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Introduction

These Treatment Guidelines have been developed to inform clinicians how to care for patients with COVID-19. Because clinical information about the optimal management of COVID-19 is evolving quickly, these Guidelines will be updated frequently as published data and other authoritative information becomes available.

The recommendations in these Guidelines are based on scientific evidence and expert opinion. Each recommendation includes two ratings: a letter (**A**, **B**, or **C**) that indicates the strength of the recommendation and a Roman numeral (**I**, **II**, or **III**) that indicates the quality of the evidence that supports the recommendation (see Table 1).

Panel Composition

Members of the COVID-19 Treatment Guidelines Panel (the Panel) were appointed by the Panel co-chairs and chosen based on their clinical experience and expertise in patient management, translational and clinical science, and/or development of treatment Guidelines. Panel members include representatives from federal agencies, health care and academic organizations, and professional societies. Federal agencies and professional societies represented on the Panel include:

- American College of Chest Physicians
- American College of Emergency Physicians
- American Thoracic Society
- Biomedical Advanced Research and Development Authority
- Centers for Disease Control and Prevention
- Department of Defense
- Department of Veterans Affairs
- Food and Drug Administration
- Infectious Diseases Society of America
- National Institutes of Health
- Pediatric Infectious Diseases Society
- Society of Critical Care Medicine
- Society of Infectious Diseases Pharmacists.

The inclusion of representatives from professional societies does not imply that their societies have endorsed all elements of this document.

The names, affiliations, and conflict of interest disclosures of the Panel members, ex-officio members, and support staff are provided in the <u>Panel Roster</u> and <u>Financial Disclosures</u>.

Development of the Guidelines

Each section of the Guidelines was developed by a working group of Panel members with expertise in the section's area of interest. Each working group was responsible for identifying relevant information and published scientific literature, and conducting a systematic, comprehensive review of that information and literature. The working groups will propose updates to the Guidelines based on the latest published research findings and evolving clinical information.

Each guideline section has been reviewed, modified as necessary, and voted on by the entire Panel. A majority vote was required for a recommendation to be included in the posted Guidelines. Panel members are required to keep all Panel deliberations and unpublished data considered during the development of the guidelines confidential.

Method of Synthesizing Data and Formulating Recommendations

The working groups critically review and synthesize the available data to develop recommendations. Aspects of the data that are considered include, but are not limited to, the type of study (e.g., case series, prospective cohort, randomized controlled trial), the quality and suitability of the methods, the number of participants, and the effect sizes observed. Each recommendation is assigned two ratings according to the scheme presented in Table 1.

Table 1. Recommendation Rating Scheme

| Strength of Recommendation | Quality of Evidence for Recommendation |
|--|---|
| A: Strong recommendation for the statement B: Moderate recommendation for the statement C: Optional recommendation for the statement | I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints II: One or more well-designed, nonrandomized trials or observational cohort studies III: Expert opinion |

It is important to note that at present, to develop the recommendations in these Guidelines, the Panel relied heavily on experience with other diseases, supplemented with evolving personal clinical experience with COVID-19, and incorporated the rapidly growing published scientific literature on COVID-19. When information existed in other published Guidelines that the Panel felt important to include in these Guidelines, the information was included with permission from the original sources.

Evolving Knowledge on Treatment for COVID-19

Currently there are no Food and Drug Administration (FDA)-approved drugs for COVID-19. However, an array of drugs approved for other indications, as well as multiple investigational agents, are being studied for the treatment of COVID-19 in several hundred clinical trials around the globe. These trials can be accessed at *ClinicalTrials.gov*. In addition, providers can access and prescribe investigational drugs or agents approved or licensed for other indications through various mechanisms, including Emergency Use Authorizations (EUA), Emergency Investigational New Drug (EIND) applications, compassionate use or expanded access programs with drug manufacturers, and/or off-label use.

For this reason, whenever possible, the Panel recommends that promising, unapproved or unlicensed treatments for COVID-19 be studied in well-designed controlled clinical trials. This includes drugs that have been approved or licensed for other indications. The Panel recognizes the critical importance of clinical research in generating evidence to address unanswered questions regarding the safety and efficacy of potential treatments for COVID-19. However, the Panel also realizes that many patients and providers who cannot access such trials are still seeking guidance about whether to use these agents.

Finally, it is important to stress that the rated treatment recommendations in these Guidelines should not be considered mandates. The choice of what to do or not to do for an individual patient is ultimately decided by the patient together with their provider.