COVID-19

Guidance for Healthcare Providers
COVID-19 treatment options

Monoclonal antibodies are an important COVID-19 treatment option for people at high risk for severe COVID-19 outcomes. The treatment is available at more than 300 registered healthcare locations across Ohio. These antibodies can help the immune system recognize and respond more effectively to the virus. Recently, use of monoclonal antibodies has increased significantly in Ohio, with thousands of doses per week now being administered at hospitals, long-term care pharmacies, community health centers, infusion centers, and other locations.

The Ohio Department of Health wants to ensure that all healthcare providers across Ohio are aware of the availability of this treatment option, and refer patients to treatment locations as appropriate. Providers caring for COVID-19 patients should determine whether antibodies are a recommended treatment for that individual, and make referrals to facilities offering the treatment option accordingly.

Early and effective treatment of any disease can help prevent progression to more serious illness, especially for patients at high risk of disease progression and hospitalization. Early intervention also has the added benefit of reducing the burden on healthcare systems by potentially preventing hospitalizations. Several novel therapeutics (e.g., monoclonal antibodies) are available under U.S. Food and Drug Administration emergency use authorization (EUA) for early outpatient treatment of mild to moderate COVID-19. In addition, new oral treatment options are currently under FDA review, and may become available in the near future.

ELIGIBILITY

Monoclonal antibodies are a treatment option to consider for people who have met all of the following criteria:
- A positive COVID-19 test.
- Within **10 days of symptom onset**.
- At increased risk for severe COVID-19 or hospitalization (risks include age, vaccination status, or certain medical conditions).

In Ohio, a patient must have a prescription order to receive monoclonal antibodies. Providers are strongly encouraged to ensure compliance with requirements for monoclonal ordering and administration under state law and the Public Readiness and Emergency Preparedness Act (PREP Act).

- Monoclonal antibody treatment is still relatively new under EUA and is recommended only for those at <u>high risk for severe disease</u>.
  - A patient must be age 12 or older and weigh at least 88 pounds, per the EUA.
  - Risk is generally based on age, specific comorbidities by age group (e.g., kidney disease, diabetes, cardiovascular disease, chronic respiratory disease, etc.) <u>and/or</u> a body mass index greater or equal to 25. Evaluating risk based upon these factors helps to ensure the treatments are being made available safely and to the Ohioans who need them the most.
  - The Centers for Disease Control and Prevention (CDC) website provides a list of risk factors for severe illness from COVID-19 on the webpage [Underlying Medical Conditions Associated with High Risk for Severe COVID-19](). The likelihood of developing severe COVID-19 increases when a person has multiple comorbidities.
- Supply of the treatments are limited.

TREATMENT OPTIONS

Clinicians who wish to consider or recommend use of these emergency authorized therapies should review the [COVID-19 Treatment Guidelines]() published by the National Institutes of Health (NIH) as well as the FDA EUA for each therapy.

A number of these treatments are intended for outpatient intravenous infusion, so clinicians and health systems should be prepared to provide care in a location and manner in which patients with COVID-19 can be safely managed. Note, REGEN-COV (also known as Regeneron) is available in two formulations (IV or subcutaneous injection), although treatment by IV infusion is strongly recommended. Subcutaneous injection is an alternate route of administration when IV infusion is not feasible and would lead to delay in treatment with REGEN-COV, according to the product's [EUA fact sheet.]()

Currently available monoclonal antibodies include:

- **REGEN-COV** (casirivimab and imdevimab) – [Fact Sheet for Healthcare Providers EUA]()
- **SOTROVIMAB** – [Fact Sheet for Healthcare Providers EUA]()
- **BAMLANIVIMAB AND ETESEVIMAB** – [Fact Sheet for Healthcare Providers EUA]()

The list of therapeutic options is subject to change as new research becomes available, and as the FDA provides EUAs for other therapeutics for the treatment of COVID-19.

OHIO TREATMENT LOCATIONS

For a list of locations across the state offering monoclonal antibody therapy, please go to the [National Infusion Center Association Infusion Center Locator](). Providers are encouraged to reach out to locations in their area to determine criteria and process for referrals and scheduling. If your hospital system or healthcare entity is already offering

monoclonal antibody therapy, continue to follow system protocols for referral and scheduling.

HOW TO REQUEST AN ALLOCATION

The U.S. Department of Health and Human Services (HHS) oversees this process, and makes allocations to states looking at factors including case rates and hospitalizations.

At this time, Ohio's allocations are being made by the Ohio Department of Health (ODH) in cooperation with state partners including the Department of Aging, healthcare associations including the Ohio Hospital Association and Ohio Association of Community Health Centers, and clinical zone leadership to ensure equitable distribution. The goal of Ohio's state-coordinated distribution system is to maintain equitable distribution geographically and across different types of facilities (hospitals and healthcare systems, long-term care facilities/pharmacies, and federally qualified health centers), factoring in current supply and utilization.

The supplies are maintained and distributed by a wholesaler contracted through HHS, and are never possessed by the state. ODH's role is to facilitate allocations and ensure fair distribution.

Healthcare providers expecting shipments through AmerisourceBergen can track the status of their shipments online.

Regional hubs are also being established to help ensure quick transfer of small quantities of mABs for immediate treatments between approved treatment locations.

If you are a facility able to provide these treatments and would like to learn more about how to enroll to receive allocations, please send an email expressing your interest to ODH at **hpp@odh.ohio.gov.**

RESOURCES

- U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR): Outpatient administration guide for healthcare providers
- U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR): COVID-19 Monoclonal Antibody Therapeutics
- U.S. Department of Health and Human Services: How Do I Know If I'm High Risk, and What Do I Do Next?
- National Institutes of Health: Coronavirus Disease 2019 (COVID-19)
- Treatment Guidelines
- National Institutes of Health: Anti-SARS-CoV2 Antibody Products
- National Infusion Center Association: Infusion Center Locator
- AmerisourceBergen: Track shipment status

ODH will share updated guidance on COVID-19 treatment options as new products become available. If you have any questions, you may contact ODH at **hpp@odh.ohio.gov** for additional information.

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For additional information, visit coronavirus.ohio.gov.

The Ohio Department of Health COVID-19 Provider website is a hub for a variety of resources for vaccine providers. Vaccine providers with questions may call the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) between 8 a.m. and 7 p.m. Mondays through Fridays or email COVIDVACCINE@odh.ohio.gov.