

# Interim-DOH Guidance on Prioritization for Use of Anti-SARS-CoV-2 Monoclonal Antibodies

Use of Monoclonal Antibody Products to Treat COVID-19 in Washington State

Updates (April 18, 2022):

- Update on sotrovimab authorization

## About Monoclonal Antibodies

Monoclonal antibodies (mAbs) for the treatment of COVID-19 are laboratory synthesized proteins specifically directed against the spike protein of the SARS-CoV-2 virus and designed to block the virus' attachment and entry into human cells. The [NIH COVID-19 Treatment Guidelines Panel](#) recommends using anti-SARS-CoV-2 mAbs for the treatment of mild to moderate COVID-19 in individuals who are at high risk for progression to severe COVID-19, as outlined in the Food and Drug Administration Emergency Use Authorizations (EUAs). When used for treatment, administration of mAbs should occur ideally within 7 days and no later than within 10 days of onset of symptoms; earlier administration may lead to better clinical outcomes.

Although the data on risk factors for severe COVID-19 in children are limited, there is substantial overlap between risk factors in children and those identified in adults, as listed above. Children with obesity, moderate to severe immunosuppression, or those with complex chronic disease and medical complexity with respiratory technology dependence are at substantially increased risk of [severe disease](#).

## Current Status on Monoclonal Antibodies

The [CDC](#) identifies the Omicron variant as the dominant strain of SARS-CoV-2 across the United States and within U.S. Department of Health & Human Services (HHS) Region 10. On April 5, 2022, the FDA issued the following statement: **Due to the high frequency of the Omicron BA.2 sub-variant, sotrovimab is not currently authorized in any U.S. region. Therefore, sotrovimab may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.** At this time, there is only one monoclonal antibody therapeutics available for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms, which is about 88 pounds) with a positive COVID-19 test, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.

[Bebtelovimab](#) works by binding to the spike protein of the virus that causes COVID-19, similar to other monoclonal antibodies. It has been authorized for intravenous [treatment but not post-exposure prophylaxis](#). Guidance for prescribers can be found at [Fact Sheet for Healthcare Providers](#).

Because they are not effective for treating severe COVID-19 disease, mAbs are not authorized for use in patients:

- Who are hospitalized due to COVID-19; OR
- Who require oxygen therapy due to COVID-19; OR
- Who are on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity and require an increase in baseline oxygen flow rate due to COVID-19.

## Recommendations

The following recommendations should be used to ensure equitable administration for those individuals who might receive the greatest benefit from SARS-CoV-2 treatment. These recommendations are not prescriptive, but rather should be used in the context of clinical decision-making and other community factors to determine the best treatment option for the specific patient, consistent with current [NIH guidelines](#).

The following underlying conditions increase the risk for progression to severe disease:

- $\geq 65$  years of age
- Cancer
- Cardiovascular disease or hypertension
- Chronic kidney disease
- Chronic lung diseases
- Chronic liver diseases
- Complex genetic or metabolic syndromes
- Diabetes
- Downs syndrome
- HIV infection
- Immunosuppression
- Limited access to care or members of communities disproportionately impacted by COVID-19
- Moderately-to-severely immunosuppressed
- Medical-related technological dependence
- Neurodevelopmental disorders
- Overweight and obesity (BMI  $\geq 25$  kg/m<sup>2</sup>)
- Pregnancy
- Sickle cell disease or thalassemia
- Severe congenital anomalies
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease
- Tobacco usage, current or former
- Substance use disorders
- Tuberculosis

## Additional Considerations

- Prioritize patients diagnosed with COVID-19 who present with symptoms  $\leq 7$  days.

- Prioritize patients who are hospitalized for a diagnosis other than COVID-19, provided they have mild to moderate COVID-19 and are at high risk for progressing to severe disease.
- Among those individuals who are [up to date](#) with vaccinations, limit use to those who are:
  - ≥ 65 years of age
  - Moderately-to-severely immunosuppressed
  - Women who are pregnant, especially those with comorbidities

Authorization of monoclonal antibodies under their EUAs is not limited to the medical conditions or factors listed above. Other medical conditions or factors may also place individual patients at high risk for progression to severe COVID-19. See [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19](#) and [People with Certain Medical Conditions](#).

Note - Prioritization of anti-SARS-CoV2 mAbs may be needed when logistical or supply constraints make it impossible to treat all eligible patients. DOH encourages the use of the [COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints](#).

**Treatment sites and other information on mAbs can be found [here](#).**

## Resources

- [Anti-SARS-CoV-2 Monoclonal Antibodies | COVID-19 Treatment Guidelines\(nih.gov\)](#)
- [IDSA Guidelines on the Treatment and Management of Patients with COVID-19 \(idsociety.org\)](#)
- [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers](#)
- [CDC Altered Immunocompetence](#)
- [CDC Yellow Book – Chapter 5 Immunocompromised Travelers](#)
- [People with Certain Medical Conditions](#)
- [Bebtelovimab Fact Sheet for Providers](#)
- [Bebtelovimab Fact Sheet for Patients, Parents and Caregivers](#)

## More COVID-19 Information and Resources

Stay up-to-date on the [current COVID-19 situation in Washington](#), [Governor Inslee's proclamations](#), [symptoms](#), [how it spreads](#), and [how and when people should get tested](#). See our [Frequently Asked Questions](#) for more information.

The risk of COVID-19 is not connected to race, ethnicity or nationality. [Stigma will not help to fight the illness](#). Share accurate information with others to keep rumors and misinformation from spreading.

- [WA State Department of Health 2019 Novel Coronavirus Outbreak \(COVID-19\)](#)
- [WA State Coronavirus Response \(COVID-19\)](#)
- [Find Your Local Health Department or District](#)
- [CDC Coronavirus \(COVID-19\)](#)
- [Stigma Reduction Resources](#)

**Have more questions about COVID-19?** Call our hotline: **1-800-525-0127**. For interpretative services, **press #** when they answer and **say your language**. (Open from 6 a.m. to 10 p.m.) For questions about your own health, COVID-19 testing, or testing results, please contact your health care provider.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 ([Washington Relay](#)) or email [civil.rights@doh.wa.gov](mailto:civil.rights@doh.wa.gov).