

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

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Public Health Preparedness and Local Health Section

Date: May 3, 2022 OPHPR-2022-002
To: Directors of Health, Acting Directors of Health
FROM: Francesca Provenzano, MPH, RS
Public Health Section Chief
RE: COVID-19 Oral Antiviral Therapeutics

Two COVID-19 oral antiviral treatments currently have an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA): Paxlovid and Lagevrio (molnupiravir). These medications are taken as pills, as directed by a healthcare professional. Early treatment for eligible patients can reduce hospitalization and death.

Oral antivirals can help fight the COVID-19 virus by blocking it from entering the body's healthy cells, boosting the immune system, or reducing the amount of active virus in the body. An oral antiviral may be able to help decrease symptoms, the seriousness of the illness, and help patients recover faster.

Who Can Receive COVID-19 Oral Antivirals?

COVID-19 therapeutics can be used to treat non-hospitalized patients who have tested positive for COVID-19 and have mild to moderate symptoms. Therapeutics supply has increased, and oral antivirals are available for any patient who might benefit. Adults ages 18 years and older may be eligible for Lagevrio (molnupiravir). Adults and children ages 12 years and older (weighing at least 88 pounds) may be eligible for Paxlovid. An oral antiviral must be started within 5 days of symptom onset. Timely diagnosis and connecting with a medical practitioner are key elements to being eligible to receive oral antivirals.

Where Can Patients Receive COVID-19 Oral Antivirals?

By Prescription Filled at a Pharmacy

Oral antivirals require a prescription. Oral antivirals are available at most retail pharmacy locations (CVS, Walgreens, Walmart, Rite Aid, Stop & Shop, Shop Rite, and Price Chopper) in Connecticut with additional sites onboarding weekly. People can be tested and treated by their health care provider, who can appropriately prescribe these oral antivirals. Patients can then fill these prescriptions at pharmacies that have the medication in stock.



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COVID-19 Antiviral Oral Therapeutics

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Other [locations](#), such as acute care hospitals, some federally qualified health centers, and pharmacies serving long term care facilities also have supplies of oral antivirals.

Test to Treat

Through the Test to Treat program, people are able to get tested and – if they are positive and treatments are appropriate for them – receive a prescription from a health care provider, and have their prescription filled or medication dispensed by the provider all at one location. The Test to Treat initiative includes sites that have health care providers available to provide timely and thorough assessment and discussion relevant to oral antiviral treatment option(s), consistent with FDA requirements regarding these drugs.

People can bring at-home test results to a Test to Treat site for assessment to receive treatment. The program does not require that an individual is tested at the Test to Treat site.

These “One-Stop Test to Treat” [sites](#) are available at many locations across the state, including pharmacy-based clinics, urgent care centers, and Health Resources Services Administration (HRSA)-supported federally-qualified health centers (FQHCs).

Is there cost associated with COVID-19 therapeutics?

Oral antivirals for COVID-19 have been purchased by the United States government and are available free of charge during the COVID-19 public health emergency. Individuals may be charged for other services provided at Test to Treat locations, such as medical assessment by a qualified healthcare professional or an administrative fee.

Where can I find more information?

For more information, please visit DPH’s COVID-19 Therapeutics website at <https://portal.ct.gov/DPH/Public-Health-Preparedness/DPH-COVID-19-Specific-Resources/COVID-19-Therapeutics>

Questions from both providers and the public about COVID therapeutics can be directed to COVIDmeds.DPH@ct.gov.

COVID-19 Therapeutics Locator: <https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com>

COVID-19 Test to Treat Locator: <https://covid-19-test-to-treat-locator-dhhs.hub.arcgis.com>

Attached: Antiviral Fact Sheet for Medical Providers
April 25, 2022 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*



ANTIVIRALS FACT SHEET FOR MEDICAL PRACTITIONERS

Which of my patients might qualify for and need treatment for COVID-19?

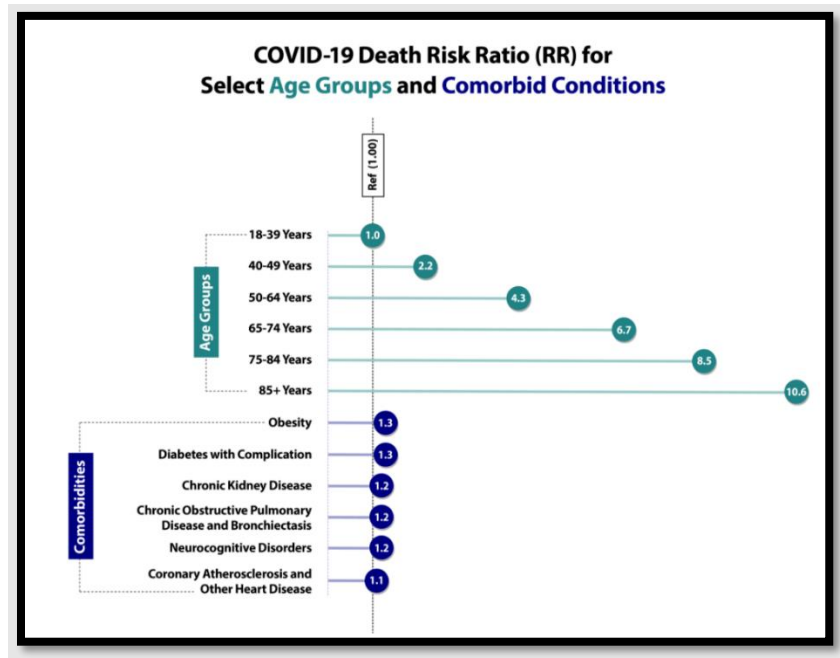
COVID-19 therapeutics can be used to treat non-hospitalized patients who have tested positive for COVID-19 and have mild to moderate symptoms. Early treatment for eligible patients can reduce hospitalization and death. Therapeutics supply has increased, and oral antivirals are available for any patient who might benefit.

Certain underlying medical conditions increase the risk for severe COVID-19 illness, and having multiple conditions increases risk. The risk associated with these underlying conditions increases with age, which is the strongest risk factor for severe COVID-19 outcomes.

We continue to learn more about the risk factors for severe COVID-19 outcomes, and this list may be updated over time.

<u>Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19</u>		
Higher risk for severe COVID-19 outcomes: good or strong evidence		
Cancer Cerebrovascular disease Chronic kidney disease* Chronic lung diseases limited to: <ul style="list-style-type: none"> • Interstitial lung disease • Pulmonary embolism • Pulmonary hypertension • Bronchiectasis • COPD (chronic obstructive pulmonary disease) Chronic liver diseases limited to: <ul style="list-style-type: none"> • Cirrhosis • Non-alcoholic fatty liver disease • Alcoholic liver disease • Autoimmune hepatitis Cystic fibrosis Diabetes mellitus, type 1 and type 2*	Disabilities <ul style="list-style-type: none"> • Attention-Deficit/Hyperactivity Disorder (ADHD) • Cerebral Palsy • Congenital Malformations (Birth Defects) • Limitations with self-care or activities of daily living • Intellectual and Developmental Disabilities • Learning Disabilities • Spinal Cord Injuries (For the list of all conditions that were part of the review, see the module below) Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)	HIV (human immunodeficiency virus) Mental health disorders limited to: <ul style="list-style-type: none"> • Mood disorders, including depression • Schizophrenia spectrum disorders • Neurologic conditions limited to dementia Obesity (BMI ≥ 30 kg/m ²)* Primary Immunodeficiencies Pregnancy and recent pregnancy Physical inactivity Smoking, current and former Solid organ or hematopoietic cell transplantation Tuberculosis Use of corticosteroids or other immunosuppressive medications
Suggestive higher risk for severe COVID-19 outcomes: supported by mostly cohort, case-control, or cross-sectional studies		
Children with certain underlying conditions Overweight (BMI ≥ 25 kg/m ² , but < 30 kg/m ²) Sickle cell disease Substance use disorders Thalassemia		
Mixed evidence for severe COVID-19 outcomes: meta-analysis or systematic review is inconclusive		
Alpha 1 antitrypsin deficiency Asthma Bronchopulmonary dysplasia Hepatitis B Hepatitis C Hypertension*		
Footnote: * indicates underlying conditions for which there is evidence for pregnant and non-pregnant people		

Age is the strongest risk factor for death from COVID-19.



Where are treatments available?

Oral antivirals (Paxlovid and Legevirio (Molnupiravir)) are available at most retail pharmacy locations (CVS, Walgreens, Walmart, Rite Aid, Stop & Shop, Shop Rite, and Price Chopper) in Connecticut with additional sites onboarding weekly. Monoclonal antibody products (Bebtelovimab) are currently available to outpatients through acute care hospitals.

If testing with rapid turn around is not available to you:

[COVID-19 Test to Treat Locator English \(arcgis.com\)](https://arcgis.com)

If the patient has already tested positive or can be tested quickly through your practice:

[COVID-19 Therapeutics Locator \(arcgis.com\)](https://arcgis.com)

How should I choose the right therapy for my patients?

Therapeutic options for individual patients will be dictated by time since symptom onset, renal status, and concurrent medications. A comparison of all available outpatient products can be found here:

[Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19 \(hhs.gov\)](https://hhs.gov)

The Infectious Disease Society of America (IDSA) has developed a helpful tool for clinical decision-making found here:

[COVID-19 Outpatient Treatment Roadmap \(idsociety.org\)](https://idsociety.org)

The National Institutes of Health (NIH) have provided further guidance on the use of COVID-19 therapeutics found here:

[Nonhospitalized Adults: Therapeutic Management | COVID-19 Treatment Guidelines \(nih.gov\)](#)

Are there important prescribing considerations for the oral antivirals??

Clinicians should refer to the Provider information sheets for full prescribing information.

Paxlovid is a combination therapy of ritonavir-boosted nirmatrelvir. Ritonavir is a strong CYP3A inhibitor that is required to increase the exposure of nirmatrelvir to a concentration that is effective against SARS-CoV-2. Paxlovid is the first line oral antiviral for the treatment of COVID-19. While drug interactions due to Ritonavir can be complex, those that can be safely managed should not preclude the use of this medication. Several tools are available to assist clinicians managing these interactions.

Paxlovid should not be used in the setting of severe renal or hepatic impairment, dose adjustment can be made for moderate renal impairment (eGFR ≥ 30 to < 60 mL/min), no dose adjustment is needed for moderate hepatic impairment.

[Liverpool COVID-19 Interactions \(covid19-druginteractions.org\)](#)

[Nirmatrelvir/Ritonavir \(Paxlovid\): What Prescribers and Pharmacists Need to Know - Ontario COVID-19 Science Advisory Table \(covid19-sciencetable.ca\)](#)

There are currently no known contraindications for co-administration of Lagevrio (Molnupiravir) with other medications. Molnupiravir should not be used in pediatric populations and is not recommended for use during pregnancy. Breastfeeding is not recommended during treatment or for 4 days after final dose.

If my patient does not meet the criteria in the Emergency Use Authorization, can I prescribe COVID therapeutics off-label?

Off-label use is not permitted under the conditions of an FDA Emergency Use Authorization (EUA).

[Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19 | FDA](#)

Is there cost associated with COVID-19 therapeutics?

Oral antivirals for COVID-19 have been purchased by the United States Government and are available free of charge during the COVID-19 public health emergency.

For more information about COVID-19 Therapeutics please see:

[COVID 19 Therapeutics \(ct.gov\)](#)

This is an official
CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
April 25, 2022, 1:00 PM ET
CDCHAN-00463

**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 [increased risk](#) for severe COVID-19 outcomes, several [treatment options](#), including antiviral medications and monoclonal antibodies, are now widely available and accessible.

Systemic corticosteroids are [not recommended](#) 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 [not recommended](#) for the treatment of COVID-19 in the absence of another indication.

Staying [up to date](#) 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 [HAN Health Advisory on December 31, 2021](#) 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 [Test to Treat](#) locations.

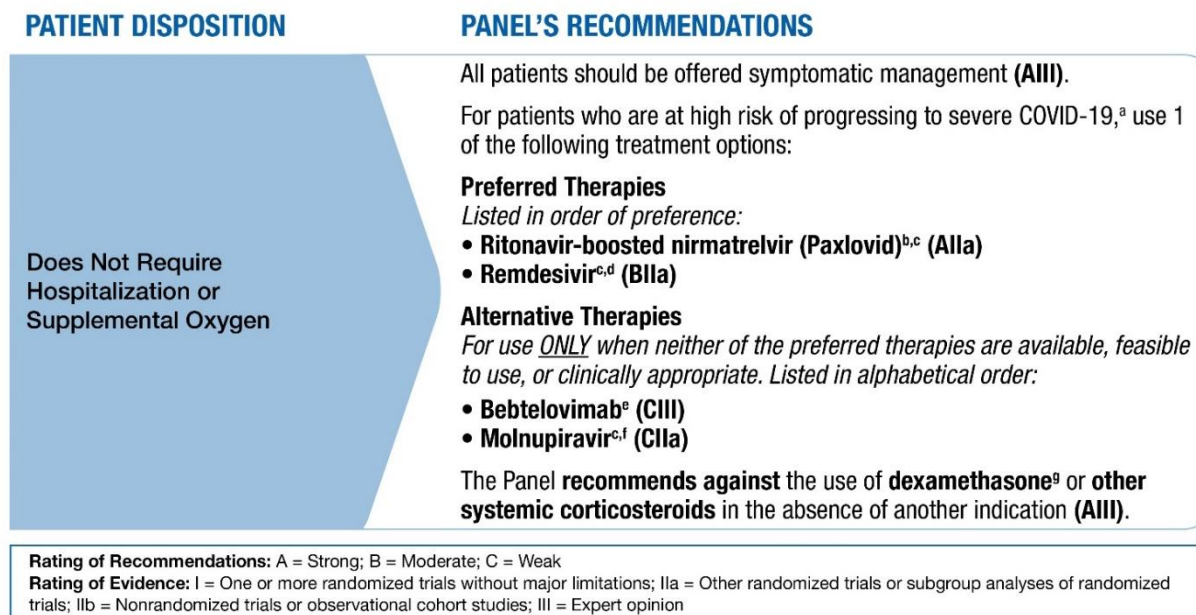
Data from CDC (1, 2) (highlighted in a [February 13, 2021 CDC/Infectious Diseases Society of America COVID-19 Clinical Call](#)) and the Food and Drug Administration (3) suggest that there has been increasing use of systemic corticosteroids and antibiotics to treat outpatients with COVID-19. However, 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 [COVID-19 Treatment Guidelines](#). 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)



^a For a list of risk factors, see the CDC webpage [Underlying Medical Conditions Associated With Higher Risk for Severe COVID-19](#).

^b Ritonavir-boosted nirmatrelvir has significant drug-drug interactions. Clinicians should carefully review a patient's concomitant medications and evaluate potential drug-drug interactions.

^c If a patient requires hospitalization after starting treatment, the full treatment course can be completed at the healthcare provider's discretion.

^d Administration of remdesivir requires 3 consecutive days of IV infusion.

^e 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.

^f 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.

^g 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

1. Obtain updated information on appropriate use of clinically indicated therapeutics through [NIH's 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 [NIH's COVID-19 Treatment Guidelines](#) for important therapeutic considerations, such as the potential for significant drug-drug interactions with ritonavir-boosted nirmatrelvir ([Paxlovid](#)) 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 [Test to Treat](#) 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 [1-800-232-0233](#) (TTY [1-888-720-7489](#)) which provides information in more than 150 languages, and for the [Disability Information and Access Line](#) at 1-888-677-1199.

Recommendations for the Public

1. 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 [Test to Treat](#) location and, if eligible, receive a prescription from a provider at that location.
2. Follow [CDC guidance on testing for COVID-19](#) and use the [Test to Treat locator](#) or call [1-800-232-0233](#) (TTY [1-888-720-7489](#)) 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 [up to date](#) 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.S. Food and Drug Administration COVID-19 Therapeutic Product Emergency Use Authorizations](#)
- [CDC COVID Data Tracker](#)

References

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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##