# What's New in the Guidelines

*Last Updated: December 14, 2020*

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:

## December 14, 2020

### The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Baricitinib for the Treatment of COVID-19

On November 19, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the use of baricitinib in combination with remdesivir in hospitalized adults and children aged ≥2 years with COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation. After reviewing the available evidence for baricitinib, the Panel has determined the following:

- There are insufficient data for the Panel to recommend either for or against the use of baricitinib in combination with remdesivir for the treatment of COVID-19 in hospitalized patients in cases where corticosteroids can be used instead.
- In the rare circumstances where corticosteroids cannot be used, the Panel recommends using baricitinib in combination with remdesivir for the treatment of COVID-19 in hospitalized, nonintubated patients who require oxygen supplementation **(BIIa)**.
- The Panel **recommends against** the use of baricitinib in the absence of remdesivir, except in a clinical trial **(AIII)**.
- There are insufficient data for the Panel to recommend either for or against the use of baricitinib in combination with corticosteroids for the treatment of COVID-19. Since both agents are potent immunosuppressants, there is potential for an additive risk of infection.
- More data are needed to clarify the role of baricitinib in the management of COVID-19. Health care providers are encouraged to discuss participation in baricitinib clinical trials with their patients.

## December 3, 2020

### Therapeutic Management of Patients with COVID-19

This section has been revised to include an Executive Summary with a more detailed discussion of the processes that are thought to drive the pathogenesis of COVID-19. These processes suggest that the effect of antiviral therapies will be greatest early in the course of COVID-19, whereas immunosuppressive/anti-inflammatory therapies are likely to have their greatest effect later in the course of the disease. Based on this understanding, the Panel updated Figure 1 to

provide guidance on the use of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing antibodies, remdesivir, and dexamethasone in patients with different severities of disease.

## December 2, 2020

### The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of the Casirivimab Plus Imdevimab Combination for the Treatment of COVID-19

On November 21, 2020, the FDA issued an EUA to make the casirivimab plus imdevimab combination available for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. After reviewing the available evidence, the Panel has determined the following:

- At this time, there are insufficient data to recommend either for or against the use of casirivimab plus imdevimab for the treatment of outpatients with mild to moderate COVID-19.
- The casirivimab plus imdevimab combination **should not be considered** the standard of care for the treatment of patients with COVID-19.
- Health care providers are encouraged to discuss participation in SARS-CoV-2 neutralizing antibody clinical trials with patients who have mild to moderate COVID-19.
- Given the possibility of a limited supply of the casirivimab plus imdevimab combination, as well as challenges distributing and administering the drugs, patients at highest risk for COVID-19 progression should be prioritized for use of the drugs through the EUA. In addition, efforts should be made to ensure that the communities that are most affected by COVID-19 have equitable access to casirivimab plus imdevimab.
- Casirivimab plus imdevimab should not be withheld from a pregnant individual who has a condition that poses a high risk of progression to severe COVID-19, if the clinician thinks that the potential benefit of the drugs outweighs the potential risk.
- Patients who are hospitalized for COVID-19 **should not receive** casirivimab plus imdevimab outside of a clinical trial.
- There are currently no comparative data to determine whether there are differences in clinical efficacy or safety between casirivimab plus imdevimab and bamlanivimab.

## November 18, 2020

### The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Bamlanivimab for the Treatment of COVID-19

On November 9, 2020, the FDA issued an EUA for bamlanivimab (LY-CoV555) for the treatment of nonhospitalized patients who are at high risk of progressing to severe COVID-19 and/or hospitalization. Based on the available data, the Panel has determined the following:

- At this time, there are insufficient data to recommend either for or against the use of bamlanivimab for the treatment of outpatients with mild to moderate COVID-19.
- Bamlanivimab **should not be considered** the standard of care for the treatment of patients with COVID-19.
- More data are needed to assess the impact of bamlanivimab on the disease course of COVID-19 and to identify those people who are most likely to benefit from the drug. Health care providers are encouraged to discuss participation in bamlanivimab clinical trials with their patients.
- Patients who are hospitalized for COVID-19 should not receive bamlanivimab outside of a clinical trial.
- Given the possibility of a limited supply of bamlanivimab, as well as challenges distributing and administering the drug, patients at highest risk for COVID-19 progression should be prioritized for use of the drug through the EUA. In addition, efforts should be made to ensure that communities most affected by COVID-19 have equitable access to bamlanivimab.
- The Panel will continue to evaluate emerging clinical data on the use of bamlanivimab for the treatment of outpatients with mild to moderate COVID-19 and anticipates updating these recommendations as more information becomes available.