What’s New in the Guidelines

Last Updated: March 24, 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:

March 24, 2022

Testing for SARS-CoV-2 Infection

The Food and Drug Administration (FDA) has issued more than 80 Emergency Use Authorizations (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 monoclonal antibodies (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 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.

March 2, 2022

The COVID-19 Treatment Guidelines Panel’s Statement on the Role of Bebtelovimab for the Treatment of High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19

On February 11, 2022, the FDA issued an EUA for the anti-SARS-CoV-2 mAb bebtelovimab for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease. The issuance of this EUA was primarily based on in vitro antiviral data showing that bebtelovimab is expected to have activity against a broad range of SARS-CoV-2 variants, including the Omicron variant of concern and its BA.1 and BA.2 subvariants.

Clinical trial data for bebtelovimab are limited to a Phase 2 randomized placebo-controlled trial in patients who were at low risk for progression to severe disease. The trial showed no unexpected safety events, and patients who received bebtelovimab had more rapid viral decay than those who received the placebo. Although there are insufficient data on hospitalization and mortality outcomes for patients at high risk of disease progression who have received bebtelovimab, the agent has a mechanism of action similar to other anti-SARS-CoV-2 mAbs that have been shown in Phase 3 trials to reduce hospitalization or death among high-risk patients.

The purpose of this statement is to provide clinicians with guidance on the role of bebtelovimab as an additional treatment option for nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease. Basing its recommendations on collective in vitro data, clinical trial results, and other factors (e.g., drug interaction potential, feasibility), the Panel has classified the 5 available treatment options as preferred or alternative therapies for use in this population. Phase 3 trials have demonstrated high efficacy for the preferred therapies. The Panel recommends 1 of the following:

Preferred therapies (listed in order of preference):

- Nirmatrelvir 300 mg with ritonavir 100 mg (Paxlovid) (AIIa); or
- Sotrovimab 500 mg (AIIa); or
- Remdesivir 200 mg (BIIa)

Alternative therapies (for use if none of the preferred therapies are available, feasible to deliver, or clinically appropriate, listed in alphabetical order):

- Bebtelovimab 175 mg (CIII); or
- Molnupiravir 800 mg (CIIa)

The statement has detailed information regarding dose, route of administration, duration of therapy, and other specific indications.