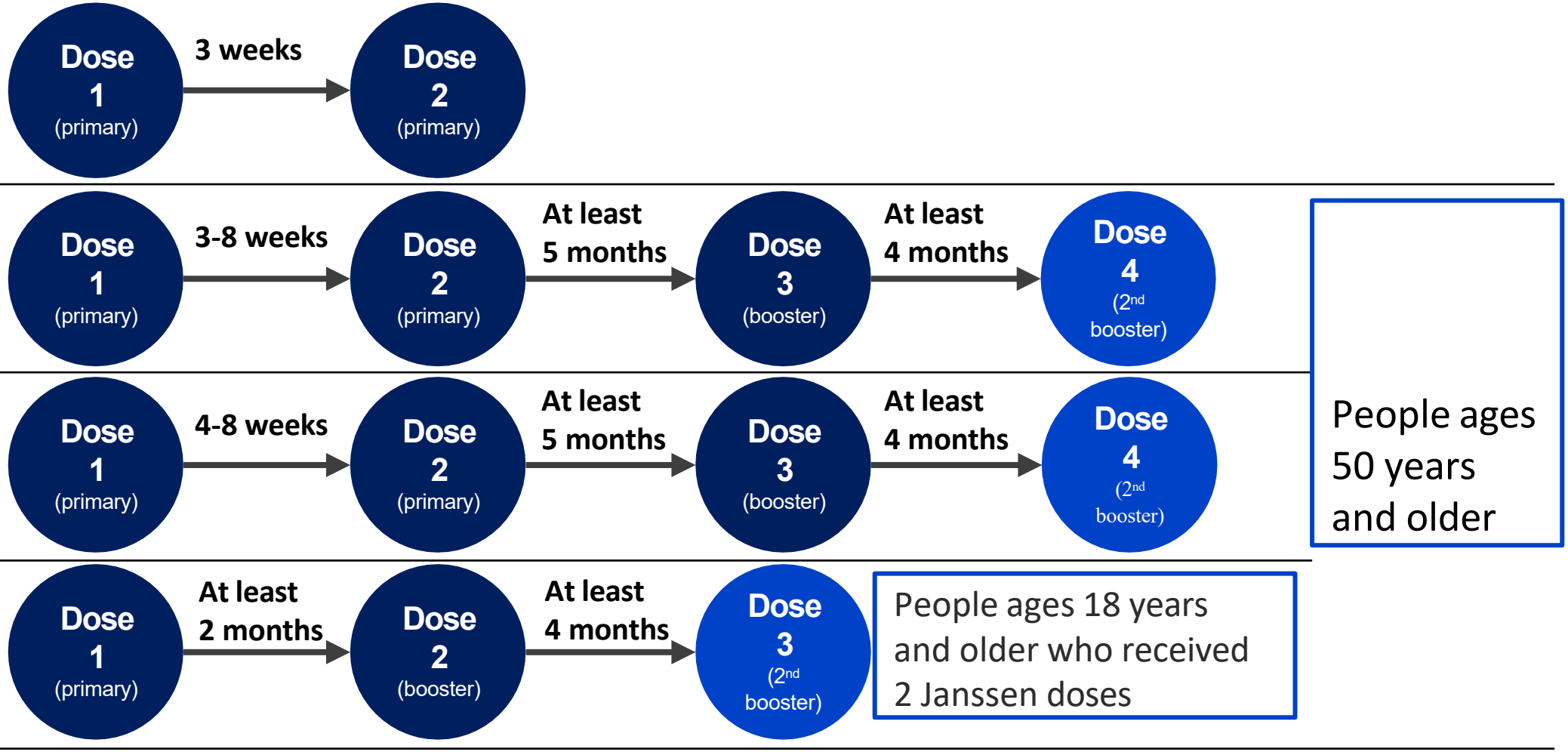
# Summary of COVID-19 Vaccines and Therapeutics

| Category or Population | What's Available? | Resources and Notes |
|---|---|---|
| **All persons age 5 years and older** | • COVID-19 vaccines<br>• COVID-19 boosters | • US CDC: Use of COVID-19 Vaccines in the United States<br>• Maine CDC: COVID-19 Vaccine Providers Portal |
| **Persons age 5 years and older with moderate or severe immunocompromise** | • COVID-19 vaccines<br>• COVID-19 boosters<br>• Long-acting antibody for pre-exposure prophylaxis | • US CDC: COVID-19 Vaccines for People who are Moderately or Severely Immunocompromised<br>• Maine CDC: COVID-19 Vaccine Providers Portal<br>• COVID-19 Pre-Exposure Prophylaxis (Provider Information) |
| **Persons exposed to COVID-19 who have not tested positive (i.e., post-exposure prophylaxis)** | • **No** treatments available | • All monoclonal antibodies previously available for post-exposure prophylaxis are not effectiveness for current COVID-19 variants. |
| **Persons with asymptomatic COVID-19 infection** | • **No** treatments available | • Symptomatic treatment only. Monitor for development of COVID-19 symptoms and treat if high-risk. Ensure readiness to test and access treatment quickly if eligible (see below) and mild symptoms develop. |
| **Persons with mild/moderate COVID-19 symptoms and a positive direct test who are UNDER 40 years old and DO NOT have any underlying conditions that place them at high risk for severe disease** | • **No** treatments available | • Symptomatic treatment only. |
| **Persons with mild/moderate COVID-19 illness, a positive direct test (PCR or antigen), and who are age 40 years or older OR have underlying conditions that place them at high risk for severe disease** | • Oral antivirals<br>• IV antivirals<br>• IV monoclonal antibodies | • For information on pharmacies that can fill a prescription from any doctor, and information on Test-to-Treat locations where patients can get tested, seen by a provider, and treated with oral or intravenous therapy, visit the COVID-19 Treatment in Maine patient webpage. |

# Summary of Recommendations by Primary Series Product and Age

**Everyone** in the age group **SHOULD** receive the dose

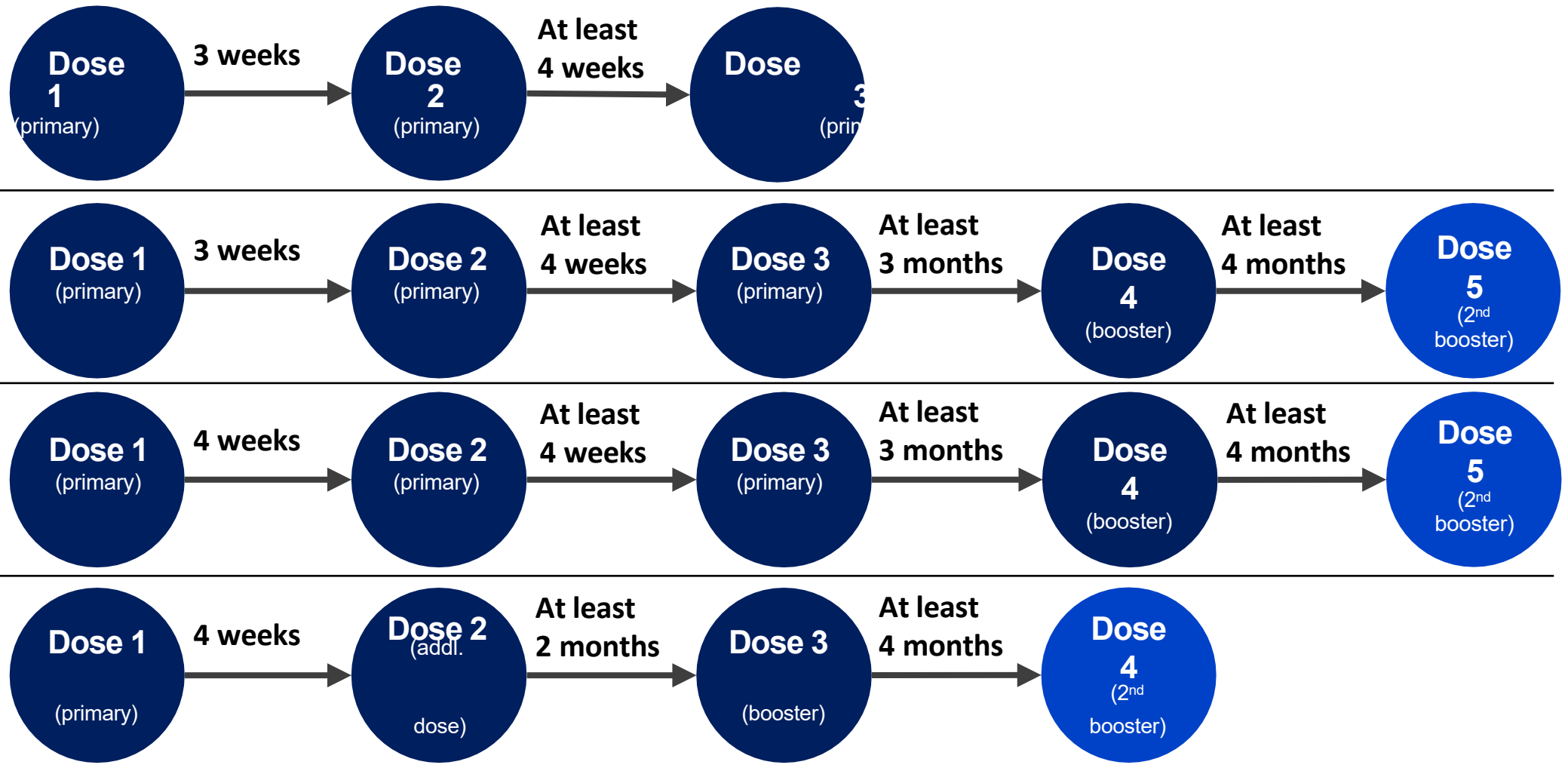
**Some people** in the age group **MAY** receive the dose



# Summary of Recommendations by Primary Series Product and Age, Moderately or Severely Immunocompromised

**Everyone** in the age group **SHOULD** receive the dose

**Some people** in the age group **MAY** receive the dose



# Up to Date

- CDC recommends everyone get up to date with their COVID-19 vaccinations.
- Being up to date means a person has received all recommended doses in their primary vaccine series, and a booster dose, when eligible.
- Receipt of a second booster dose is not necessary to be considered up to date at this time.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html

# Eligible People Who May Consider Getting the 2nd Booster Dose As Soon As Possible

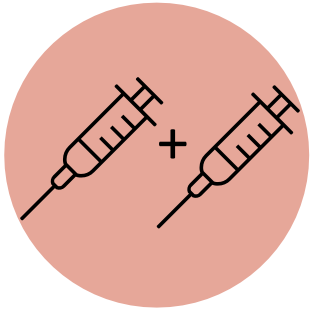
- People with certain underlying medical conditions that increase the risk of severe COVID-19 illness
- People who are moderately or severely immunocompromised
- People who live with someone who is immunocompromised, at increased risk for severe disease, or who cannot be vaccinated due to age or contraindication
- People at increased risk of exposure to SARS-CoV-2, such as through occupational, institutional, or other activities (e.g., travel or large gatherings)
- People living or working in an area where the COVID-19 community level is medium or high

# 2nd Booster Doses

- Some populations **may** receive a second booster dose using an mRNA COVID-19 vaccine **at least 4 months** after the first booster dose

People ages 50 years and older

People ages 12 years and older who are moderately or severely immunocompromised



People ages 18 years and older who received Janssen as both primary and booster dose

# 2nd Booster Dose Product

- 2nd booster dose should be an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna).
- Janssen COVID-19 Vaccine is not authorized for use as a second booster.
- Booster doses may be heterologous.
  - Eligible people ages 12–17 years can only receive Pfizer-BioNTech COVID-19 Vaccine.
- The dosage is the same as the first booster dose
  - Pfizer-BioNTech (gray or purple cap): 0.3 mL (30 mcg)
  - Moderna (red cap): 0.25 mL (50 mcg)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

# Eligible People Who May Consider Waiting to Receive a 2nd Booster Dose

- People with recent SARS-CoV-2 infection within the past 3 months
- People who may be hesitant about getting another recommended booster dose in the future, as a booster dose may be more important in the fall and/or if a variant-specific vaccine is needed.

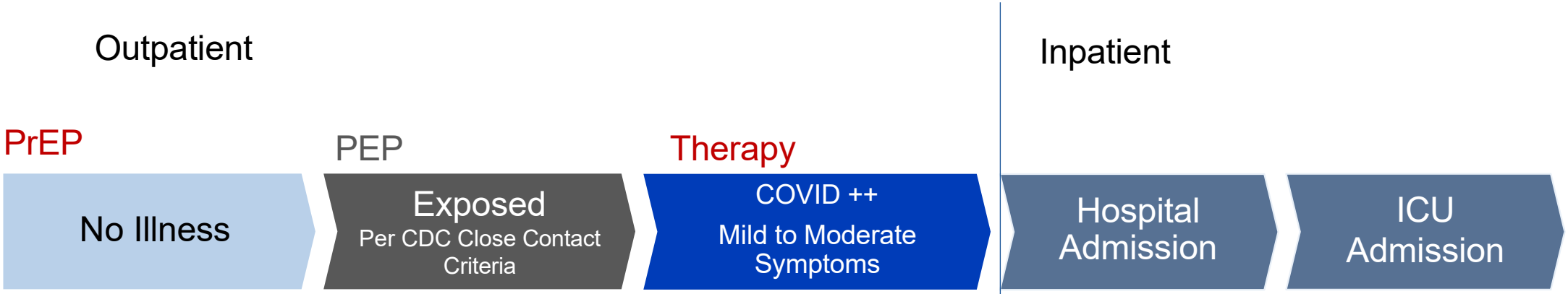
# Who Is Moderately or Severely Immunocompromised?

People are considered moderately or severely immunocompromised if they have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress their immune response

*US CDC: COVID-19 Vaccines for Moderately or Severely Immunocompromised People (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html)*

# Stages of COVID-19 Therapeutics (PrEP)




**COVID-19 VACCINES**

**Monoclonal Antibodies for PrEP**

- Evusheld (tixagevimab + cilgavimab, AZ)

# Evusheld (tixagevimab and cilgavimab) – AstraZeneca
## *Monoclonal Antibody for IM Injection*


[Evusheld Product Information]

https://www.evusheld.com

# Evusheld (tixagevimab and cilgavimab): Repeat Dosing

- The SARS-CoV-2 variants that will be circulating in the United States when Evusheld (tixagevimab and cilgavimab) may need to be re-dosed are **not known** at this time and therefore repeat dosing recommendations cannot be made.

- The Fact Sheets will be revised with repeat dosing recommendations in the future when more data are available.

**For more information,** Fact Sheet for Healthcare Providers: Evusheld (tixagevimab and cilgavimab) (https://www.fda.gov/media/154701/download)

# Eligibility & Prioritization for COVID-19 PrEP

## Maine Category 1

- Lung Transplant Recipient (any time frame)
- Small Bowel Recipient (any time frame)
- Receipt of immunosuppressive medication within past 12 months (any condition, oncology or non-oncology):
  - Anti-thymocyte globulin (ATG)
  - Alemtuzumab
  - Anti-B-Cell Therapy: Rituximab, Ocrelizumab, Ofatumumab
- Patients with hematologic malignancies who are on active therapy
- Allogeneic Stem Cell Transplant, within 12 months of Transplant
- Autologous Stem Cell Transplant, within 6 months of Transplant
- Recipient of more than one active Transplant, different Organs (any time frame)
- Receipt of anti-CD19 or anti-BCMA (CAR)-T-Cell Immunotherapy, within six months of treatment
- Primary or Secondary T-Cell Immunodeficiency, including Severe Combined Immunodeficiency:
  - Agammaglobulinemia (XLA/ARAG)
  - Common Variable Immunodeficiency (CVID) and similar phenotype with T-cell dysfunction
  - Defects of Innate Immunity with predominant susceptibility to Viral Infections (e.g., WHIM Syndrome)
- Additional pediatric conditions (age 12–17 years):
  - Combined immune deficiencies with or without immune dysregulation (e.g., APDS, STAT3 GOF, ALPS)
  - Primary immune regulatory disorders with or without immune deficiency (e.g., APECED, XIAP)
  - High-risk or relapsed acute lymphoblastic leukemia/lymphoblastic lymphoma on intensive therapy (not maintenance therapy)

## Maine Category 2

- Allogeneic stem cell transplant, more than 12 months since transplant
- Autologous stem cell transplant, more than 6 months since transplant
- Multiple myeloma, on maintenance therapy
- Any solid tumor, on active myelosuppressive chemotherapy
- Any solid organ transplant recipient not otherwise eligible in Category 1
- Other chronic leukemias, on treatment
- *Patients in lower categories with more than one qualifying condition*

## Maine Category 3

- Active treatment with high-dose corticosteroids (i.e., more than 20 mg prednisone or equivalent per day when administered for two weeks or longer)
- Active treatment with other biologic agents that are immunosuppressive or immunomodulatory, not otherwise listed in Categories 1–2
- Advanced or untreated HIV infection:
  - HIV with CD4 less than 200/$mm^3$ (if aged less than 14 years, CD4% less than 15%)
  - AIDS-defining illness

## Maine Category 4

- Persons 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, e.g., severe allergic reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

# Evusheld access in the State of Maine

Patients who currently qualify for treatment, or who have questions about eligibility or whether to get this drug, should contact their primary care provider. Patients who do not have a primary care provider should contact a healthcare facility for further information on how to access EVUSHELD at that healthcare facility. Maine CDC is NOT able to coordinate treatment for individual patients.

Healthcare providers can contact any of the healthcare systems or facilities in Maine that have Evusheld to refer their patient(s) for Evusheld treatment.

Healthcare systems/healthcare facilities that would like to start getting their own Evusheld supply should contact Kristen McAuley (kristen.m.mcauley@maine.gov) at Maine CDC to request details on how to get an allocation.

| Healthcare System/Facility | Location(s) |
|---|---|
| Central Maine Medical Center | Lewiston |
| Eastern Maine/Northern Light Hospital | Bangor |
| MaineGeneral | Augusta |
| MaineHealth/Maine Medical Center | Portland |
| N.E. Cancer Specialists | Multiple |
| Redington Fairview Hospital | Skowhegan |
| York Hospital | York |

For more information, go to *Maine CDC: COVID-19 Pre-Exposure Prophylaxis: Information for Providers* (https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/prophylaxis.shtml)

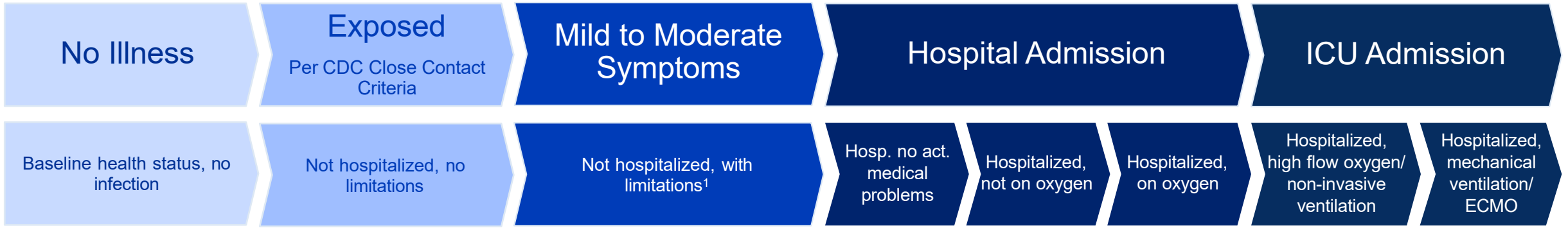
# Hemostatic Considerations for Evusheld

EVUSHELD is a new combination monoclonal antibody administered as two concomitant IM injections in the gluteal muscle. Maine is experiencing extreme scarcity of blood products to support patients should they have a bleed or hematoma from a deep muscle injection. Thus, strong considerations and judicious clinical discretion is advised for those patients who may be at risk for bleeding from a deep muscle injection.

- Contraindications for administration in patients who otherwise meet the eligibility per EUA criteria include:
  - Clinically significant heritable bleeding disorder or bleeding diathesis despite a normal platelet count.
  - Platelet count <20,000/uL.
  - On anticoagulation with warfarin, direct acting oral anticoagulation (DOACs) drug(s), or heparin agents,unless they can be safely held in advance.
  - Dual antiplatelet therapy for stent or other considerations.
- As experience with this drug expands and as stress on the blood supply lessens, these parameters will be re-evaluated.

# COVID-19 Outpatient Treatment

# Summary of COVID-19 Preventative Agents & Therapeutics




Veklury® (remdesivir, Gilead)[2]

**COVID-19 VACCINES**

**Monoclonal Antibodies for PrEP**

- Evusheld (tixagevimab + cilgavimab, AZ)

**None currently authorized for use in any US state or territory.**

**Oral Antivirals**

- Paxlovid (nirmatrelvir + ritonavir, Pfizer)
- Lagevrio (molnupiravir, Merck)

**Monoclonal Antibodies for Treatment**

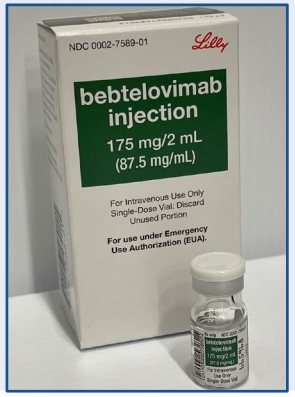
- Bebtelovimab (Lilly)

**Please see NIH Current Inpatient Therapies (https://www.covid19treatmentguidelines.nih.gov/therapies/)**

[1] Therapeutic Management of Nonhospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/

[2] Therapeutic Management of Hospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/

# Overview of COVID-19 Outpatient Therapy

| Class | Oral | Intravenous |
|---|---|---|
| **Antivirals** | Paxlovid     molnupiravir | remdesivir   |
| **Monoclonal antibodies** | |   bebtelovimab |

# COVID-19 Outpatient Therapy Summary

| Drug name | Paxlovid (ritonavir/nirmatrelvir) | bebtelovimab | Veklury (remdesivir) | Lagevrio (molnupiravir) |
|---|---|---|---|---|
| **Effectiveness** | 88% | Unknown | 87% | 30% |
| **Age allowed for use** | ≥ 12 years | ≥ 12 years | Any age* | ≥ 18 years |
| **Initiate within # days of symptom onset** | 0–5 days | 0–7 days | 0–7 days | 0–5 days |
| **Route of administration** | Oral | Intravenous | Intravenous | Oral |
| **Duration of treatment** | 5 days | 1 day | 3 days | 5 days |
| **Pros** | • High efficacy<br>• Oral | • High efficacy<br>• Single IV infusion | • High efficacy<br>• Greater experience | • Oral<br>• No drug-drug interaction concerns |
| **Cons** | • Ritonavir-related drug-drug interactions | • Requires IV infusion | • Requires 3 days of IV infusion | • Low efficacy<br>• Not authorized for age <18y<br>• Avoid in pregnancy<br>• Mutagenicity concerns |

**Remdesivir is FDA-approved for non-hospitalized patients 12 years and older (40 kg and up). It is also available under FDA EUA for patients <12 years old (3.5 to 40 kg).*

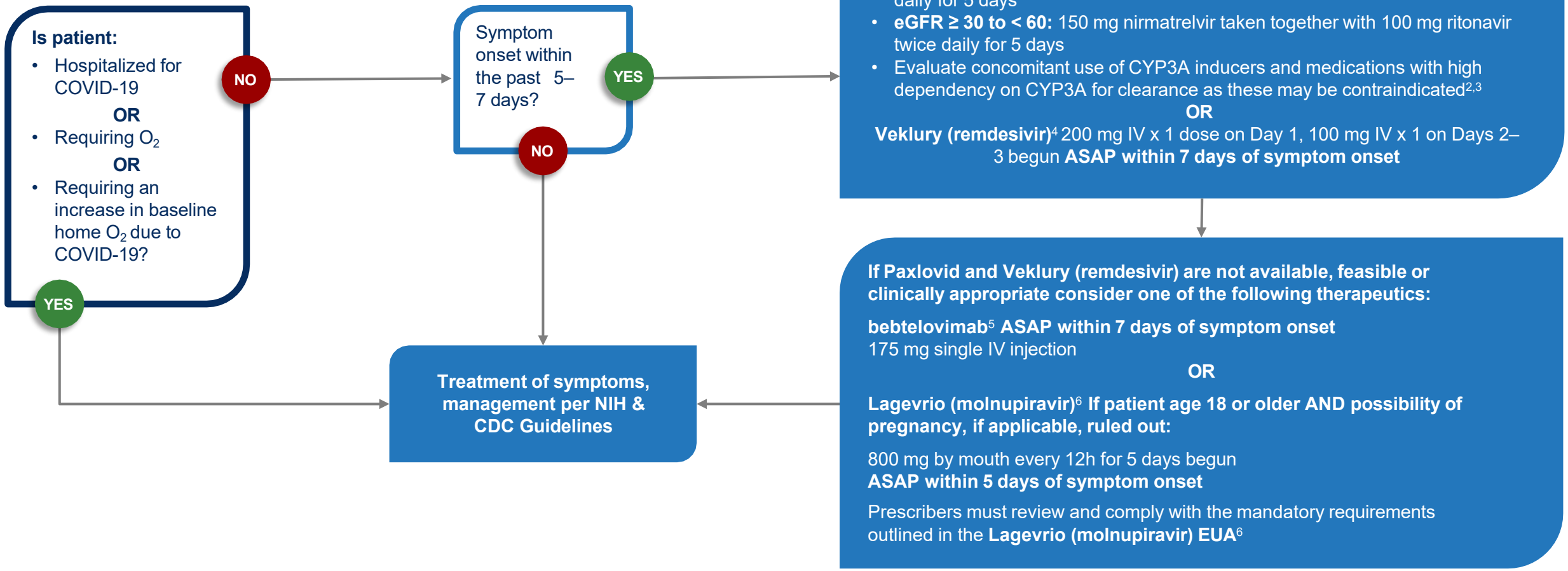
# COVID-19 Outpatient Therapy Selection

| Drug/route | Key features | Eligible population | Key considerations for use |
|---|---|---|---|
| **Paxlovid** (nirmatrelvir/ ritonavir) (PO) | • Oral (5 days)<br>• Start within 0–5 days after COVID-19 symptoms begin | **Individuals 12+ years old at high risk for progression to severe COVID-19** | • Treatment of choice for non-hospitalized patients (per NIH guidelines).<br>• Providers should check for drug-drug interactions and make medication changes that can be accomplished safely. Renal dosing adjustment is needed for patients with GFR between 30–60; Paxlovid cannot be used for GFR <30. |
| **Veklury** (remdesivir) (IV) | • Intravenous (once-daily therapy for 3 days)<br>• Start within 0–7 days after COVID-19 symptoms begin | **Individuals 28 days old and older at high risk for progression to severe COVID-19** | • 2nd-line treatment option per NIH treatment guidelines. This is the best option for patients who cannot take Paxlovid due to drug-drug interactions.<br>• Requires insurance coverage and multiple days of IV infusion. Currently only available at a few facilities, and primarily for outpatients under 12 years old.<br>• Consider for eligible patients who are hospitalized for a non-COVID-19 cause if Paxlovid is not available in inpatient formulary or oral access is unavailable. |
| **Bebtelovimab** (IV) | • Intravenous (1 dose)<br>• Start within 0–7 days after COVID-19 symptoms begin | **Individuals 12 years old and older at high risk for progression to severe COVID-19** | • Best pick for patients presenting between 6–7 days after symptom onset (outside the Paxlovid treatment window) or who cannot take oral drugs for any reason.<br>• Also the best pick for patients unable to get Paxlovid due to drug-drug interaction that can't be addressed safely, severe kidney or liver disease, or concerns about the patient's ability to complete 5 days of outpatient therapy. |
| **Lagevrio** (molnupiravir) (PO) | • Oral (5 days)<br>• Start within 0–5 days after COVID-19 symptoms begin | **Individuals 18 years old and older at high risk for progression to severe COVID-19** | • Best pick for patients who cannot get Paxlovid due to drug-drug interaction or severe kidney or liver disease, and who do NOT have access to IV therapy.<br>• Lower effectiveness than the other three therapies.<br>• Avoid in pregnancy if other treatment options are available. |

# 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] 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

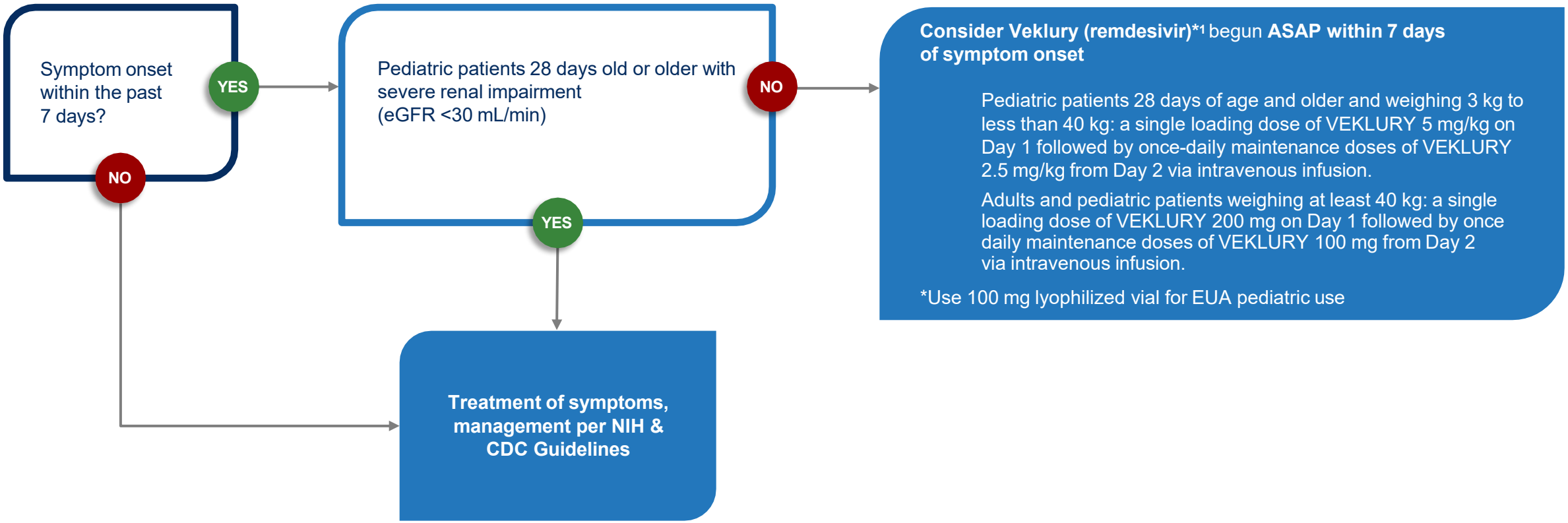
[6] Lagevrio EUA. https://www.fda.gov/media/155054/download


ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

April 18, 2022

# Clinical Decision Aid for Pediatric Patients

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





**Reference:**

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


ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

April 18, 2022

# COVID-19 Therapeutics Treatment Landscape

## Antivirals

- Lagevrio is recommended for use only where other outpatient treatment options (Paxlovid, mAbs, or Veklury®) are not accessible or clinically appropriate.
- Intravenous Veklury (remdesivir) has been approved for use for outpatient treatment and authorized for inpatient and outpatient use for certain pediatric populations.

## mAbs

- Bebtelovimab remains effective against all variants of concern, including Omicron.
- The Omicron variant is not neutralized by bamlanivimab/etesevimab or REGEN-COV®, therefore these products are not currently authorized for use based on the EUA.

# Eligibility Criteria for Outpatient TREATMENT of Mild-to-Moderate COVID-19 Infection in High-Risk Patients

**Mild to moderate COVID-19 cases** early in infection, who are at **high risk for progressing to severe COVID-19 and/or hospitalization;**[1] with following criteria:

- Adult or pediatric patients 12 years of age and older weighing more than 40kg
  - Exception: Lagevrio (molnupiravir) authorized in adult patients 18 years of age and older
- Confirmation via **positive PCR or antigen test**
- Treatment **as soon as possible** following positive viral test and **within 5-7 days* of symptom onset**
- Patient symptomatic but **not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy) due to COVID-19**

**Monoclonal antibodies (mAbs) and Oral Antivirals (OAVs) given EUA for mild to moderate symptoms of COVID-19 are *not authorized* for use in patients:**

- Who are hospitalized due to COVID-19, OR
- Who require oxygen therapy due to COVID-19, OR
- Who 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

[1]CDC's Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html)

*Patient eligibility with respect to time since symptom onset varies across agents. See product fact sheets for product-specific durations.

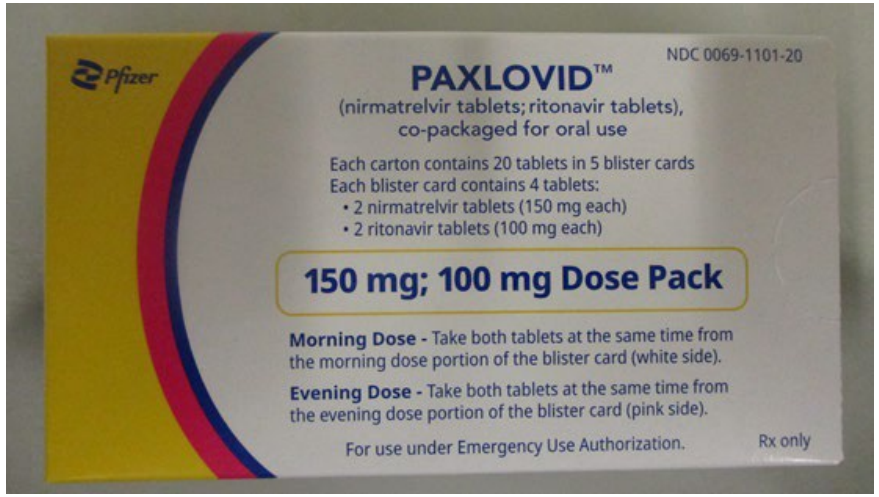
# PEDIATRIC Eligibility Criteria for Outpatient TREATMENT of Mild-to-Moderate COVID-19 Infection in High-Risk Patients

- Pediatric patients weighing **3 kg to less than 40 kg and aged 28 days or older** with mild to moderate COVID-19 who are:
  - Hospitalized, or
  - Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.
- Confirmation via positive PCR or antigen test
- Treatment **as soon as possible** after diagnosis of symptomatic COVID-19 and **within 7 days of symptom onset**

**Only applies to Veklury (remdesivir)[1]**

[1]**For additional Veklury pediatric information,** Veklury Prescribing Information (https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf)

# Paxlovid (nirmatrelvir and ritonavir) – Pfizer
## *Oral Antiviral*


[Paxlovid Product Information](https://www.pfizer.com/products/product-detail/paxlovidtm)
https://www.pfizer.com/products/product-detail/paxlovidtm

# Paxlovid (nirmatrelvir and ritonavir) Formulation and Packaging

FDA has updated the Paxlovid EUA to authorize an additional dose pack presentation of Paxlovid with appropriate dosing for patients within the scope of this authorization with **moderate** renal impairment.



## Standard Dose*

300 mg nirmatrelvir;100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

## Renal Dose

150 mg nirmatrelvir;100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

*Standard Dose pack may be adapted for renal dosing. See instructions on next slide.

# Paxlovid (nirmatrelvir and ritonavir)
# Renal Adjustment Instructions for Pharmacists for Standard Dose Pack

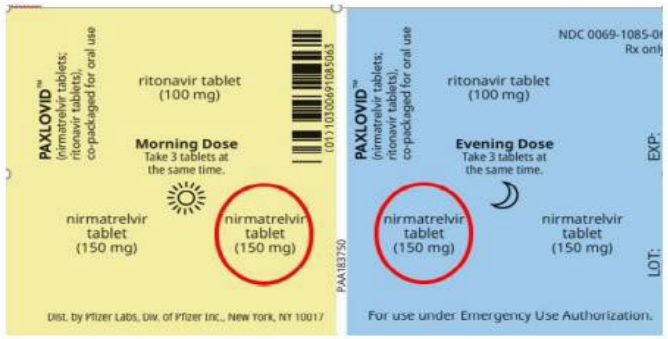



**Figure 1: Remove the nirmatrelvir tablets circled in red from the blister card**

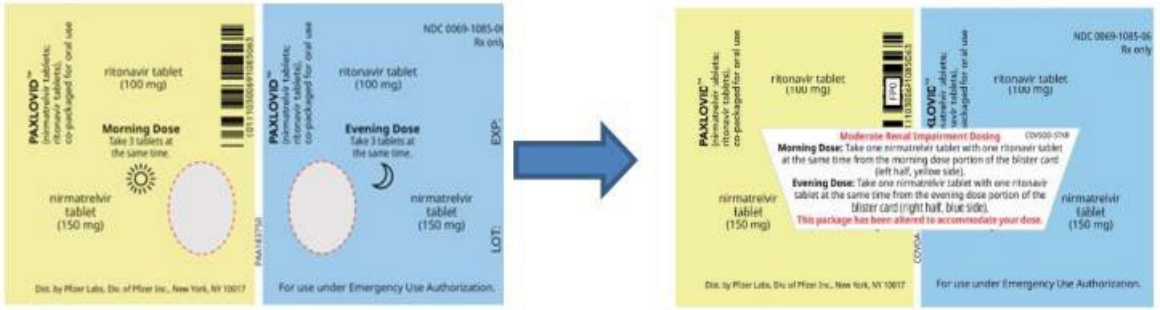



**Figure 2: Placement of sticker over empty blister cavities and pre-printed dosing instruction after removal of nirmatrelvir tablets**

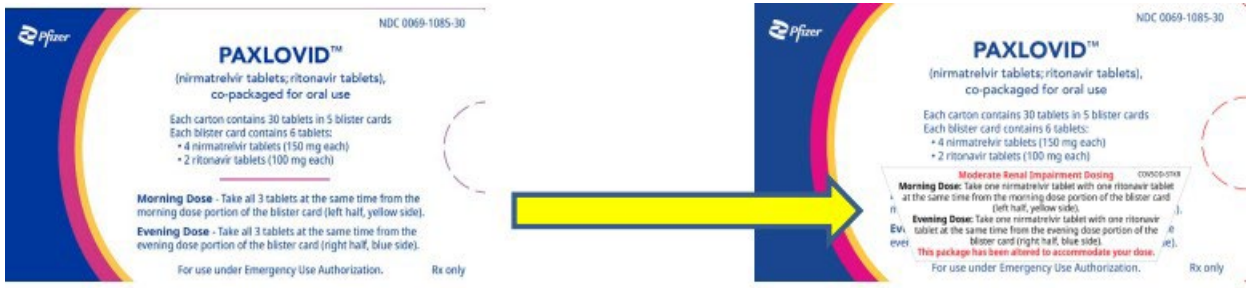



**Figure 3: Placement of sticker over pre-printed dosing regimen on carton**

Pharmacist Instruction Sheet: https://www.covid19oralrx-hcp.com/files/Clean_EUA-105-mitigation-plan-for-moderate-renal-impairment-01-11-22.pdf

# Paxlovid (nirmatrelvir and ritonavir) Provider Checklist

- ❑ Positive SARS-CoV-2 test
- ❑ Age ≥12 years
- ❑ Weight ≥40 kg
- ❑ High-risk criteria met
- ❑ Symptoms consistent with mild-moderate COVID-19
- ❑ Symptom onset with **5 days***
- ❑ Not hospitalized due to COVID-19
- ❑ If clinically indicated, assess patient renal function
  - eGFR ≥60 mL/min, standard dosing
  - eGFR ≥30 to <60 mL/min, dose modification
  - eGFR <30 mL/min, not recommended
- ❑ If clinically indicated, assess patient hepatic function
  - Child-Pugh Class C, contraindicated
- ❑ **Assess patient's home medication list for drug-drug interactions**
  - See next slide for more detail

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:
Please fill prescription by _____[insert date]_____. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.

# Paxlovid (nirmatrelvir and ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers

Medical History

- □ Positive SARS-CoV-2 test
- □ Age ≥ 12 years of age and weighing at least 40 kg
- □ Has one or more risk factors for progression to severe COVID-19
- □ Symptoms consistent with mild to moderate COVID-19
- □ Symptom onset within 5 days. Please fill prescription by [insert date].
- □ Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- □ No known or suspected severe renal impairment (eGFR < 30 mL/min)
  - •Note that a dose reduction is required for patients with moderate renal impairment (eGFR ≥30-<60 mL/min); see the Fact Sheet for Healthcare Providers.
  - •Prescriber may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. Providers may consider ordering a serum creatinine or calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis based on history or exam.
- □ No known or suspected severe hepatic impairment
- □No history of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download

# Paxlovid (nirmatrelvir and ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers (continued)

Concomitant Medications

□ HMG-CoA reductase inhibitors (statins)

- Patient is taking lovastatin or simvastatin, which are contraindicated with PAXLOVID coadministration: The statin can be held 12 hours prior to the first dose of PAXLOVID treatment, held during the 5 days of treatment, and restarted 5 days after completing PAXLOVID.
- Patient is taking atorvastatin or rosuvastatin: Temporary discontinuation of atorvastatin and rosuvastatin during treatment with PAXLOVID should be considered depending on statin dose. Atorvastatin and rosuvastatin do not need to be held prior to or after completing PAXLOVID.

□Hormonal contraceptives containing ethinyl estradiol: Patient is taking a hormonal contraceptive containing ethinyl estradiol: The need for an additional non-hormonal method of contraception during the 5 days of PAXLOVID treatment and until one menstrual cycle after stopping PAXLOVID should be recommended.

□Medications for HIV-1 Treatment: Patient is taking medications for the treatment of HIV-1 infection: With the exception of maraviroc3, HIV antiretroviral medications can be co-administered with PAXLOVID without dose adjustment, but arranging follow-up by the HIV care provider to monitor for side effects is recommended

Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID

□ Patient is not taking any medications listed below

□ Patient is taking one or more meds listed in YELLOW and dose adjustment, holding of medication, or increased monitoring is planned

See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download

# Paxlovid (nirmatrelvir and ritonavir) Contraindications*

| | |
|---|---|
| Hypersensitivity Reactions | • History of clinically significant hypersensitivity reactions (e.g., TEN, SJS) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product |
| Drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with severe/life-threatening reactions* | • Alpha1-adrenoreceptor antagonists: alfuzosin<br>• Analgesics: pethidine, piroxicam, propoxyphene<br>• Antianginal: ranolazine<br>• Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine<br>• Anti-gout: colchicine<br>• Antipsychotics: lurasidone, pimozide, clozapine<br>• Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine<br>• HMG-CoA reductase inhibitors: lovastatin, simvastatin<br>• PDE5 inhibitor: sildenafil (Revatio) when used for PAH<br>• Sedative/hypnotics: triazolam, oral midazolam |
| Drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir concentrations may be associated with loss of virologic response or resistance* | • Anticancer drugs: apalutamide<br>• Anticonvulsant: carbamazepine, phenobarbital, phenytoin<br>• Antimycobacterials: rifampin<br>• Herbal product: St John's Wort (*hypericum perforatum)* |

***NOT COMPLETE LIST OF ALL DDI's. ALWAYS USE Liverpool Covid-19 interaction checker AND CLINICAL JUDGMENT** (https://covid19-druginteractions.org)
**For more information see:** NIH COVID-19 Treatment Guidelines Panel's Statement on Ritonavir-Boosted Nirmatrelvir (Paxlovid) (https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/); Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir and ritonavir) (https://www.fda.gov/media/155050/download); **and** Pfizer's Toolkit (https://pfizermedical.pfizerpro.com/infectious-disease)

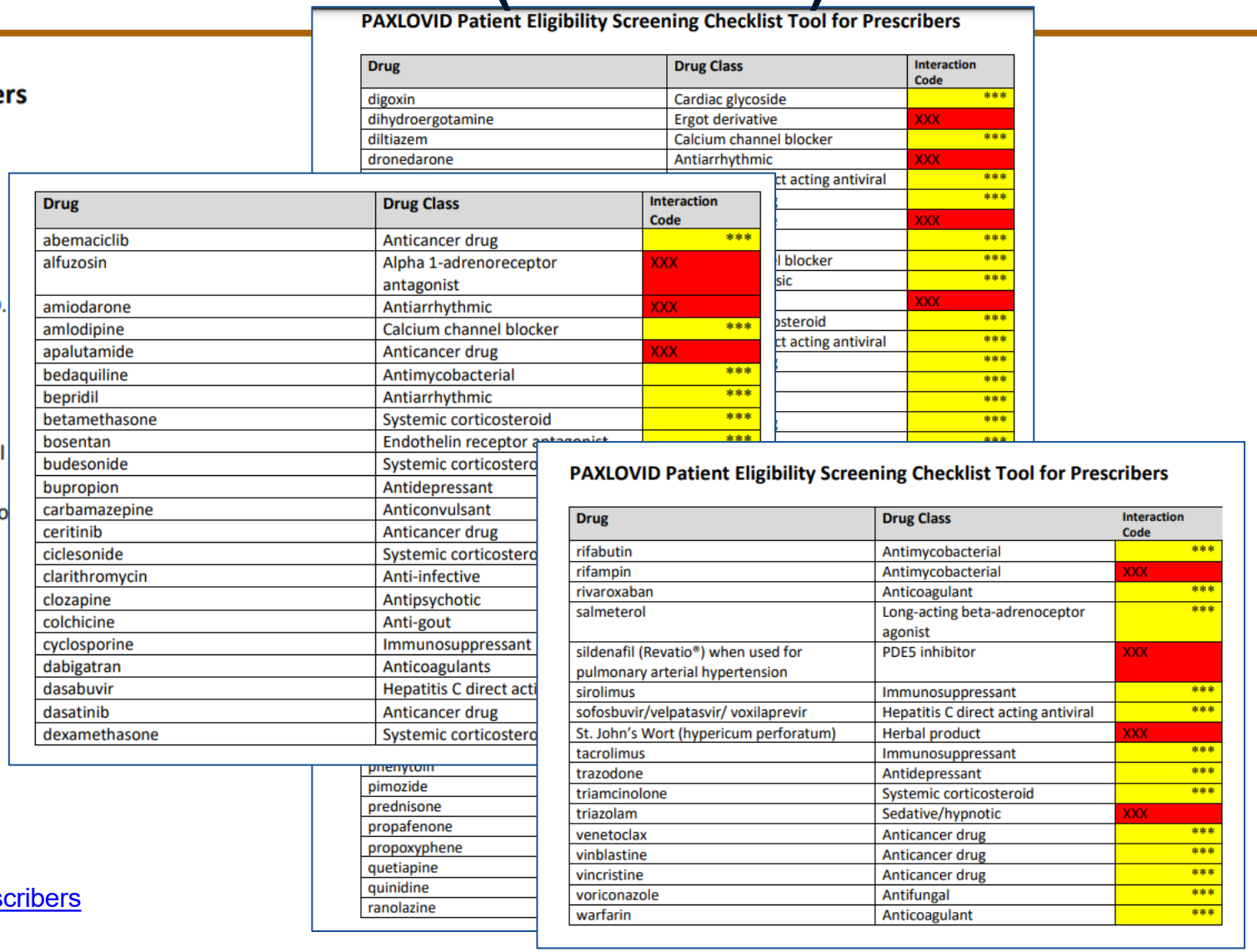
# Paxlovid (nirmatrelvir and ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers (continued)

## PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

**Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID (listed alphabetically by generic name)**

Interaction Codes:

| | |
|---|---|
| XXX | Coadministration of this drug with PAXLOVID is CONTRAINDICATED. For further information, refer to the Fact Sheet for Healthcare Providers and the individual Prescribing Information for the drug. |
| *** | Coadministration of this drug with PAXLOVID should be avoided and/or holding of this drug, dose adjustment of this drug, or special monitoring is necessary. Consultation with the prescriber of the potentially interacting drug is recommended. For further information refer to the Health Care Provider Fact Sheet and the individual Prescribing Information for the drug. |



PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

| Drug | Drug Class | Interaction Code |
|---|---|---|
| abemaciclib | Anticancer drug | *** |
| alfuzosin | Alpha 1-adrenoreceptor antagonist | XXX |
| amiodarone | Antiarrhythmic | XXX |
| amlodipine | Calcium channel blocker | *** |
| apalutamide | Anticancer drug | XXX |
| bedaquiline | Antimycobacterial | *** |
| bepridil | Antiarrhythmic | *** |
| betamethasone | Systemic corticosteroid | *** |
| bosentan | Endothelin receptor antagonist | *** |
| budesonide | Systemic corticosteroid | *** |
| bupropion | Antidepressant | *** |
| carbamazepine | Anticonvulsant | *** |
| ceritinib | Anticancer drug | *** |
| ciclesonide | Systemic corticosteroid | *** |
| clarithromycin | Anti-infective | *** |
| clozapine | Antipsychotic | *** |
| colchicine | Anti-gout | *** |
| cyclosporine | Immunosuppressant | *** |
| dabigatran | Anticoagulants | *** |
| dasabuvir | Hepatitis C direct acting antiviral | *** |
| dasatinib | Anticancer drug | *** |
| dexamethasone | Systemic corticosteroid | *** |
| digoxin | Cardiac glycoside | *** |
| dihydroergotamine | Ergot derivative | XXX |
| diltiazem | Calcium channel blocker | *** |
| dronedarone | Antiarrhythmic | XXX |
| phenytoin | | |
| pimozide | | |
| prednisone | | |
| propafenone | | |
| propoxyphene | | |
| quetiapine | | |
| quinidine | | |
| ranolazine | | |

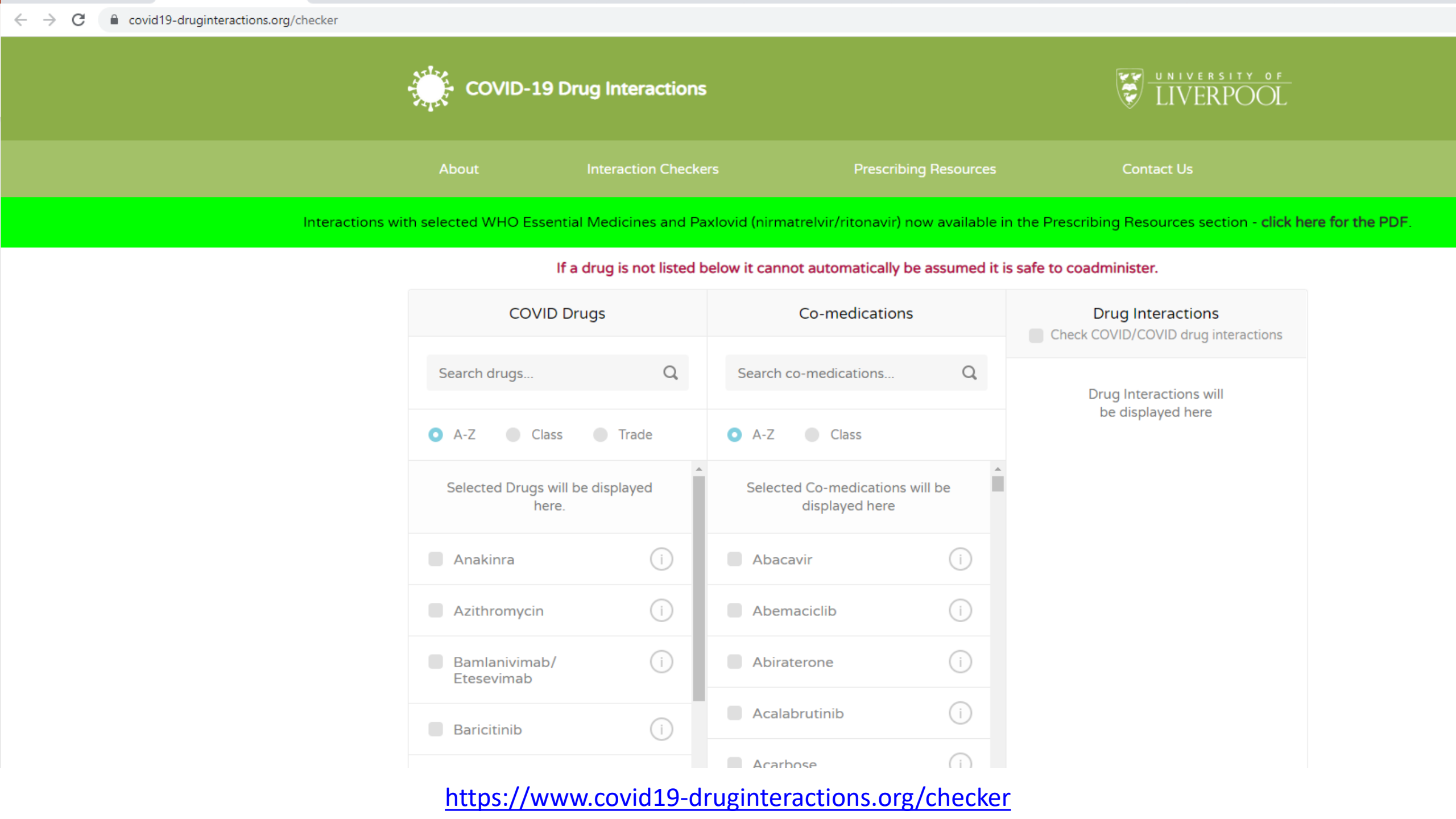
PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

| Drug | Drug Class | Interaction Code |
|---|---|---|
| rifabutin | Antimycobacterial | *** |
| rifampin | Antimycobacterial | XXX |
| rivaroxaban | Anticoagulant | *** |
| salmeterol | Long-acting beta-adrenoceptor agonist | *** |
| sildenafil (Revatio®) when used for pulmonary arterial hypertension | PDE5 inhibitor | XXX |
| sirolimus | Immunosuppressant | *** |
| sofosbuvir/velpatasvir/ voxilaprevir | Hepatitis C direct acting antiviral | *** |
| St. John's Wort (hypericum perforatum) | Herbal product | XXX |
| tacrolimus | Immunosuppressant | *** |
| trazodone | Antidepressant | *** |
| triamcinolone | Systemic corticosteroid | *** |
| triazolam | Sedative/hypnotic | XXX |
| venetoclax | Anticancer drug | *** |
| vinblastine | Anticancer drug | *** |
| vincristine | Anticancer drug | *** |
| voriconazole | Antifungal | *** |
| warfarin | Anticoagulant | *** |

See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers
https://www.fda.gov/media/158165/download

# Additional Paxlovid Prescribing Resources

1. University of Liverpool COVID-19 Drug Interactions: https://covid19-druginteractions.org/checker
2. FDA PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers: https://www.fda.gov/media/158165/download
3. 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
4. NIH COVID-19 Treatment Guidelines - Ritonavir-Boosted Nirmatrelvir (Paxlovid): https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-/
5. 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/




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

**Paxlovid Drug-Drug Interaction Tool**

***CI** – Contraindicated, do not prescribe Paxlovid  Do not prescribe Paxlovid with concurrent opioids + benzodiazepines  OK – No expected interactions
UWC – Use with caution, probable interaction  W8D – Withhold for 8 days when starting Paxlovid  R*/* - Reduce dose by fraction for 8 days when starting Paxlovid

Acetaminophen Tylenol - OK
Abatacept Orencia - OK
Acyclovir Zovirax - OK
Adalimumab Humira - OK
Albuterol - OK
Alendronate - OK
Alfuzosin - W8D
Allopurinol - OK
Alprazolam Xanax - R1/2
Amantadine - OK
Amiodarone - ***CI**
Amitriptyline Elavil - OK
Amlodipine Norvasc - R1/2
Amoxicillin - OK
Amphetamine Adderall - OK
Apalutamide Erleada - ***CI**
Apixaban Eliquis 2.5 mg BID - ***CI**
Apixaban Eliquis 5-10 mg BID - R1/2
Aripiprazole Abilify - R1/2
Aspirin - OK
Atenolol Tenormin - OK
Atomoxetine Strattera - OK
Atorvastatin Lipitor - W8D
Avanafil Stendra for ED - W8D
Avanafil for pulm art. HTN - ***CI**
Azithromycin Zpak - OK
Baclofen Lioresal - OK
Beclomethasone Qvar - OK
Benazepril Lotensin - OK
Benzonatate Tessalon - OK
Bevacizumab Avastin - OK
Bisoprolol - OK
Bosentan Tracleer - ***CI**
Brexpiprazole Rexulti - R1/2
Budesonide Pulmicort - R1/2
Bumetanide Bumex - OK
Buprenorphine - UWC *Rx Narcan*
Bupropion Wellbutrin - OK
Buspirone Buspar - 2.5mg/d max
Calcium - OK
Calcium carb Tums - OK
Canagliflozin Invokana - OK
Captopril - OK
Carbamazepine Tegratol - ***CI**
Carvedilol Coreg - OK
Cephalexin Keflex - OK
Cetirizine - OK
Cimetidine - OK
Ciprofloxacin - OK
Cisapride Propulsid - ***CI**
Citalopram Celexa - OK
Clindamycin - OK
Clonazepam Klonopin - ***CI**
Clonidine Catapres - OK
Clopidogrel Plavix low risk - UWC
Clopidogrel Plavix high risk - ***CI**
Chlorpheniramine - OK
Clozapine Clozaril - ***CI**
Codeine - R1/2
Colchicine - ***CI**
Cyclobenzaprine - OK
Cyclosporin Sandimmune - ***CI**
Dabigatran Pradaxa - ***CI**
Dapagliflozin Farxiga - OK
Desloratadine Clarinex - OK
Desvenlafaxine Pristiq - OK
Dexlansoprazole Dexilant - OK
Dexmethylphenidate Focalin - OK
Dextromethorphan - OK
Diazepam Valium - ***CI**
Dicyclomine Bentyl - OK
Dihydroergotamine - ***CI**
Diltiazem Cardizem - UWC
Diphenhydramine - OK
Disopyramide Norpace - ***CI**
Dofetilide Tikosyn - ***CI**
Donepezil Aricept - OK
Doxycycline - OK
Dronedarone Multaq - ***CI**
Dulaglutide Trulicity - OK
Duloxetine Cymbalta - OK
Dutasteride Avodart - OK
Edoxaban - 30mg/d max
Eletriptan Relpax - W8D
Elexa/Teza/Ivac Trikafta - ***CI**
Empagliflozin Jardiance - OK
Etanercept Enbrel - OK
Eplerenone - ***CI**
Ethanol - OK
Ergotamine - ***CI**
Escitalopram Lexapro - OK
Esomeprazole Nexium - OK
Estrogen - OK
Eszopiclone Lunesta - 2mg/d max
Everolimus - ***CI**
Exenatide Byetta - OK
Famotidine Pepcid - OK
Felodipine Plendil - UWC
Fentanyl - ***CI**
Fexofenadine Allegra - OK
Finasteride Propecia - OK
Finerenone - ***CI**
Flecainide Tambocor - ***CI**
Flibanserin - ***CI**
Fluoxetine Prozac - OK
Fluticasone nasal inh Flonase - R1/2
Fluticasone oral inh Flovent - R1/2
Folic acid - OK
Furosemide Lasix - OK
Gabapentin Neurontin - OK
Glecaprevir/Pibrentasvir - ***CI**
Glimepiride - OK
Glipizide Glucotrol - OK
Glyburide - OK
Guaifenesin Mucinex - OK
Guanfacine Intuniv - R1/2
Hydrochlorothiazide HCTZ - OK
Hydrocodone - R1/2
Hydroxychloroquine Plaquenil - **CI***
Hydroxyzine Vistaril - OK
Ibandronate Boniva - OK
Ibuprofen - OK
Infliximab Remicade - OK
Insulin - OK
Ipratropium Atrovent- OK
Isosorbide Imdur - OK
Ivabradine - ***CI**
Ivermectin - OK
Ketoconazole - 200 mg/d max
Ketorolac Toradol - OK
Labetalol - OK
Lamotrigine Lamictal - OK
Lansoprazole Prevacid - OK
Lemboexant DayVigo - R1/2
Levalbuterol Xopenex - OK
Levetiracetam Keppra - OK
Levocetirizine Xyzal - OK
Levofloxacin - OK
Levomilnacipran Fetzima - OK
Levothyroxine Synthroid - OK
Liraglutide Victoza - OK
Lisdexamphetamine Vyvanse - OK
Lisinopril - OK
Lithium - OK
Lomitapide - W8D
Loratadine Claritin - OK
Losartan Cozaar - OK
Lorazepam Ativan - OK *unaffected*
Lovastatin - W8D
Lumateperone - ***CI**
Meloxicam Mobic - OK
Memantine Namenda - OK
Metaxalone Skelaxin - OK
Mesalamine Asacol - OK
Metformin - OK
Methadone - UWC *possible withdrawal*
Methocarbamol Robaxin - OK
Methotrexate - OK
Methylergonovine - ***CI**
Methylphenidate Concerta - OK
Metoprolol Toprol - OK
Metronidazole Flagyl - OK
Mexiletine - ***CI**
Mirtazapine Remeron - OK
Mometasone nasal inh Nasonex - OK
Mometasone oral inh Asmanex - OK
Montelukast Singulair - OK
Morphine - UWC *possible withdrawal*
Nadolol - UWC
Naloxone - OK
Naproxen Alleve - OK
Nebivolol Bystolic - OK
Nicardipine - UWC
Nifedipine Procardia - UWC
Nitrofurantoin Macrobid - OK
Nitroglycerin - OK
Norethindrone - *use backup one cycle*
Olmesartan Benicar - OK
Omalizumab Xolair - OK
Omega-3 fatty acid Lovasa - OK
Omeprazole Prilosec - OK
Ondansetron Zofran - OK
Oseltamivir Tamiflu - OK
Oxybutynin Ditropan - R1/2
Oxycodone - R3/4
Oxymetazoline - OK
Pantoprazole Protonix - OK
Paroxetine Paxil - OK
Phenazopyridine Pyridium - OK
Phenergen - OK
Phenobarbital - ***CI**
Phenytoin Dilantin - ***CI**
Pimavanserin - 10 mg/d max
Pimozide - ***CI**
Pink bismuth Pepto - OK
Pioglitazone Actos - OK
Piroxicam Feldene - W8D
Prasugrel Effient - OK *unaffected*
Prazosin Minipress - OK
Pravastatin Pravachol - OK *unaffected*
Prednisone – R1/2
Pregabalin Lyrica - OK
Primidone - ***CI**
Propafenone - ***CI**
Propranolol Inderal - OK
Pseudoephedrine - OK
Quetiapine Seroquel - ***CI**
Quinidine - ***CI**
Ramelteon Rozerem – R1/2
Ranibizumab Lucentis - OK
Ranolazine - ***CI**
Rifampin/Rifapentine - ***CI**
Rimagepant Nurtec - ***CI**
Risedronate Actonel - OK
Risperidone Risperdal - ***CI**
Rituximab Rituxan - OK
Rivaroxaban Xarelto - ***CI**
Rivastigmine Exelon - OK
Rizatriptan Maxalt - OK
Ropinirole Requip - OK
Rosuvastatin Crestor - W8D
Salmeterol Serevent - ***CI**
Saxagliptin Onglyza – 2.5 mg/d max
Scopolamine - OK
Semaglutide Wegovy -OK
Senna - OK
Sertraline Zoloft - OK
Sildenafil Viagra for ED - W8D
Sildenafil for pulm art. HTN - ***CI**
Silodosin Rapaflo - W8D
Simvastatin Zocor - W8D
Sirolimus Rapamune - ***CI**
Sitagliptin Januvia - OK
Sotalol Betapace - OK
St John's Wort - ***CI**
Sumatriptan Imitrex - OK
Suvorexant Belsomra – W8D
Tacrolimus Prograf – W8D
Tadalafil Cialis for ED - W8D
Tadalafil for pulm art. HTN - ***CI**
Tamsulosin Flomax - W8D
Telmisartan Micardis - OK
Testosterone - OK
Ticagrelor Brilinta - ***CI**
Tiotropium Spiriva - OK
Tizanidine Zanaflex - OK
TMP-SMX Bactrim - OK
Topiramate Topamax - OK
Tramadol Ultram - UWC
Trastuzumab Herceptin - OK
Trazodone – W8D
Turmeric - OK
Ubrogepant Ubrelvy – W8D
Valacyclovir Valtrex - OK
Valproate Depakote - UWC
Valsartan Diovan - OK
Vardenafil Levitra for ED - W8D
Vardenafil for pulm art. HTN - ***CI**
Venlafaxine Effexor - OK
Verapamil Calan – R1/2
Vilanterol Breo Ellipta - ***CI**
Vilazodone Viibryd – 20 mg/d max
Vitamin B6, B12, C, D - OK
Vorapaxar - ***CI**
Vortioxetine Trintellix - OK
Warfarin – UWC *may lower INR*
Zaleplon Sonata - OK
Zinc - OK
zoledronic acid - OK
Zolmitriptan Zomig - OK
Zolpidem Ambien - R1/2

# Paxlovid Drug-Drug Interaction Tool

(Aaron Karmes, DO, St Josephs Hospital)
akarmes@covh.org

May contain errors  Updated 3/21/22

# Paxlovid prescription best practices

- **Essential elements of a Paxlovid prescription**
  - **Numeric dose of each active ingredient within PAXLOVID**
  - **Dispense-by date (i.e., within 5 days of symptom onset)**
  - ***Optional:*** **Renal function**
  - ***Optional:*** **Medication list reviewed/reconciled**

- *Prescribers writing prescriptions for Paxlovid should include the dispense-by date (i.e., within 5 days of the symptom onset date) and are encouraged to include information about the patient's renal function and a statement that the patient's medication list has been reviewed/reconciled. For further information, refer to FDA's PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers (https://www.fda.gov/media/158165/download).*

# New! Clinical Resources for Paxlovid

- Paxlovid is now widely available in community pharmacies.
- Although the number of COVID-19 hospitalizations has decreased dramatically since early 2022, some high-risk patients are still getting sick enough to require hospital admission.
- Early treatment with Paxlovid and other available authorized or approved therapeutics could make a difference.

**FDA Paxlovid clinical resources now available**

Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers

Q&A with FDA Director of the Office of Infectious Diseases

# CDC Health Advisory
# COVID-19 Rebound After Paxlovid Treatment

- The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or "COVID-19 rebound."

- **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 treatment helps prevent hospitalization and death due to COVID-19. COVID-19 rebound has been reported to occur between 2 and 8 days after initial recovery and is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative.
- **A brief return of symptoms may be part of the natural history of SARS-CoV-2 (the virus that causes COVID-19) infection in some persons, independent of treatment with Paxlovid and regardless of vaccination status**.
- Limited information currently available from case reports suggests that persons treated with Paxlovid who experience COVID-19 rebound have had mild illness; there are no reports of severe disease.

COVID-19 Rebound After Paxlovid Treatment (cdc.gov)

# COVID-19 rebound

- Some treated patients experience recurrent symptoms and test positivity
- Study data indicate a proportion of untreated patients with similar symptoms
- No evidence of viral mutations as a result of Paxlovid treatment
- No indication for additional treatment with Paxlovid or other therapies
- Same isolation precautions regardless of receiving treatment or not

- ***Resources:***
  - FDA Updates on Paxlovid for Health Care Providers (https://www.fda.gov/drugs/news-events-human-drugs/fda-updates-paxlovid-health-care-providers, last updated 5/4/22)
  - Pfizer COVID-19 Treatment Adverse Event Report: https://paxaes.pfizersafetyreporting.com/
  - FDA: How Consumers Can Report an Adverse Event or Serious Problem to FDA (https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda)

# Lagevrio (molnupiravir) – Merck
## *Oral Antiviral*

Lagevrio™
molnupiravir 200 mg capsules


[Lagevrio (molnupiravir) Product Information]
https://www.molnupiravir-us.com/

# Lagevrio (molnupiravir) Provider Checklist

- ❑ Positive SARS-CoV-2 test
- ❑ Age ≥18 years
- ❑ Alternate COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate
- ❑ High-risk criteria met
- ❑ Symptoms consistent with mild-moderate COVID-19
- ❑ Symptom onset with **5 days***
- ❑ Not hospitalized due to COVID-19
- ❑ Assessment pregnancy and breastfeeding status (if applicable)
- ❑ Provide appropriate counseling
  - Females of childbearing potential treated: 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 Lagevrio (molnupiravir)*
  - Breastfeeding is not recommended for the *duration of treatment and for **4 days** after the last dose of Lagevrio (molnupiravir)*
  - Males of reproductive potential treated: if 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 of Lagevrio (molnupiravir)*

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:

Please fill prescription by _____[insert date]_____. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.

# Lagevrio (molnupiravir) Prescriber Requirements

**All Patients**

1. Provide electronic or hard copy of patient fact sheet
2. Document* that patient has received an electronic or hard copy of the patient fact sheet
3. Review the information contained within the patient factsheet with the patient and counsel patient on the known and potential benefits and risks of Lagevrio (molnupiravir)
4. Advise patients on need for contraception use as appropriate
   - Females of childbearing potential treated: 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 Lagevrio (molnupiravir)*
   - Breastfeeding is not recommended for the *duration of treatment and for **4 days** after the last dose of Lagevrio (molnupiravir)*
   - Males of reproductive potential treated: if 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 of Lagevrio (molnupiravir)*
5. The prescribing healthcare provider and/or the provider's designee must report all medication errors and serious adverse events potentially related to Lagevrio (molnupiravir) within 7 calendar days from the healthcare provider's awareness of the event
   - Complete and submit the report online: www.fda.gov/medwatch/report.htm
     https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

***How and where documentation occurs is at the discretion of the prescribing health care provider and their clinical site.**

# Lagevrio (molnupiravir) Prescriber Requirements (continued)

## Individuals of Childbearing Potential

1. Assess whether pregnant or not
   - Report of last menstrual period in an individual who has regular menstrual cycles, uses a reliable method of contraception correctly and consistently or has had a negative pregnancy test
   - Negative pregnancy test (recommended but not required if other criteria are not met)
2. If pregnant:
   - Counsel the patient regarding the known and potential benefits and potential risks of Lagevrio (molnupiravir) use during pregnancy
   - Document* that the patient is aware of the known and potential benefits and potential risks of Lagevrio (molnupiravir) use during pregnancy
   - Make the individual aware of the pregnancy surveillance program
   - If the pregnant individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck, the prescribing healthcare provider must provide the patient's name and contact information to Merck (at 1-877-888-4231 or pregnancyreporting.msd.com)
3. If not pregnant:
   - Make the individual and their partner aware of the pregnancy surveillance program and encourage them to participate should they become pregnant
   - Review contraception requirements per Lagevrio Providers Fact Sheet (https://www.fda.gov/media/155054/download)

***How and where documentation occurs is at the discretion of the prescribing health care provider and their clinical site.**

# Bebtelovimab – Eli Lilly
## *Monoclonal Antibody for IV Injection (IV Push)*


bebtelovimab Product Information

http://www.lillyantibody.com/bebtelovimab

# Strategies for conserving bebtelovimab supply

| | |
|---|---|
| **Best practices** | • Paxlovid is first-line therapy for patients presenting within 5 days of onset of COVID-19 symptoms: address drug interactions that can be altered safely<br>• Bebtelovimab referral form that requires reason for not prescribing Paxlovid |
| **Common situations where bebtelovimab is appropriate for use** | • Patients presenting at 6-7 days after symptom onset<br>• Drug-drug interactions that cannot be addressed safely<br>• GFR <30 (i.e., renal insufficiency too extreme to dose-adjust Paxlovid)<br>• Swallowing issues (including severe throat pain from COVID-19)<br>• Concerns over loss to follow-up or inability to complete Paxlovid course |
| **Common situations where bebtelovimab is questionable (and possibly avoidable)** | • Default treatment option for pregnancy<br>• Unable to assess renal function for Paxlovid<br>• Drug-drug interactions “too complicated” for provider to navigate<br>• Patient preference (heard that mAb is better, or prior experience)<br>• Provider preference (without medical/behavioral rationale)<br>• Patients unwilling to risk side-effects from Paxlovid (rebound/isolation) |

# Veklury (remdesivir) – Gilead
## *Antiviral for IV Infusion*


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

# remdesivir monitoring (MaineHealth)

- Parameters measured under the definition ‘vital signs’ (VS): Temp, HR, RR, blood pressure, $O_2$ sat

- **Dose 1: (total of 4 sets)**
  - VS before infusion
  - VS at 15 mins (halfway through 30 min infusion)
  - VS at 30 mins (end of infusion)
  - VS after 15 min monitoring (prior to discharge)

- **Dose 2 & 3: (total of 3 sets)**
  - VS before infusion
  - VS at 15 mins (halfway through 30 min infusion)
  - VS at 30 mins (end of infusion, this serves as the prior to discharge VS as well)

# Remdesivir: Gilead patient assistance program

- Gilead program that covers assistance for commercially-insured patients
  - Patients who are not insured can get relieve via the Cares Act and Provider Relief Fund

- The amount of financial assistance depends on the patient's health insurance plan, deductible, and level of need
  - There is a copay coupon for those with commercial insurance, depending on the type of insurance

- Resources for HCPs: https://www.gileadadvancingaccess.com/hcp/resources
  - sample letter of medical necessity, sample letter of appeal and prior authorization checklist)

- Enrollment form: https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf
  - Can be completed online and then saved (you can download the application)

# Who to Treat for COVID-19

# NIH COVID-19 Treatment Guidelines

- The COVID-19 Treatment Guidelines Panel (the Panel) has recommended several therapeutic agents for the treatment and prevention of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19.

- These anti-SARS-CoV-2 therapeutics are of greatest benefit for non-hospitalized patients who have risk factors for progression to severe COVID-19. The risks for progression are substantially higher for those who are not vaccinated or who are vaccinated but not expected to mount an adequate immune response to the vaccine.


**Please see the NIH COVID-19 Treatment Guidelines for more information.**
(https://www.covid19treatmentguidelines.nih.gov/therapies/)

# **Who is at risk for severe disease?** (for patients)

- Cancer
- Chronic kidney disease
- Chronic liver disease
- Chronic lung diseases
- Cystic Fibrosis
- Dementia or other neurological conditions
- Diabetes (type 1 or type 2)
- Disabilities
- Heart conditions
- HIV infection
- Immunocompromised state (weakened immune system)
- Mental health conditions
- Overweight and obesity
- Physical inactivity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease
- Substance use disorders
- Tuberculosis
- Children with medical complexity

*US CDC: People with Certain Medical Conditions* (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html)

# Who is at risk for severe disease? (for providers)

**Higher risk for severe COVID-19 outcomes**

- Cancer
- Cerebrovascular disease
- Chronic kidney disease*
- *Chronic lung diseases:*
  Interstitial lung disease, Pulmonary embolism, Pulmonary hypertension, Bronchiectasis, COPD (chronic obstructive pulmonary disease)
- *Chronic liver diseases:*
  Cirrhosis, Non-alcoholic fatty liver disease, Alcoholic liver disease, Autoimmune hepatitis
- Cystic fibrosis
- Diabetes mellitus, type 1 and type 2*
- *Disabilities:*
  Attention-Deficit/Hyperactivity Disorder (ADHD): Cerebral Palsy, Congenital Malformations (Birth Defects), Limitations with self-care or activities of daily living, Intellectual and Developmental Disabilities, Learning Disabilities, Spinal Cord Injuries, other disabilities [full list on webpage]
- Heart conditions (e.g., heart failure, coronary artery disease, or cardiomyopathies)
- HIV (human immunodeficiency virus)
- *Mental health disorders:*
  Mood disorders (including depression), Schizophrenia spectrum disorders
- Neurologic conditions limited to dementia
- Obesity (BMI ≥30 kg/$m^2$)*
- Primary Immunodeficiencies
- Pregnancy and recent pregnancy
- Physical inactivity
- Smoking, current and former
- Solid organ or hematopoietic cell transplantation
- Tuberculosis
- Use of corticosteroids or other immunosuppressive medications

**Suggestive higher risk for severe COVID-19 outcomes**

- Children with certain underlying conditions
- Overweight (BMI ≥25 kg/$m^2$, but <30 kg/$m^2$)
- Sickle cell disease
- Substance use disorders
- Thalassemia

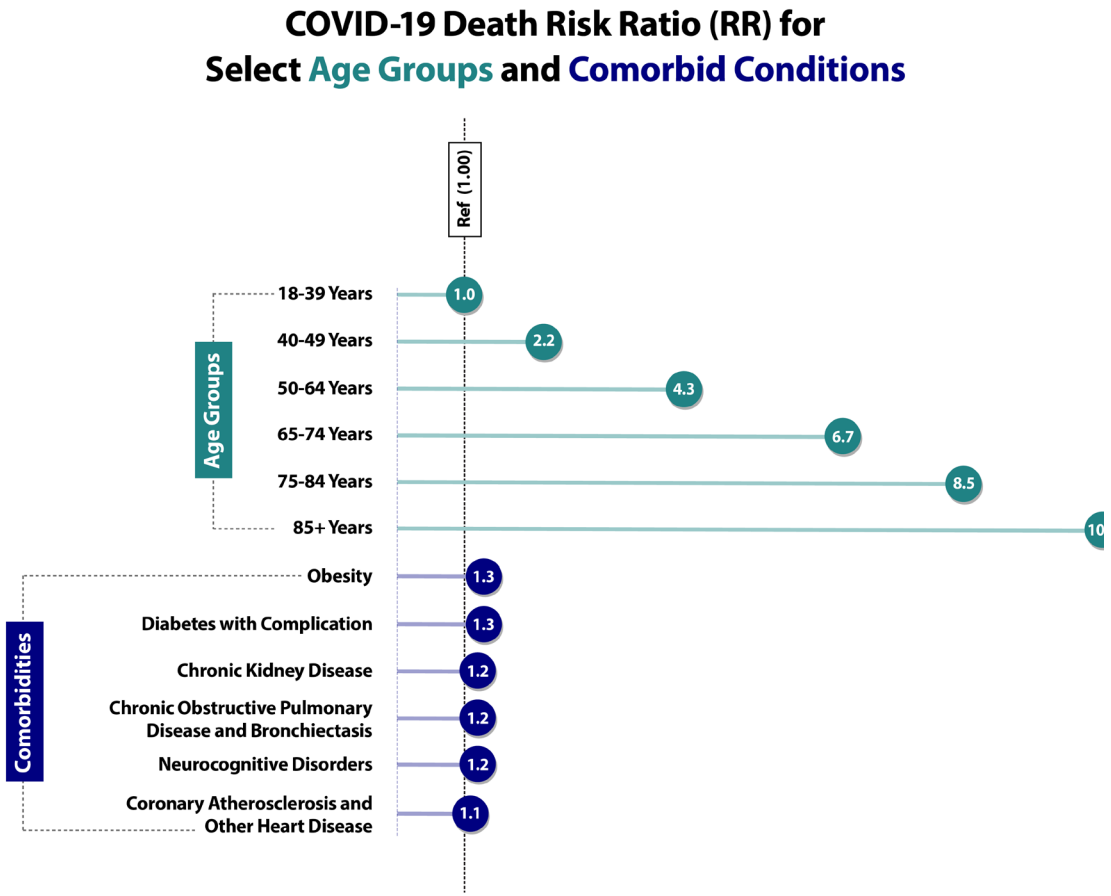
**Mixed evidence**

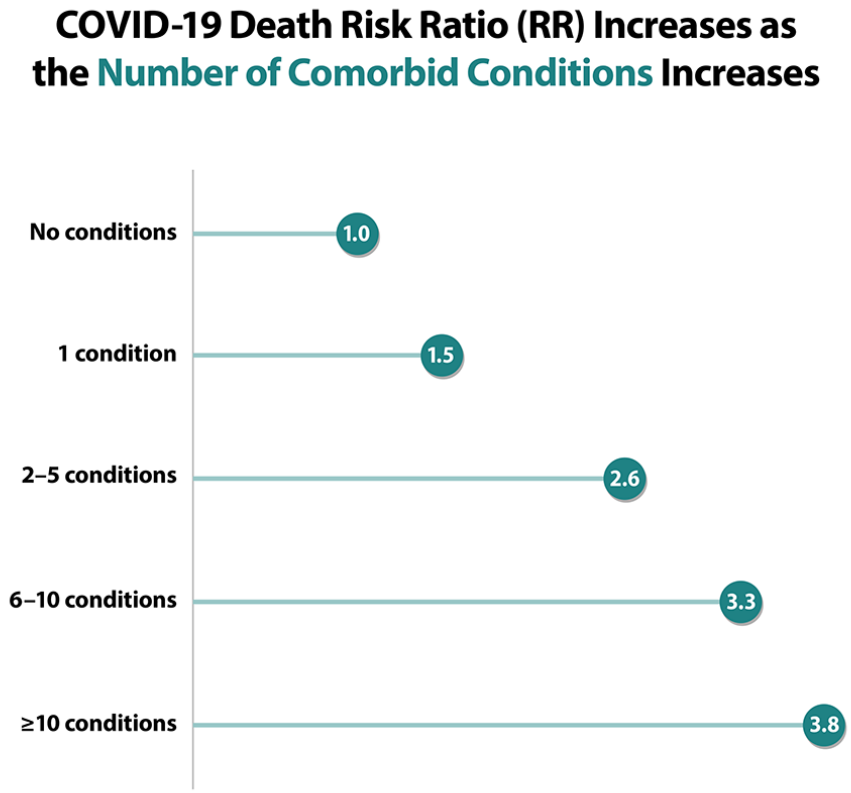
- Alpha 1 antitrypsin deficiency
- Asthma
- Bronchopulmonary dysplasia
- Hepatitis B
- Hepatitis C
- Hypertension*

** indicates underlying conditions for which there is evidence for pregnant and non-pregnant people*

*US CDC: Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals*
(https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html)

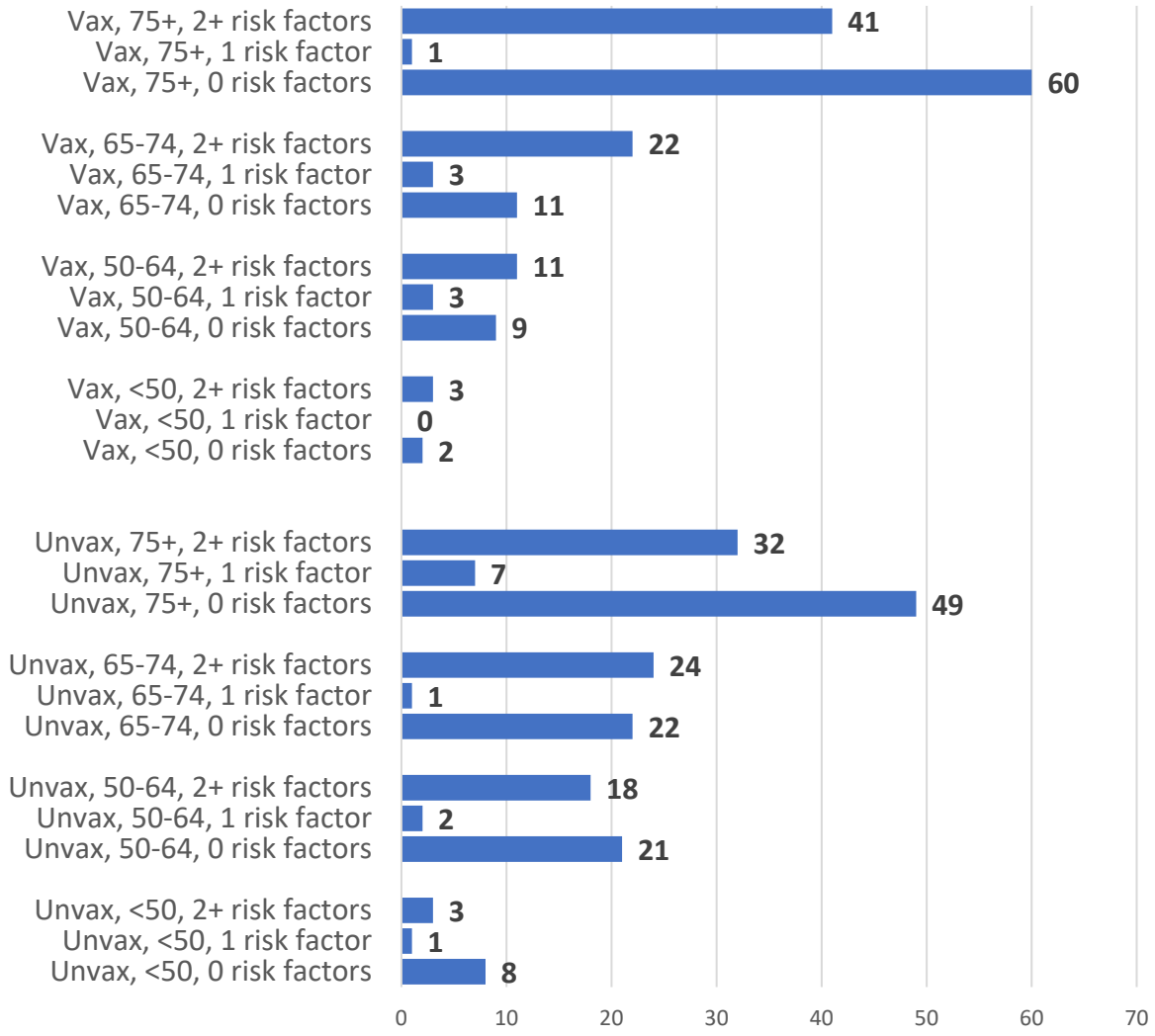
# Who is at risk for severe disease?

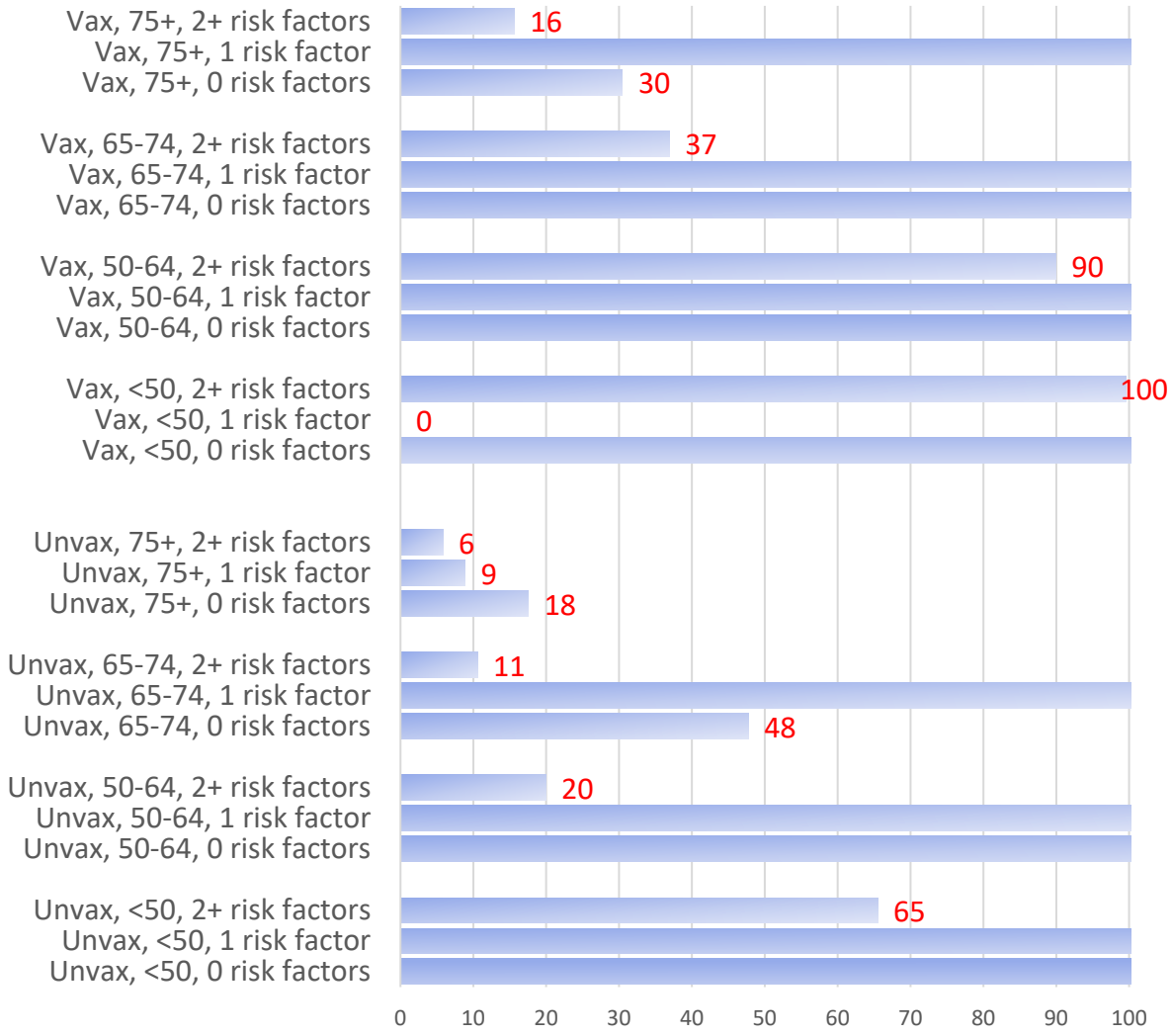



CDC: Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html)

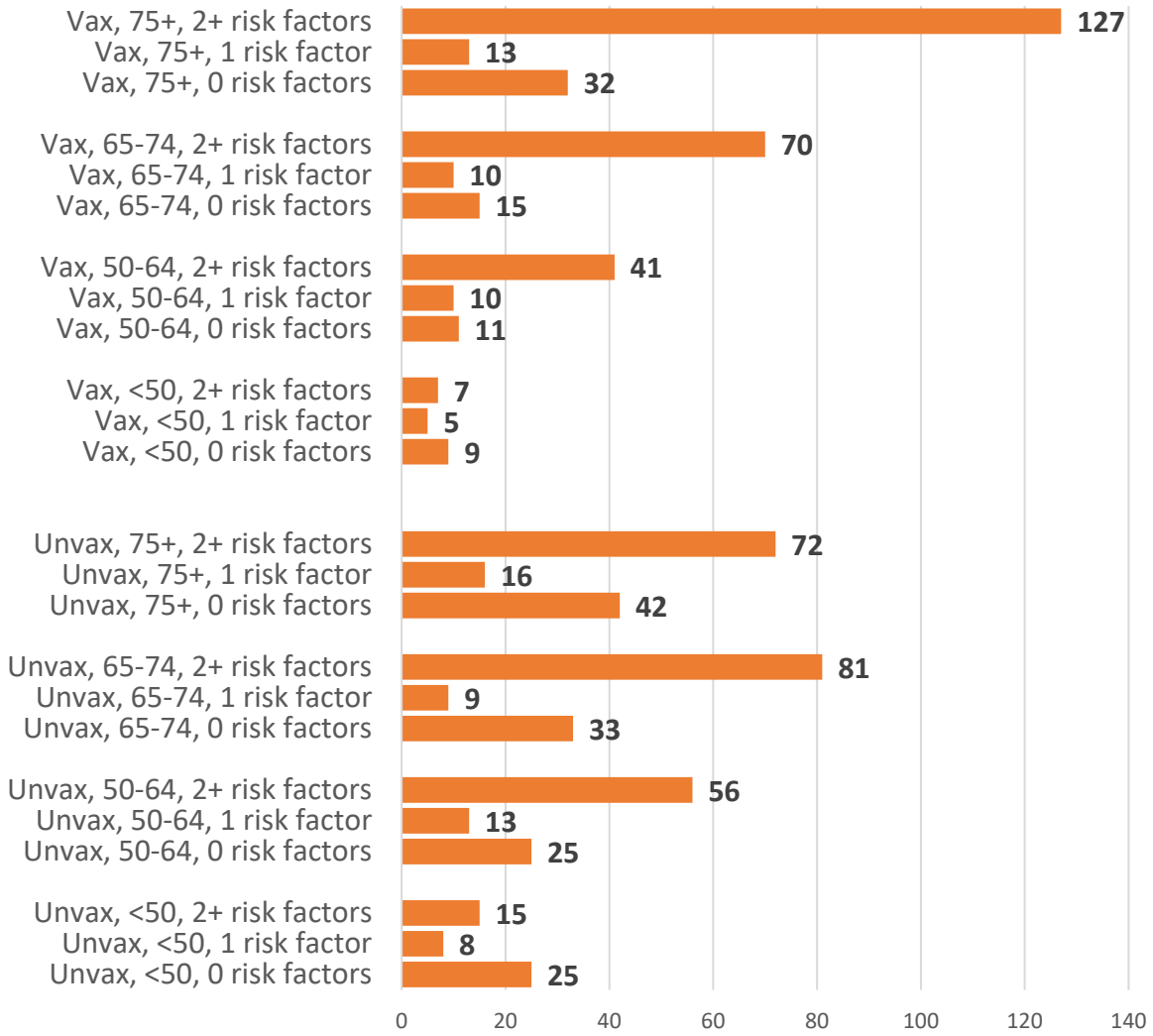
# COVID-19 deaths and NNT, Maine, Jan–Feb 2022

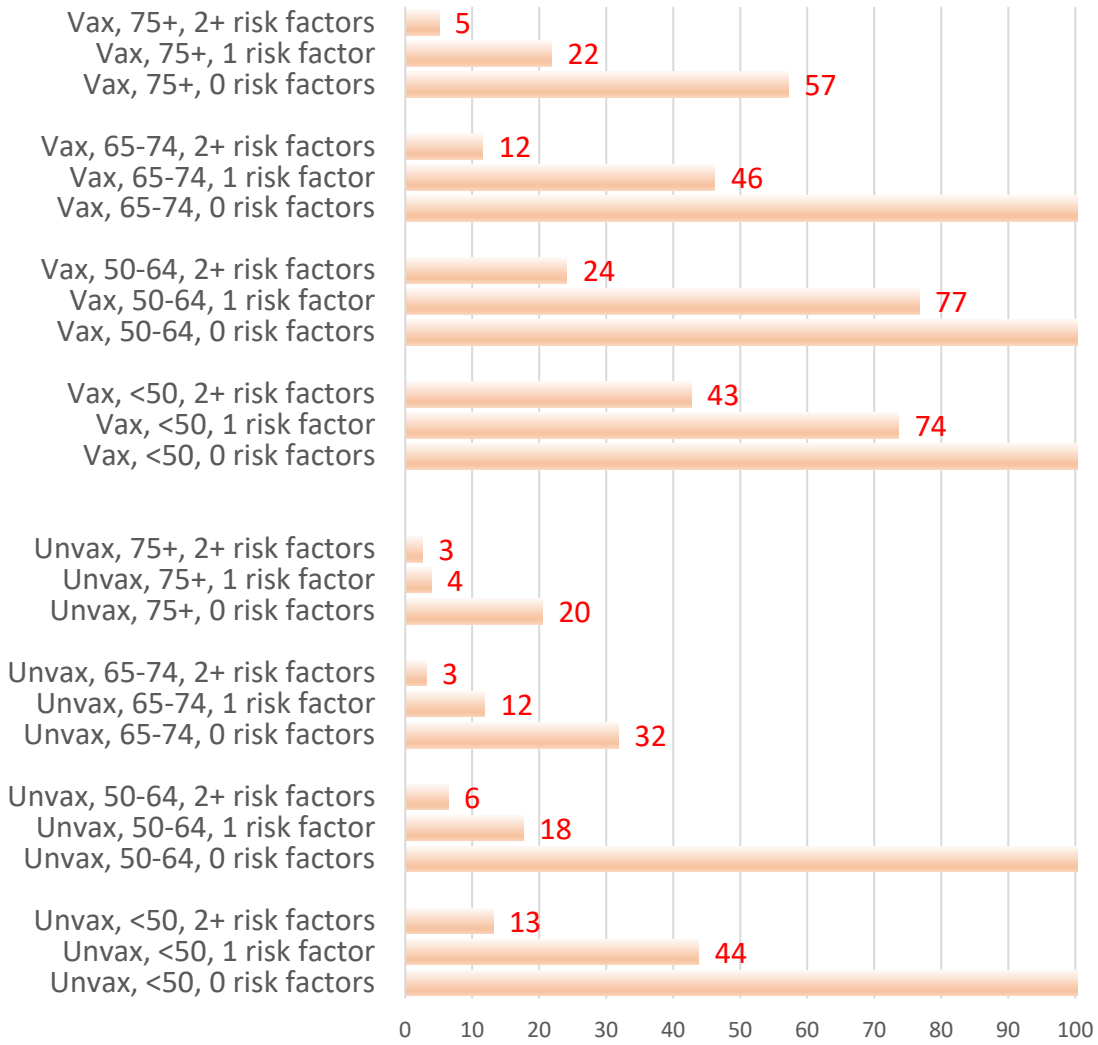



*Maine CDC internal data, preliminary findings*

# COVID-19 hospitalizations and NNT, Maine, Jan–Feb 2022




*Maine CDC internal data, preliminary findings*

# Considerations for COVID-19 Outpatient Treatment

| Category | Groups* |
|---|---|
| ***High*** **Risk for Severe Disease** | • All adults age 40 years and older<br>• People with clinical risk factors placing them at higher risk for severe COVID-19 disease |
| ***Higher*** **Risk for Severe Disease** | • Unvaccinated, 65+ years<br>• Vaccinated, 65+ years, 1+ clinical risk factors<br>• Unvaccinated or Vaccinated, 2+ risk factors<br>• Residing in a congregate facility |
| ***Highest*** **Risk for Severe Disease** | • Moderately/Severely Immunocompromised<br>• Unvaccinated or Vaccinated, 75+ years<br>• Unvaccinated, 50+ years, 1+ clinical risk factors<br>• Unvaccinated, Pregnant |

**Notes:*

***Unvaccinated:*** *a person who has not received 2 doses of an mRNA vaccine or 1 dose of the J&J vaccine.*

***Vaccinated:*** *a person who has received 2 doses of an mRNA vaccine or 1 dose of the J&J vaccine. Vaccinated persons who have not received a booster dose are at higher risk for severe disease than those who are boosted.*

***Clinical risk factors:*** *some of the most important Underlying Medical Conditions Associated with High Risk for Severe COVID-19 (US CDC) include age, cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromising conditions or receipt or immunosuppressive medications, obesity (BMI ≥30), pregnancy, and sickle cell disease.*

***Immunocompromising conditions:*** *Moderately or Severely Immunocompromised People (US CDC) include people who have been receiving active cancer treatment for tumors or cancers of the blood, received an organ transplant and are taking medicine to suppress the immune system, received a stem cell transplant within the last 2 years or taking medicine to suppress the immune system, moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome), advanced or untreated HIV infection, or active treatment with high-dose corticosteroids or other drugs that suppress the immune response.*

***Pregnant:*** *COVID-19 patients who are pregnant and unvaccinated are at higher risk for severe disease than those who are vaccinated. Women in their postpartum period, and those who are vaccinated and have additional risk factors, are also at elevated risk.*

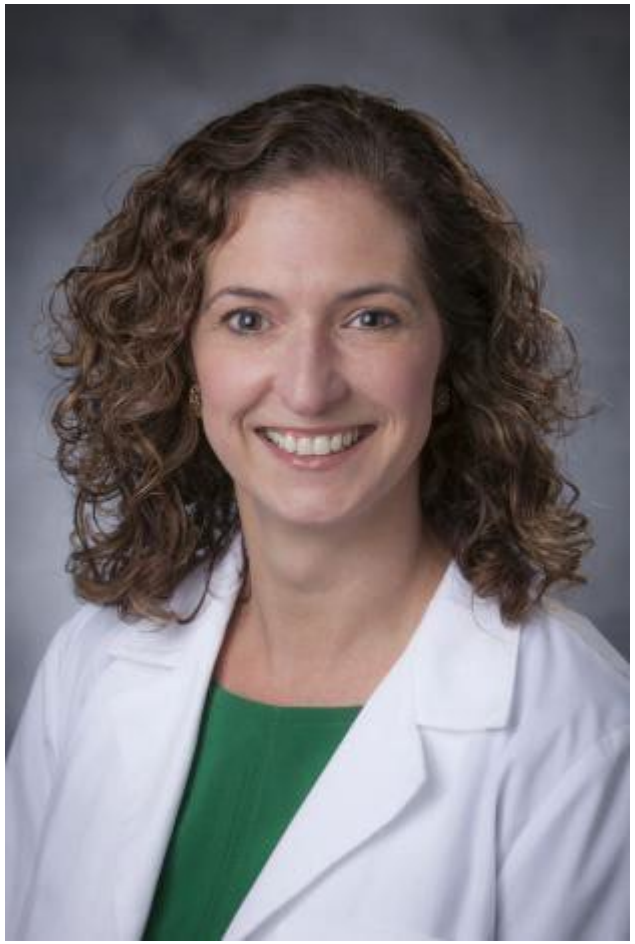
***Congregate facility:*** *Includes persons living in nursing homes, assisted living facilities, jails prisons, and homeless shelters who do not meet higher-level criteria.*

ACOG
The American College of Obstetricians and Gynecologists

# COVID-19 THERAPEUTICS: USE & CHALLENGES IN OBSTETRIC CARE

Brenna L. Hughes, MD, FACOG

June 3, 2022



**Brenna Hughes, MD**

**Chief of the Division of Maternal Fetal Medicine and Vice Chair for Quality and Obstetrics at Duke, Co-chair for the American College of Obstetricians and Gynecologists COVID-19 Task Force, Chair of the Society for Maternal-Fetal Medicine COVID-19 Task Force and a member of NIH COVID-19 Treatment Guidelines Panel**

# COVID-19 AND PREGNANCY

- Pregnant individuals at increased risk of severe illness including ICU admission, need for mechanical ventilation, and death
- Pregnant patients with COVID-19 are at increased risk of adverse pregnancy and fetal/infant outcomes
- **Equitable access to potentially lifesaving treatments is essential in this population**

# COVID-19 THERAPEUTICS AND PREGNANT PEOPLE

- Pregnant and lactating individuals excluded from nearly all clinical trials for COVID-19 therapeutics
  - This limitation makes it difficult to make evidence-based recommendations on the use of SARS-CoV-2 therapies in these vulnerable patients and potentially limits their COVID-19 treatment options. (NIH)
- ACOG is looked to for guidance in this space, with little or no data to inform recommendations as mentioned above

# ACOG FREQUENTLY ASKED QUESTIONS

- Traditional ACOG Guidance: Clinical Practice Guidelines, Clinical Consensus, and Practice Advisories
- In the space of rapidly changing and evolving data and information, began to develop Frequently Asked Questions which could be reviewed and updated rapidly.
  - Currently over 100 FAQs being maintained
- Limited & evolving data, rapidly changing recommendations in the space of COVID-19 therapeutics has limited ACOG's ability to provide members with evidence-based COVID-19 treatment recommendations

# ACOG GUIDANCE (FAQ): MONOCOLONAL ANTIBODIES

- Obstetric care clinicians may consider the use of monoclonal antibodies for the treatment of non-hospitalized COVID-19 positive pregnant individuals with mild to moderate symptoms, particularly if one or more additional risk factors are present (e.g. BMI >25, chronic kidney disease, diabetes mellitus, cardiovascular disease).

- Post-exposure prophylaxis should be considered for inadequately vaccinated individuals who have been exposed to SARS-CoV-2 (NIH).

ACOG

# ACOG GUIDANCE (FAQ): PAXLOVID

- Obstetric care clinicians may consider the use of [Paxlovid] for the treatment of non-hospitalized COVID-19 positive pregnant individuals with mild to moderate symptoms, particularly if one or more additional risk factors are present (e.g. body mass index >25, chronic kidney disease, diabetes mellitus, cardiovascular disease).
- Clinicians should weigh the available data against the individual risks of COVID-19 in pregnancy in each situation.

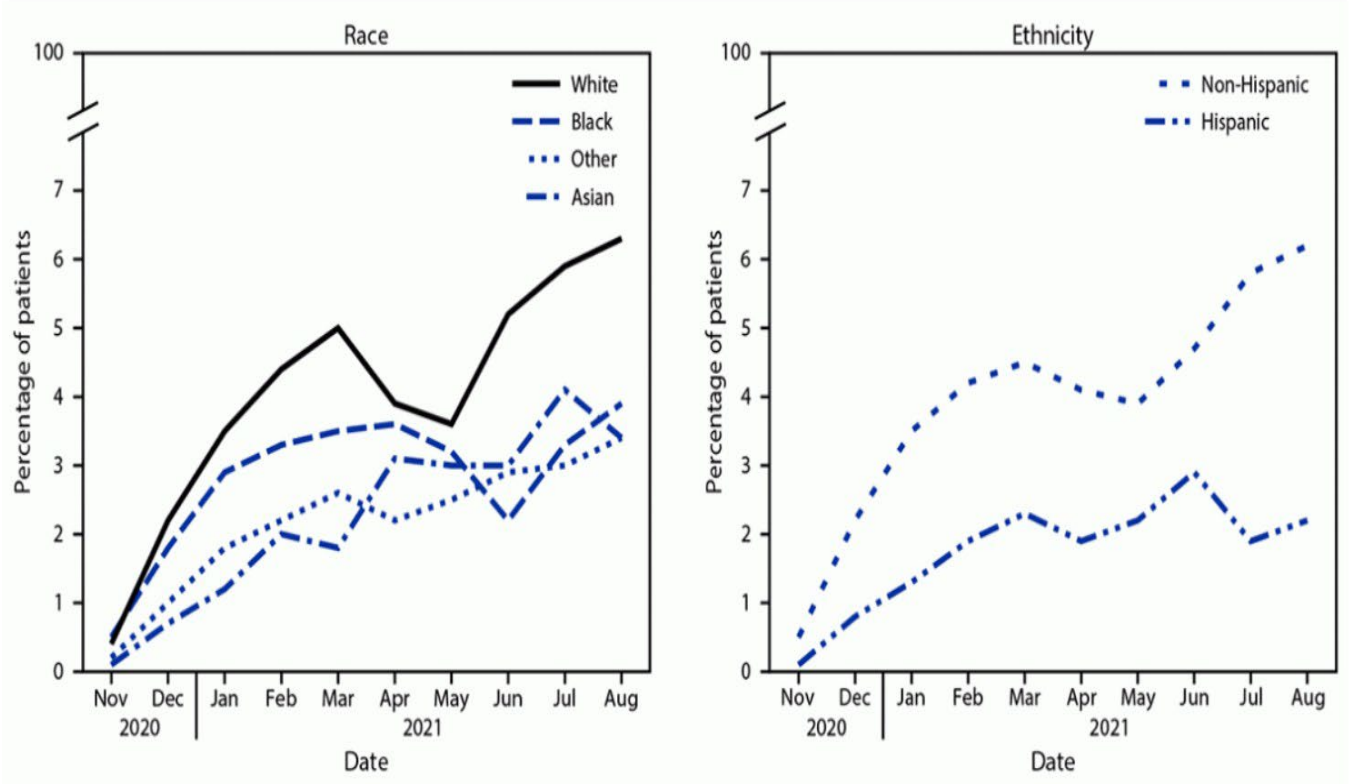
# IMPLEMENTATION CHALLENGES

- Lack of knowledge about COVID-19 therapeutics among obstetric providers
- Lack of or incorrect knowledge about pregnancy risks among non-obstetric providers
- Patient hesitancy due to lack of data in pregnancy
- Frequently changing guidance due to lack of monoclonal efficacy based on strain, rapidly changing scientific landscape

# HEALTH EQUITY CONCERNS

- An analysis of data from 41 health care systems found that White and non-Hispanic patients received monoclonal antibody treatment more often than Black, Asian, and Other race [including American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and multiple or Other races] patients with positive SARS-CoV-2 test results.
- As with other COVID-19 treatments, vaccines, and prevention practices, **efforts should be made to ensure that communities most affected by SARS-CoV-2 have equitable access to these treatments.**

FIGURE. Monthly* percentage of COVID-19 patients (n = 805,276) receiving monoclonal antibody treatment,† by race§ and ethnicity¶ — 41 health care systems in the National Patient-Centered Clinical Research Network — United States, November 2020–August 2021




Wiltz JL, Feehan AK, Molinari NM, et al. Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19 — United States, March 2020–August 2021. MMWR Morb Mortal Wkly Rep 2022;71:96–102.
DOI: http://dx.doi.org/10.15585/mmwr.mm7103e1external icon.

# Accessing Outpatient Treatment in Maine

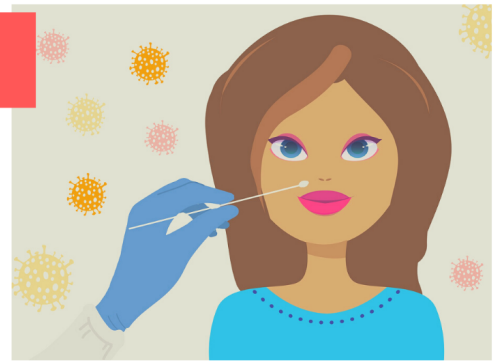
# DON'T DELAY: TEST EARLY, TREAT EARLY

## KNOW YOUR RISK.

If you are at high risk for severe illness from COVID-19, know how to access treatment quickly. It could save your life.

## GET TESTED.

Feeling unwell or have COVID-19 symptoms? TEST EARLY. If you test positive and have symptoms you may be eligible for treatment.



## GET TREATED.

If you test positive and have symptoms, EARLY TREATMENT IS CRITICAL, even when symptoms are mild.

Sites across Maine offer testing. assesment, and treatment. Others sites offer access to medicine if you already have a prescription from your doctor.

***For more info & to find treatment: https://www.maine.gov/covid19/treatment or call 1-888-445-4111***

*Source: Maine CDC*

# DON'T DELAY: TEST EARLY, TREAT EARLY

## WHO IS CONSIDERED HIGH RISK?

**Adults over 40 years old and people of any age with the following:**

- Cancer
- Chronic kidney disease
- Chronic liver disease
- Chronic lung diseases
- Cystic fibrosis
- Dementia or other neurological conditions
- Diabetes (Types 1 & 2)
- Disabilities
- Heart conditions
- HIV Infection
- Immunocompromised state
- Mental health conditions
- Overweight and obesity
- Physical inactivity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem transplant
- Stroke or cerebrovascular disease
- Substance use disorders
- Tuberculosis

## WHAT SHOULD YOU DO IF YOU TEST POSITIVE FOR COVID-19?

**Seek treatment promptly.**

**Find a location:**
maine.gov/covid19/treatment

**Or for help finding treatment:**
1-888-445-4111

Source: Maine CDC.

https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/providers.shtml

# COVID-19 Treatment in Maine (for patients)

STATE OF MAINE
Covid-19 Response
Office of the Governor

Home → Clone of COVID-19 Treatment in Maine

## COVID-19 Treatment in Maine

### Treatment is available for COVID-19

COVID-19 treatment is highly effective at preventing a mild or moderate illness from progressing to becoming severe and life-threatening. Treatment is available across Maine for older adults and for people at high risk of getting very sick from COVID-19.

Don't wait until you're very ill. COVID-19 treatment works best if started within the first 5–7 days after symptoms begin. Treatment is only available for people with COVID-19 symptoms and a positive COVID-19 test, which can include an at-home test. You will need a prescription to get treated. Most medications are provided free of charge, but you may be asked for insurance information.

COVID-19 treatment is not a replacement for vaccination Learn more about the COVID-19 vaccine and where to get vaccinated in Maine.

If you are not currently infected with COVID-19, talk to your doctor to find out whether you should get treatment should you have COVID-19 in the future. Have a plan for how to get tested quickly for COVID-19 if you develop symptoms.

***People who receive treatment should continue to follow guidance for isolation (PDF) and mask around others.***

### How to Get Treated

Here's what to do if you're experiencing symptoms of COVID-19.

### Where to Get Treated

Find a pharmacy to fill your prescription for COVID-19 treatment, or find a test-to-treat facility in Maine.

### Frequently Asked Questions

See our FAQ for more info or call 1-888-445-4111 and our experts can help you navigate next steps.

**https://www.maine.gov/covid19/treatment**

### Where to Get Treated

#### Where can I fill a prescription in Maine?

**If you have already received a prescription for medication** you can find a pharmacy at this link for locations to fill a prescription.

#### Where can I get tested, be seen by a provider, and get treated (Test-to-Treat site) in Maine?

**Your doctor can prescribe medication for COVID-19. Additionally, anyone in Maine can go to any of the following locations to get tested, be seen by a medical provider, and get treated.**

All sites are open to the public.

Find a provider nearest you and contact that location for more information before going to any of these locations.

If you need assistance finding a provider, call 1-888-445-4111.

Most medications are provided free of charge; but you may be asked for insurance information.

| Provider | Address | Contact Info |
|---|---|---|
| Bridgton Hospital | 10 Hospital Drive, Bridgton | 207-330-7352 |
| Cary Medical Center | 163 Van Buren Rd, Caribou ME 04736 | 207-498-3111 |
| Central Maine Medical Center | 300 Main Street, Lewiston, ME 04240 | 207-330-7352 |
| ConvenientMD Urgent Care Bangor | 543 Broadway, Bangor, ME 04401 | 207-922-1300 More info |
| ConvenientMD Urgent Care Brunswick | 193 Bath Road, Brunswick, ME 4011 | 207-424-2272 More info |
| ConvenientMD Urgent Care Portland | 191 Marginal Way, Portland ME 04101 | 207-517-3838 More info |
| Franklin Memorial Hospital | 111 Franklin Health Commons, Farmington, ME 04938 | 207-778-6031 |
| Houlton Regional Hospital | 20 Hartford St, Houlton, ME 04730-1891 | 207-521-2118 |

ASPR Office of the Assistant Secretary for Preparedness & Response

English Español 简体中文

Need help finding a place to get medication? Call 1-800-232-0233 (TTY 888-720-7489)

### Get medication for COVID-19

COVID-19 medications are now available through your doctor, local pharmacies, and health clinics.
If you have COVID-19 symptoms and test positive, do not wait to get treated.
You must take oral COVID-19 medication within 5 days of your first COVID-19 symptoms.
Use the tool below to find a location that is right for you.

**Find COVID-19 Medication**

Augusta, ME, USA

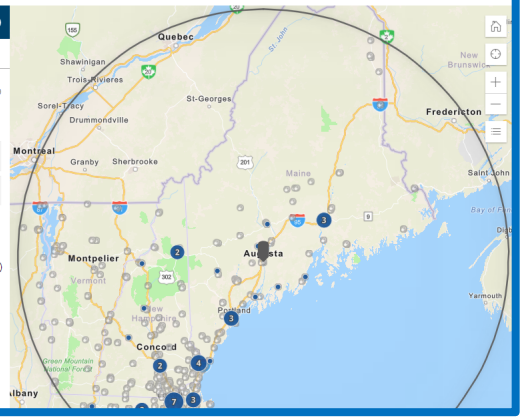
200.2 mi

0 250

Results:2068

Locations with testing, medical visits, and medication (Test-to-Treat) 101

Locations to fill a prescription 1967




**How to get medication**

1. Locations to get testing, medical visits, and medication (Test-to-Treat)

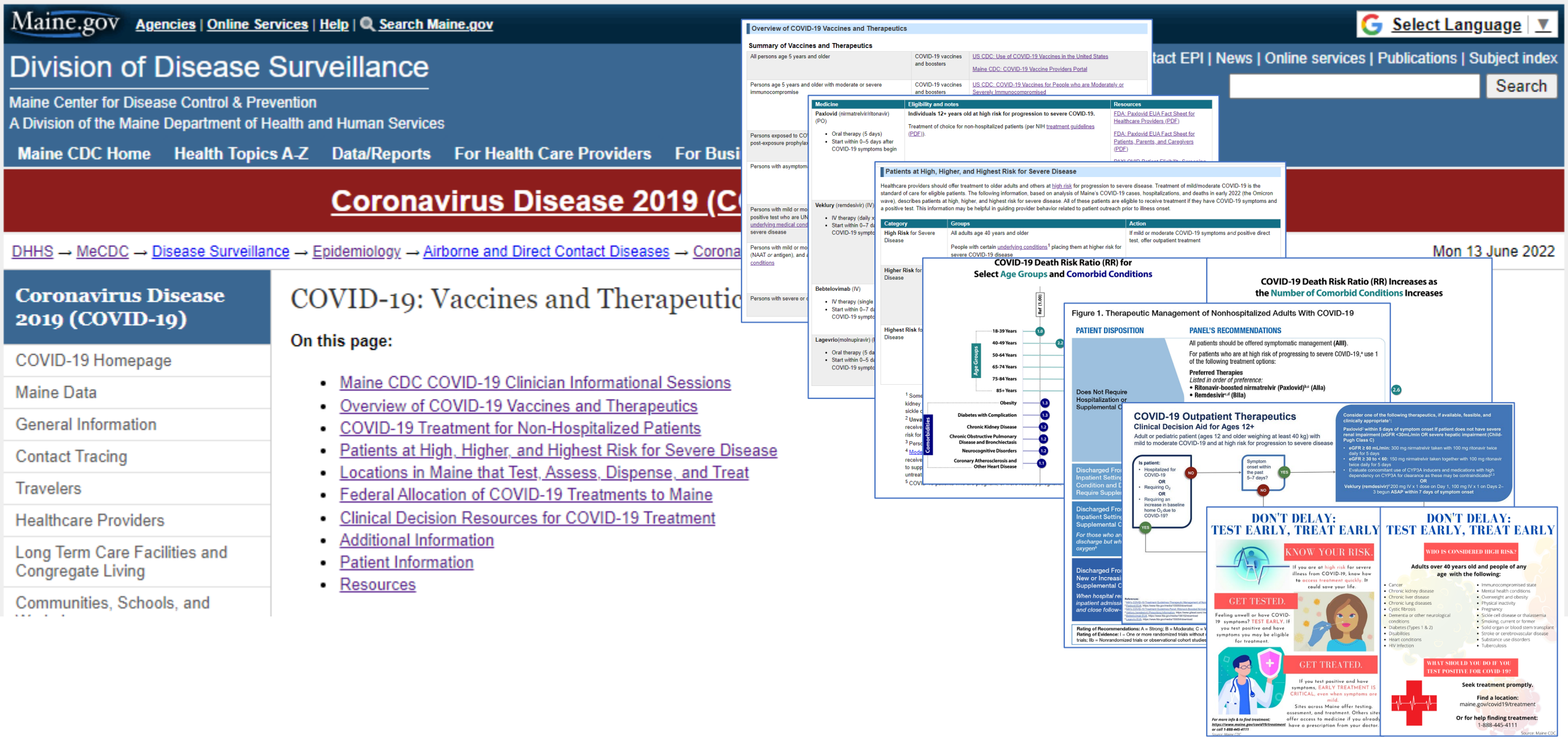
Some pharmacy clinics and health centers can prescribe and give you medication at the same location.

Learn more about the Test-to-Treat program.

2. Locations to fill a prescription

Any healthcare provider can evaluate and prescribe you COVID-19 medication just as they normally would. You can fill those prescriptions at any location in this tool.

# Provider information: COVID-19 treatment




https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/covid19-treatment.shtml

# Key resources

- **Maine CDC: COVID-19 provider information**
  https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/providers.shtml
- **COVID-19 Vaccines and Therapeutics** (Provider Information)
  https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/covid19-treatment.shtml
- **Maine CDC: COVID-19 Treatment in Maine** (Patient Information)
  https://www.maine.gov/covid19/treatment
- **Maine CDC: Health Advisories**
  https://www.maine.gov/dhhs/mecdc/newhan.shtml
- **NIH: Coronavirus Disease 2019 (COVID-19) Treatment Guidelines**
  https://www.covid19treatmentguidelines.nih.gov
- **ASPR: COVID-19 Therapeutics**
  https://aspr.hhs.gov/COVID-19/Therapeutics

# Long-Term Care Pharmacy Partners Program

- Continuing partnership with pharmacies serving long-term care facilities (LTCFs) for **direct receipt of oral antivirals** up to specific threshold at locations that provide direct access of product to LTC community
- Uses separate federal cache that **does not impact allocations to states/territories**
- Aids states by identifying long-term care supporting pharmacies (LTCPs) within their jurisdictions
- Identified LTCPs have ability to open order with guard rails, closely tied to utilization
- Ensures maximum visibility by states and territories on product supplies in LTCPs and LTCFs
- Ensures equitable distribution of therapeutics
- Provides efficient and flexible logistical and distribution structure to meet current and future demand for therapeutics when and where needed

# Why are patients still dying from COVID-19?

**Key messages for healthcare providers:**

- Become familiar with COVID-19 treatments for outpatients
- Talk to your high-risk patients about the value of treatment
- Encourage high-risk patients to have a plan to get tested and treated before they get sick

**Key messages for high-risk patients:**

- COVID-19 treatments are safe and effective and drastically reduce the risk of severe disease
- Treatment must be started within the first few days after symptom onset to be effective
- Have a plan to get tested, evaluated, and treated if you develop symptoms of COVID-19

# Recommendations for healthcare providers

- Continue to encourage COVID-19 vaccination in everyone age 5 years or older, including booster vaccination in everyone age 12 years or older.
- Encourage high-risk patients to get vaccinated and get a booster. Immunocompromised patients should receive an additional vaccine dose and are eligible to receive pre-exposure prophylaxis
- Communicate with your high-risk patients that treatment for COVID-19 is available in Maine and needs to be started soon after symptom onset. Encourage high-risk patients to have a plan to get promptly tested, evaluated, and treated if they get sick.
- Obtain further information on clinical use of products through
  - NIH's COVID-19 Treatment Guidelines
  - Assistant Secretary for Preparedness and Response Public Health Emergency COVID-19 Therapeutics site
  - Professional societies such as IDSA's Guidelines on the Management of Patients with COVID-19

# Additional Information

U.S. Department of Health and Human Services

ASPR Office of the Assistant Secretary for Preparedness & Response

# HHS/ASPR COVID-19 Therapeutics Weekly Clinical Rounds

**Michael R. Anderson, MD, MBA, FAAP, FCCM**
**Senior Advisor (ctr)**

**June 10, 2022**

# *Overview of COVID-19 Therapeutics*

# Summary of COVID-19 Preventative Agents & Therapeutics

| No Illness | Exposed<br>Per CDC Close Contact Criteria | Mild to Moderate Symptoms | Hospital Admission | | | ICU Admission | |
|---|---|---|---|---|---|---|---|
| Baseline health status, no infection | Not hospitalized, no limitations | Not hospitalized, with limitations[1] | Hosp. no act. medical problems | Hospitalized, not on oxygen | Hospitalized, on oxygen | Hospitalized, high flow oxygen/ non-invasive ventilation | Hospitalized, mechanical ventilation/ ECMO |

Veklury® (remdesivir, Gilead)[2]

**COVID-19 VACCINES**

**Monoclonal Antibodies for PrEP**

- Evusheld (tixagevimab + cilgavimab, AZ)

**None currently authorized for use in any US state or territory.**

**Oral Antivirals**

- Paxlovid (nirmatrelvir + ritonavir, Pfizer)
- Lagevrio (molnupiravir, Merck)

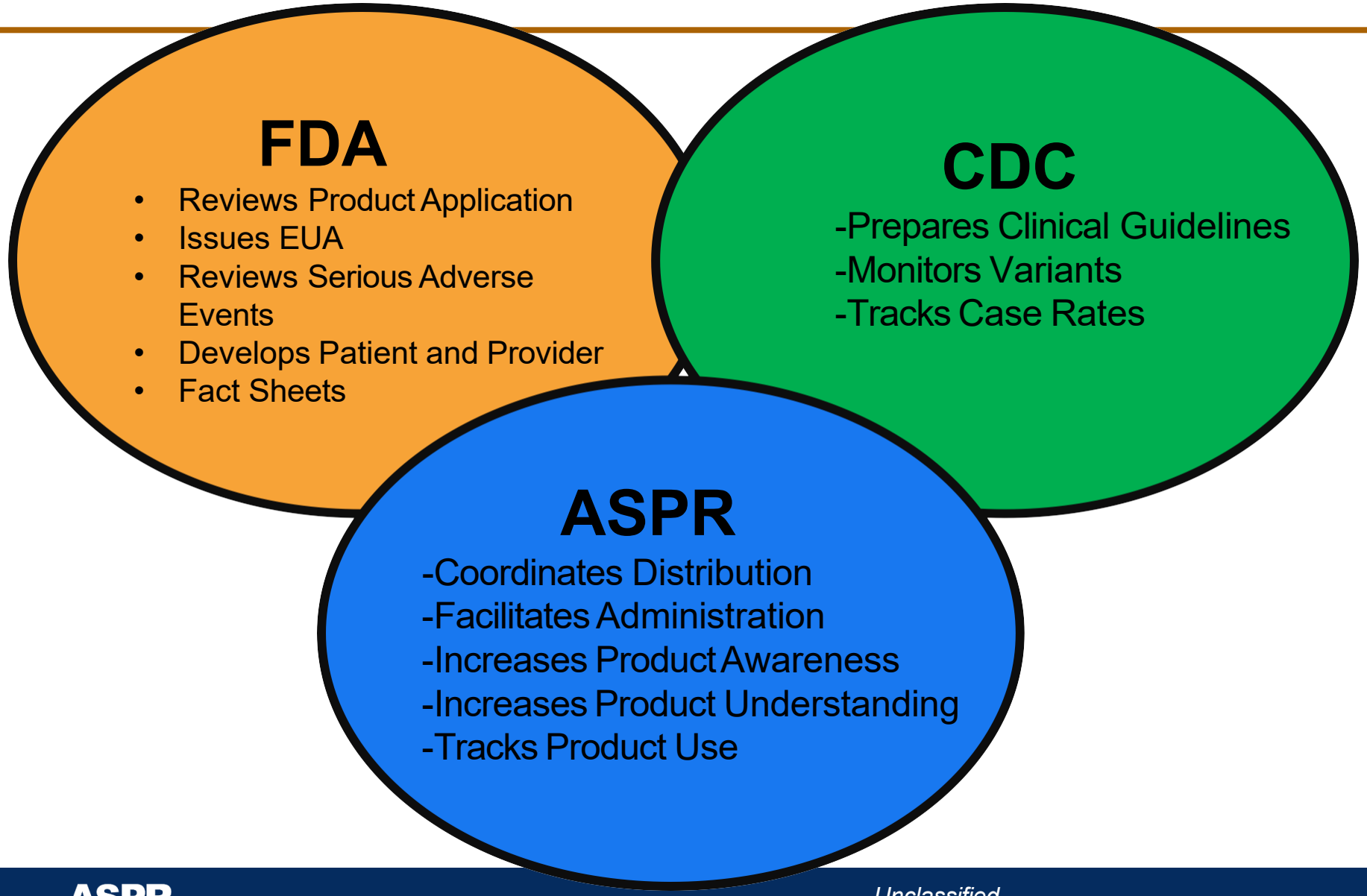
**Monoclonal Antibodies for Treatment**

- Bebtelovimab (Lilly)

**Please see NIH Current Inpatient Therapies**
(https://www.covid19treatmentguidelines.nih.gov/therapies/)

[1] Therapeutic Management of Nonhospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/
[2] Therapeutic Management of Hospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/

# Federal Support of COVID-19 Therapeutics




**NIH**
Issues clinical guidelines for COVID-19 treatment

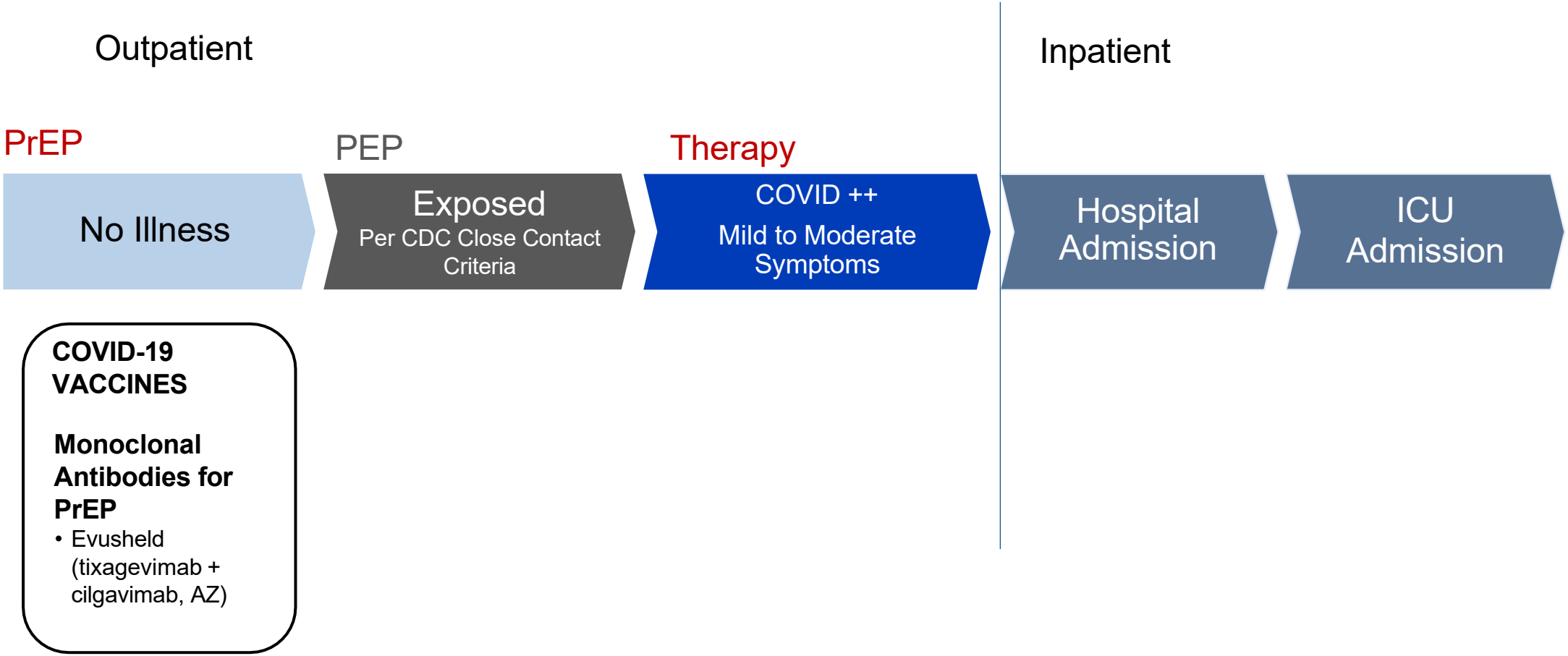
**CMS/HRSA**
Manages reimbursement

**Regional Emergency Coordinators**
Federal emergency coordinators supporting state and territorial agencies by geographic region

**State and Territorial Agencies**
Facilitate distribution and administration

# *Pre-Exposure Prophylaxis (PrEP)*

# Stages of COVID-19 Therapeutics (PrEP)



# Evusheld (tixagevimab and cilgavimab) – AstraZeneca
## *Monoclonal Antibody for IM Injection*


[Evusheld Product Information]

https://www.evusheld.com

# Evusheld (tixagevimab and cilgavimab) Authorization

Evusheld (tixagevimab and cilgavimab) is indicated for PrEP of COVID-19 in adults and pediatric (12 years of age and older, weighing at least 40 kg):

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, **AND**

- 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, **OR**
- 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 (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

**For more information,** Fact Sheet for Health Care Providers for Evusheld (tixagevimab co-packaged with cilgavimab) (https://www.fda.gov/media/154701/download)

# Evusheld (tixagevimab and cilgavimab): Limitations of Authorized Use

- Evusheld (tixagevimab and cilgavimab) is not authorized for use:
  - *For treatment of COVID-19.*
  - *For post exposure prophylaxis (PEP) of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.*
- PrEP with Evusheld (tixagevimab and cilgavimab) is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise[1] who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, Evusheld (tixagevimab and cilgavimab) should be administered at least 2 weeks after last vaccination.
- Evusheld (tixagevimab and cilgavimab) may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Evusheld belongs (i.e., antiinfectives).

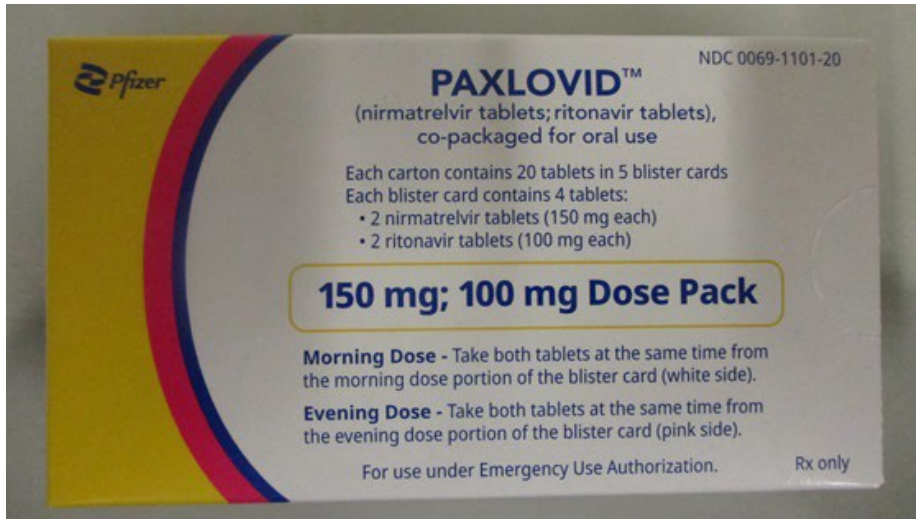
[1] CDC Clinical Considerations for COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

# *Treatments*

# Paxlovid (nirmatrelvir and ritonavir) – Pfizer *Oral Antiviral*

## Standard


## Renal




Paxlovid Product Information
https://www.pfizer.com/products/product-detail/paxlovidtm

# Paxlovid (nirmatrelvir and ritonavir) Authorization

- FDA has issued an EUA for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults (12 years of age and older weighing more than 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization and death, as soon as possible after diagnosis of COVID-19 and **within 5 days** of symptom onset.
- Paxlovid includes: nirmatrelvir (a SARS-CoV-2 main proteases inhibitor) and ritonavir (a CYP34A inhibitor)
- Limitations of authorized use:
  - Not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19
  - Paxlovid is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19
  - Not authorized for use longer than 5 consecutive days
- Paxlovid (nirmatrelvir and ritonavir) may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Paxlovid (nirmatrelvir and ritonavir) belongs (i.e., anti-infectives).

**For more information,** Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir and ritonavir) (https://www.fda.gov/media/155050/download)

# Paxlovid (nirmatrelvir and ritonavir)

## Dosage and Administration

- **eGFR ≥ 60 mL/min**: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for 5 days.
- **Dose reduction for moderate renal impairment eGFR ≥ 30 mL/min to < 60 mL/min:** 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) taken together twice daily for 5 days.
- **eGFR <30 mL/min:** currently not recommended
- **Severe hepatic impairment (Child-Pugh Class C):** currently not recommended

## Contraindications and Precautions

- History of clinically significant hypersensitivity reactions to the active ingredients or any other components.
- Co-administration with drugs highly dependent on CYP3A for clearance may result in life-threatening reactions[1].
- Co-administration with potent CYP3A inducers may result in reduced nirmatrelvir plasma concentrations and potential loss of virologic response.
- The concomitant use of Paxlovid (nirmatrelvir and ritonavir) and certain other drugs may result in potentially significant drug interactions.
- Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir.
- Paxlovid (nirmatrelvir and ritonavir) use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

[1] Liverpool Covid-19 interaction checker https://covid19-druginteractions.org/

**For more information,** Fact Sheet for Healthcare Providers for Paxlovid (nirmatrelvir and ritonavir) (https://www.fda.gov/media/155050/download)

# Paxlovid (nirmatrelvir and ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers

Medical History

- □ Positive SARS-CoV-2 test
- □ Age ≥ 12 years of age and weighing at least 40 kg
- □ Has one or more risk factors for progression to severe COVID-19
- □ Symptoms consistent with mild to moderate COVID-19
- □ Symptom onset within 5 days
- □ Not requiring hospitalization due to severe or critical COVID-19 at treatment initiation
- □ No known or suspected severe renal impairment (eGFR < 30 mL/min)
  - •Note that a dose reduction is required for patients with moderate renal impairment (eGFR ≥30-<60 mL/min); see the Fact Sheet for Healthcare Providers.
  - •Prescriber may rely on patient history and access to the patient's health records to make an assessment regarding the likelihood of renal impairment. Providers may consider ordering a serum creatinine or calculating the estimated glomerular filtration rate (eGFR) for certain patients after assessment on a case-by-case basis based on history or exam.
- □ No known or suspected severe hepatic impairment
- □No history of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or other components of the product

See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download

# Paxlovid (nirmatrelvir and ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers (continued)

Concomitant Medications

□ **Assess patient's home medication list for drug-drug interactions**

- See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download

□ HMG-CoA reductase inhibitors (statins)

- Patient is taking lovastatin or simvastatin, which are contraindicated with PAXLOVID coadministration: The statin can be held 12 hours prior to the first dose of PAXLOVID treatment, held during the 5 days of treatment, and restarted 5 days after completing PAXLOVID.
- Patient is taking atorvastatin or rosuvastatin: Temporary discontinuation of atorvastatin and rosuvastatin during treatment with PAXLOVID should be considered depending on statin dose. Atorvastatin and rosuvastatin do not need to be held prior to or after completing PAXLOVID.

□Hormonal contraceptives containing ethinyl estradiol: Patient is taking a hormonal contraceptive containing ethinyl estradiol: The need for an additional non-hormonal method of contraception during the 5 days of PAXLOVID treatment and until one menstrual cycle after stopping PAXLOVID should be recommended.

□Medications for HIV-1 Treatment: Patient is taking medications for the treatment of HIV-1 infection: With the exception of maraviroc3, HIV antiretroviral medications can be co-administered with PAXLOVID without dose adjustment, but arranging follow-up by the HIV care provider to monitor for side effects is recommended

Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID

□ See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers https://www.fda.gov/media/158165/download

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:

Please fill prescription by _____[insert date]_____. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.

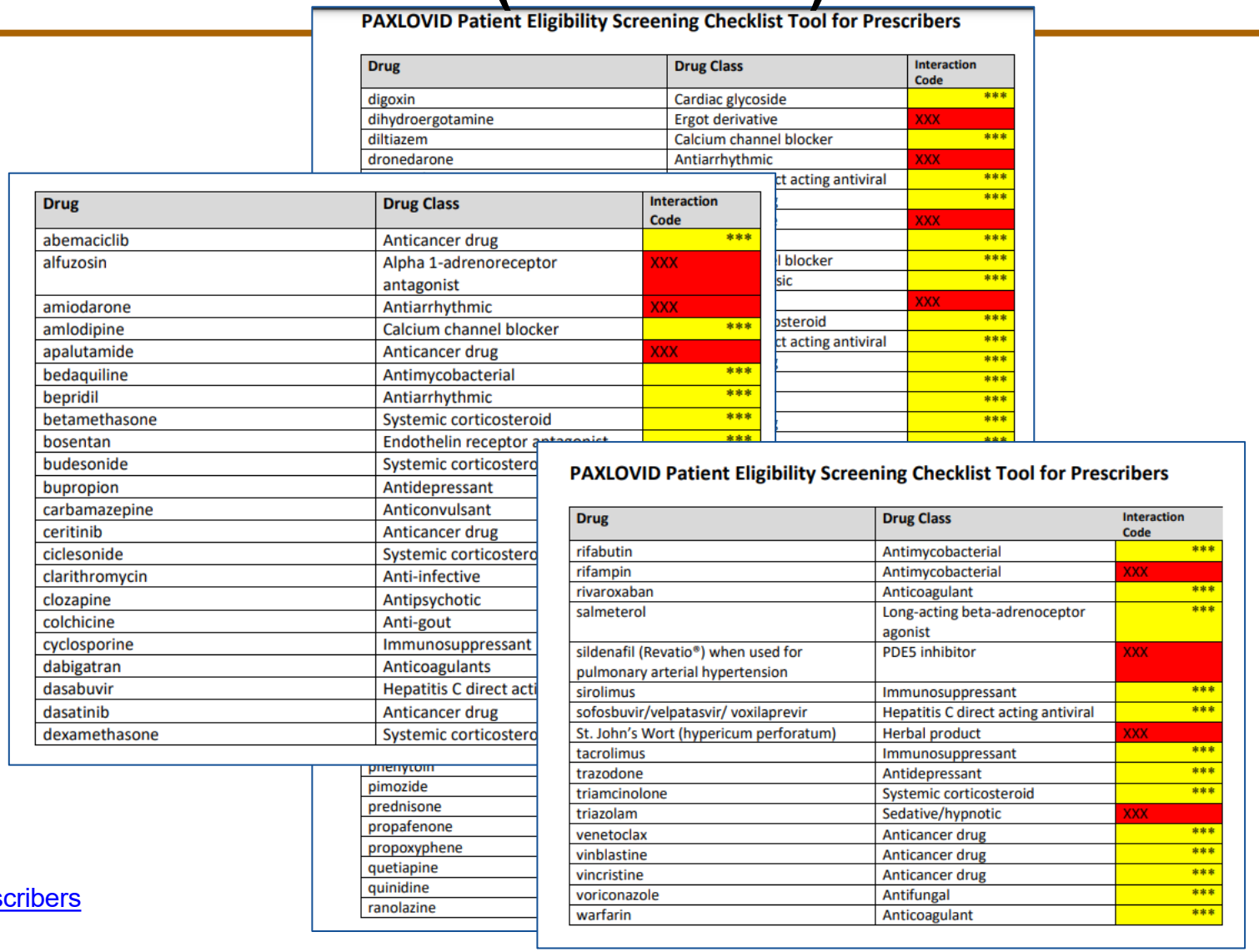
# Paxlovid (nirmatrelvir and ritonavir) Patient Eligibility Screening Checklist Tool for Prescribers (continued)

## PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

**Other Drugs with Established and Other Potentially Significant Drug Interactions with PAXLOVID (listed alphabetically by generic name)**

Interaction Codes:

| | |
|---|---|
| XXX | Coadministration of this drug with PAXLOVID is CONTRAINDICATED. For further information, refer to the Fact Sheet for Healthcare Providers and the individual Prescribing Information for the drug. |
| *** | Coadministration of this drug with PAXLOVID should be avoided and/or holding of this drug, dose adjustment of this drug, or special monitoring is necessary. Consultation with the prescriber of the potentially interacting drug is recommended. For further information, refer to the Health Care Provider Fact Sheet and the individual Prescribing Information for the drug. |



PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

| Drug | Drug Class | Interaction Code |
|---|---|---|
| abemaciclib | Anticancer drug | *** |
| alfuzosin | Alpha 1-adrenoreceptor antagonist | XXX |
| amiodarone | Antiarrhythmic | XXX |
| amlodipine | Calcium channel blocker | *** |
| apalutamide | Anticancer drug | XXX |
| bedaquiline | Antimycobacterial | *** |
| bepridil | Antiarrhythmic | *** |
| betamethasone | Systemic corticosteroid | *** |
| bosentan | Endothelin receptor antagonist | *** |
| budesonide | Systemic corticosteroid | *** |
| bupropion | Antidepressant | *** |
| carbamazepine | Anticonvulsant | *** |
| ceritinib | Anticancer drug | *** |
| ciclesonide | Systemic corticosteroid | *** |
| clarithromycin | Anti-infective | *** |
| clozapine | Antipsychotic | *** |
| colchicine | Anti-gout | *** |
| cyclosporine | Immunosuppressant | *** |
| dabigatran | Anticoagulants | *** |
| dasabuvir | Hepatitis C direct acting antiviral | *** |
| dasatinib | Anticancer drug | *** |
| dexamethasone | Systemic corticosteroid | *** |
| digoxin | Cardiac glycoside | *** |
| dihydroergotamine | Ergot derivative | XXX |
| diltiazem | Calcium channel blocker | *** |
| dronedarone | Antiarrhythmic | XXX |
| phenytoin | | |
| pimozide | | |
| prednisone | | |
| propafenone | | |
| propoxyphene | | |
| quetiapine | | |
| quinidine | | |
| ranolazine | | |

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

| Drug | Drug Class | Interaction Code |
|---|---|---|
| rifabutin | Antimycobacterial | *** |
| rifampin | Antimycobacterial | XXX |
| rivaroxaban | Anticoagulant | *** |
| salmeterol | Long-acting beta-adrenoceptor agonist | *** |
| sildenafil (Revatio®) when used for pulmonary arterial hypertension | PDE5 inhibitor | XXX |
| sirolimus | Immunosuppressant | *** |
| sofosbuvir/velpatasvir/ voxilaprevir | Hepatitis C direct acting antiviral | *** |
| St. John's Wort (hypericum perforatum) | Herbal product | XXX |
| tacrolimus | Immunosuppressant | *** |
| trazodone | Antidepressant | *** |
| triamcinolone | Systemic corticosteroid | *** |
| triazolam | Sedative/hypnotic | XXX |
| venetoclax | Anticancer drug | *** |
| vinblastine | Anticancer drug | *** |
| vincristine | Anticancer drug | *** |
| voriconazole | Antifungal | *** |
| warfarin | Anticoagulant | *** |

See table in Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers
https://www.fda.gov/media/158165/download

# Paxlovid (nirmatrelvir and ritonavir) – Pfizer *Oral Antiviral*



## Standard Dose

300 mg nirmatrelvir;100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

**Minimum Order Quantity**: 20

## Renal Dose

150 mg nirmatrelvir;100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

**Minimum Order Quantity**: 5

Paxlovid Product Information
https://www.pfizer.com/products/product-detail/paxlovidtm

# Paxlovid (nirmatrelvir and ritonavir)
## Renal Adjustment Instructions for Pharmacists for Standard Dose Pack

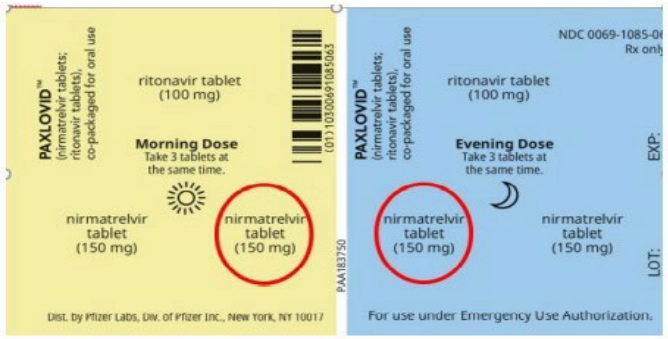



**Figure 1: Remove the nirmatrelvir tablets circled in red from the blister card**

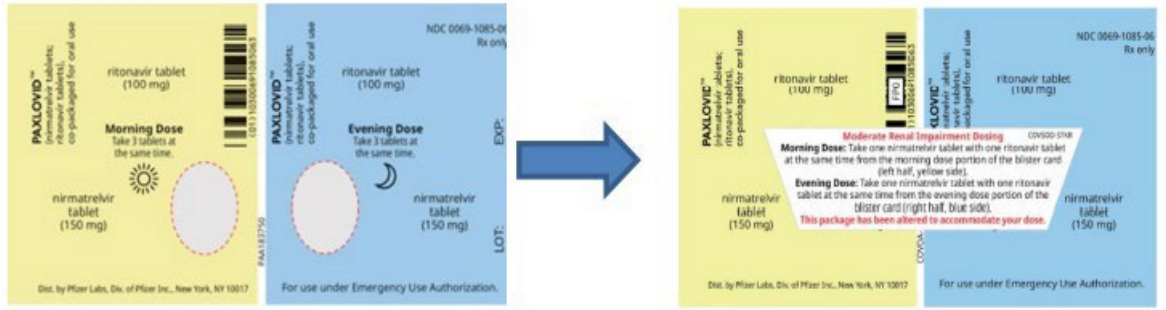



**Figure 2: Placement of sticker over empty blister cavities and pre-printed dosing instruction after removal of nirmatrelvir tablets**


**Figure 3: Placement of sticker over pre-printed dosing regimen on carton**

Pharmacist Instruction Sheet: https://www.covid19oralrx-hcp.com/files/Clean_EUA-105-mitigation-plan-for-moderate-renal-impairment-01-11-22.pdf

# 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/

# Lagevrio (molnupiravir) – Merck
## *Oral Antiviral*

Lagevrio™
molnupiravir 200 mg capsules


[Lagevrio (molnupiravir) Product Information]
https://www.molnupiravir-us.com/

# Lagevrio (molnupiravir) Authorization

- Lagevrio (molnupiravir) has been authorized by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 outpatient treatment options approved or authorized by FDA are not accessible or clinically appropriate.
- Not authorized for:
  - Patients less than 18 years of age
  - Initiation of treatment in patients requiring hospitalization due to COVID-19
  - Use longer than 5 consecutive days
- Lagevrio (molnupiravir) may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Lagevrio (molnupiravir) belongs (i.e., anti-infectives).

**For more information,** Fact Sheet for Healthcare Providers for Lagevrio (molnupiravir) (https://www.fda.gov/media/155054/download)

# Lagevrio (molnupiravir) Provider Checklist

- ❑ Positive SARS-CoV-2 test
- ❑ Age ≥18 years
- ❑ Alternate COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate
- ❑ High-risk criteria met
- ❑ Symptoms consistent with mild-moderate COVID-19
- ❑ Symptom onset with **5 days***
- ❑ Not hospitalized due to COVID-19
- ❑ Assessment pregnancy and breastfeeding status (if applicable)
- ❑ Provide appropriate counseling
  - Females of childbearing potential treated: 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 Lagevrio (molnupiravir)*
  - Breastfeeding is not recommended for the *duration of treatment and for **4 days** after the last dose of Lagevrio (molnupiravir)*
  - Males of reproductive potential treated: if 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 of Lagevrio (molnupiravir)*

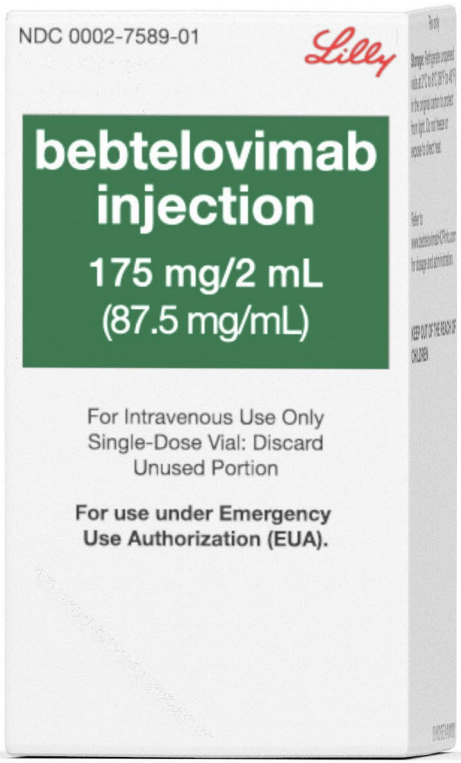
*Prescriber is encouraged to include a note to the pharmacist in the prescription stating:

Please fill prescription by [insert date]. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.

Prescriber Checklist for Lagevrio (molnupiravir) (fda.gov)

# *IV Therapies*

# Bebtelovimab – Eli Lilly
## *Monoclonal Antibody for IV Injection (IV Push)*




bebtelovimab Product Information

http://www.lillyantibody.com/bebtelovimab

# Bebtelovimab Authorization

- FDA has issued an EUA to permit the emergency use of bebtelovimab for the treatment of mild-to-moderate 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 are not clinically appropriate or accessible

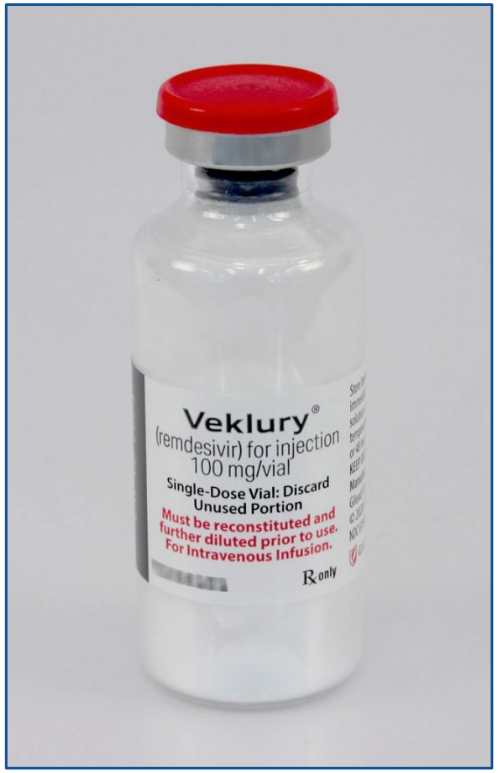
  *Per EUA: FDA does not consider Veklury® (remdesivir) to be an adequate alternative to bebtelovimab for this authorized use because it may not be feasible or practical for certain patients (e.g., it requires a 3-day treatment duration)*

  *Per NIH Guidelines: The Panel recommends using bebtelovimab as an alternative therapy **ONLY** when ritonavir-boosted nirmatrelvir (Paxlovid) and remdesivir are not available, feasible to use, or clinically appropriate **(CIII)**. Treatment should be initiated as soon as possible and within 7 days of symptom onset. See Therapeutic Management of Nonhospitalized Adults With COVID-19 for further guidance.*

- Bebtelovimab is not authorized for use in patients:
  - Who are hospitalized due to COVID-19, **OR**
  - Who require oxygen therapy due to COVID-19, **OR**
  - Who 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).

**For more information,** Fact Sheet for Healthcare Providers for Bebtelovimab.(https://www.fda.gov/media/156152/download)

# Veklury (remdesivir) – Gilead
## *Antiviral for IV Infusion*




Veklury Product Information
https://www.vekluryhcp.com/

# Veklury (remdesivir) – Outpatient Use

- FDA **approved** expanded use of Veklury (remdesivir) to certain **non-hospitalized** adults and pediatric patients for treatment of mild-to-moderate COVID-19 disease (Jan 21, 2022), including:
  - Adults and pediatric patients 28 days of age and older and weighing at least 3 kg with positive results of direct SARS-CoV-2 viral testing, **AND**
  - Who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death
- The treatment course of Veklury (remdesivir) should be initiated as soon as possible after diagnosis of symptomatic COVID-19 has been made and **within 7 days** of symptom onset. The recommended total duration of treatment for non-hospitalized patients is 3 days.

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

# Resources

# Related 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