



COVID-19 Therapeutics Team | Weekly Provider Updates

February 3, 2022

Dear Clinician,

We write to you to provide updates on COVID-19 therapeutic drugs that are available for outpatients in Maryland and inform you of the updated guidance for COVID-19 therapeutics.

Policy & Program Updates

As a reminder, due to Omicron being the dominant variant of concern (VOC), the U.S. Food and Drug Administration (FDA) [updated the Emergency Use Authorization \(EUA\) fact sheets](#) authorization for two monoclonal antibodies: bam/ete and REGEN-COV. These treatments are not authorized for use anywhere in the United States due to their ineffectiveness against the Omicron variant. Subsequently, HHS/ASPR will not include bam/ete and REGEN-COV in state allocations of COVID-19 therapeutics.

Sites Receiving a New Product Allocation Starting this week beginning 1/31/22:

MDH Allocations take into consideration utilization, supply on hand, equity, and other available treatments such as if the site is receiving monoclonal antibodies.

- Evusheld: Zion Ambulatory Center and Soleil Pharmacy
- Molnupiravir: Apple Discount Drugs, Medley Pharmacy, and LifeLine Pharmacy

Updates on Monoclonal Antibodies (mAb) – referral resources found in the appendix

- **Sotrovimab** is the only mAb that is currently authorized for treatment of COVID-19 (not authorized for post-exposure prophylaxis). Supply is allocated to Maryland weekly from the Federal government and this week Maryland received a very limited allocation.
 - Where appropriate, consider utilizing antiviral therapy when sotrovimab is unavailable.
- **Evusheld** is distributed to hospital and health system sites for moderately to severely immunocompromised patients as a pre-exposure prophylaxis monoclonal antibody (supply controlled by the Federal government). It is not a substitute for vaccination.
 - Many sites are now accepting community provider referrals for Evusheld. Please reference Appendix A for a listing of sites accepting referrals and Appendix B for the referral forms.

Updates on Oral Antiviral Agents – prescribing information found in the appendix

- **Paxlovid** and **Molnupiravir** are now available to individuals with mild to moderate COVID-19 illness who are at high risk for progression to severe COVID-19.

- Additional information can be found in the [Paxlovid Point-of-Care Reference Guide](#).
- Oral antivirals are currently allocated to pharmacies on a biweekly basis (supply controlled by the Federal government).
- In order to avoid sending prescriptions and patients to a pharmacy that has depleted its stock, the Federal government has provided a [COVID-19 Therapeutics Locator](#) that is updated on a daily basis. Please check these prior to sending prescriptions to pharmacies to ensure the product is available. The updated information may lag behind actual inventory levels depending on the frequency of reporting by the pharmacy to HHS.

Updates on Other Therapeutics

- **Remdesivir's** [EUA](#) was recently expanded to allow for outpatient treatment in adult and pediatric patients (all ages, weighing at least 3.5kg or 7.7lbs). This agent is now available for order by both hospital and non-hospital providers, pending release to be provided by the producer, Gilead Pharmaceuticals. Email c19therapies@amerisourcebergen.com to get started with the ordering.
- If there are questions regarding insurance coverage/payment of Remdesivir, please reference the [Medicare Administrative Contractors \(MACs\)](#) information.

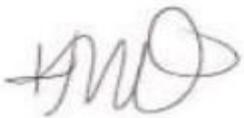
Reminders

Supplies of therapeutics are limited. MDH recommends providers follow the [NIH COVID-19 Treatment Guidelines](#) developed for prioritization of COVID-19 therapeutics. If a monoclonal antibody treatment is unavailable, consider using antiviral therapy where appropriate.

Early COVID-19 testing and rapid return of results are critical. Diagnosis of COVID-19 symptomatic patients with rapid antigen tests has been demonstrated to be both sensitive and specific. These tests can be done in providers' offices, at testing sites, or by home testing kits.

Thank you for your ongoing work and continuous support for patients across Maryland as we collaborate efforts to prevent and mitigate the impacts of COVID-19.

Sincerely,



Howard Haft, MD, MMM, CPE, FACPE
Executive Director
Maryland Primary Care Program

Appendix A: COVID-19 Therapeutics and Indications

Evusheld

The FDA issued an EUA on December 8, 2021 for AstraZeneca's Evusheld for pre-exposure prophylaxis (i.e., prevention) of COVID-19 in certain individuals ages 12 or older and weighing at least 40 kg [about 88 lbs] who are immunocompromised but uninfected and have not been exposed to COVID-19. Evusheld is not a replacement for vaccination and can be used for individuals who have medical contraindications to or allergic reactions when receiving any COVID-19 vaccines. Evusheld can be repeated in six months if there is still circulating SARS-2 coronavirus in the region.

The following is the [FDA list of conditions](#) from the EUA that may result in impaired ability to mount an immune response to vaccines:

- 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, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV); and
- 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.

Providers interested in referring their patients for treatment should contact:

Adventist Health System (internal referrals only)	Luminis Health Anne Arundel Medical Center
Atlantic General Hospital	Mercy Medical Center (contact COVIDAntibody@mdmercy.com to refer)
Calvert Health Medical Center (fax CalvertHealth referral form attached to 410-535-8224 or send referral form to COVIDTX@calverthealthmed.org)	Soleil Pharmacy (fax rx and supporting diagnosis information to 410-582-8728 to initiate referral)
ChristianaCare Union	Sinai Hospital
MedStar Health System (contact rebecca.n.kumar@gunet.georgetown.edu , calvin.williams@medstar.net , or glenn.w.wortmann@medstar.net to discuss referral)	Tidalhealth Peninsula Regional (internal referrals through EPIC, or fax TidalHealth referral form attached to 410-543-7485)
Frederick Health Hospital	University of Maryland Medical System

Meritus Medical Center (referral form link)	UPMC Western Maryland
Johns Hopkins Health System	National Institutes of Health
Kaiser Permanente	Hatzalah of Baltimore (provider referral link)
Luminis Doctors Community Medical Center	St Agnes Hospital (Accepting referrals by staff providers only to cancer center)
Zion Ambulatory Care (email zioninfusions@gmail.com or call 443-505-4035 to initiate referral)	Garrett Regional Medical Center (fax rx and supporting diagnosis information to 301-533-4102 to initiate referral)

Sotrovimab (An infusion monoclonal therapeutic agent, by referral)

Sotrovimab received an EUA from the FDA for the treatment of nonhospitalized COVID-19 patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease. In the clinical trials for these agents, anti-SARS-CoV-2 mAbs reduced the risk of hospitalization or death by 70% to 85% compared to placebo. In-vitro studies indicate that sotrovimab remains active against the Omicron variant.

View the [most recent provider referral form](#) for monoclonal infusion sites for sotrovimab and the [CRISP electronic referral starter guide](#) for guidance on referrals.

Remdesivir (An infusion antiviral therapeutic agent, by prescription)

Remdesivir was studied in nonhospitalized patients with mild to moderate COVID-19 who were at high risk of progressing to severe disease. The [PINETREE study](#) depicted that 3 consecutive days of IV remdesivir resulted in an 87% relative reduction in the risk of hospitalization or death compared to placebo. Remdesivir is expected to be active against the Omicron VOC, although in-vitro and in-vivo data are currently limited. Considering remdesivir requires IV infusion for 3 consecutive days, there may be logistical constraints to administering remdesivir in many settings, but it is an option if other therapeutics are not available.

Remdesivir is currently approved by the FDA for use in hospitalized individuals and has recently been authorized for outpatient use for treatment of non-hospitalized patients at high risk for COVID-19 disease progression within seven days of onset of symptoms. The State has begun providing this agent to pharmacies that serve congregate care facilities. Additional access by non-hospital pharmacies is now available to providers with active ABC accounts. Email c19therapies@amerisourcebergen.com to get started with the ordering.

Oral Antivirals

Summary Points:

- Oral antivirals must be used as soon as possible and **within 5 day of symptom onset.**

- Paxlovid has significant drug interactions. It is essential to complete medication review before prescribing this medication. Additional information can be found in the [Paxlovid Point-of-Care Reference Guide](#).
- Molnupiravir should be used only when alternative options are not available.
- Visit [COVID-19 Public Therapeutic Locator](#) to identify potential pharmacies that may have Paxlovid and Molnupiravir available to the community.
- Prior to sending the prescription to the pharmacy, it is strongly recommended that the prescriber call **the pharmacy and speak with the pharmacist**. Conversation with the pharmacist allows the confirmation of inventory and promotes the collaboration with the prescriber. This is especially valuable when sending to a pharmacy that the patient typically does not use, so that medication interactions can be reviewed.

Paxlovid (An oral antiviral therapeutic agent, by prescription)

Paxlovid received EUA from the FDA on December 22, 2021. The drug is indicated for the treatment of COVID-19 among diagnosed patients ages 12 and over who weigh 40 kg or more, are within 5 days of the onset of symptoms, have mild to moderate symptoms, and do not require hospitalization but are at risk for progression to severe disease based on underlying conditions. It is taken as three pills twice a day for five days, and the full course is required to achieve the benefit of the medication.

Paxlovid has significant drug-drug interactions with many medications. Prescribers and pharmacists should carefully review the patient's medications to assure there is no interaction. In addition, Paxlovid must be renally dosed. More information about drug-drug interactions can be found in [The COVID-19 Treatment Guidelines Panel's Statement Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir \(Paxlovid\) and Concomitant Medications](#).

Molnupiravir (An oral antiviral therapeutic agent, by prescription)

Molnupiravir received EUA from the FDA on December 23, 2021. The drug is indicated for the treatment of COVID-19 among patients ages 18 and over who weigh 40 kg or more, test positive for COVID-19, are within five days of the onset of symptoms, have mild to moderate symptoms, and do not require hospitalization but are at risk for progression to severe disease based on underlying conditions. Molnupiravir is not indicated during pregnancy. It is taken as four pills twice a day for five days, and the full course is required in order to achieve the benefit of the medication.

Due to its lower efficacy as well as potential safety concerns, Molnupiravir should only be considered when other options are not available. Molnupiravir is not recommended in pregnancy, given there may be a potential for mutagenicity. Molnupiravir is also not recommended in women of childbearing age or pediatric populations due to the limited data and potential bone growth toxicity in the pediatric population.

Prescribers may visit the [COVID-19 Public Therapeutic Locator](#) managed by the U.S. Department of Health & Human Services (HHS) to determine which pharmacies have these therapeutics. Paxlovid and Molnupiravir inventory information is updated daily at 6 AM. Area pharmacies have recommended the following be included on prescriptions sent in order to expedite the process and assure patient safety:

- **Do not dispense on or after this date (MM/DD/YYYY).** Paxlovid and Molnupiravir should be dispensed within 5 days from symptom onset.
- Paxlovid Only: Information about the Renal Function (i.e., eGFR) as paxlovid dose is adjusted based on renal function.

Appendix B: Evusheld Referral Forms

The following are the referral forms for Evusheld for Calvert Health, Soleil Pharmacy, and Tidal Health.

Evusheld (Tixagevimab and Cilgavimab) Order Set

Allergies:

No Known

Weight in kg:

Height:

Criteria for Use

*Clinical Indication (please select all that apply): Pre-exposure prophylaxis of coronavirus disease 2019 in adults who are not currently infected with SARS-CoV-2 and who have not had known recent exposure 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 COVD-19 or vaccination

Please check conditions that apply:

___ Active treatment for solid tumor and hematologic malignancies

___ Receipt of solid-organ transplant and taking immunosuppressive therapy

___ Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (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/mm³, 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 (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B cell depleting agents)

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 to a cCOVID-19 vaccine and/or COVD-19 vaccine component

MEDICATIONS:

Evusheld (Tixagevimab 150 mg/1.5 mL and Cilgavimab 150 mg/ 1.5 ml) administered as separate, consecutive intramuscular injections x 1

Monitor the patient clinically for at least 1 hour

LIP Signature: _____ **Date:** _____ **Time:** _____

Printed name of referring Provider _____

Contact Phone number _____

All Entries MUST be LEGIBLE

Illegible orders will not be honored without clarification. Authorization is given for dispensing an equivalent drug by generic name unless the drug prescribed is followed by the designation **Medical Necessity**.

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801 Landmark Drive, Suite B • Glen Burnie, MD 21061 • t. 443.281.9157 • f. 410.582.8728 • soleilpharmacy.com

COVID-19 Pre-Exposure Prophylaxis Order Form (EVUSHELD)

First Name: _____ Last Name: _____ Date of Birth: ____/____/____
Age: _____ Sex: Male Female Other Phone: _____ SSN: _____
Height: _____ Weight: _____ Street Address: _____
City: _____ State: _____ Zip: _____

Indication - Emergency Use Authorization (non-FDA approved) for **pre**-exposure prophylaxis of COVID-19 in those not currently infected with SARS-CoV-2 and have not had a known recent exposure **and**:

- Have moderate-severe immune compromise **or**
- Cannot receive a COVID-19 vaccine due to history of severe adverse reaction (e.g. allergic reaction) to a COVID-10 vaccine and/or its components

Limitations of Use - Not authorized for:

- Treatment of COVID-19
- **Post**-exposure prophylaxis
- A substitute for vaccination
- Those recently vaccinated against COVID-19 (wait at least 2 weeks to administer EVUSHELD in these individuals)

Important Information:

- Patients must wait for a 1-hour observation and clinical monitoring period post administration (in case of serious hypersensitivity reaction)

Warnings:

- Hypersensitivity: Possible, as with any IgG1 monoclonal antibodies
- Bleeding disorders: As with any IM injection, use caution
- Cardiovascular events: Potential risk of MI and cardiac failure

Vaccination Status:

If vaccinated, indicate date of last vaccine: _____

- Fully vaccinated & boosted Fully vaccinated but not boosted Partially vaccinated Unvaccinated

Inclusion Criteria I - The patient must meet **ALL** of the following:

- 12+ years of age and weighing at least 40 kg
- Not currently infected with SARS-CoV-2
- Have not had a known recent exposure

Inclusion Criteria II - The patient must meet **ONE** of the following:

- Have moderate-severe immune compromise (due to a medical condition such as active cancer/advanced or untreated HIV/solid organ transplant or receipt of immunosuppressive medications or treatments)
- Cannot receive a COVID-19 vaccine due to history of severe adverse reaction (e.g. allergic reaction) to a COVID-10 vaccine and/or its components

Medication Order:

EVUSHELD - Tixagevimab 150mg/1.5mL & Cilgavimab 150mg/1.5mL (two separate, consecutive IM injections)

Prescriber Name

Prescriber Signature

Date

Time

Phone: (443) 281-9157 Fax: (410) 582-8728

801 Landmark Drive, Glen Burnie, MD 21061

TidalHealth Referral Form
Evusheld® for Covid-19 Pre-exposure Prophylaxis

Please complete the information on this referral form and upon completion **fax to 410-543-7485**

First Name: _____ Last Name: _____

DOB: _____ Age: _____ Sex: M F Other _____ Unknown

Patient's Preferred Language • English • Spanish • Other _____

Address: _____

City: _____ State: _____ County: _____ Zip: _____

Phone: mobile _____ home _____ Other _____

**Vaccination Status: _____

Allergies: _____ Other: _____

Please check appropriate boxes:

Approved use of tixagevimab plus cilgavimab (Evusheld) is for PrEP of Covid-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg):

- Not currently infected with SARS-CoV-2 (consider testing if any signs/symptoms present)
- Have not had a known recent exposure to an individual infected with SARS-CoV-2

AND

(Must check one below) Have a 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

- 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 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 your immune response

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 (severe allergic reaction) to a Covid-19 vaccine(s) and/or Covid-19 vaccine component(s)

- I, the referring provider, have discussed tixagevimab plus cilgavimab (Evusheld) therapy and the EUA status with the patient and the patient has consented to receive this treatment.
- I, the referring provider have arranged appropriate follow-up for this patient.
- Please initiate the hypersensitivity protocol as needed for any reaction to the treatment.

PROVIDER NAME (print)

PROVIDER SIGNATURE

DATE