

# 1: What's New in the Guidelines

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*Last Updated: June 17, 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:

## June 17, 2021

### [The COVID-19 Treatment Guidelines Panel's Statement on the Updated Emergency Use Authorization of the Anti-SARS-CoV-2 Monoclonal Antibody Combination Casirivimab Plus Imdevimab for the Treatment of COVID-19](#)

On June 3, 2021, the Food and Drug Administration (FDA) updated the Emergency Use Authorization (EUA) of the anti-SARS-CoV-2 monoclonal antibody combination casirivimab plus imdevimab for the treatment of nonhospitalized individuals with COVID-19. The authorized dosage has been reduced from a single intravenous (IV) infusion of casirivimab 1,200 mg plus imdevimab 1,200 mg to casirivimab 600 mg plus imdevimab 600 mg. In addition, the same doses of casirivimab and imdevimab may now be administered by subcutaneous (SQ) injection when IV infusion is not feasible or may delay treatment.

The Panel currently recommends that nonhospitalized patients with COVID-19 who are at high risk for disease progression receive one of three authorized anti-SARS-CoV-2 monoclonal antibody regimens (see the [Panel's Statement on the Emergency Use Authorizations of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19](#)). The Panel has reviewed the data that were provided in the updated EUA for casirivimab plus imdevimab and reported publicly. For the casirivimab plus imdevimab combination regimen (if selected from the three authorized regimens), the Panel recommends:

- Using the dose of **casirivimab 600 mg plus imdevimab 600 mg (AIIa)**.
- Using IV infusion of **casirivimab plus imdevimab (AIIa)**.
- When IV infusion is not feasible or would lead to delay in treatment, SQ injection of **casirivimab plus imdevimab** can be used as an alternative route of administration (**BIII**).

The [Panel's statement](#) includes a detailed discussion of the clinical data supporting these recommendations.

June 11, 2021

[The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorizations of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19](#)

On May 26, 2021, the FDA issued an EUA for the anti-SARS-CoV-2 monoclonal antibody sotrovimab (previously VIR-7831) for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progression to severe COVID-19.

**Recommendation**

The Panel's statement is an update to include sotrovimab in recommendations for the use of the authorized anti-SARS-CoV-2 monoclonal antibodies:

- The Panel recommends using one of the following anti-SARS-CoV-2 monoclonal antibodies, listed in alphabetical order, to treat nonhospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the EUA criteria:
  - **Bamlanivimab plus etesevimab**; *or*
  - **Casirivimab plus imdevimab**; *or*
  - **Sotrovimab**.

Please see the [full statement](#) for considerations regarding the use of these agents. For example, some of the considerations relate to SARS-CoV-2 variants of concern or interest.

**EUA Criteria Expanded to Include Additional Medical Conditions and Factors**

On May 14, 2021, the FDA updated the EUA criteria for all authorized anti-SARS-CoV-2 monoclonal antibodies for this indication by broadening the list of medical conditions and other factors that may put patients at increased risk of progression to severe COVID-19.

The quality of the data that supports the Panel's recommendations for the use of these anti-SARS-CoV-2 monoclonal antibodies differs based on the criteria for high risk of severe COVID-19 used. Consequently, the Panel weighed the strength of the recommendations based on the evidence for the risk of progression. Treatment is recommended based on the FDA EUA criteria for:

- Patients with high-risk conditions that were represented in clinical trials (**AIIa**), *and*
- Patients with other medical conditions and factors that had limited representation in clinical trials (**BIII**); however, in cases where the patient has an immunocompromising condition or is receiving immunosuppressive therapy, the rating is **AIII**.

The [Panel's statement](#) includes a detailed discussion of the rationale for these recommendations, information on the expanded EUA criteria, and a list of the criteria with the Panel's ratings.

May 27, 2021

[The COVID-19 Treatment Guidelines Panel's Statement on Baricitinib for the Treatment of Adults With COVID-19](#)

On December 14, 2020, the Panel released a statement regarding the EUA issued by the FDA to make baricitinib available for certain patients with COVID-19. The Panel's statement included recommendations based on the scientific evidence supporting the baricitinib EUA.

Since the statement was released, the Panel has reviewed the preliminary results (not yet peer reviewed) from COV-BARRIER, a trial of baricitinib in hospitalized adults. Based on this review, the Panel has

updated its recommendations on the use of baricitinib for the treatment of adults with COVID-19, as outlined below.

- The Panel recommends using either **baricitinib (BIIa)** or **tocilizumab (BIIa)** (listed alphabetically) in combination with **dexamethasone** alone or **dexamethasone plus remdesivir** for the treatment of COVID-19 in hospitalized patients on high-flow oxygen or noninvasive ventilation who have evidence of clinical progression or increased markers of inflammation.
- Among hospitalized patients with hypoxemia who require supplemental oxygen therapy, there is insufficient evidence to identify which patients would benefit from the addition of baricitinib or tocilizumab to dexamethasone (with or without remdesivir). Some Panel members would add either baricitinib or tocilizumab to patients who are exhibiting signs of systemic inflammation and rapidly increasing oxygen needs while on dexamethasone, but who do not yet require high-flow oxygen or noninvasive ventilation.
- In the rare circumstance when 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**).
- There is insufficient evidence for the Panel to recommend either for or against the use of baricitinib in combination with dexamethasone for the treatment of COVID-19 in hospitalized patients who require invasive mechanical ventilation.
- The Panel **recommends against** the use of **baricitinib** in combination with **tocilizumab** for the treatment of COVID-19, except in a clinical trial (**AIII**). Because both baricitinib and tocilizumab are potent immunosuppressants, there is the potential for an additive risk of infection.
- There is insufficient evidence for the Panel to recommend either for or against the use of baricitinib for the treatment of COVID-19 in children.

The [Panel's statement](#) includes a detailed discussion of the clinical data supporting these recommendations.