

February 4, 2022

Monoclonal Antibodies (mAb) and COVID-19 Treatment Updates



Q: Did the FDA remove the authorization to use certain Monoclonal Antibodies to treat COVID-19 due to resistance to the omicron variant?

A: Yes. The FDA has made a revision to remove authorization to use of REGEN-COV (Casirivimab/Imdevimab) and bamlanivimab plus etesevimab in the US. It is estimated that now more than 99% of COVID cases are omicron and these treatments are now resistant. The FDA stated the risk of exposing patients to potential side effects now exceeds any benefit. These mAb's can no longer be dispensed.

Q: Are there any outpatient therapies that are expected to work against the omicron variant at this time?

A: Yes. The National Institutes of Health (NIH) panel has recommended outpatient treatment recommendations in order of preference based on efficacy and convenience of use:

1. Paxlovid (nirmatrelvir 300 mg plus ritonavir 100 mg) orally twice daily for 5 days
2. Sotrovimab 500 mg, administered as a single intravenous (IV) infusion
3. Remdesivir (Veklury) 200 mg IV on Day 1, followed by remdesivir 100 mg IV on Days 2 and 3
4. Molnupiravir 800 mg orally twice daily for 5 days

These therapies are authorized or approved to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death.

Treatment considerations must include availability of the products and the competencies of the facility in administering and monitoring.

Q: When is IV Sotrovimab considered a good treatment option?

A: Sotrovimab is retaining effectiveness against Omicron and is a good option if oral Paxlovid is not available or contraindicated. To help determine if a patient is a good candidate for Sotrovimab, please review the link below for a Treatment Decision Worksheet to assist providers in the clinical decision-making process.

<https://paltc.org/sites/default/files/Sotrovimab%20Treatment%20Decision%20Worksheet.pdf>

Q: What is the pharmacy availability of these recommended therapies at Consonus?

A: Paxlovid and Molnupiravir: Our pharmacies have received some allocations, but availability can change daily. Please check with the pharmacist before ordering.

Sotrovimab IV: We have received some allocations. Check with the pharmacist on supply before ordering.

Remdesivir (Veklury) IV: This is not yet available to us. FDA has expanded the use of treatment to certain non-hospitalized patients. Previously, the use of Veklury was limited to patients requiring hospitalization. It is a commercially available product and is not provided at no charge from the government. Please check on availability, cost, and ensure nurse competencies for administration and monitoring before use.

