TEST-TO-TREAT OVERVIEW & TALKING POINTS

Updated March 16, 2022

This information is based on currently available scientific evidence, reports, and expert opinion, and is subject to change. This document is accurate as of March 2022 and will be frequently updated as new evidence and information becomes available.

What is Test-to-Treat? What does it mean in the context of COVID-19?

Test-to-treat programs seek to combine early detection of infection with timely access to effective treatments, with the goals of preventing disease progression on the individual level and transmission at the population level. Common globally for conditions like malaria and HIV, test-to-treat for COVID-19 is the latest available mechanism, via improved testing capacity and novel therapeutics, to minimize the worst outcomes of COVID-19 as it continues to spread throughout the country and globe.

Highly effective vaccines continue to be the best line of defense against COVID-19. However, antiviral and monoclonal antibody treatments are available now to significantly reduce the risk of hospitalization and death for those who are at higher risk for severe outcomes, including the unvaccinated and immunocompromised. This document reviews the outpatient therapies available to treat COVID-19 as well as emerging programs and initiatives to better integrate testing and treatment for populations most at risk to severe outcomes of COVID-19.

What are the treatments currently available, and how do they compare?

The graphic below from HHS' Office of the Assistant Secretary of Preparedness and Response (ASPR) outlines the preventative and therapeutic agents available for COVID-19. For the purpose of this review, we refer to the therapies authorized for use in individuals with no symptoms to moderate symptoms who are therefore eligible for outpatient treatment versus those in need of hospital admission and inpatient therapeutics. The two primary classes of interest are monoclonal antibodies (as pre-exposure prophylaxis, i.e PrEP; post-exposure prophylaxis**, i.e. PEP, and treatment) as well as oral and intravenous antivirals for treatment. Each of these agents and uses is discussed in greater detail below. Note that some of the monoclonal antibodies previously used for PEP are no longer in use due to lack of efficacy against the Omicron variants; regulators constantly evaluate the toolkit of available treatments in response to new variants.

Summary of COVID-19 Preventative Agents & Therapeutics

[1] NIH COVID-19 Treatment Guidelines https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/
Therapeutic Management of Nonhospitalized Adults With COVID-19 https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/

Agent	Intended Use	Eligibility	Route of Admin	Considerations*
Antivirals: These treatments help to stop the virus that causes COVID-19 from reproducing in your body. They also can reduce infectious period and reduce the risk of onward transmission to others.				
Nirmatrelvir/Ritonavir (Paxlovid) *NIH-Preferred Treatment for most patients; see guidelines below* FDA Fact Sheet NIH Treatment Guidelines	Treatment	EUA for those 12+ with confirmed mild-to-moderate COVID-19 who are at high risk of developing a severe case of COVID-19; prioritization criteria vary by state (see below)	Oral, tablet form	Can interfere with many commonly prescribed drugs, including two statins to treat high cholesterol and several epilepsy drugs, leading to health problems, if the drug dosages aren't adjusted. It isn't indicated for people with some serious health conditions, such as severe liver disease, and there are special considerations for pregnant and breastfeeding individuals.
Molnupiravir FDA Fact Sheet	Treatment	EUA for those 18+ with confirmed mild-to-moderate COVID-19 who have at least one risk factor and are at high risk of developing a severe case of the disease	Oral, tablet form	Not recommended for those who are pregnant. Only recommended when other FDA-authorized COVID-19 treatments are inaccessible or inappropriate.
Remdesivir FDA Fact Sheet	Treatment	Full FDA approval for patients who have mild to moderate COVID-19 and are not yet hospitalized, if they are at high risk for severe disease	IV Infusion over 3 consecutive days	The NIH guidelines for treating COVID-19 recommend Remdesivir if Nirmatrelvir/Ritonavir or Sotrovimab are not available. (Note: WHO guidelines recommend against Remdesivir).
Monoclonal antibodies (mAbs): These treatments infuse antibodies that bind to the virus and prevent it from infecting the cells of your body. These generally require an infusion at a treatment center. More information on mAbs can be found here.				
Tixagevimab/ Cilgavimab (Evusheld) FDA Fact Sheet	Pre-exposure Prophylaxis (PrEP)	Recommended for people who cannot produce a strong immune response to vaccination (immunocompromised)	Intramuscular injection	The FDA states it can be used to protect people who are immunocompromised, potentially up to a year, and as a preventative measure in adults who have been exposed to the virus.
Bebtelovimab FDA Fact Sheet	Treatment	For non-hospitalized patients (12+ and at least 40kg) at high risk of developing severe disease.	IV infusion	The FDA recommends the drug as an alternative if other antibody treatments are inaccessible or clinically inappropriate.

| Sotrovimab

FDA Fact Sheet	Treatment	For high-risk people (12+ and at least 40kg) recently diagnosed with COVID-19	IV infusion or injection	The NIH recommends Sotrovimab for high-risk people recently diagnosed with Covid-19 if Nirmatrelvir/Ritonavir is not available, and prefer Sotrovimab over Remdesivir or Molnupiravir for such patients.

Note that Partners In Health does not provide medical advice, diagnosis or treatment in the United States and the considerations reported here are drawn from key U.S. regulatory bodies at the time this document was published. Always seek the advice of a physician or other qualified health care provider with any questions regarding a medical condition. More information on available COVID-19 therapeutics can be found here.

COVID-19 Antivirals

COVID-19 antivirals Nirmatrelvir/Ritonavir and Molnupiravir were long awaited but remain in short supply (Paxlovid in particular). Demand has also been variable around the country, leading to a perplexing situation where doses sit unused in many areas despite the limited supply. This may be the case for a number of reasons, and as supply grows, so must awareness and access. As these pills require a confirmed positive test result and a prescription to access, individuals may face logistic challenges in acquiring them within the brief window of time (5 days post symptom onset) during which they are effective. These logistical challenges and practical barriers (including access to primary care providers and COVID-19 testing) may disproportionately impact communities that could most benefit – those at highest risk of severe outcomes from infection due to structural racism and occupational risk factors.

"They have to identify that they have symptoms. They have to then get a test, get a test result, contact a provider, someone who can prescribe, get that prescription and then go pick up that prescription. That's six different steps." -
Dr. Cameron Webb, Senior Advisor to White House COVID Response Team

Attention on these drugs recently increased after the announcement of the federal Test-to-Treat Initiative set to launch in March 2022. While this program is a step towards improved access, it appears that large chain pharmacies will be the first sites selected, and "hundreds" of sites doesn't translate to large-scale availability nationwide. Antivirals will still be available through health care providers and other pharmacies, but supply and demand challenges remain. For more information on the Test-to-Treat initiative, see below, visit HHS.gov or view HHS fact sheet.

The federal Test-to Treat Initiative

The federal Test-to-Treat Initiative aims to help make COVID-19 testing and treatments free and easily accessible at one-stop locations such as pharmacies, pharmacy-based clinics, community health centers/FQHCs, Long-Term Care Facilities, and U.S. Department of Veterans Affairs (VA) facilities. It is part of the National COVID-19 Preparedness Plan, and sets out to minimize the time between a positive test result and receiving an effective, potentially lifesaving COVID-19 treatment – particularly for marginalized communities that have been disproportionately ravaged by COVID-19.

People who test positive for COVID-19 will be eligible to be assessed by an on-site qualified health care provider, and if treatment is deemed appropriate for them, will receive a course of either Molnupiravir or Nirmatrelvir/Ritonavir. People may also continue to be able to be tested and treated by their own health care providers who can appropriately prescribe oral antivirals at locations where they are being distributed. People may also bring at-home test results to a Test-to-Treat site for assessment to receive treatment. More information can be found [here](#).

Who is eligible to receive antiviral treatments?

Due to extremely limited supply, there is some statewide variation in who can receive treatments. In general, states are defining eligibility according to the following criteria, but states may also have prioritization schemes among these broad eligibility categories. These will likely change as supply increases.

- Individuals 65 and older
- Individuals (12+ for Nirmatrelvir/Ritonavir and 18+ for Molnupiravir) with [underlying medical conditions](#) such as heart disease, obesity, diabetes, and cancer. See a comprehensive list of risk factors [here](#).

To obtain the treatments, patients must also:

- Have a positive test result (PCR or antigen)
  - At-home tests acceptable in most cases
- Have mild to moderate COVID-19 symptoms
- Be able to start treatment within 5 days of symptom onset

Where/how can individuals access treatments?

Antivirals are currently available in limited quantities at pharmacies and clinics around the country. You can check for state and local COVID-19 therapeutics availability using the [ASPR Therapeutic Distribution Locator](#) or the [HHS Health Data COVID-19 Public Therapeutic Locator.](#) A qualified health care provider with prescribing authority – such as a nurse practitioner, doctor, or physicians' assistant who is licensed to prescribe drugs – is required to prescribe treatment for COVID-19. Pharmacists are not currently able to prescribe oral antivirals.

The federal Test-to-Treat Initiative currently operates in a much smaller number of pharmacies, FQHCs, and VA hospitals. It will take some time for a Test-to-Treat program to reach certain areas. A federal Test-to-Treat website with more information on how to find Test-to-Treat locations, along with sites where people can get free masks, tests, vaccines, and other COVID-19 resources is in development with anticipated launch in mid-March. Individuals can consider the following options if Test-to-Treat centers are not yet available nearby:

- Check the website of [local hospital](#) to see if they offer care for people who test positive
- Go to an [urgent care center](#)
- Contact a [local health department](#) for referral to care
- Visit a [community health center](#)

If they do not have a regular doctor to contact about COVID-19 treatments, they can also call 1-877-332-6585 (English) or 1-877-366-0310 (Spanish).

What are the potential side effects?

Because each therapeutic can have varying side effects and interactions with other drugs, it is important that an individual have a thorough medical evaluation by a licensed professional to decide if therapeutics are the right choice. See a more detailed list of side effects, interactions, and other considerations [here](#).

Does this mean vaccination is no longer important?

Far from it. Vaccination and boosting remains the best option for protection from hospitalization and death from COVID-19. While the antiviral medications are effective in treating COVID-19 and are available to some pending eligibility, they are not a means of preventing COVID-19. It is critical for everyone who can get vaccinated for COVID-19 to do so.

Are these only available for vaccinated people?

Treatment for COVID-19 is available for those who are eligible, regardless of vaccination status.

How much do these treatments cost? Are they covered by insurance?

The cost of Nirmatrelvir/Ritonavir is $530 and Molnupiravir is $700; however, these are currently free to eligible patients under the U.S. public health emergency declaration. Under the federal Test-to-Treat Initiative, treatments will be provided by the federal government and made free and accessible to everyone. More information about therapeutics coverage not a part of Test-to-Treat can be found here.

Other Implementation Considerations + Equity Implications

As noted above, there is varying and often low demand for these potentially lifesaving treatments. There may be a role for local health departments and community messengers to equip patients eligible for the treatments above with the information they need to know, including when to test and how to access treatment. The CDC provides a general patient-facing overview of available treatments. Other state and local health departments have developed informational handouts/fact sheets to be distributed alongside rapid tests as well as at community events.

See example fact sheets from the Minnesota Department of Health:

- COVID-19 Medication: Monoclonal Antibodies
- COVID-19 Medications: Antivirals
- COVID-19 Medications: Evusheld