What’s New in the Guidelines

Last Updated: February 1, 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 last month are as follows:

**February 1, 2022**

The Panel periodically publishes statements that provide up-to-date guidance for clinicians on various aspects of COVID-19 treatment. During this update, the information and recommendations from several recently published statements were incorporated into the appropriate sections of the Guidelines.

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

This section has been updated to include the following:

**Pre-Exposure Prophylaxis (PrEP):**

- This section now incorporates the information from the Panel’s statement on using the anti-SARS-CoV-2 monoclonal antibodies (mAbs) tixagevimab plus cilgavimab (Evusheld) as PrEP. This includes the Panel’s recommendation on using these mAbs as PrEP in certain patients who do not have SARS-CoV-2 infection but who are at risk of progressing to severe COVID-19 if infected.
- The Panel emphasizes that tixagevimab plus cilgavimab is not a substitute for COVID-19 vaccination and should not be used in unvaccinated individuals for whom COVID-19 vaccination is recommended and who are anticipated to have an adequate response.

**Post-Exposure Prophylaxis (PEP):**

- The Panel recommends against the use of the anti-SARS-CoV-2 mAbs bamlanivimab plus etesevimab and casirivimab plus imdevimab as PEP because they have markedly reduced susceptibility to the B.1.1.529 (Omicron) variant of concern (VOC), which is currently the dominant SARS-CoV-2 variant in the United States.

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

The text and figure have been updated to incorporate the information from the Panel’s statement on therapies for high-risk, nonhospitalized patients. A table with dosing recommendations for each of the recommended drugs has been added to this section.

This section was also updated to incorporate information from the Panel’s statement on patient prioritization for outpatient therapies. During surges in cases of SARS-CoV-2 infection, when logistical or supply constraints make it impossible to offer therapy to all eligible patients, those who are at the
highest risk of clinical progression should be prioritized to receive these therapies. In addition, a table from the statement has been added to this section. The table offers guidance on prioritizing groups of patients for anti-SARS-CoV-2 therapy based on 4 key elements: age, vaccination status, immune status, and risk factors for clinical progression.

**Anti-SARS-CoV-2 Monoclonal Antibodies**

The Omicron VOC is now the dominant SARS-CoV-2 variant in the United States. Because the Omicron VOC is expected to have markedly reduced susceptibility to the anti-SARS-CoV-2 mAbs bamlanivimab plus etesevimab and casirivimab plus imdevimab, this section has been updated to reflect the Panel’s recommendations against the use of these mAbs for the treatment of patients with mild to moderate COVID-19. The Panel continues to recommend sotrovimab as a treatment option for high-risk, nonhospitalized patients with mild to moderate COVID-19, as it retains in vitro activity against the Omicron VOC.

The table on SARS-CoV-2 variants and their susceptibility to anti-SARS-CoV-2 mAbs has been updated to include susceptibility information for tixagevimab plus cilgavimab.

**Special Considerations in People With HIV**

The Panel notes that people with advanced or untreated HIV who do not have SARS-CoV-2 infection and who have not been recently exposed to SARS-CoV-2 are eligible to receive tixagevimab plus cilgavimab as PrEP. People with HIV who are on ritonavir- or cobicistat-based antiretroviral (ARV) regimens and who are prescribed ritonavir-boosted nirmatrelvir (Paxlovid) for the treatment of COVID-19 can continue their ARV regimens without dosage modifications.

**January 19, 2022**

**The COVID-19 Treatment Guidelines Panel’s Statement on Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19**

The Panel has updated this statement to address the fact that the Omicron VOC is now the dominant SARS-CoV-2 variant in the United States. Because the anti-SARS-CoV-2 mAbs bamlanivimab plus etesevimab and casirivimab plus imdevimab are predicted to have markedly reduced activities against this VOC, and because real-time testing to identify rare, non-Omicron variants is not routinely available, the Panel recommends against the use of these anti-SARS-CoV-2 mAbs (AIII).

**January 5, 2022**

**The COVID-19 Treatment Guidelines Panel’s Statement on Tixagevimab Plus Cilgavimab (Evusheld) for Pre-Exposure Prophylaxis for SARS-CoV-2 Infection**

On December 8, 2021, the Food and Drug Administration issued an Emergency Use Authorization (EUA) for the anti-SARS-CoV-2 mAbs tixagevimab plus cilgavimab (Evusheld). The EUA allows this combination to be used as PrEP in certain individuals who, if infected, are at high risk of progressing to severe COVID-19.

The Panel recommends using **tixagevimab plus cilgavimab** as SARS-CoV-2 PrEP for adults and adolescents (aged ≥12 years and weighing ≥40 kg) who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 infection, **AND** who:

- Are moderately to severely immunocompromised and may have an inadequate immune response to COVID-19 vaccination (BIIa); or
• Are not able to be fully vaccinated with any available COVID-19 vaccines due to a documented history of severe reactions to a COVID-19 vaccine or any of its components (AIIa).

The statement includes a list of moderately or severely immunocompromising conditions that will qualify an individual to receive tixagevimab plus cilgavimab as SARS-CoV-2 PrEP under the EUA. It also includes a detailed discussion of the clinical data that support the recommendations.

**The COVID-19 Treatment Guidelines Panel’s Statement on Anticoagulation in Hospitalized Patients With COVID-19**

Several randomized controlled trials have evaluated the role of therapeutic doses of heparin in reducing venous thromboembolism or mortality in patients hospitalized for COVID-19. This statement includes the Panel’s recommendations on the use of anticoagulation therapy in hospitalized, nonpregnant adults with COVID-19 who are receiving supplemental oxygen. These recommendations are presented according to whether the patient is receiving intensive care unit level of care.

The statement includes additional recommendations on the use of anticoagulation therapy in pregnant adults with COVID-19 and discusses the clinical data supporting the Panel’s recommendations.