Maryland
DEPARTMENT OF HEALTH

COVID-19 Therapeutics Team | Monkeypox Therapeutics Team
Updates

November 22, 2022

Dear Clinician,

We write to you to provide updated guidance on COVID-19 therapeutic medications that are available for outpatients in Maryland and also to inform you of relevant updates on Monkeypox therapy.

Update on COVID-19 Treatment Resistance with New Variants

On November 10, The Centers for Disease Control and Prevention (CDC) reported that certain SARS-CoV-2 Omicron subvariants circulating in the United States are increasing and are likely to be resistant to some anti-SARS-CoV-2 monoclonal antibodies (mAbs). In our region (Region 3), the dominant variants are BQ.1.1 (26.9%) and BQ.1 (23.2%), for a combined percentage of 50.1% (CDC Variant Proportions page, 11/19/2022)

- BQ.1 and BQ.1.1 are resistant to bebtelovimab
- BA.4.6, BA.2.75.2, BF.7, BQ.1, and BQ.1.1 are likely to be resistant to tixagevimab plus cilgavimab (Evusheld)

What Clinicians Can Do

- Discuss the possibility of lower treatment effectiveness with patients.
- Use Paxlovid, remdesivir, or molnupiravir which are currently available antiviral treatments and continue to retain activity against these new subvariants.
- Discontinue use of bebtelovimab for treatment of mild to moderate COVID-19.
- Consult the current NIH guidelines for Covid therapeutics.

Paxlovid, remdesivir, and molnupiravir are expected to be active against these resistant subvariants and are preferred treatments for COVID-19 disease. In order of treatment preference:

1) Ritonavir-boosted nirmatrelvir (Paxlovid) is recommended to treat adults and pediatric patients (≥12 years and ≥40 kg) with mild to moderate disease, starting within 5 days of symptom onset.
2) Remdesivir (Veklury)
    - Providers are encouraged to offer outpatient remdesivir (Veklury), especially for high risk and significantly immunocompromised patients for whom Paxlovid may not be clinically appropriate.
    - The FDA approved expanded use of remdesivir to certain non-hospitalized adults and pediatric patients (≥28 days and ≥3 kg) for treatment of mild-to-moderate COVID-19 disease, starting within 7 days of symptom onset.
    - Please contact Stephanie Vojtek at Stephanie.Vojtek@maryland.gov if you are

interested in becoming a remdesivir provider. Current remdesivir Provider Referral Information can be found in Appendices B and C.

3) Molnupiravir is recommended as an alternative option for adults within 5 days of symptom onset, but ONLY when the preferred therapies are not available, feasible to use, or clinically appropriate.

MPX Therapeutics

Monkeypox cases have declined since mid-August 2022 in the United States; however, new cases—including clinically severe cases —continue to occur. While there are currently no treatments specifically approved for monkeypox, therapeutics developed for patients with smallpox have been deployed during the current outbreak. The CDC recently published an update on managing monkeypox in patients receiving therapeutics. If your facility does not already have access to therapeutics and you are interested in obtaining them, complete the MPX Therapeutics site enrollment form. Providers with additional questions or concerns can contact 410-767-6700 during business hours or 410-795-7365 after hours and ask for the on-call physician.

Sincerely,

Howard Haft, MD, MMM, CPE, FACPE
Senior Medical Advisor, COVID-19 and MPX Therapeutics Team
Maryland Department of Health

Appendix A: Evusheld Provider Referral Information

Independent Providers/PCPs interested in obtaining a supply of Evusheld to administer to their patients should contact Stephanie Vojtek at Stephanie.Vojtek@maryland.gov. We will make our best effort to provide a supply Evusheld to all interested providers until we have exhausted our Federal allocation.

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	LifeBridge Health Hospitals (Internal referrals only)
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 (referral form attached to 240-566-3959, or provider referral link here)	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, patient self-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)
Chase Brexton Health	Holy Cross Hospital
FirstCall Medical Center (referral form attached)	Arthritis and Pain Associates of PG County (Call 301-345-5600 to discuss referral)
THRIVE Clinic at UM Midtown (Call 410-225-8369 to discuss referral)	

Appendix B: Remdesivir Provider Referral Information

Table 2. How to Refer a Patient for Remdesivir		
Baltimore City	BCCFH State Center: Infusion Site	Submit a form via secure, HIPAA-compliant upload.
Montgomery County	Adventist Takoma Park	Fax form to 301-891-6120, Crisp referral

Appendix C: Evusheld Referral Forms

See referral forms PDF for Evusheld for Calvert Health, Soleil Pharmacy, FirstCall Medical Center, and Tidal Health.

Monoclonal Antibody Infusion - EVUSHELD
Physician Referral Form

Referring Provider:_____ Date:_____

PCP Provider:_____ Phone #:_____

Patient Name:_____ DOB:_____

Patient Address:_____

City:_____State:_____Zipcode:_____

Phone #:_____

Email: _____

12 years or older _____Moderate or Severe

Immunocompromised

Height:_____Weight: _____BMI:_____

Allergies (Medication/ Food/ Seasonal) _____

_____

_____

Medical HX (pertinent to Evusheld administration): _____

_____

_____

Medications (please attach list to referral)

Date of Exposure/Symptoms:_____

Does the Patient require Oxygen YES or NO (L)_____

_____

Primary Insurance: _____Policy # _____

_____ Group #_____ (staff must obtain copy of card)

Secondary Insurance:_____Policy #_____

_____

Group # _____(staff must obtain copy of card)

FAX REFERAL TO 410-721-1207 OR EMAIL TO

INFUSIONCENTER@FIRSTCALLMEDICALCENTER.COM

443-459-1059 FOR QUESTIONS ABOUT SCHEDULING

Internal use only

Patient 's appointment _____

Patient insurance verified YES _____ NO _____

Patients Chart prepared_____

Allergy Questionnaire on patients chart_____

Registration Signature : _____

Date : _____

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

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 COIVD-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 COIVD-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 _____

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 _____