Special COVID-19 Update: Paxlovid and Other Therapeutics

Maryland Department of Health

Maryland Primary Care Program

Program Management Office

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Agenda

❖ Why Therapeutics?

❖ Paxlovid

❖ Remdesivir

❖ Monoclonal Antibodies

❖ Molnupiravir (Lagevrio)

❖ Evusheld

❖ Data on Therapeutics

❖ Therapeutics Resources

❖ Call to Action

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Why Therapeutics?

Why use COVID-19 Therapeutics?

❖ Safe

❖ Effective

❖ Available at pharmacies across the state

❖ Managing the pandemic by preventing hospitalization and death

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NIH Guidance on Outpatient Therapeutic Preferences

1) Paxlovid - by prescription (preferred)
2) Remdesivir - by prescription (preferred)
3) Molnupiravir - by prescription
4) ***NEW: Bebtelovimab - by referral***

Sotrovimab not effective against BA.2

[NIH guidelines link](#)

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The Efficacy of Therapeutics is Clear

COVID-19 Therapeutic	Administration Type	Efficacy
Paxlovid	Oral Antiviral	88% effective
Remdesivir	IV	87% effective
Bebtelovimab	IV	—
Molnupiravir	Oral Antiviral	30% effective
Bam/Ete, Regen and Sotrovimab	mAb	0% effective

Bebtelovimab was not studied in a clinical trial against a placebo

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Source: NIH | COVID-19 Treatment Guidelines

CDC Definition of "Certain Medical Conditions"

The full list of people who may be eligible based on age or medical conditions can be found at the [CDC's website](#).

In general, people who are over age 65 or have chronic medical conditions may be at increased risk of severe disease.

People with the following conditions should speak to their providers about treatment options as soon as they test positive:

- Older adults
- People with disabilities or those who live in congregate care settings
- Chronic kidney, lung, or heart disease
- Cystic fibrosis
- Dementia or other neurological conditions
- Diabetes
- Disabilities
- HIV/AIDS
- Immunocompromised status or weakened immune system
- Immune disease
- Mental health conditions such as depression, schizophrenia spectrum disorders
- Overweight or 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

Paxlovid

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Paxlovid

❖ Oral antiviral agent

❖ "Preferred" option for treating COVID-19

❖ [EUA indications](#) and [Healthcare Providers Fact Sheet](#)

❖ [Safety](#): Adverse events (incidence ≥1% and ≥5 subject difference) were dysgeusia, diarrhea, hypertension, and myalgia

❖ Efficacy: 88% effective at preventing severe disease or hospitalization relative to placebo

❖ Renal dosing: Alternative presentation available

❖ Drug-Drug interactions: List of DDI available on page 10 of EUA

➢ Resource: [PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers (fda.gov)](#)

Paxlovid Formulation and Packaging

FDA 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.
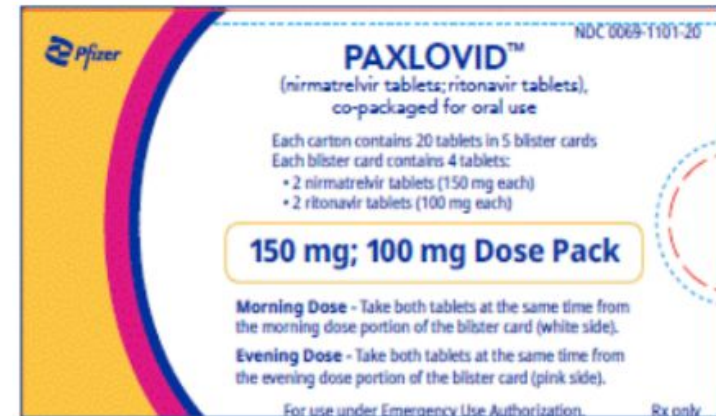
Standard Dose

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.

Paxlovid Rebound

❖ Occurs in low percent

❖ May remain or again become positive at day 5 or beyond

❖ May or may not become symptomatic

❖ No evidence of severe disease or hospitalization

❖ Caution regarding transmissibility and need to continue masking

❖ CDC Health Alert Network Health Advisory

❖ FDA Updates on Paxlovid for Health Care Providers

Remdesivir

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Remdesivir Outpatient Treatment

❖ Approved for outpatient treatment for adults and children >28 days old weighing at least 3.5 kg or 7.7 lbs

❖ Three one-hour antiviral infusions given over three days

❖ J-code granted by CMS-MAC contractors setting prices

❖ Updated information to address Medicare payment for RVD in two locations: the COVID-19 toolkit and in the Medicare FFS Billing FAQs (Q30, Page 146)

❖ Changes were made to add remdesivir to include an updated COVID-19 fee schedule to the Maryland Medicaid System

❖ Well suited for congregate care settings and pediatric patients due to logistical issues

❖ **Commercially available to all providers**

Monoclonal Antibodies

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Bebtelovimab (mAb)

❖ Alternative option for COVID-19 treatment

❖ EUA and [Healthcare Providers Fact Sheet](#)

❖ Safety: Most common adverse reactions were infusion-related reactions, pruritus, and rash

❖ In Vitro efficacy: Prophylactic administration to male Syrian golden hamsters (n=5 to 8 per group) resulted in 2 to 4 $\log_{10}$ decreases in viral genomic RNA and viral replication (subgenomic RNA) from lung tissue, as well as decreases in lung weight and improvements in body weight compared to controls

❖ Should be used <u>only</u> when the preferred treatment options are not available, feasible to use, or clinically appropriate

Molnupiravir (Lagevrio)

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Molnupiravir/Lagevrio

❖ Oral antiviral agent

❖ Alternative option for COVID-19 treatment when others are not available or not indicated

❖ EUA and [Healthcare Providers Fact Sheet](#)

❖ Safety: LAGEVRIO is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth, or in pregnant or lactating women

❖ 30% effective at preventing severe disease and death compared to placebo

Evusheld

Evusheld

❖ Pre-exposure prophylaxis for people who are moderate to severely immunocompromised (or for whom vaccine is contraindicated)

❖ Not a substitute for vaccination

❖ [EUA](EUA) and Healthcare Providers Fact Sheet

❖ Safety: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. A causal relationship between EVUSHELD and these events has not been established
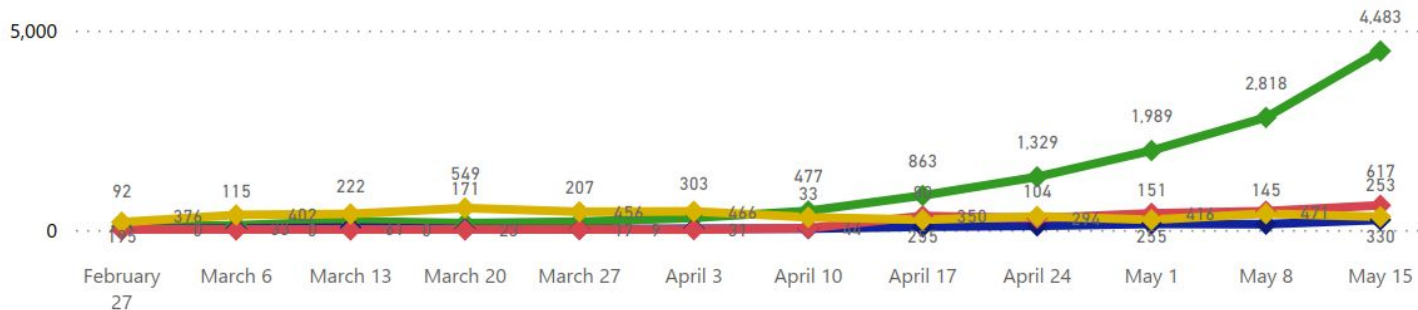
Data on Therapeutics

Data on Current Use

Recent spike in utilization based on increase in cases and greater awareness of therapeutic options

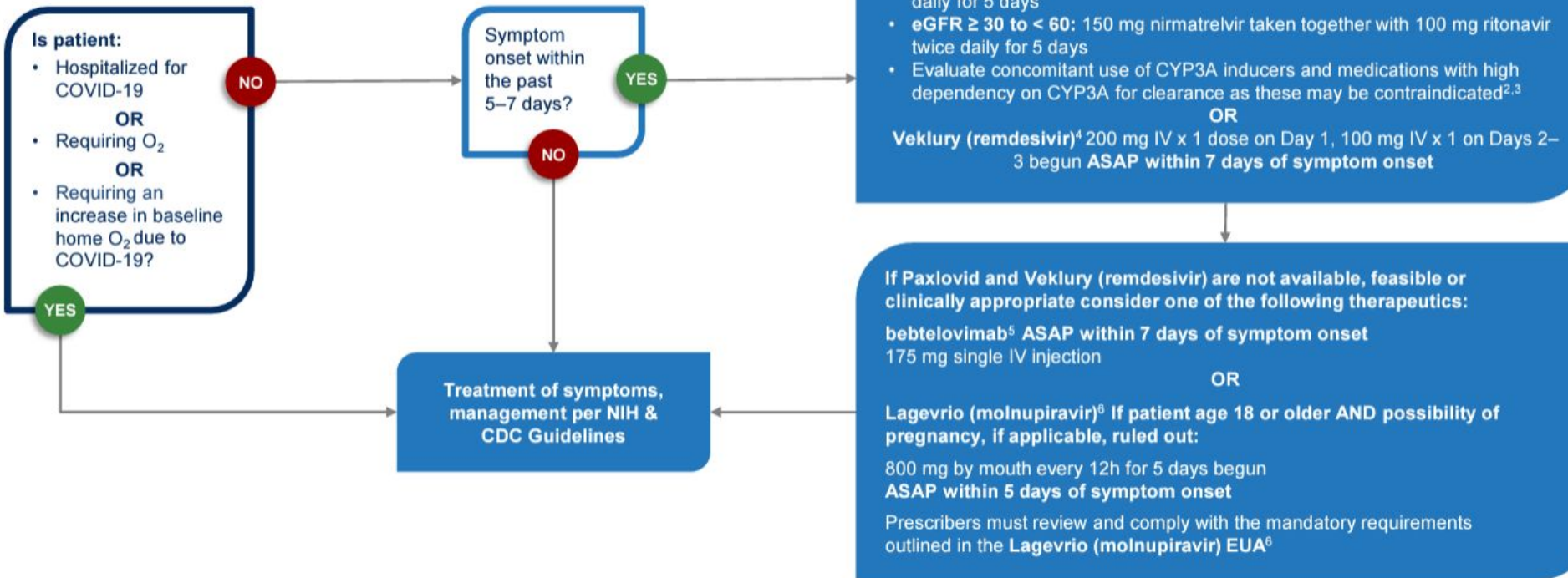| Therapeutic	Most Recent Weekly Utilization (April 25 - May 15)	To-Date Utilization
Paxlovid	4,483	14,757 (Introduced January 2022)
Molnupiravir	293	1,562 (Introduced January 2022)
Bevbtelovimab	617	2,299 (Introduced February 2022)
Evusheld	330	5,555 (Introduced December 2021)

Therapeutics Resources

COVID-19 Outpatient Therapeutics
Clinical Decision Aid for Ages 12+

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

Is patient:
- Hospitalized for COVID-19
  OR
- Requiring O$_2$
  OR
- Requiring an increase in baseline home O$_2$ due to COVID-19?

NO →

Symptom onset within the past 5–7 days?

YES →

NO ↓

YES ↓

Treatment of symptoms, management per NIH & CDC Guidelines

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

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

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

OR

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

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

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

OR

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

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

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

Reference:
[1]NIH's COVID-19 Treatment Guidelines Therapeutic Management of Nonhospitalized Adults With COVID-19.
[2]Paxlovid EUA . https://www.fda.gov/media/155050/download
[3]NIH's COVID-19 Treatment Guidelines Panel: Ritonavir-Boosted Nirmatrelvir (Paxlovid).
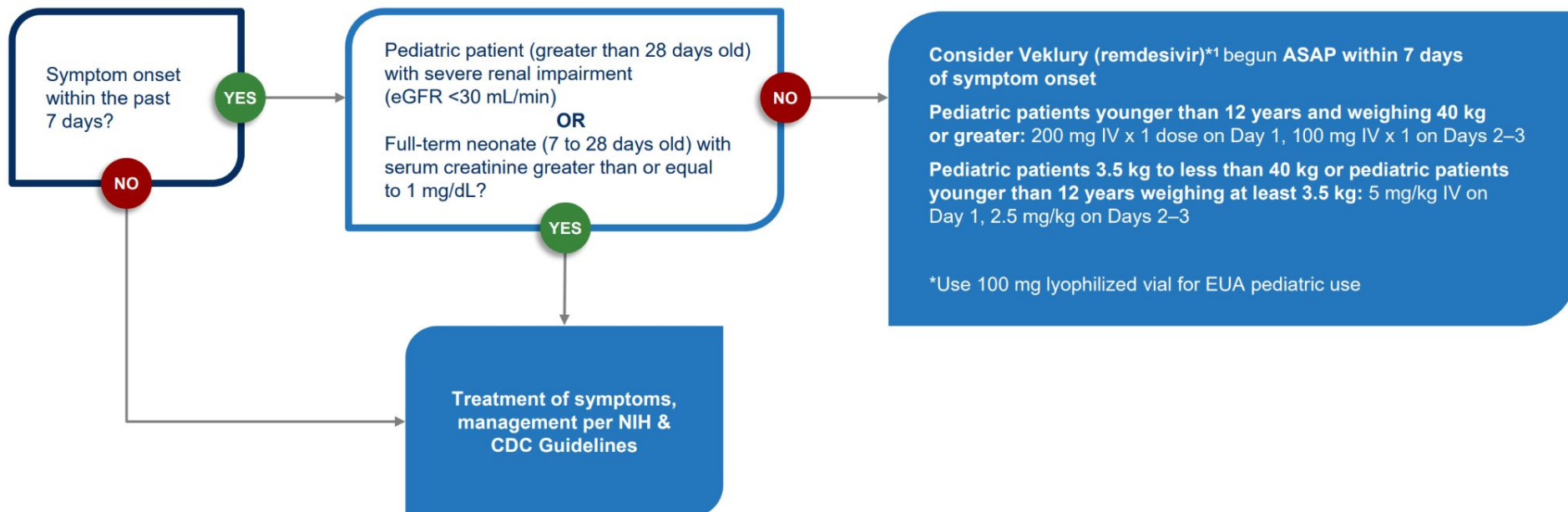[4]Veklury (remdesivir) Prescribing Information.
https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf
[5]Bebtelovimab EUA . https://www.fda.gov/media/156152/download
[6]Lagevrio EUA . https://www.fda.gov/media/155054/download

Clinical Decision Aid for Pediatric Patients

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

**Symptom onset within the past 7 days?**

YES →

Pediatric patient (greater than 28 days old) with severe renal impairment (eGFR <30 mL/min)

OR

Full-term neonate (7 to 28 days old) with serum creatinine greater than or equal to 1 mg/dL?

NO →

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

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

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

*Use 100 mg lyophilized vial for EUA pediatric use

NO (from symptom onset) →
YES (from renal impairment) →

Treatment of symptoms, management per NIH & CDC Guidelines

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

Oral Agent Inventory Confirmation

❖ Check inventory prior to ordering to ensure availability:

➢ Use this [Federal Therapeutics Locator website](#) to identify where you can refer patients and the inventory available at those locations:
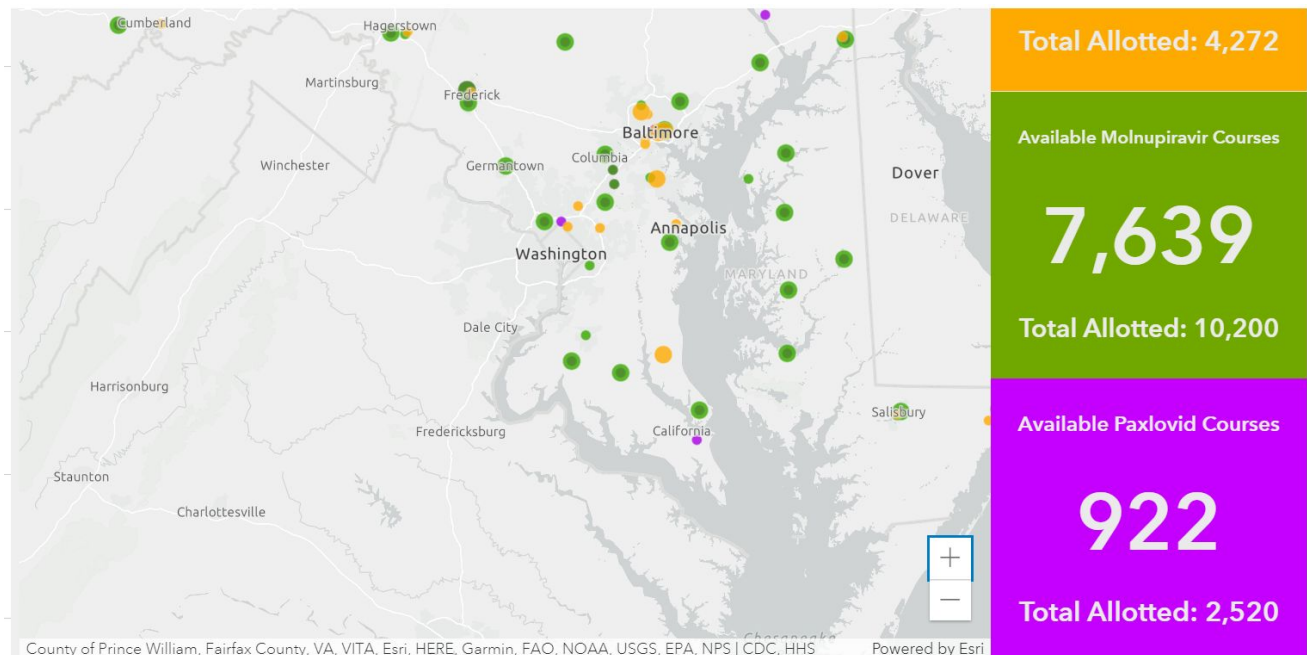
Oral Antiviral Access Points
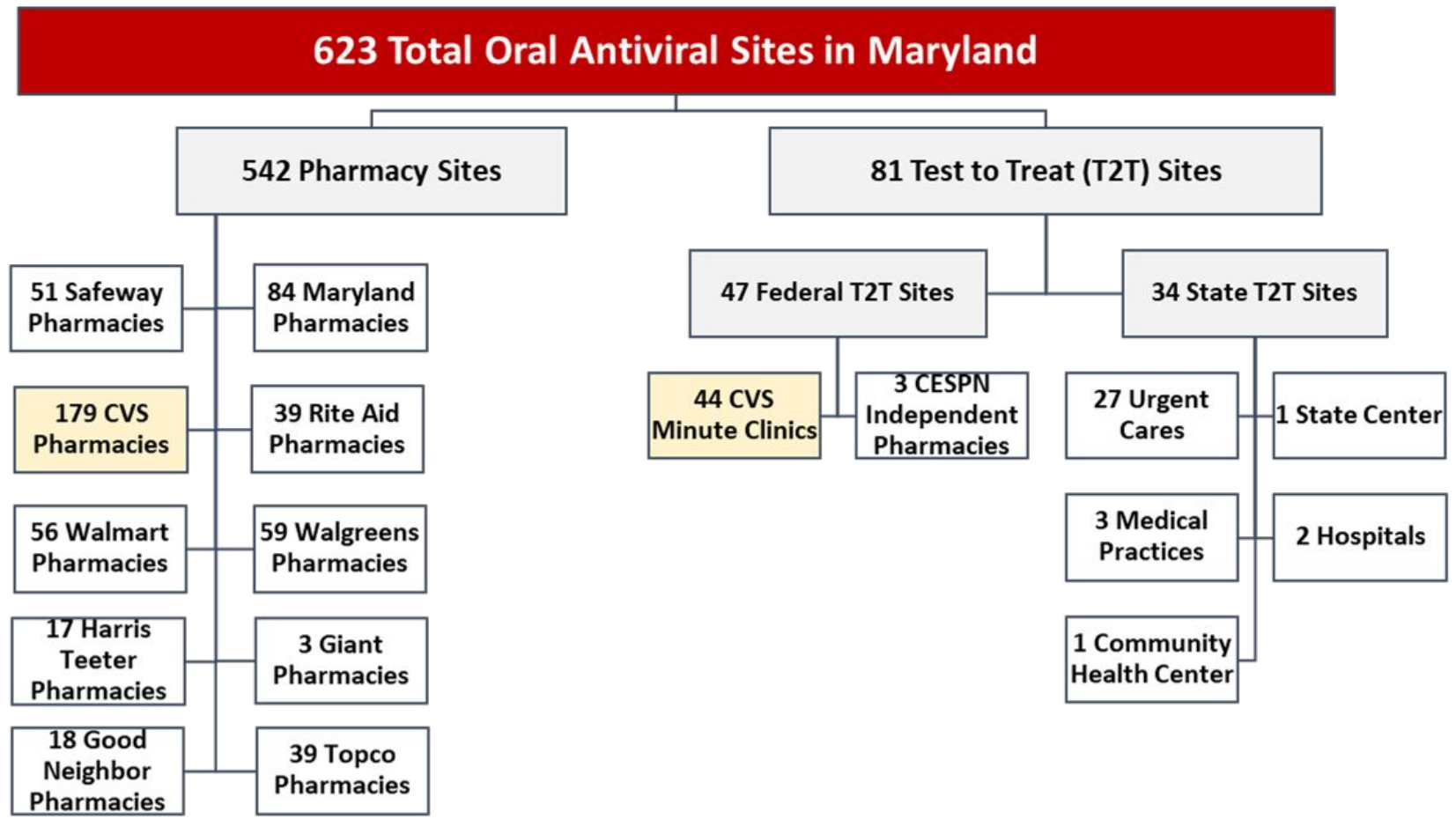
Oral Antiviral Access Points per Tiberius as of 12 May 2022
High Paxlovid utilizers are highlighted in yellow

Other Therapeutics Access Points

❖ 40 mAb infusion sites

➢ Hospital/hospital systems, Independent infusion centers, Independent pharmacies, Institutional pharmacies, Mobile infusion services, Alternate care sites

Figure 2. Therapeutics Sites in Maryland by Therapeutic Type

● Antivirals - 554
● Bebtelovimab - 39
● Evusheld - 65

Microsoft Bing
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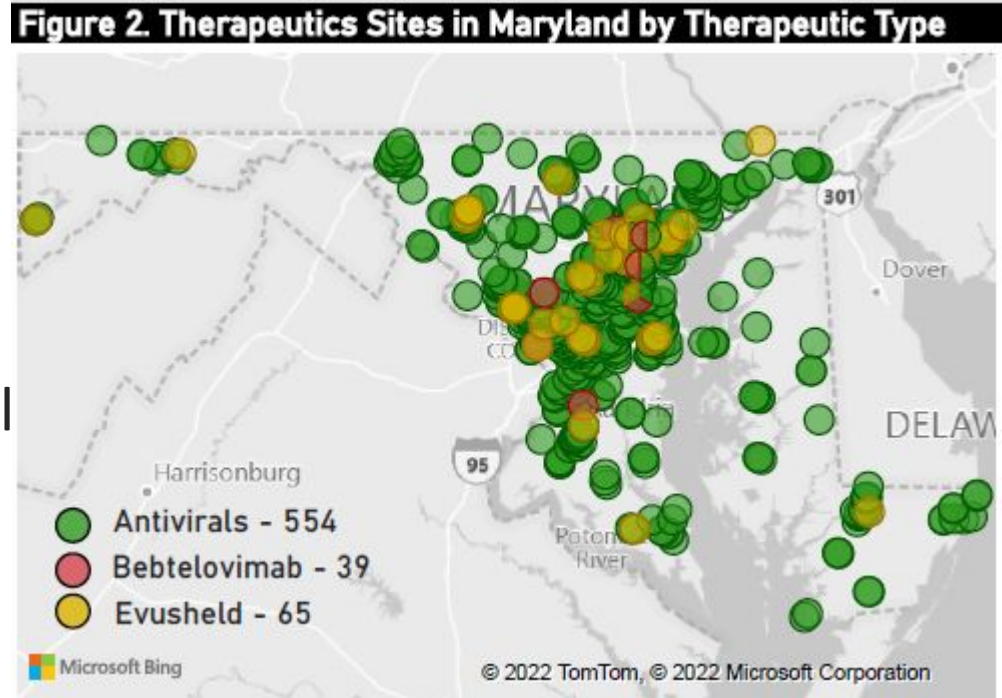
❖ 88 Evusheld Providers

➢ Hospital/hospital systems. Specialty clinics, Infusion centers

Test to Treat (T2T) Sites

❖ "One-stop shop" for rapid testing, clinical evaluation, oral antiviral treatment for those who are eligible
❖ 81 T2T sites in Maryland
➢ Federal
   ■ 44 CVS/pharmacy MinuteClinics
   ■ Independent pharmacies
➢ State
   ■ Urgent Cares
   ■ Medical Practices
   ■ 2 Hospitals
   ■ 1 Community Health Center

Figure 1. Therapeutics Sites for Test Treat Sites (T2T)
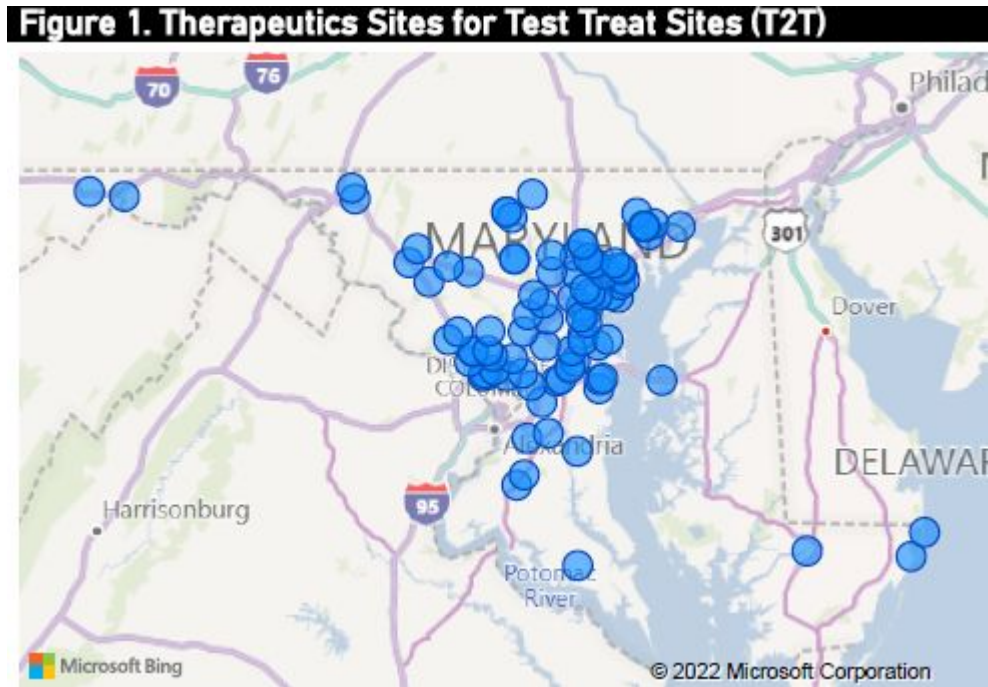
Provider-Based Sites

❖ Therapeutics team is actively adding practices that can effectively deploy therapeutics

❖ Evusheld
  ➢ Hospitals & health systems, <mark>asthma/allergy,</mark> <mark>rheumatology, GI, dermatology, hematology/oncology providers</mark>

❖ Antivirals
  ➢ Pharmacies, urgent care clinics, large health centers
  ➢ Test to Treat: urgent care clinics, <mark>provider offices</mark>

❖ Monoclonal Antibodies
  ➢ Hospitals & health systems, infusion centers that can accept outside referrals

If interested in becoming a therapeutic provider, email Danielle.Lohan1@maryland.gov to initiate the process.

Driving Therapeutics Utilization

1 Provider Communications

- Biweekly Provider Memo
- Biweekly MHA Stakeholder Call
- Primary Care Program Webinar
- Direct Calls (ad hoc)
- CovidLink Provider Resources Page

2 Constituent Outreach

- CovidLink Treatment Options Page
- CovidLink FAQs
- 30-second TV spot, part of Max Your Vax campaign
- Flyer (T2T)
- Contact tracing text message link and script
- Social media

3 General Resources

- HHS/ASPR Test to Treat website
- BCCFH Self-Referral Link
- Hatzalah Evusheld Self-Referral Link

4 Outreach Strategies

- MDH Therapeutics Team primarily relies on provider outreach to disseminate information
- Providers are asking for additional support in raising public awareness for COVID therapeutics

The therapeutics team is driving utilization through communication efforts with providers, constituents, and the public.

Call to Action

Point-of-Care Tests

❖ [Order](#) and use point-of-care tests to rapidly diagnose <u>symptomatic</u> patients

❖ Tests can be conducted outside of a lab setting including congregate care facilities, physician offices, etc. Results typically ready in ~ 15 minutes

❖ Note: The FDA has updated and expanded the expiry dates for the Abbott BinaxNOW tests

➢ Further information including kit lot numbers, original expiration dates, and updated expiration dates can be found [here](#)

Key Points

> ***Timing is critical*** → ***the sooner the better***

❖ Point-of-care tests are free and available for provider offices

❖ Utilize the [NIH guidelines for prioritization](#) of therapeutics

❖ Supply of Paxlovid and other therapeutics is plentiful

❖ Refer eligible patients for Paxlovid, other oral antivirals, and Bebtelovimab

➢ Paxlovid [Point-of-Care Reference Guide](#)

❖ Therapeutics are essential in decreasing hospitalizations and deaths from COVID

❖ Primary care practices can link diagnosis and treatment using existing infrastructure

Call to Action

1. Inform all patients of availability of COVID treatment. Identify all eligible patients **as early as possible- home tests are acceptable**

2. **Prescribe, dispense and or refer for appropriate therapies** as early in the patient course as possible- **<u>requires clinical decision making</u>**

3. Consider stocking therapeutics on-site

   - Contact Danielle.Lohan1@maryland.gov if you are interested in stocking therapeutics

4. Tell us what you think: [Fill out 5-question survey](#)

Questions and Answers

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CME

CME Accreditation and Designation

❖ This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of MedChi, The Maryland State Medical Society, and The Maryland Department of Health. MedChi is accredited by the ACCME to provide continuing medical education for physicians.

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❖ Presenters and Planners: Howard Haft, MD, has reported no relevant financial relationships to disclose.

❖ MedChi CME Reviewers: The reviewers from the MedChi Committee On Scientific Activities (COSA) for this activity have reported no relevant financial relationships to disclose.

❖ *Attendees can receive CME credit by completing [this evaluation](#) after each webinar. MedChi will then be in contact with the certificate*

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Appendix

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Vaccine Resources

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General Vaccine Resources

❖ CDC Covid-19 Vaccination Communication Toolkit - ready made materials, how to build vaccine confidence, social media messages

❖ New York Times Vaccine Tracker - information on every Covid vaccine in development

❖ New York Times Vaccine Distribution Tracker – information on the distribution of Covid vaccines in the United States

❖ MDH Covidlink Vaccine Page - information on vaccine priority groups in Maryland

❖ CDC Vaccine Storage and Handling Toolkit

❖ Project ECHO Webinar - webinar on vaccines and Long Term Care Facilities, relevant for primary care

❖ CDC Moderna vaccine storage

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Outreaching to Patients

❖ Information and education

➢ [Public Health Collaborative toolkit](#) for 5-11 Pfizer vaccines

➢ [Public Health Collaborative toolkit](#) for COVID-19 boosters

➢ [Public Health Collaborative messaging](#) for Omicron variant

❖ Communication resources

➢ *New: Free Johns Hopkins University COVID Vaccine Ambassador Training

✔ [Coursera link](#)

➢ The National Hispanic Medical Association - [Vaccinate for All Toolkit](#) (available in [Spanish](#))

➢ [Vaccine Communication & Outreach Strategies in Primary Care](#)

Stay "Up To Date" with Vaccines

❖ The CDC is now using the term "<u>Up To Date</u>" to indicate individuals that have obtained their primary COVID-19 vaccine series and any eligible booster doses

➤ Examples of patients that are **up to date**:

■ 12+ patient has obtained doses 1 and 2 of Pfizer and a booster dose five months later

■ 18+ patient that is immunocompromised has obtained doses 1, 2, and 3 of Moderna and a booster dose five months later

➤ Examples of patients that are **not up to date**:

■ 18+ patient has *only* obtained doses 1 and 2 of Moderna more than five months ago

❖ Definition of "fully vaccinated" indicates individuals that have completed the primary series

Pfizer 'Gray Cap'

❖ Beginning 12/23, a new Pfizer vaccine formulation will become available (Pfizer Tris-sucrose Adult Formulation)

❖ For all 12+ individuals

❖ Changes to ordering and handling:
   ➢ They will have a gray cap
   ➢ Will be available in smaller 300-dose configuration
   ➢ Does not require diluent
   ➢ May be stored at 2-8°C(36-46°F) for up to 10 weeks

Practices should use current remaining Pfizer inventory before ordering the Tris-Adult formulation

More on 'Gray Cap'
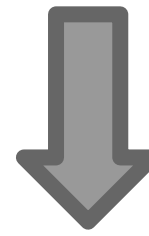
Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older[1,2]	12 years and older[3]	5 through 11 years[4] ("Age 5y to <12y" on vial label)
Vial Cap Color	Purple	Gray	Orange
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial*	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)

❖ Pfizer Vaccine Formulation/Presentation Guide
❖ Pfizer trainings are ongoing and additional information is in the announcements section of this slide deck

Heterologous Dosing - Mixing and Matching

❖ The CDC has now advised that booster doses can be a different vaccine type than the primary series

  ⬜ Ex: An individual that originally obtained Moderna for doses 1 and 2, can now obtain Moderna, Pfizer, or J&J for a booster if they are eligible for a booster dose

❖ All Moderna booster doses are a **half dose**, regardless of the individual's primary vaccine type

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Therapeutics Information and Resources

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Moderate to Severe Immunocompromise

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
- Additional information on immunocompromised classifications can be found on the CDC website here

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Monoclonal Treatment Eligibility

❖ **Who Qualifies for Treatment?**

➢ **mAb treatment is for adults and adolescents (12 and older) who:**

✓ Recently tested positive for COVID-19

✓ Are within 10 days of first experiencing symptoms

✓ Do not need to be hospitalized for COVID-19

✓ Weigh at least 88 pounds

➢ **Are in one of the following high-risk categories:**

✓ Are age 55 to 64 AND have cardiovascular disease, hypertension, chronic respiratory diseases or COPD

✓ Have diabetes, obesity, kidney disease or other serious chronic conditions

✓ Are 65 years old or older

✓ Are pregnant

✓ For adolescents: high BMI, sickle cell disease, heart disease, neurodevelopmental disorders, a medical-related technological dependence, asthma or other chronic respiratory disease

✓ Or who have been determined by their healthcare provider to be at high risk for worsening and/or hospitalization

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[NIH Guidelines](#) on Prioritization Patient Level

❖ Treatment only now

   ➢ No PEP with Sotrovimab

❖ Unvaccinated over vaccinated

❖ Other priorities to consider

   ➢ Early in course

   ➢ B cell abnormalities

   ➢ Solid organ transplants

   ➢ Severe underlying conditions

Tier	Risk Group
1	• Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); *or* • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
2	• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
3	• Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.
4	• Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.

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Source: [NIH](#)

Patient Facing Resources

❖ Website
  ➢ Landing page-- general page
  ➢ FAQ-- detailed information about mAb
❖ Contact tracing
  ➢ Direct text message to all contacts and people with positive tests (ages 18+) linking to Landing Page (Eng. & Sp.)
  ➢ mAb information sent to Interviewed Cases & Exposed Contacts at conclusion of contact tracing interview
❖ Site Access and PEP status
  ➢ Flyer with treatment location list, PEP information, and self-referral information

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Provider-Facing Resources

❖ Webinars - over 100

❖ Clinician Letters

➤ "Checklist" to assist providers in determining patient eligibility for mAbs.

❖ Ease in making referral

➤ Option 1: CRISP eREFERRAL for Monoclonal Antibody Infusion

➤ Option 2: Maryland Referral Form for Monoclonal Antibody Infusion Treatment (Updating to include sites where PEP is available)

➤ Some sites allow patients to self-refer for evaluation (listed on referral materials)

Practice mAb Referral Workflow

1) Daily, go into the CRISP ENS PROMPT to view new positive Covid-19 test results for your patients

2) For Covid-positive patients, assess every patient for mAb eligibility

3) For eligible patients, call the patient to recommend mAb treatment

   a) See this patient-facing website

4) Refer the patient to mAb treatment through CRISP or externally
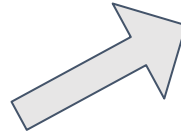
Paxlovid is **contraindicated** with **drugs that are highly dependent on CYP3A for clearance** and for which elevated concentrations are associated with serious and/or life-threatening reactions

- Alpha$_1$-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: Dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

Paxlovid is **contraindicated** with **drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance**. Paxlovid _cannot_ be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort

Source: FDA Fact Sheet

Paxlovid Prescribing Resources

1. [PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers](#)
   a. https://www.fda.gov/media/158165/download
2. People with Certain Medical Conditions
   a. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
3. [University of Liverpool COVID-19 Drug Interactions](#): **(Downloadable App available)**
   a. https://covid19-druginteractions.org/checker
4. [Pfizer Drug Interaction Checker](#):
   a. https://www.pfizermedicalinformation.com/en-us/drug-interaction-checker?product=PAXLOVID%E2%84%A2+%7C+nirmatrelvir+tablets%3B+ritonavir+tablets&product2=Alfuzosin
5. [NIH COVID-19 Treatment Guidelines - Ritonavir-Booster Nirmatrelvir (Paxlovid)](#):
   a. https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ritonavir-boosted-nirmatrelvir--paxlovid-/
6. [CDC/IDSA COVID-19 Clinician Call: All About Paxlovid; Plus Variants Update](#):
   a. https://www.idsociety.org/multimedia/clinician-calls/cdcidsa-covid-19-clinician-call-all-about-paxlovid-plus-variants-update/
7. [FDA Updates for Paxlovid Prescribers](#):
   a. https://www.fda.gov/drugs/news-events-human-drugs/fda-updates-paxlovid-health-care-providers

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Evusheld Availability

❖ PCPs can contact one of the following hospitals that receives an allocation to determine if referrals are possible:

Adventist Healthcare Fort Washington Medical Center	Luminis Doctors Community Medical Center
Adventist Healthcare Takoma Park Campus	Luminis Health Anne Arundel Medical Center
Adventist Shady Grove Medical Center	Mercy Medical Center
Adventist White Oak Medical Center	Meritus Medical Center
Atlantic General Hospital	Sinai Hospital
CalvertHealth Medical Center	Tidalhealth Peninsula Regional
ChristianaCare Union	UMMC
Franklin Square Hospital	UPMC Western Maryland
Frederick Health Hospital	National Institute of Health
Garrett Regional Medical Center	Hatzalah of Baltimore
Johns Hopkins Health System	St Agnes Hospital
Kaiser Permanente	

Testing

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Refer for Testing

❖ Use [this toolkit](#) to guide testing protocols and communication

❖ Consider PCR testing for asymptomatic patients

➢ Review [this webinar](#) (beginning at 51:00) for PCR testing options

❖ Refer patients for testing at [one of these sites](#)

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New CDC Quarantine and Isolation Guidelines

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New CDC Quarantine and Isolation Guidelines

If You Test Positive for COVID-19 (Isolation)

Everyone, regardless of vaccination status:

- Stay home for 5 days
- If asymptomatic after 5 days, you can leave your house
- Continue to wear a mask around others for 5 additional days
- You may test at day 5 and without symptoms:
  - If positive, continue to isolate to day 10
  - If negative, end isolation and continue to wear a mask around others until day 10

If you have a fever or other symptoms, continue to stay home until symptoms resolve

(Quarantine guidelines on next slide)

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Source: CDC, CDC

New CDC Quarantine and Isolation Guidelines

If You Were Exposed to Someone with COVID-19 (Quarantine)

If you are unvaccinated or overdue for a booster:

- Stay home for 5 days. After that continue to wear a mask around others for 5 additional days.
- If you can't quarantine you must wear a mask for 10 days.
- Test on day 5 if possible.

If you develop symptoms, get a test and stay home.

If you are vaccinated and boosted:

- Wear a mask around others for 10 days.
- Test on day 5, if possible.

If you develop symptoms, get a test and stay home

Source: CDC

Quarantine in High-Risk Congregate Settings

High-Risk Congregate Settings:

Everyone, regardless of vaccination status:

- High-risk congregate settings that have a high risk of secondary transmission
    - Examples: Correctional facilities, detention centers, homeless shelters, and cruise ships
- Residents quarantine for 10 days regardless of vaccination and booster status
- CDC setting-specific guidance

Source: CDC

Maryland's Official Health Insurance Marketplace: Open Enrollment Information

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General Resources and Links

Available and Free PPE

❖ MDH has free and available PPE

➢ Supplies that are available include KN95 masks and N95 masks

❖ To request free PPE, fill out pages 3-4 of this [PPE request form](#) and submit the information to your local Health Department contact listed on pages 1-2

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COVID-19 mAb Treatment Criteria

❖ Patient Criteria

➢ Use clinical judgment

➢ Have BMI >= 35

➢ Have chronic kidney disease

➢ Have diabetes

➢ Are currently receiving immunosuppressive treatment

➢ Are >= 65 years old

➢ Are >=55 years old and have

■ Cardiovascular disease, or

■ Hypertension, or

■ Chronic obstructive pulmonary disease/other chronic respiratory disease

➢ Are 12 – 17 years old AND have

■ BMI >=85th percentile for their age and gender based on CDC growth charts, or

■ Sickle cell disease, or

■ Congenital or acquired heart disease, or

■ Neurodevelopmental disorders, or

■ A medical-related technological dependence, or

■ Asthma

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Source: FDA

Scheduling In-Office Appointments

❖ Patient calls in for an appointment

➤ Reception screens patient on the phone using the [pre-visit screening template](#)
➤ Schedule in-office visits for different groups: At-risk and vulnerable patients on certain days, healthier patients on other days
➤ Schedule telehealth and non-office-based care for other patients including follow-ups and patients uncomfortable with office visits

❖ Check In

➤ Practice remote check in and limited front-desk contact
➤ Consider using a triage zone outside of office or main area;
➤ Or use a barrier at the front desk
➤ Design your office to accommodate patients who come in specifically for Covid testing and triage, separate from patients who arrive for non-Covid related and elective procedures
  ■ Ensure patients and staff do not cross between Covid and non-Covid areas
  ■ Set aside a specific area for patients who come in for testing to wait and be triaged

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Scheduling In-Office Appointments

❖ Checking out

  ➢ Practice remote check out, limit front desk exposure;

  ➢ Or use a barrier at the front desk

❖ If patient is paying co-pays, etc., set up credit card reader outside of the barrier

❖ Other workflow resources

  ➢ [Care management workflows](#)

  ➢ [BMJ telemedicine workflow graphics](#)

  ➢ [CDC flowchart to identify and assess 2019 novel Coronavirus](#)

  ➢ [CDC telephone evaluation flow chart for flu](#)

  ➢ [CDC guidance for potential Covid-19 exposure associated with international or domestic travel](#)

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CDC Guidelines for Covid Patient Management

❖ Healthy people can be monitored, self-isolated at home

❖ People at higher risk should contact healthcare providers early, even if illness is mild

❖ Older adults and people with severe underlying chronic medical conditions are at higher risk, need closer contact

❖ Emergency Department and hospitals only when needed - not for screening or low risk/minimal disease

Guidelines are important and powerful tools, but remember providers' clinical experience and judgment are key to care

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Personal Protective Equipment (PPE) Sources and Requests

❖ Practices should initially request PPE through their usual vendors

❖ Practices should make their PPE requests through their local health departments

❖ Maryland PPE Manufacturers List – next slide

❖ National and international PPE supplier list

❖ PPE request form

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Personal Protective Equipment (PPE) Sources and Requests

❖ Increasing Maryland's supply of PPE – one of the 4 building blocks on the Road to Recovery

❖ Maryland has launched the [Maryland Manufacturing Network Supplier Portal](#), an online platform that helps connect Maryland suppliers with buyers in need of critical resources

❖ For additional business resources during Covid-19, visit [businessexpress.maryland.gov/coronavirus](#)

❖ Providers may also request PPE from the non-profit ['Get Us PPE'](#)

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Provider/Patient Mental Health Resources

❖ Providers

➢ "Helping the Helpers and Those They Serve," a [webinar series](#) from the Maryland Department of Health Behavioral Health Administration and MedChi

➢ [Heroes Health Initiative](#)

❖ Patients

➢ [Ask Suicide-Screening Questions toolkit](#)

➢ CDC [list of resources](#) for coping with stress

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Health Equity Resources

❖ Maryland Department of Health Office of Minority Health and Health Disparities (MHHD)

❖ Maryland Department of Health Minority Outreach and Technical Assistance Program overview

❖ MHHD fiscal year 2020 minority outreach and technical assistance program information

❖ Description of the term "health disparity"

❖ Implicit bias test

❖ "Hundreds of Days of Action as a Start to Address Hundreds of Years of Inequality" – New England Journal of Medicine article by Maulik Joshi, DrPH

❖ "Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine" – discussion draft for public comment by Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, The National Academies of Science, Engineering, Medicine

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Telehealth Resources

❖ [Maryland Health Care Commission Telehealth](#)

❖ [Maryland Health Care Commission Telehealth Readiness Assessment Tool](#)

❖ [U.S. Department of Health and Human Services Health Insurance Portability and Accountability Act (HIPAA) for Professionals](#)

❖ [American Telehealth Association](#)

❖ [Maryland Telehealth Alliance](#)

❖ [National Consortium of Telehealth Resource Centers](#)

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Support for Patients at Home

❖ Food

  ➢ Meals on Wheels

❖ Caregivers

  ➢ Visiting nurses and caregivers

❖ Emotional support

  ➢ Support from family

  ➢ Phone calls and video chat to fight loneliness

  ➢ MD Department of Aging Senior Call Check Program

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Food Resources

❖ Nutrition: Inform patients that children can receive three free meals/day at sites listed on:

➢ Maryland Summer Meals   Howard County

➢ Montgomery County   Anne Arundel County

➢ Prince Georges County   St. Mary's County

➢ Charles County   Harford County

➢ Frederick County   Calvert County

❖ Free meals available from 42 rec centers in Baltimore

➢ Call 311 for locations and to schedule pickup time

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Resources for Specific Groups

❖ Community- and Faith-Based Organizations (https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-community-faith-organizations.html)

❖ Mass Gatherings and Large Community Events (https://www.cdc.gov/coronavirus/2019-ncov/community/mass-gatherings-ready-for-covid-19.html)

❖ Non-Pharmaceutical Interventions for Specific Groups (https://www.cdc.gov/nonpharmaceutical-interventions/index.html)

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Resources and References

❖ Maryland Department of Health Coronavirus Website (https://coronavirus.maryland.gov)

❖ CDC Coronavirus Website (https://www.cdc.gov/coronavirus/2019-nCoV/index.html)

❖ CDC National data on Covid-19 infection and mortality (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html)

❖ CDC Interim Guidance for Homes and Communities (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html)

❖ CDC Interim Guidance for Businesses (https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-business-response.html)

❖ CDC Interim Guidance for Childcare and Schools (https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-for-schools.html)

❖ CDC Travel Website (https://wwwnc.cdc.gov/travel/)

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Articles

❖ "Effectiveness of Mask Wearing to Control Community Spread of SARS-CoV-2"

❖ "COVID-19 Vaccines vs Variants—Determining How Much Immunity Is Enough"

❖ "SARS-CoV-2–Specific Antibodies in Breast Milk After COVID-19 Vaccination of Breastfeeding Women"

❖ "Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study"

❖ "Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy"

❖ "Sequelae in Adults at 6 Months After COVID-19 Infection"

❖ "How COVID-19 Affects the Brain"

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