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Health Alert
Omicron Variant Update:
Therapeutics Changes for Outpatient Treatment of Mild to Moderate COVID-19
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Background

The [B.1.1.529 \(Omicron\) variant of concern \(VOC\)](#) has become the dominant variant in all areas of the [United States](#), including [California](#). Two of the anti-SARS-CoV-2 monoclonal antibody products that have received Emergency Use Authorizations (EUAs) from the US Food and Drug Administration (FDA), bamlanivimab/etesevimab and casirivimab/imdevimab (REGEN-COV), are not effective against the Omicron variant and are no longer authorized for use as a treatment or as a post-exposure prophylaxis (PEP) for use in any U.S. state, territory, or jurisdiction as of January 24, 2022. The anti-SARS-CoV-2 monoclonal antibody Sotrovimab is expected to retain activity against Omicron. Remdesivir (Veklury) has recently received FDA approval for outpatient treatment of mild to moderate COVID-19 disease and is active against the Omicron variant. Both FDA authorized oral anti-viral agents, ritonavir-boosted nirmatrelvir (Paxlovid) and molnupiravir, are effective against the Omicron variant. Supply of the most effective therapeutic options against Omicron currently remain limited.

Remdesivir Use in Adult and Pediatric Outpatients

Remdesivir (Veklury), an IV anti-SARS-CoV-2 antiviral with FDA approval as an inpatient treatment, was recently also [approved](#) by the FDA for the treatment of mild-to-moderate COVID-19 disease in outpatients who are at high risk of severe COVID-19. Clinical trial data showed that three consecutive days of IV remdesivir resulted in an [87% relative risk reduction](#) in hospitalizations or deaths compared to placebo. Remdesivir has been added to the National Institutes of Health (NIH) outpatient treatment [guidelines](#). Remdesivir is active against the Omicron variant.

Use of remdesivir in outpatients is now approved in [adults and children](#) ≥ 12 years of age (weighing ≥ 40 kg) and the FDA has granted [emergency use authorization](#) for Remdesivir for pediatric outpatients less than 12 years of age and/or weighing 3.5 kg to < 40 kg. Doses must be [adjusted](#) to body weight for pediatric patients. This new authorization means that there is still a treatment option for the youngest pediatric outpatients who are at high risk of disease progression, even though bamlanivimab/etesevimab is no longer available.

Remdesivir is not allocated by the federal government but is available commercially from the distributor, AmerisourceBergen. For billing purposes, the Centers for Medicare & Medicaid Services has approved the Healthcare Common Procedure Coding System (HCPCS) J0248 for outpatient administration of remdesivir. All payers can use this code for dates of service on or after December 23, 2021.

FDA Limits Use of Bamlanivimab/Etesevimab and Casirivimab/imdevimab (REGEN-COV)

On January 24, 2022 the FDA announced that casirivimab/imdevimab (REGEN-COV) and bamlanivimab/etesevimab [are no longer authorized for use in any U.S. state](#) given that Omicron variant prevalence is [now over 99% nationally](#). At this time these monoclonal antibodies are not being allocated by the US Department of Health and Human Services (HHS) and the California Department of Public Health (CDPH) will not be distributing these products to California jurisdictions. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these therapeutics, then use of these treatments may be authorized in these regions. The loss of these therapeutic options means that currently there are no FDA authorized options for the [post-exposure prophylaxis](#) of COVID-19. For the treatment of mild-to-moderate COVID-19 disease in outpatients at high risk for progression, providers should use one of the outpatient treatment options with activity against the Omicron variant suggested in the [NIH guidelines](#).

Patient Prioritization with Limited Product Available

The supply of treatment options effective against the Omicron variant is limited, and the quantity of product [allocated to California](#) by HHS is expected to remain lower than demand. The NIH has created a [prioritization framework](#) for identifying patients at highest risk for progression to severe disease, considering age, vaccination status, immune status, and clinical risk factors. This is a helpful framework when determining which patients may be at highest risk for progression to severe disease while supply is limited.

At this time, while supplies remain limited, CDPH recommends focusing on treating outpatients meeting NIH tier 1 and 2 [criteria](#). Once adequate supplies are present, providers may broaden to treat patients in the remaining tiers.

New Therapeutic Resources

HHS has launched a new [therapeutics locator](#) website for providers which currently includes locations and quantities of Evusheld, Paxlovid and Molnupiravir. This site is not a guarantee of availability, and providers should work with local sites to ensure availability. Additionally, the [CDPH Therapeutics webpage](#) provides general information for the public and providers and further details on CDPH's allocations strategies for each of the therapeutic products with activity against Omicron.