

January 11, 2022

Updated COVID-19 Prevention, Treatment Information for Clinicians

Federal agencies continue to encourage patients' vaccination prior to discharge to congregate settings; new information on therapeutics for high-risk patients may aid treatment efforts

The federal government, through the Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC), over the past month has released a series of updated, clinically important information that may be of critical interest as hospital leaders and staff work to provide patients with the best possible protection and care against COVID-19.

The AHA is supporting these federal efforts by compiling for clinicians the latest information to enable easy sharing, with links to recent announcements and underlying supporting documents. These resources focus on **patients' vaccination prior to discharge to congregate, long-term care facilities** and the **availability of therapeutics for COVID-19 patients at high risk of severe outcomes**.

Details follow.

VACCINATING PATIENTS PRIOR TO DISCHARGE TO CONGREGATE SETTINGS

Nationwide, nearly all health care organizations are experiencing staff shortages coupled with growing incidences of COVID-19 transmission in their communities. Vaccination continues to offer patients the best protection against severe COVID-19 illness and disease, particularly for individuals at high risk of severe outcomes. Such patients include the elderly and those with underlying health conditions who are immunocompromised or face other risks.

Many such individuals are discharged to nursing homes, rehabilitation centers or other congregate living facilities when they are ready to leave the hospital. The CDC [encourages](#) hospitals to vaccinate those patients prior to discharge to such congregate settings if they have no health concerns that would preclude vaccination against COVID-19.

This step can reduce the patient's near-term chances of re-hospitalization with COVID-19, along with the coronavirus' spread among other patient populations. Hospitals are urged to work with their states to ensure they have an adequate supply of vaccines on

hand to enable the patient to receive their first or second dose of vaccine, or booster shots for eligible patients.

AVAILABILITY OF THERAPEUTICS FOR COVID-19 PATIENTS AT HIGH RISK OF SEVERE OUTCOMES

Monoclonal antibody therapeutics. The rapid spread of the SARS-CoV-2 omicron variant highlighted shortcomings of several monoclonal antibody therapies that had previously been useful in saving lives and preventing hospitalizations during the delta surge. Data indicates that GlaxoSmithKline's Sotrovimab is the only available monoclonal antibody that is effective against omicron; as such, this treatment is in very limited supply.

Antiviral medications. The Food and Drug Administration (FDA) in December granted emergency use authorization for Pfizer's Paxlovid and Merck's Molnupiravir antiviral medications, due in part to their apparent effectiveness against the SARS-CoV-2 omicron variant. These treatments are now available, albeit in limited supply, as production ramps up by their respective manufacturers.

Additionally, the antiviral medication Evusheld is now authorized by the FDA for emergency use. Evusheld is intended for use as a prophylactic treatment against COVID-19 for those who are not infected and not exposed to COVID-19, as well as those who cannot get vaccinated due to medical reasons who are at high risk of severe outcomes from COVID-19. This is a relatively small portion of the population.

Determining patient prioritization for antivirals and monoclonal antibody COVID-19 treatments. The National Institutes of Health has provided an [interim statement](#) with guidance on the ethical determination of which patients will receive available therapies.

This guidance emphasizes the following prioritization:

- treatment of COVID-19 over post-exposure prophylaxis following exposure;
- treatment of COVID-19 in unvaccinated or incompletely vaccinated individuals with clinical factors that put them at risk for serious illness, and vaccinated individuals who are likely unable to mount adequate immune responses; and
- Evusheld's use as pre-exposure prophylaxis for severely immunocompromised individuals over moderately immunocompromised individuals.

Distribution and supply. Because the demand for treatments for high-risk patients at present outstrips supply, the Assistant Secretary for Preparedness and Response (ASPR) is working to ensure fair and equitable national distribution of the available supply. Each week, ASPR learns how many treatment courses of each of these monoclonal antibodies and other therapeutics will be available; it then uses data submitted to HHS by hospitals and other entities to project the number of newly diagnosed adult COVID-19 cases, while also projecting numbers of hospitalizations. This enables ASPR to determine a proportional allocation to states.

ASPR notifies the appropriate point of contact in each state's department of health/public health of its projection. Each state's point of contact then makes distribution decisions

using whatever method their state has chosen. This distributional information is provided to AmerisourceBergen, which is under contract with the federal government to distribute available medications to identified sites per state officials' instructions.

Allocated medications are intended to reach these sites late in the week of distribution; however, weather and other transportation difficulties can impact actual times of arrival.

ASPR on a Jan. 10 stakeholder call announced that its best estimate is that companies producing antiviral treatments will be able to supply between now and the end of the month:

- 300,000 courses of Evusheld,
- 200,000 courses of Paxlovid, and
- 800,000 courses of Molnupiravir.

Information on projected available courses of monoclonal antibodies was not provided.

Remdesivir. In addition to the aforementioned therapies, Gilead's remdesivir treatment has proved to be an effective therapy for those who are early in their diagnosis of COVID-19 and at high risk of hospitalization or death. Supplies of remdesivir are relatively robust; as such, it is not currently being allocated by ASPR. Instead, hospitals and other sites who can transfuse patients with this medication can order it through the commercial market.

For remdesivir to be effective, it must be administered across three transfusions, which requires that patients be able to get to transfusions site on each of three days to receive their treatment. While FDA's EUA for remdesivir specified this therapeutic was to be used for inpatient treatment, an NIH treatment panel has recently [recommended](#) its use in the outpatient setting. CMS on Jan. 7 also indicated its willingness to cover this outpatient off-label use in a [special edition of MLN Connects](#). Hospitals should contact their MAC with questions.

FURTHER QUESTIONS

If you have questions, please contact AHA at 800-424-4301.