What’s New in the Guidelines

Last Updated: April 8, 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:

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Anti-SARS-CoV-2 monoclonal antibodies are available through Food and Drug Administration Emergency Use Authorizations (EUAs). Data are emerging on these monoclonal antibodies, including preliminary data from a Phase 3 trial of casirivimab plus imdevimab, and on the in vitro susceptibility of SARS-CoV-2 variants to anti-SARS-CoV-2 monoclonal antibodies. After reviewing the available data, the Panel has updated its recommendations on the use of anti-SARS-CoV-2 monoclonal antibodies in outpatients with mild to moderate COVID-19 who are at high risk of disease progression.

Based on the available evidence, the Panel has determined the following:

- The Panel recommends using one of the following combination anti-SARS-CoV-2 monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the EUA criteria (listed in alphabetical order):
  - Bamlanivimab 700 mg plus etesevimab 1,400 mg (AIIa); or
  - Casirivimab 1,200 mg plus imdevimab 1,200 mg (AIIa).

- Treatment should be started as soon as possible after the patient receives a positive result on a SARS-CoV-2 antigen or nucleic acid amplification test (NAAT) and within 10 days of symptom onset.

- There are no comparative data to determine whether there are differences in clinical efficacy or safety between bamlanivimab plus etesevimab and casirivimab plus imdevimab.

- There are SARS-CoV-2 variants, particularly those that contain the mutation E484K, that reduce the virus’ susceptibility to bamlanivimab and, to a lesser extent, casirivimab and etesevimab in vitro; however, the clinical impact of these mutations is not known.

- In regions where SARS-CoV-2 variants with reduced in vitro susceptibility to bamlanivimab plus etesevimab are common, some Panel members would preferentially use casirivimab plus imdevimab while acknowledging that it is not known whether in vitro susceptibility data correlate with clinical outcomes.
• Because clinical outcome data are limited and there are concerns regarding decreased susceptibility of variants, the Panel recommends against the use of bamlanivimab monotherapy (AIII).

• If combination products are not available, the use of bamlanivimab monotherapy can be considered for people who meet the EUA criteria on a case-by-case basis.

• The Panel recommends against the use of anti-SARS-CoV-2 monoclonal antibodies for patients who are hospitalized because of COVID-19, except in a clinical trial (AIIa). However, their use should be considered for persons with mild to moderate COVID-19 who are hospitalized for a reason other than COVID-19 but who otherwise meet the EUA criteria.

The Panel’s statement includes a detailed discussion of the rationale for these recommendations.