Washington State Department of Health

Updated August 19, 2021
DOH 821-123

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

Summary of August 19, 2021 changes

- Added information on use of REGEN-COV, including a subcutaneous injection option and expanded EUA for use as post-exposure prophylaxis.
- Updated information on the EUA for Tocilizumab
- Updated information on the pause in federal distribution of bamlanivimab and etesevimab.
- Added information about Medicare coverage of monoclonal antibody products

Background

Monoclonal antibodies are laboratory-made proteins that bind to the spike protein of SARS-CoV-2 and block the virus' attachment and entry into human cells. These therapeutic products are available for the treatment of mild to moderate COVID-19 in adult and pediatric patients (≥12 years old and ≥40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization.

On **November 9, 2020**, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational monoclonal antibody (mAb) therapy bamlanivimab. On **November 21, 2020**, the FDA issued another EUA for a combination monoclonal antibody product casirivimab plus imdevimab. And on **February 04, 2021**, an EUA for the emergency use of bamlanivimab and etesevimab administered together was issued.

On **March 18, 2021**, the FDA revised its fact sheets on mAbs to address emerging SARS-CoV-2 variants. Based on these data, the FDA on **April 16, 2021** revoked the EUA that allowed use of bamlanivimab **when administered alone**, but stated "alternative monoclonal antibody therapies remain available under EUA, including REGEN-COV (casirivimab and imdevimab, administered together), and bamlanivimab and etesevimab, administered together, for the same uses as previously authorized for Bamlanivimab alone."

The research demonstrating the benefits of monoclonal antibodies for treatment of COVID-19 continues to grow. You can find a summary of the research on these treatments here. As of April 12, 2021, Regeneron has reported on the results of their REGEN-COV Phase 3 prevention and treatment trials that were run in conjunction with the National Institute of Allergy and Infectious Diseases (NIAID).

Clinical Updates

On June 3, 2021, the FDA updated the EUA of REGEN-COV (combination casirivimab plus imdevimab) for the treatment of nonhospitalized individuals with COVID-19. The authorized dosage was reduced from a single intravenous (IV) infusion of casirivimab 1,200 mg plus imdevimab 1,200 mg to casirivimab 600 mg plus imdevimab 600 mg.

In addition, on **June 3rd** the same doses of casirivimab and imdevimab **may now be administered by subcutaneous injection** when IV infusion is not feasible or may delay treatment.

On **June 24, 2021,** The U.S. Food and Drug Administration approved Actemra (Tocilizumab) for emergency use in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. Under the terms of the EUA, health care providers may only administer tocilizumab to hospitalized patients with severe COVID-19 illness.

As of **June 25, 2021**, the Office of the Assistant Secretary for Preparedness and Response (ASPR) has paused national distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab) until further notice. This is in response to an increased prevalence of variants that are potentially resistant to the treatment. Learn more about the pause in bamlanivimab/etesevimab distribution.

On **June 30, 2021** the Infectious Disease Society of America (IDSA) updated its previous guidance to suggest casirivimab/imdevimab, bamlanivimab/etesevimab, or sotrovimab for ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease. Patients who are admitted to the hospital for reasons other than COVID-19, and who have mild-moderate COVID-19, may also receive these therapies. The recommendation for bamlanivimab/etesevimab is still in effect as of **August 16, 2021**. Check the IDSA website for the most recent guidance.

The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel, as of **July 8, 2021**, recommended using casirivimab plus imdevimab or sotrovimab to treat nonhospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression. Treatment should be started as soon as possible after the patient receives a positive COVID-19 test and within 10 days of symptom onset. The NIH panel **recommended against the use of bamlanivimab plus etesevimab** due to an increase in the prevalence of potentially resistant variants.

On **July 30, 2021**, the U.S. Food and Drug Administration revised the emergency use authorization (EUA) for REGEN-COV (casirivimab and imdevimab, administered together) authorizing REGEN-COV for emergency use as **post-exposure prophylaxis** (prevention) for COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death. REGEN-COV is **not authorized for pre-exposure prophylaxis** to prevent COVID-19 before being exposed to the SARS-CoV-2 virus -- only after exposure to the virus. Health care providers should review the EUA fact Sheet for detailed information about the use of REGEN-COV for post-exposure prophylaxis.

Availability of monoclonal antibody products in Washington

The U.S. Department of Health and Human Services began allocating monoclonal antibody products to states in November 2020, with state health departments then allocating these therapeutics to eligible healthcare providers. That process has changed and providers can now directly order monoclonal antibody therapeutics from the distributor, AmerisourceBergen.

Per COVID-19 hospital reporting guidance that went into effect on **June 10, 2021**, sites will be required to provide ABC with a board of pharmacy license or physician letter of authorization; attest to their designated class of trade and that they will administer the authorized product according to the term of the FDA issued EUA; and provide utilization data via either TeleTracking or NHSN.

Sites may order product based on established minimum amounts; subsequent orders are subject to a maximum amount based on previous orders and utilization. The Department of Health will be informed of therapies ordered within Washington for awareness. There is a federal review for orders >48 patient courses, but the review will not delay shipping.

Casirivimab/imdevimab supply is currently ample and sites should not hesitate to request additional supply; DOH recommends sites order sufficient supply to meet their next 2-week anticipated utilization.

Sotrovimab and tocilizumab have not been purchased and distributed by the federal government. You may purchase these products through typical purchasing channels.

Facilities interested in ordering monoclonal antibody products should follow the direct ordering process for COVID-19 therapeutics. For assistance or questions about this ordering process, contact Ezra.stark@doh.wa.gov.

Administration of monoclonal antibody products in Washington

Healthcare providers administering monoclonal antibody products in Washington are required to follow the manufacturer and EUA guidance as outlined in the links below:

- REGEN-COV (casirivimab with imdevimab)
- Sotrovimab
- Tocilizumab

Monoclonal antibody therapeutic treatment locations can vary throughout the state. Patients should coordinate with their health care provider before contacting a location to receive treatment. Infusion locations that provide monoclonal antibody treatment can be found using the NICA Infusion Center Locator or the ASPR Therapeudics distribution locator.

Healthcare providers must communicate to patients or parents/caregivers information consistent with the "Casirivimab plus Imdevimab Fact Sheet for Patients, Parents and Caregivers," "Sotrovimab Fact Sheet for Patients," or "Tocilizumab fact sheet for Patients, Parents and Caregivers" prior to the patient receiving the medication.

Reimbursement process for mAbs therapeutic under EUA

During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions (when furnished consistent with their respective EUAs) the same way it covers and pays for COVID-19 vaccines. Under initial phase of treatment, drug cost will likely be paid by US government under advanced purchase agreements.

The approach to paying for these products as COVID-19 vaccines during the PHE allows a broad range of providers and suppliers to administer these treatments, including but not limited to:

- Freestanding and hospital-based infusion centers
- Home health agencies
- Nursing homes
- Entities with whom nursing homes contract to administer treatment

Health care providers administering the infusions of monoclonal antibody products to treat COVID-19 will follow the same enrollment process as those administering the COVID-19 vaccines. Get provider enrollment information.

Please reference Centers for Medicare & Medicad Services for more information or reference their Covid-19 FAQs.

Monoclonal Antibody Resources for Health Care Providers

- Monoclonal Antibody Playbook (w/ PEP Update July 30, 2021)
- Direct Ordering Process
- Resources for Clinicians
- Administering mAbs at you facility
- COVID-19 mAb communications toolkit with communications resources for:
    - Administration sites
    - Healthcare providers
    - Patients
    - Digital media tools

HHS/ASPR call center is available to answer questions and provide information related to monoclonal antibody therapeutic treatments at 1-877-332-6585 (English) or 1-877-366-0313 (Spanish).

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.

A person's race/ethnicity or nationality does not, itself, put them at greater risk of COVID-19. However, data are revealing that communities of color are being disproportionately impacted by COVID-19- this is due to the effects of racism, and in particular, structural racism, that leaves some groups with fewer opportunities to protect themselves and their communities.

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,** Monday – Friday, 6 a.m. to 10 p.m., Weekends: 8 a.m. to 6 p.m. For interpretative services, **press #** when they answer and **say your language.** For questions about your own health, COVID-19 testing, or testing results, please contact a 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.