

## **CDC Health Advisory:**

Updated Information on Availability and Use of Treatments for Outpatients with Mild to Moderate COVID-19 Who are at Increased Risk for Severe Outcomes of COVID-19

April 26, 2022

The Centers for Disease Control and Prevention (CDC) issued a <u>Health Advisory</u> to update healthcare providers about the availability and use of recommended outpatient therapies for COVID-19 and to advise against using unproven treatments that have known or potential harms for outpatients with mild to moderate COVID-19. Healthcare providers are asked to please review the full CDC advisory included below. In addition, local information for providers regarding availability and access of outpatient COVID-19 therapeutics is provided.

## Treatment Availability and Access in Los Angeles (LA) County:

- Outpatient therapeutics for COVID-19 are widely available.
   The oral medications Ritonavir-boosted nirmatrelvir (Paxlovid) and molnupiravir (Lagevrio) are available by prescription in over 300 LA pharmacies and clinical sites across the County. Visit LA County Department of Public Health (DPH) Provider therapeutics webpage for information about these locations. The webpage also has information about how to procure the parenteral treatments bebtelovimab and remdesivir (Veklury) and the pre-exposure prophylactic medication Tixagevimab/cilgavimab (Evusheld).
- Healthcare providers are asked to proactively contact their patients who are at
  higher risk for severe outcomes of COVID-19 to let them know about these potentially
  lifesaving drugs and how to access them quickly should they become infected with
  COVID-19 and have symptoms. Tell your patients how to contact your office/facility to
  get a prescription. Please note that the CDC list of higher risk conditions is broad and
  includes older age (e.g., age 65 and older) as well common conditions such as diabetes,
  depression, obesity, physical inactivity, and current and former smokers among many
  others.
- Patients who are unable to access oral COVID-19 therapeutics through their own provider should be referred to a Test to Treat program or the DPH Public Health Call Center (833-540-0473 open 7 days a week 8:00 am-8:30 pm).
   Both of these services provide access to COVID-19 testing, evaluation, and if eligible, oral COVID-19 treatment.
- The <u>Provider therapeutics webpage</u> has information on how to procure medication, Test to Treat, the Call Center, and outpatient therapeutics, as well as resources such as sample prescriptions.
- Information for patients about medicine to treat and prevent COVID-19 is available at <a href="mailto:ph.lacounty.gov/covidmedicines">ph.lacounty.gov/covidmedicines</a> (English) and <a href="ph.lacounty.gov/covidmedicines">ph.lacounty.gov/covidmedicamentos</a> (Spanish). A one-page flyer is available in multiple languages on the webpage.

• Clinical sites or pharmacies that are interested in receiving Paxlovid, molnupiravir (Lagevrio) or Evusheld or in being listed as a Test to Treat site are encouraged to contact LAC DPH at DPH-Therapeutics@ph.lacounty.gov.

**Reminder:** Staying <u>up to date</u> with COVID-19 vaccination is still the best way to prevent serious outcomes of COVID-19. In addition, 2nd boosters are now available to certain patients at higher risk for severe outcomes (i.e., those aged 50 years and older, those who are aged 12 and older who are immunocompromised, and those who received two doses of Janssen vaccine). The CDC has created a <u>2nd booster dose discussion guide</u> to assist providers in counseling these patients as well as a <u>patient 2nd booster dose resource</u> and <u>webpage</u>. For additional information regarding vaccinations please refer to <u>COVID-19 Vaccines: Provider Summary Table</u> and the <u>COVID-19 Vaccine Healthcare Provider Information Hub.</u>

Healthcare providers should read the full CDC Health Advisory below.

# This is an official CDC HEALTH ADVISORY

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## Updated Information on Availability and Use of Treatments for Outpatients with Mild to Moderate COVID-19 Who are at Increased Risk for Severe Outcomes of COVID-19

#### **Summary**

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to update healthcare providers, public health departments, and the public about the availability and use of recommended therapies for COVID-19 and to advise against using unproven treatments that have known or potential harms for outpatients with mild to moderate COVID-19. For patients with mild to moderate COVID-19 who are not hospitalized and who are at <a href="increased risk">increased risk</a> for severe COVID-19 outcomes, several <a href="treatment options">treatment options</a>, including antiviral medications and monoclonal antibodies, are now widely available and accessible.

Systemic corticosteroids are <u>not recommended</u> to treat patients with mild to moderate COVID-19 who do not require supplemental oxygen; patients who are receiving dexamethasone or another corticosteroid for other indications should continue therapy for their underlying conditions as directed by their healthcare providers. Antibacterial therapy is <u>not recommended</u> for the treatment of COVID-19 in the absence of another indication.

Staying <u>up to date</u> with COVID-19 vaccination is still the best way to prevent serious outcomes of COVID-19, including severe disease, hospitalization, and death.

#### **Background**

Early outpatient treatment of COVID-19 can avert serious, potentially life-threatening illness and reduce burden on the healthcare system. CDC issued a <u>HAN Health Advisory on December 31, 2021</u> to address using therapeutics in the outpatient setting for people with COVID-19. At that time, Omicron cases were increasing rapidly in the United States and some COVID-19 therapeutics were in short supply. Now antivirals for COVID-19 are widely available and can be accessed with a provider prescription at pharmacies nationwide and at <u>Test to Treat locations</u>.

Data from CDC (1, 2) (highlighted in a February 13, 2021 CDC/Infectious Diseases Society of America COVID-19 Clinical Call) and the Food and Drug Administration (3) suggest that there has been increasing use of systemic corticosteroids and antibiotics to treat outpatients with COVID-19. However, these drugs can cause harm and provide no demonstrated benefit in patients with COVID-19 with no supplemental oxygen requirement or bacterial coinfection. Short courses of systemic corticosteroids have been associated with adverse events such as hyperglycemia, gastrointestinal bleeding, psychosis, infections, and longer-term effects (4–7).

The National Institutes of Health (NIH) provides <u>COVID-19 Treatment Guidelines</u>. The guidelines panel provides treatment options and recommends against using systemic corticosteroids to treat patients with mild to moderate COVID-19 who do not require supplemental oxygen (**Figure**). Patients who are receiving dexamethasone or another corticosteroid for other indications should continue therapy for their

underlying conditions as directed by their healthcare providers. Systemic corticosteroids are recommended for hospitalized patients with COVID-19 who require supplemental oxygen or higher-level respiratory support.

The guidelines panel also recommends against using antibacterial therapy for COVID-19 in the absence of another indication. Antibacterial drugs have no benefit in treating viral infections and can cause harm.

Figure. Therapeutic Management of Nonhospitalized Adults with COVID-19 (from NIH COVID-19 Treatment Guidelines, last updated: April 8, 2022)

## PATIENT DISPOSITION

**Does Not Require** 

Hospitalization or

Supplemental Oxygen

## PANEL'S RECOMMENDATIONS

All patients should be offered symptomatic management (AIII).

For patients who are at high risk of progressing to severe COVID-19,<sup>a</sup> use 1 of the following treatment options:

## **Preferred Therapies**

Listed in order of preference:

- Ritonavir-boosted nirmatrelvir (Paxlovid)b,c (Alla)
- Remdesivir<sup>c,d</sup> (Blla)

#### **Alternative Therapies**

For use <u>ONLY</u> when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:

- Bebtelovimabe (CIII)
- Molnupiravir<sup>c,f</sup> (Clla)

The Panel recommends against the use of dexamethasone<sup>9</sup> or other systemic corticosteroids in the absence of another indication (AIII).

Rating of Recommendations: A = Strong; B = Moderate; C = Weak

Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion

- <sup>a</sup> For a list of risk factors, see the CDC webpage <u>Underlying Medical Conditions Associated With Higher</u> Risk for Severe COVID-19.
- <sup>b</sup> Ritonavir-boosted nirmatrelvir has significant drug-drug interactions. Clinicians should carefully review a patient's concomitant medications and evaluate potential drug-drug interactions.
- <sup>c</sup> If a patient requires hospitalization after starting treatment, the full treatment course can be completed at the healthcare provider's discretion.
- <sup>d</sup> Administration of remdesivir requires 3 consecutive days of IV infusion.
- <sup>e</sup> Bebtelovimab is active in vitro against all circulating Omicron subvariants, but there are no clinical efficacy data from placebo-controlled trials that evaluated the use of bebtelovimab in patients who are at high risk of progressing to severe COVID-19. Therefore, bebtelovimab should be used only when the preferred treatment options are not available, feasible to use, or clinically appropriate.
- Molnupiravir has lower efficacy than the preferred treatment options. Therefore, it should be used only when the preferred options are not available, feasible to use, or clinically appropriate.
- <sup>9</sup> There is currently a lack of safety and efficacy data on the use of this agent in outpatients with COVID-19; using systemic glucocorticoids in this setting may cause harm.

## **Recommendations for Healthcare Providers**

- Obtain updated information on appropriate use of clinically indicated therapeutics through <u>NIH's</u> COVID-19 Treatment Guidelines.
- 2. Prescribe COVID-19 therapeutics for patients when clinically indicated.
  - There are considerable differences in efficacy, risk profiles, and use restrictions between the two oral antivirals. Healthcare providers need to be familiar with these distinctions to

- make clinical decisions and inform patients. In addition, initiating treatment with these oral antivirals must begin within five days of symptom onset to maintain product efficacy.
- Please see <u>NIH's COVID-19 Treatment Guidelines</u> for important therapeutic considerations, such as the potential for significant drug-drug interactions with ritonavirboosted nirmatrelvir (<u>Paxlovid</u>) and dosing regimens for patients with renal impairment.
- 3. Obtain information on **access to outpatient COVID-19 treatments**, including pharmacies where antivirals for COVID-19 are distributed and Test to Treat locations.
- 4. Do not use **dexamethasone and other systemic corticosteroids** to treat patients with mild to moderate COVID-19 who do not require hospitalization or supplemental oxygen; these drugs have no proven benefit in these patients and can cause harm.
- 5. Do not use **antibacterial therapy** to treat COVID-19 in the absence of another indication; these drugs have no benefit for treating viral infections and can cause harm.
- 6. To prevent serious outcomes of COVID-19, including severe disease, hospitalization, and death, encourage all patients to remain up to date with COVID-19 vaccination.
  - People who are immunocompromised or severely allergic to COVID-19 vaccines may receive tixagevimab co-packaged with cilgavimab (Evusheld), a long-acting combination monoclonal antibody therapy given by intramuscular injection for pre-exposure prophylaxis of COVID-19. To find Evusheld distribution locations, providers can go to the COVID-19 Therapeutics Locator, call the support line at 1-800-232-0233 (TTY 888-720-7489), or contact their individual state or territorial health planners.

## Recommendations for Public Health Departments and Public Health Jurisdictions

- 1. Maintain awareness of **locations of available therapeutics** within your jurisdictions, including pharmacies where antivirals for COVID-19 are distributed and <u>Test to Treat</u> locations.
- 2. Communicate ongoing and up-to-date information on therapeutics for COVID-19 and their availability to healthcare providers within your jurisdiction.
- **3.** Disseminate information for the Test to Treat call center at <u>1-800-232-0233</u> (TTY <u>1-888-720-7489</u>) which provides information in more than 150 languages, and for the <u>Disability Information</u> and Access Line at 1-888-677-1199.

#### **Recommendations for the Public**

- If you test positive and are an older adult or someone who is at increased risk of getting very sick from COVID-19, treatment is available. Contact a healthcare provider right away after a positive test to determine if you are eligible for treatment, even if your symptoms are mild. You can also visit a <u>Test to Treat</u> location and, if eligible, receive a prescription from a provider at that location.
- Follow <u>CDC guidance on testing for COVID-19</u> and use the <u>Test to Treat locator</u> or call <u>1-800-232-0233</u> (TTY <u>1-888-720-7489</u>) to find a testing location that can provide treatment if you test positive.
- 3. **Don't delay**: Treatment must be started within the first few days of when your symptoms started to be effective.
- 4. Staying <u>up to date</u> with **COVID-19 vaccination** is still the best way to prevent serious outcomes of COVID-19, including severe disease, hospitalization, and death.

#### For More Information

- CDC COVID-19 Treatment website
- NIH COVID-19 Treatment Guidelines
- NIH COVID-19 Treatment Guidelines: Therapeutic Management of Nonhospitalized Adults with COVID-19
- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- NIH COVID-19 Treatment Guidelines: Prevention of SARS-CoV-2 Infection
- Office of the Assistant Secretary for Preparedness & Response (ASPR) Test to Treat website

- <u>U.S. Food and Drug Administration COVID-19 Therapeutic Product Emergency Use</u> Authorizations
- CDC COVID Data Tracker

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The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

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**Health Alert** Requires immediate action or attention; highest level of importance

**Health Advisory** May not require immediate action; provides important information for a specific incident or situation Unlikely to require immediate action; provides updated information regarding an incident or situation

HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##