What’s New in the Guidelines

Last Updated: September 15, 2021

The Coronavirus Disease 2019 (COVID-19) Treatment Guidelines is published in an electronic format that can be updated in step with the rapid pace and growing volume of information regarding the treatment of COVID-19.

The COVID-19 Treatment Guidelines Panel (the Panel) is committed to updating this document to ensure that health care providers, patients, and policy experts have the most recent information regarding the optimal management of COVID-19 (see the Panel Roster for a list of Panel members).

New Guidelines sections and recommendations and updates to existing Guidelines sections are developed by working groups of Panel members. All recommendations included in the Guidelines are endorsed by a majority of Panel members (see the Introduction for additional details on the Guidelines development process).

Major revisions to the Guidelines within the last month are as follows:

**September 15, 2021**

**The COVID-19 Treatment Guidelines Panel’s Statement on Bamlanivimab Plus Etesevimab for the Treatment of Mild to Moderate COVID-19 in Nonhospitalized Patients**

On June 25, 2021, the distribution of bamlanivimab plus etesevimab was paused in the United States because of the increase in the combined frequencies of the Gamma (P.1) and Beta (B.1.351) SARS-CoV-2 variants of concern circulating across the country. In recent months, the Delta (B.1617.2, non-AY.1/AY.2) variant has become the predominant variant circulating in all states. Because the combination of bamlanivimab plus etesevimab retains activity against the Delta variant, as of September 2, 2021, the use and distribution of these anti-SARS-CoV-2 monoclonal antibodies (mAbs) have been resumed in all U.S. states, territories, and jurisdictions.

With the availability of bamlanivimab plus etesevimab, the Panel has updated its recommendations.

The Panel recommends using one of the following anti-SARS-CoV-2 mAb regimens (listed alphabetically and not in order of preference) to treat nonhospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression (see Anti-SARS-CoV-2 Monoclonal Antibodies for the rating of the recommendations based on the risk of progression to COVID-19):

- **Bamlanivimab 700 mg plus etesevimab 1,400 mg** intravenous (IV) infusion in regions where the combined frequency of potentially resistant variants is low (see the Emergency Use Authorization (EUA) fact sheet).
- **Casirivimab 600 mg plus imdevimab 600 mg** IV infusion or subcutaneous injection; or
- **Sotrovimab 500 mg** IV infusion

The Panel’s statement includes discussion of the rationale that support these recommendations.

**September 3, 2021**

**The COVID-19 Treatment Guidelines Panel’s Statement on the Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment or Prevention of SARS-CoV-2 Infection When There Are Logistical Constraints**

The Panel recommends using anti-SARS-CoV-2 mAbs for the treatment of mild to moderate COVID-19...
and for post-exposure prophylaxis (PEP) of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19, as outlined in the Food and Drug Administration (FDA) EUAs. While there are currently no shortages of these mAbs, logistical constraints (e.g., limited space, not enough staff who can administer therapy) can make it difficult to administer these agents to all eligible patients. In this statement, the Panel offers suggestions for how to prioritize the use of mAbs for treatment or PEP when there are logistical constraints for administering therapy.

**August 25, 2021**

**Therapeutic Management of Hospitalized Adults With COVID-19**

This section has been updated to add new recommendations on when to use dexamethasone in combination with either IV sarilumab or oral tofacitinib in certain hospitalized patients with COVID-19.

- The Panel recommends **IV sarilumab** as an alternative to **IV tocilizumab** only when IV tocilizumab is not available or not feasible to use (BIIa).
- The Panel recommends **tofacitinib** as an alternative to **baricitinib** only when baricitinib is not available or not feasible to use (BIIa).

Clinical data and rationales supporting these recommendations are summarized in the updated section. Additions to this section also include changes to Figure 2 (including the footnotes) to reflect these new recommendations, as well as a new table outlining the dosing regimens and duration of therapy for the drugs recommended in Figure 2.

**August 17, 2021**

**The COVID-19 Treatment Guidelines Panel’s Statement on the Emergency Use Authorization of Casirivimab Plus Imdevimab as Post-Exposure Prophylaxis for SARS-CoV-2 Infection**

Vaccination remains the most effective way to prevent SARS-CoV-2 infection. However, despite widespread availability of SARS-CoV-2 vaccines, a number of individuals are either not fully vaccinated or cannot mount adequate responses to the vaccine. Some of these people, if infected, are at high risk of progression to serious COVID-19. On July 30, 2021, the FDA expanded the EUA indication for the anti-SARS-CoV-2 mAbs casirivimab plus imdevimab to allow this combination to be used as PEP for selected individuals, as described below.

The Panel recommends using **casirivimab 600 mg plus imdevimab 600 mg** administered as subcutaneous injections (AI) or an IV infusion (BIII) as PEP for people who are at high risk for progression to severe COVID-19 if infected with SARS-CoV-2 **AND** who have the following vaccination status **AND** exposure history:

- **Vaccination Status:**
  - Not fully vaccinated (defined as people who were never vaccinated or those who received the second vaccine dose in a two-dose series or a single-dose vaccine <2 weeks ago); or
  - Fully vaccinated, but not expected to mount an adequate immune response (e.g., those with immunocompromising conditions, including those who are taking immunosuppressive medications)

**AND**

- **Exposure History to SARS-CoV-2:**
  - Had a recent exposure to an individual with SARS-CoV-2 infection that is consistent with the Centers for Disease Control and Prevention close contact criteria; or
• At high risk of exposure to an individual with SARS-CoV-2 infection because of recent occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes, prisons)

The Panel’s statement includes additional recommendations on the use of casirivimab plus imdevimab and a detailed discussion of the clinical data that support these recommendations.