What's New in the Guidelines

Last Updated: April 8, 2022

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 past month are as follows:

April 8, 2022

Therapeutic Management of Nonhospitalized Adults With COVID-19

The Panel previously recommended the anti-SARS-CoV-2 monoclonal antibody (mAb) sotrovimab as a treatment option for certain nonhospitalized patients with COVID-19. Although sotrovimab is active against the Omicron BA.1 and BA.1.1 subvariants, it has substantially decreased in vitro activity against the Omicron BA.2 subvariant that has recently become the dominant subvariant in the United States.

Because the Omicron BA.2 subvariant is now the dominant circulating subvariant in all regions of the United States, the distribution of sotrovimab has been paused, and the Panel no longer recommends using sotrovimab to treat COVID-19. The recommendations and rationale for using sotrovimab have been removed from this section.

Table 3c. Characteristics of SARS-CoV-2 Antibody-Based Products

This section includes information about the pause in the distribution of sotrovimab and updated dosing information for tixagevimab plus cilgavimab (Evusheld).

April 1, 2022

Therapeutic Management of Nonhospitalized Adults With COVID-19

The Omicron BA.2 subvariant is rapidly becoming the dominant subvariant in many regions of the United States. Previously, the Panel recommended sotrovimab, an anti-SARS-CoV-2 mAb, as 1 of the preferred therapies for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease. Even though sotrovimab is active against the Omicron BA.1 and BA.1.1 subvariants, it has substantially decreased in vitro activity against the BA.2 subvariant. The Food and Drug Administration (FDA) recently updated the Emergency Use Authorization (EUA) for sotrovimab to note that it is not authorized for use in geographic regions where infection is likely to have been caused by nonsusceptible SARS-CoV-2 variants, and distribution of sotrovimab has been paused in these regions.

As a result of these recent changes and the increasing prevalence of the BA.2 subvariant across all regions, the Panel no longer recommends sotrovimab as a preferred therapy for nonhospitalized patients.
with mild to moderate COVID-19 who are at high risk of progressing to severe disease.

The Panel’s revised recommendations are outlined below.

**Preferred Therapies**

*Listed in order of preference:*

- Ritonavir-boosted nirmatrelvir (Paxlovid) (AIIa)
- Remdesivir (BIIa)

**Alternative Therapies**

*For use ONLY when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:*

- Bebtelovimab (CIII)
- Molnupiravir (CIIa)

For use ONLY in regions where the Omicron BA.2 subvariant is not the dominant subvariant and in situations where none of the preferred or alternative options are available, feasible to use, or clinically appropriate:

- Sotrovimab (CIII)

The text and Figure 1 in Therapeutic Management of Nonhospitalized Adults With COVID-19 have been updated to include the rationale that supports these new recommendations. This section also now incorporates information from the Panel’s previously published statement on the role of bebtelovimab in the treatment of these patients.

**Table 3c. Characteristics of SARS-CoV-2 Antibody-Based Products**

This section includes new information on bebtelovimab, distribution information for sotrovimab, and updated dosing information for tixagevimab plus cilgavimab (Evusheld).

March 24, 2022

**Testing for SARS-CoV-2 Infection**

The FDA has issued more than 80 EUAs for SARS-CoV-2 serologic or antibody tests since the start of the pandemic. These tests are authorized for detecting SARS-CoV-2 antibodies, but their ability to predict protective immunity has not been validated.

The Panel previously recommended against the use of serologic testing to determine whether a person is immune to SARS-CoV-2 infection. Recently, there has been an increasing interest in using serologic testing to guide decisions about administering additional vaccines or anti-SARS-CoV-2 therapy to certain individuals. Based on the available information, the Panel has determined that there is insufficient evidence to recommend either for or against the use of SARS-CoV-2 serologic testing to assess for immunity or to guide clinical decisions on the use of COVID-19 vaccines or anti-SARS-CoV-2 mAbs in certain people.

**Prevention of SARS-CoV-2 Infection**

In December 2021, the FDA issued an EUA to allow the anti-SARS-CoV-2 mAbs tixagevimab 150 mg plus cilgavimab 150 mg (Evusheld) to be used as pre-exposure prophylaxis (PrEP) in certain individuals. Recent in vitro data has shown that the BA.1 and BA.1.1 subvariants of the Omicron variant have a
decreased susceptibility to tixagevimab and cilgavimab. As a result, on February 24, 2022, the FDA revised the EUA to increase the dose to tixagevimab 300 mg plus cilgavimab 300 mg for those who are receiving these anti-SARS-CoV-2 mAbs for the first time. For those who received the originally authorized dose, the revised EUA recommends administering an additional dose of tixagevimab 150 mg plus cilgavimab 150 mg as soon as possible. These new recommendations are based on pharmacokinetic/pharmacodynamic modeling projections. To date, there are no clinical data that support the efficacy of these new doses.

In this revised section, the Panel provides new recommendations on the dosing of tixagevimab and cilgavimab and discusses some important limitations to the current recommendations.

**Prioritization of Anti-SARS-CoV-2 Therapies for the Treatment and Prevention of COVID-19 When There Are Logistical or Supply Constraints**

This new section incorporates information from the Panel’s previously published statement on patient prioritization for outpatient therapies, which was released in December 2021.

**Granulocyte-Macrophage Colony-Stimulating Factor Inhibitors**

The text and clinical data table for this section have been updated to include recently published data.