



DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

September 27, 2021

Dear Colleague:

We are writing to ensure that you have the critical information needed regarding monoclonal antibodies (mAb) and are proactively providing this treatment to individuals with or exposed to COVID-19. **The Maryland Department of Health (MDH) strongly recommends mAbs when clinically indicated.**

Monoclonal antibodies are a critical tool in the battle against COVID-19 and are effective against variants, including the highly contagious Delta variant. Currently, the Federal Food and Drug Administration (FDA) has authorized three mAb products under Emergency Use Authorization (EUA).

MAbs Recommended for COVID-19 Treatment or Post-Exposure Prophylaxis

Monoclonal antibodies have been approved for treatment of mild to moderate COVID-19 infection in individuals who are at high risk for progressing to severe disease or as a post-exposure prophylaxis for unvaccinated or immunocompromised individuals who are high risk for progression to severe COVID-19.

	Administration Route	Treatment	Post-Exposure Prophylaxis
Bamlanivimab and Etesevimab	Intravenous infusion	Indicated	Indicated
REGEN-COV	Intravenous infusion or Subcutaneous injection	Indicated	Indicated
Sotrovimab	Intravenous infusion	Indicated	NOT indicated

NOTE: Sotrovimab is only commercially available at this time and not provided via the Federal allocation system.

Please speak to your patients and recommend this treatment when indicated. Maryland currently has sufficient quantities of mAb (REGEN-COV and bam/etes) at no cost to the provider or patient. We strongly encourage you to offer these critical mAbs to patients upon request if eligible and refer them to one of the [current infusion centers located across the state](#).

To assess whether individual patients meet the clinical criteria for monoclonal antibodies, please see Attachment: Monoclonal Antibody Checklist. If your patient meets the criteria, we highly recommend a referral or administration of mAbs.

Referral Resources

There are 80 facilities across Maryland that administer mAbs in an out-patient setting. To refer a patient, please use the CRISP platform [eReferral Tool](#) or the Maryland Department of Health (MDH) [Maryland Referral Form](#). MDH also has a variety of [Provider Resources](#) related to mAb for further information.

Again, we strongly urge you to proactively use this effective, critical treatment and greatly appreciate the role you are playing in Maryland's fight against COVID-19.

Additional Resources

For further information we strongly encourage you to attend webinars hosted by MDH relating to monoclonal antibodies and other COVID-19 items every other [Wednesday](#). Additional information for providers and patients about monoclonal antibodies is available from the [Federal Department of Health and Human Services](#).

Sincerely,



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Deputy Secretary for Public Health
Services



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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. <ul style="list-style-type: none"> • 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 Moderna 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>.