**VDH Clinical Criteria for Administration of COVID-19 Therapeutics**

**for Treatment of COVID-19**

**(Monoclonal Antibodies (mAbs) and Oral Antivirals)**

**December 27, 2021**

The U.S. FDA has issued Emergency Use Authorizations (EUAs) for the use of the following therapeutics for treatment of COVID-19 in high-risk patients with mild to moderate symptoms:

Sotrovimab - GlaxoSmithKline (mAb)

Paxlovid - Pfizer (oral antiviral) – NEW

Molnupiravir – Merck (oral antiviral) – NEW

Bamlanivimab/etesevimab (“Bam/Ete”) - Eli Lilly (mAb) \*

REGEN-COV (casirivimab/imdevimab) - Regeneron Pharmaceuticals (mAb) \*

\* HHS is evaluating current use as in vitro data shows these products are not likely to be effective against the Omicron variant of SARS-CoV-2.

Currently, COVID-19 therapeutic agents are in limited supply in the U.S. and the Commonwealth. VDH will allocate these resources in a manner which maximizes their clinical benefit and protects against systemic unfairness and inequity. In general (but not exactly), VDH recommends these resources be used according to the current [NIH 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](https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/) dated December 23, 2021. This document focuses on outpatient COVID-19 treatment prioritization, not preventive therapy against COVID-19. VDH concurs with the NIH Treatment Panel’s approach to preventive therapy (pre-exposure prophylaxis with EVUSHELD).

**A. General principles**:

* Treatment of COVID-19 over post-exposure prophylaxis (PEP) of SARS-CoV-2 infection.
* Vaccinated patients should remain eligible for COVID-19 therapeutics if they develop breakthrough infections and unvaccinated patients who develop COVID-19 should not be penalized by withholding COVID-19 therapeutics.

**B. Patient Prioritization for Treatment of Mild to Moderate COVID-19 in Outpatients**

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| **Tier** | **Risk Group** |
| 1 | Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions# below) |
| 2 | Regardless of vaccination status, individuals at the highest risk of severe disease who do not meet criteria in Tier 1 (anyone aged > 75 years, or anyone > 65 years with one or more additional risk factor(s) for progression to severe COVID-19)  |
| 3 | Regardless of vaccination status, individuals at risk of severe disease not included in Tiers 1 or 2 (anyone aged 66-74 years, or anyone aged <65 years with one or more clinical risk factors for progression to severe COVID-19) |
| 4 | After careful consideration by a licensed prescriber, patients with one or more high-risk condition(s) who meet the EUA criteria for the treatment drug may also receive COVID-19 therapeutics (mAbs or oral antivirals) |

**# Immunocompromising conditions**

● Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)

● Patients receiving Bruton tyrosine kinase inhibitors

● Chimeric antigen receptor T cell recipients

● Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication

● Patients with hematologic malignancies who are on active therapy

● Lung transplant recipients

● Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)

● Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents

● Patients with severe combined immunodeficiencies

● Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm3

CDC Underlying Medical Conditions Associated with High Risk for Severe COVID-19: Information for Healthcare Providers (see [www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html](http://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html))

**C. Use of MAbs or Remdesivir for Treatment of COVID-19 When Omicron is Predominant Variant**

During a situation in which the Omicron variant represents the majority of COVID-19 infections in a region, VDH concurs with NIH’s recommendation regarding the use of IV Sotrovimab or IV Remdesivir as the drugs of choice to treat non-hospitalized patients with mild to moderate COVID-19 who are at high-risk of clinical progression to more severe illness. Sotrovimab must be used according to its Emergency Use Authorization; however, remdesivir (an FDA approved medication) may be used off-label in accordance with the prescriber’s direction. See [The 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](https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/).

**D. References**

# [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](https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/) - from NIH, updated December 23, 2021

# [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers](https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html) - from CDC, updated October 14, 2021