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Covid-19 Therapeutics Update:

Maryland Department of Health

13 January 2022

NIH Guidance on Outpatient Therapeutic Preferences

1) Paxlovid first when no contraindications
2) Sotrovimab when available
3) Remdesivir – off label
4) Molnupiravir – if no other
5) Bam/etes or Regen-Cov if Delta

NIH guidelines link

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Paxlovid- Oral Antiviral

- FDA authorized an EUA for Paxlovid on 12/22
- USG purchased 10 million courses for first half of 2022
  - 960 doses for Maryland
- Eligibility
  - Intended for mild-to-moderate Covid in **12+ adults** weighing at least 40 kilograms that test positive and are at high risk for progression to severe Covid-19
  - Medication must be initiated within *5 days* of the onset of symptoms
- Study data
  - Paxlovid appears to reduce the risk of hospitalization and death by 89%
- Dosage information in FDA Fact Sheet

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Source: Pfizer, FDA EUA, FDA Fact Sheet

Sotrovimab- IV monoclonal antibody

- Ages 12 and over, 40 kg or more
- EUA for symptomatic high risk patients within first 10 days after od symptoms, sooner is better
- Reduces the risk of hospitalization and death 87% compared to placebo
- Allocated weekly by HHS to state, limited supply
- State allocates to infusion centers based on algorithm

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Remdesivir for Outpatient Therapy

- FDA off label use - currently only shipping to hospitals
- For individuals 12 years and older and weighing 40 kg or more
- Treatment
  - Remdesivir 200 mg IV on Day 1, followed by Remdesivir 100 mg IV daily on Days 2 and 3
  - Initiated as soon as possible and within 7 days of symptom onset
- Study data
  - 3 consecutive days of IV Remdesivir resulted in an 87% relative reduction in risk of hospitalization or death compared to placebo

Source: NEJM, FDA

Molnupiravir- Oral Antiviral

- FDA authorized an EUA for Molnupiravir on 12/23
- USG allocating 300,000 courses initially (3.1 million total)
  - 4,500 doses for Maryland
- Eligibility
  - Intended for mild-to-moderate Covid in **18+ adults** weighing at least 40 kilograms that test positive and are at high risk for progression to severe Covid-19
  - Medication must be initiated within *5 days* of the onset of symptoms
  - *Not indicated during pregnancy*- needs post use contraception
- Study data
  - Molnupiravir appears to cut the risk of hospitalization and death by 30%

Source: Merck, FDA EUA, FDA Fact Sheet

Evusheld - Long Acting Prophylaxis

- On 12/8, the FDA issued an EUA for Evusheld
  - Moderate to severe immune compromise
  - Unable to take vaccine due to severe allergy to all
  - IM dosing at 6 month intervals
  - Age 12 years and older
- Allocation
  - Began in late December, now increasing
  - Allocation directly to hospital partners
  - Prioritization programs at JHH and UMMS
  - Referrals done in hospitals
  - Referrals expanding as early as next week
- Clinician letter with hospital information sent out

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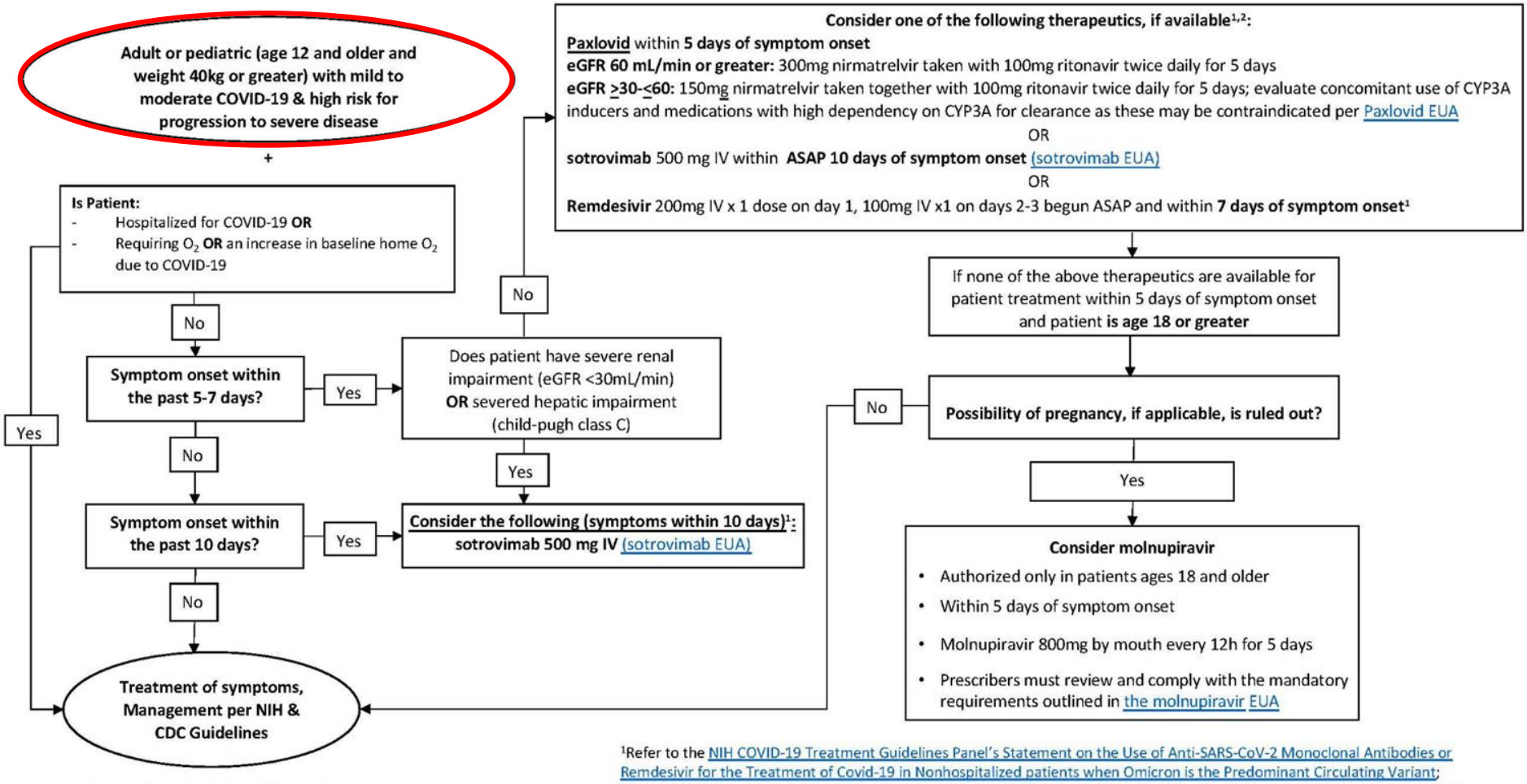
Source: FDA, FDA Fact Sheet



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

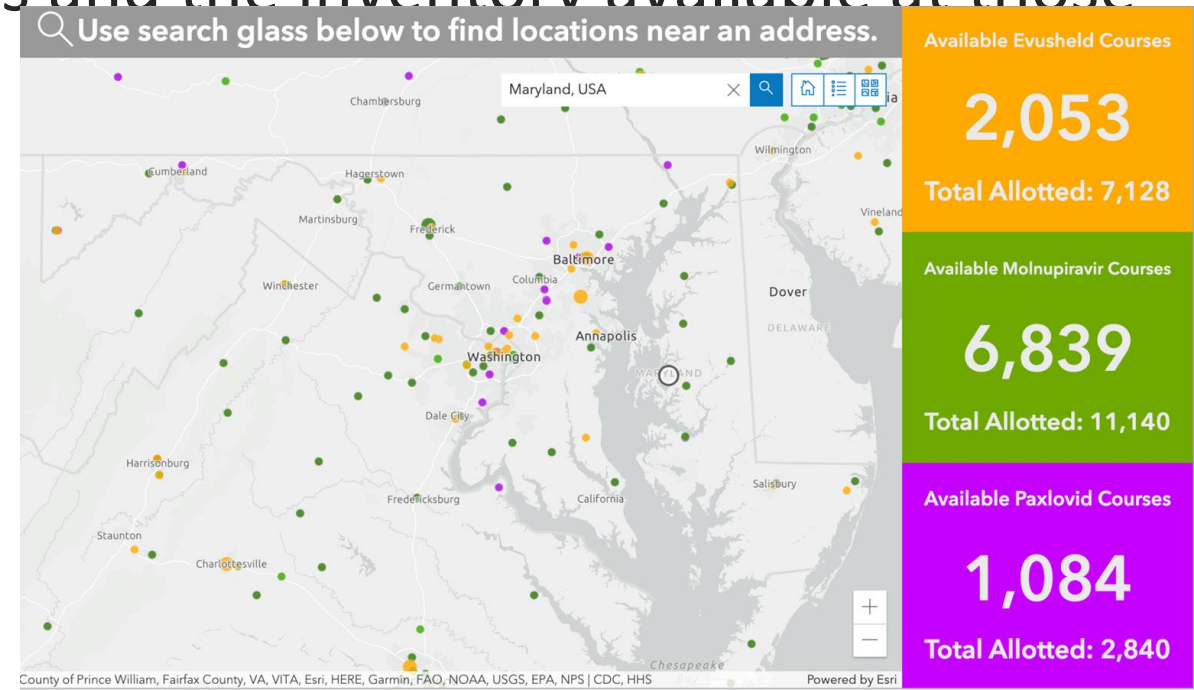
December 30, 2021

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2] COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)

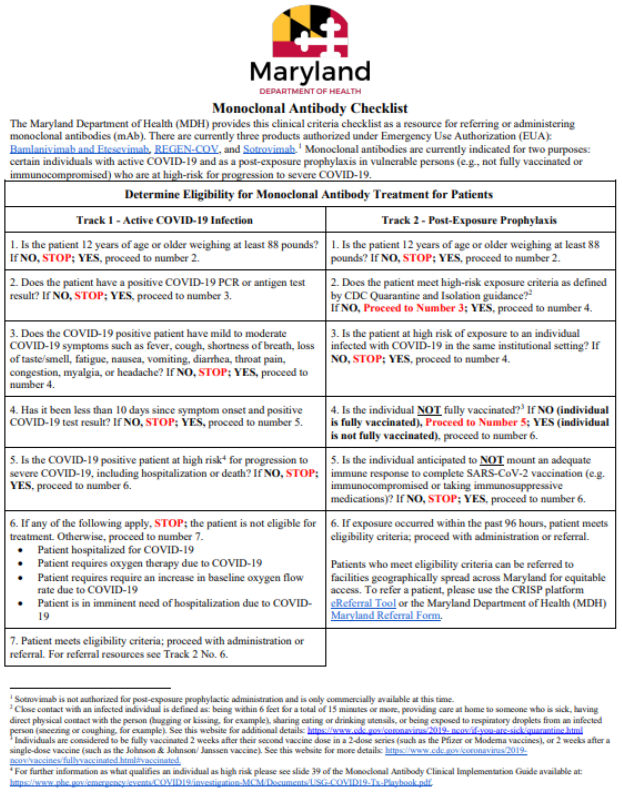
Oral Agent Inventory Confirmation

- Check inventory prior to ordering to ensure availability:
  - Check website at MedChi.org updated regularly
  - Use this HHS finder tool to identify where you can refer patients and the inventory available at those locations:



Monoclonal Antibody Referrals

- Referral Options
  - Option 1: CRISP eREFERRAL for Monoclonal Antibody Infusion
  - Option 2: Maryland Referral Form for Monoclonal Antibody Infusion Treatment (Updated weekly)
  - Some sites allow patients to self-refer for evaluation (listed on referral materials)



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Monoclonal Antibody Checklist

The Maryland Department of Health (MDH) provides this clinical criteria checklist as a resource for referring or administering monoclonal antibodies (mAb). There are currently three products authorized under Emergency Use Authorization (EUA): Bamlanivimab and Etesevimab, REGEN-COV, and Sotrovimab.[1] Monoclonal antibodies are currently indicated for two purposes: certain individuals with active COVID-19 and as a post-exposure prophylaxis in vulnerable persons (e.g., not fully vaccinated or immunocompromised) who are at high-risk for progression to severe COVID-19.

Determine Eligibility for Monoclonal Antibody Treatment for Patients	
Track 1 - Active COVID-19 Infection	**Track 2 - Post-Exposure Prophylaxis**
1. Is the patient 12 years of age or older weighing at least 88 pounds? If **NO, STOP; YES**, proceed to number 2.	1. Is the patient 12 years of age or older weighing at least 88 pounds? If **NO, STOP; YES**, proceed to number 2.
2. Does the patient have a positive COVID-19 PCR or antigen test result? If **NO, STOP; YES**, proceed to number 3.	2. Does the patient meet high-risk exposure criteria as defined by CDC Quarantine and Isolation guidance?[2] If **NO, Proceed to Number 3; YES**, proceed to number 4.
3. Does the COVID-19 positive patient have mild to moderate COVID-19 symptoms such as fever, cough, shortness of breath, loss of taste/smell, fatigue, nausea, vomiting, diarrhea, throat pain, congestion, myalgia, or headache? If **NO, STOP; YES**, proceed to number 4.	3. Is the patient at high risk of exposure to an individual infected with COVID-19 in the same institutional setting? If **NO, STOP; YES**, proceed to number 4.
4. Has it been less than 10 days since symptom onset and positive COVID-19 test result? If **NO, STOP; YES**, proceed to number 5.	4. Is the individual **NOT** fully vaccinated?[3] If **NO (individual is fully vaccinated), Proceed to Number 5; YES (individual is not fully vaccinated)**, proceed to number 6.
5. Is the COVID-19 positive patient at high risk[4] for progression to severe COVID-19, including hospitalization or death? If **NO, STOP; YES**, proceed to number 6.	5. Is the individual anticipated to **NOT** mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g. immunocompromised or taking immunosuppressive medications)? If **NO, STOP; YES**, proceed to number 6.
6. If any of the following apply, **STOP;** the patient is not eligible for treatment. Otherwise, proceed to number 7. • Patient hospitalized for COVID-19 • Patient requires oxygen therapy due to COVID-19 • Patient requires require an increase in baseline oxygen flow rate due to COVID-19 • Patient is in imminent need of hospitalization due to COVID-19	6. If exposure occurred within the past 96 hours, patient meets eligibility criteria; proceed with administration or referral. Patients who meet eligibility criteria can be referred to facilities geographically spread across Maryland for equitable access. To refer a patient, please use the **CRISP** platform eReferral Tool or the Maryland Department of Health (MDH) Maryland Referral Form.
7. Patient meets eligibility criteria; proceed with administration or referral. For referral resources see Track 2 No. 6.	

[1] Sotrovimab is not authorized for post-exposure prophylactic administration and is only commercially available at this time.
[2] Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details: https://www.cdc.gov/coronavirus/2019- ncov/if-you-are-sick/quarantine.html
[3] Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Modema vaccines), or 2 weeks after a single-dose vaccine (such as the Johnson & Johnson/ Janssen vaccine). See this website for more details: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fullyvaccinated.html#vaccinated.
[4] For further information as what qualifies an individual as high risk please see slide 39 of the Monoclonal Antibody Clinical Implementation Guide available at: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf

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Store Name	Address	County	Courses of Molnupiravir	Courses of Paxlovid
Walgreens 17857	101 Bishop Murphy Dr, Frostburg, MD 21532	Allegany	200	1
Walgreens 12266	209 N 3rd St, Oakland, MD 21550	Garrett	199	2
Walgreens 13892	17703 Virginia Ave, Hagerstown, MD 21740	Washington	200	0
Walgreens 10402	11745 Rousby Hall Rd, Lusby, MD 20657	Calvert	0	71
Walgreens 10063	6300 Crain Hwy, La Plata, MD 20646	Charles	179	30
Walgreens 17917	12701 Laurel Bowie Rd, Laurel, MD 20708	Prince George's	198	0
Walgreens 10905	640 Sunburst Hwy, Cambridge, MD 21613	Dorchester	3	0
Walgreens 15284	900 N Washington St, Baltimore, MD 21205	Baltimore City	197	1
Walgreens 12130	909 Mount Hermon Rd, Salisbury, MD 21804	Wicomico	198	0
Walgreens 6779	9616 Harford Rd, Baltimore, MD 21234	Baltimore County	58	0
Walgreens 17944	110 Mitchells Chance Rd, Edgewater, MD 21037	Anne Arundel	0	0
Walgreens 11949	5585 Twin Knolls Rd, Columbia, MD 21045	Howard	394	0
Walgreens 19380	6970 Crestwood Boulevard, Frederick, MD 21703	Frederick	194	0
Walgreens 10977	301 E Pulaski Hwy, Elkton, MD 21921	Cecil	200	0
Walgreens 11763	701 Washington Ave, Chestertown, MD 21620	Kent	198	0
Walgreens 19966	19927 Century Blvd, Germantown, MD 20874	Montgomery	143	0

As of 1/11:

- Available Paxlovid: **221**
- Molnupiravir: **3,804**

More info on MedChi.org

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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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