Maryland
DEPARTMENT OF HEALTH

COVID-19 Therapeutics Team | Weekly Provider Updates

January 27, 2023

Dear Clinician,

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

FDA Update Regarding Evusheld

The U.S. Food and Drug Administration (FDA) announced on January 26, 2023, that the Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) has been revised and based on this revision, Evusheld is not currently authorized for use in the U.S. This is because it is unlikely to be active against more than 90% of the SARS-CoV-2 variants currently circulating in the U.S. based on the latest CDC data.

According to the most recent CDC Nowcast data, certain SARS-CoV-2 variants are projected to make up more than 90% of the variants currently circulating in the U.S. This means that Evusheld is not expected to provide protection against developing COVID-19 if exposed to those variants. Given that a COVID-19 infection is likely to be caused by one of these non-susceptible variants, and consistent with the terms and conditions of the Letter of Authorization, Evusheld is not currently authorized for emergency use in any U.S. region at this time. HHS and AstraZeneca have paused distribution of Evusheld until further notice by the Agency.

Prevalence of Variants

- According to CDC NowCast Data for the period 1/15/2023 - 1/21/2023, XBB.1.5 is at **59.7%** for **Region 3** (our region) followed by BQ.1.1 at 20.8%
- We are tracking behind Region 2. There current rate for XBB.1.5 is 86.8%
- The United States current rate for XBB.1.5 is 49.1%

Preferred Treatments for COVID-19

Paxlovid, remdesivir, and molnupiravir are expected to be active against these resistant subvariants and are preferred treatments for COVID-19. 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)
   On January 21, 2022, FDA approved expanded use of remdesivir (Veklury) to certain non-hospitalized adults and pediatric patients for the treatment of mild-to-moderate COVID-19 symptoms. According to the National Institute of Health (NIH) prioritization

guidelines, remdesivir is the second most preferred treatment option following Paxlovid. However, the administration of remdesivir poses logistical barriers as the recommended total treatment is 3 successive days of intravenous infusion. Remdesivir for outpatient treatment access in Maryland is currently limited to two sites: the infusion centers supported by the Maryland Department of Health (MDH) at BCCFH/State Center and the Alternate Care Site (ACS) Takoma Park.

- 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 the attached form.**

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.

Therapeutics Locator Tool to Include Outpatient Remdesivir Providers

- Initiative will allow visibility of Remdesivir outpatient infusion sites on the HHS COVID-19 Therapeutics Locator to assist in matching patients at high risk of severe COVID-19 to the medications that can prevent disease progression
- Any infusion site opting into this initiative will be featured on the COVID-19 Therapeutics Locator as an outpatient Remdesivir provider.
- To opt into this initiative, infusion sites can provide their information here

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
Senior Medical Advisor, Maryland Department of Health

Appendix A: Remdesivir Provider Referral Information

Table 1. How to Refer a Patient for Outpatient Remdesivir		
County	**Site**	**Referral Method**
Baltimore City	BCCFH State Center: Infusion Site **No cost to patients*	Submit a form via secure, HIPAA-compliant upload ***(preferred)***; call 410-649-6122, or fax attached form to 410-328-2349
Montgomery County	Adventist Takoma Park	Fax attached form to 301-891-6120

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Maryland Referral Form:
Outpatient Remdesivir (Veklury) Treatment for COVID-19

Please complete the information on this form if your patient could benefit from remdesivir treatment. This form should be sent to the infusion site with closest proximity to the patient.

**First Name: _____ ** Last Name: _____

**DOB: __/__/_____ **Age: _____ **Sex: ☐ M ☐ F ☐ Other _____ ☐ Unknown

**Patient's Preferred Language ☐ English ☐ Spanish ☐ Other _____

**Address Line 1: _____ Address Line 2: _____

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

**Phone: _____☐ cell ☐ home Secondary Phone: _____☐cell ☐home

**Allergies (medication/food/other):

**Please include a list of conditions that place this patient at risk of severe COVID-19 illness (you may free text or attach a recent clinic note or other documentation as necessary):

**Is the patient taking Plaquenil (hydroxychloroquine)? Please note that this medication theoretically reduces the efficacy of remdesivir. You may consider also prescribing molnupiravir for your patient if that is a safe and effective treatment.

**Is the patient pregnant or breastfeeding?

**Vaccination and Booster Status:

**Please explain why this patient cannot take Paxlovid:

The (**) indicates a required field.

Patient Eligibility

Please consider whether oral antiviral medications are appropriate for your patient before referring for remdesivir infusions; according to NIH guidelines, Paxlovid is the most preferred treatment option. Please see the NIH's patient prioritization framework to allow the highest risk patients to access remdesivir. Healthcare providers should consider the benefit-risk for an individual.

COVID-19 Treatment: Outpatient Remdesivir

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.

Indications:

☐ Treatment of mild-to-moderate COVID-19 infection in patients with positive results of a SARS-CoV-2 viral test and risk factors for progression to severe COVID-19 illness.

Date of positive COVID-19 test_____ Date of symptom onset _____

I, the referring provider, am the patient's Primary Care Provider (PCP) or other continuity provider and have arranged for the patient to follow up with me/my designee following remdesivir infusion. Or I am an ED or Urgent Care provider who will update the patient's PCP about his/her remdesivir infusion to arrange follow up. If the patient does not have a PCP, I will refer him/her to an appropriate provider and ensure that follow up has been arranged. [Note: Ideal timing of follow up visit is approximately 7 days post-infusion.]

** ☐ **Indicates Provider Agreement**

I, the referring provider, have advised or will advise the patient that if his/her clinical status declines by the time of the infusion appointment, the treatment may no longer be appropriate for him/her. The patient's clinical status will be re-evaluated at the infusion center at the appointment time. If the patient is deemed in need of hospital care, s/he will be referred immediately.

** ☐ **Indicates Provider Agreement**

I, the referring provider, agree to share this referral with either of the remdesivir infusion centers located in Baltimore and Takoma Park depending on travel distances and available appointments

** ☐ **Indicates Provider Agreement**

**Provider Signature: _____ Date: _____

The remdesivir infusion staff will communicate with the referring provider regarding such matters as treatment inappropriateness for patient, ultimate completion of treatment for patient, adverse events, or an alternative infusion site referral etc.

The (**) indicates a required field.

Information about remdesivir (Veklury) can be found here: prescribing information.

Name of Referring Site: _____

Point of Contact: _____

Address: _____

Phone Number: _____

Email address: _____

Fax Number: _____

Preferred mode of contact: ☐ Phone ☐ Fax ☐ Email

Patient's Primary/Continuity Care Provider (if different from above)

Office Name:_____

Address: _____

Phone Number: _____

Email address: _____

Fax Number: _____

Preferred mode of contact: ☐ Phone ☐ Fax ☐ Email

Remdesivir Provider Referral Information

County	Site	Associated Cost	Referral Method
Baltimore City	BCCFH State Center: Infusion Site *UMMC Downtown Campus* *Green St and Lombard St* *Baltimore MD 20912*	No cost to patients	Submit a form via secure, HIPAA-compliant online form ***(preferred)***; call 410-649-6122, or fax attached form to 410-328-2349
Montgomery County	Adventist Takoma Park *7600 Carroll Ave, Takoma Park, MD 20912*	No cost to patients	Fax attached form to 301-891-6120

The (**) indicates a required field.

Information about remdesivir (Veklury) can be found here: prescribing information.