AIM Association of Immunization Managers

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COVID-19 Treatments

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This document is an update of two previous talking points documents:

- *First approved oral antiviral for COVID-19, December 2021*
- *Differences between Monoclonal antibodies and vaccines, September 2021*

Who should receive treatment for COVID-19 disease?

People who are positive for COVID-19 and have one or more medical condition that increases their risk of becoming very sick or another serious outcome from COVID-19 may be eligible for treatment.

What are some of the health conditions that increase your risk of severe COVID-19 disease, including potential hospitalization or death as a result of COVID-19 infection?

A person's risk of severe illness from COVID-19 increases with the addition of other underlying medical conditions, such as:

Conditions of Concern:

- Cancer
- Chronic Kidney Disease
- Chronic Liver Disease
- Chronic Lung Diseases, Asthma, COPD, etc.
- Cystic Fibrosis
- Dementia or other Neurological Conditions
- Diabetes (Types 1 or 2)
- Stroke or Cerebrovascular Disease

Those with:

- Disabilities
- Heart Conditions
- HIV Infection
- Compromised Immune Systems
- Mental Health Conditions
- Sickle Cell Disease or Thalassemia
- Tuberculosis
- Substance Use Disorders

Those who are:

- Overweight or Obese
- Physically Inactive
- Pregnant
- Smokers (current or former)
- Solid Organ or Blood Stem Cell Transplant Recipients

Who else may be at increased risk of severe COVID-19 disease?

- Older adults are at the highest risk of getting very sick from COVID-19. The number of deaths among people over age 65 is 97 times higher than the number of deaths among people aged 18 to 29 years.
- Some people are at increased risk of getting very sick or dying from COVID-19 because of where they live, work or due to lack of access to health care. This includes many people from racial and ethnic minority groups and people with disabilities.
    - Studies have shown people from racial and ethnic minority groups are also dying from COVID-19 at younger ages. People in racial and ethnic minority groups are often younger when they develop chronic medical conditions and may be more likely to have more than one medical condition.
    - A study published in January 2022, revealed Black, Hispanic, Asian and 'Other' race patients received therapy to treat severe COVID-19 disease, such as monoclonal antibody therapy, less often than did White patients during the period from November 2020 to August 2021.
    - People with disabilities are more likely than those without disabilities to have chronic health conditions or live in shared group (also called "congregate") settings. They also face more barriers in accessing healthcare. Studies have shown some people with certain disabilities are more likely to get COVID-19 and have worse outcomes.

How do I know if I am eligible for treatment?

Contact a health professional if you test positive for COVID-19 to find out if you may be eligible for treatment. It is best to do so even if your symptoms are mild. Treatment must be started within the first few days of becoming infected to help you.

What treatments are available for COVID-19 disease outside of the hospital?

- If you have symptoms, your healthcare provider may recommend certain therapies to help relieve symptoms or to support your body's immune system. These include:
  - Medications to reduce fever (such as acetaminophen or ibuprofen).
  - Staying hydrated: drinking water or, if necessary, receiving intravenous fluids at a healthcare facility
  - Getting plenty of rest to help the body fight the virus.

What steps should you take if you are sick with COVID-19?

- If you are at higher risk than most for increased illness or complications from COVID-19 due to a medical condition or other reason, your healthcare provider may recommend one of the following treatments:
  - Monoclonal antibody treatments
  - Oral antiviral medications
- The National Institutes of Health (NIH) currently (April 2022) recommends one of the following treatments (listed in order of preference) for patients who are not hospitalized but have mild to moderate COVID-19 disease and are at high risk of progressing to severe disease:
  - Paxlovid (oral tablet, antiviral)
  - Remdesivir (IV infusion, antiviral)
- If the above treatments are unavailable, not easy to deliver, or are not appropriate for the patient (for example, because they may interact with other medicines the patient is taking), then one of the following treatments may be substituted:
  - Bebtelovimab (IV infusion, monoclonal antibody)
  - Molnnupiravir (oral tablet, antiviral)
- As scientists learn more, guidance may change. Stay informed at https://www.covid19treatmentguidelines.nih.gov/therapies/.

What do the FDA and the NIH want the public to know about these treatments?

- Monoclonal antibody treatments and antiviral treatments are not a substitute for receiving COVID-19 vaccination and COVID-19 booster doses.

  - Vaccines are given to prevent infection. It takes up to 2 weeks after getting a COVID-19 vaccine to begin receiving protection.
  - The goal of giving someone a COVID-19 vaccine is to train a healthy immune system to protect from a future COVID-19 Infection by developing antibodies (fighting cells against the spike protein). For several months after COVID-19 vaccination, your body continues to produce these fighting cells. Protection from vaccines may last months to years.

- Get your COVID-19 vaccine and booster dose/s if eligible. For further details, visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

What are these treatments and how do they work?

Monoclonal antibody treatments

- COVID-19 monoclonal antibodies help to prevent someone who has tested positive for COVID-19 and is at high risk of getting worse, from getting severely ill from COVID-19 disease and becoming hospitalized.
- COVID-19 monoclonal treatments work by giving your body antibodies (fighting cells) to fight off the spike protein (antigen) from the Covid-19 virus. These monoclonal antibodies attach to the spike protein of the virus so the virus will not work. They allow our body's immune system to recognize and respond better to the virus.
- COVID-19 monoclonal antibodies work best when given to someone with a positive test as soon as possible or within five to seven days of when they develop any symptoms of COVID-19. Some COVID-19 monoclonal antibodies may not work as well if someone is already severely ill, in the ICU or on a ventilator.
- Your healthcare provider will decide whether COVID-19 monoclonal antibodies are appropriate to treat your illness. You will need a doctor's prescription to receive monoclonal antibodies.
- Some monoclonal antibodies may not work as well against variants. The FDA continues to monitor all authorized monoclonal antibodies to see if they will work against COVID-19 variants, including the Delta and Omicron variants and subvariants.
- For people with breakthrough infections (meaning developing COVID-19 disease after having had the COVID-19 vaccination), monoclonal antibodies may be considered by the healthcare provider.
- Monoclonal antibodies are NOT vaccines.
- Some scientists believe protection from monoclonal antibodies may last up to a month or longer. Scientists are still learning the duration of protection.
- In some rare circumstances, your healthcare provider may recommend monoclonal antibodies, such as Evushield (PrEP), to reduce the risk of infection prior to (pre-exposure prophylaxis or PreP) or after exposure (post-exposure prophylaxis). For more details, visit: NIH PrEP and PEP.

Oral Antiviral treatments

- Oral antiviral medications can be used to reduce the ability of the virus to multiply and spread through the body by targeting specific parts of the COVID-19 virus.
    - The following two oral medications are recommended by the NIH in order of preference:
        - Paxlovid (Ritonavir-boosted nirmatrelvir)
        - Molnupiravir

Paxlovid

In December 2021, the FDA issued an EUA (Emergency Use Authorization of an unapproved medication) for the first two oral antiviral treatments, Paxlovid and Lagevrio (Molnupiravir), to treat mild to moderate COVID-19 disease. Paxlovid and Molnupiravir are not a substitute for receiving COVID-19 vaccination and a COVID-19 booster dose.

Who is eligible to receive Paxlovid?

People who:

- Are 18 years and older and children 12 years and older (who weigh at least 40 kg (88 pounds) and have **mild to moderate** COVID-19 disease
- Are not hospitalized
- Have tested positive for SARS-CoV-2 testing, are at high risk for progression to severe COVID-19, including hospitalization or death.

How is Paxlovid given? How does the medicine work?

- The name of the medication is Paxlovid (generic Nirmatrelvir tablets and Ritonavir tablets, co-packaged for oral use). It is manufactured by Pfizer Labs.
- The medicine is available by prescription only from a licensed healthcare provider. Take the medicine as prescribed by mouth.
- It is recommended to take Paxlovid as soon as possible after being diagnosed with COVID-19 and within the first five days of developing symptoms.
- The medicine works by stopping one of the proteins in the COVID-19 virus from replicating (making copies of itself).
- EUA Fact Sheets that provide important information about using Paxlovid are available for healthcare providers and patients and caregivers. These fact sheets include dosing instructions, potential side effects (such as diarrhea, muscle aches), drug interactions and information about who is able to prescribe Paxlovid.

Are there people who should not take Paxlovid?

- People who are allergic to Paxlovid or any of its ingredients.
- Paxlovid may also interact with certain other medications. It is best to inform your healthcare provider of any medical conditions you have and of any medicines you are taking (including herbal and over-the-counter medications) before taking Paxlovid. Your healthcare provider will then carefully review this to ensure you can safely take Paxlovid.
- People with chronic medical conditions, including kidney or liver disease, hepatitis, or HIV disease, should first check with their healthcare provider to see if they may take Paxlovid.

Lagevrio (Molnupiravir)

Lagevrio (Molnupiravir) is authorized by the U.S. Food and Drug Administration (FDA) for the treatment of mild to moderate COVID-19 in adults at high risk of progressing to severe disease, and for whom alternative antiviral therapies are not accessible or clinically appropriate.

Who is eligible to receive Lagevrio (Molnupiravir)?

People who:

- Are 18 years and older and have **mild to moderate** COVID-19 disease
- Are not hospitalized
- Have tested positive for SARS-CoV-2, are at high risk for progression to severe COVID-19, including hospitalization or death.

  **Molnupiravir should only be used when Paxlovid or Remdesivir cannot be used instead.*

How is Lagevrio (Molnupiravir) given? How does the medicine work?

- The name of the medication is Lagevrio. The generic name is Molnupiravir. It is manufactured by Merck and Co., Inc.
- The medicine is available by prescription only from a licensed healthcare provider. Take the medicine by mouth as prescribed.
- It is recommended to take Molnupiravir as soon as possible after being diagnosed with COVID-19 and within the first five days of developing symptoms.

- The medicine works by attacking the COVID-19 virus.
- EUA Fact sheets that provide important information about using Molnupiravir are available for healthcare providers and patients and caregivers. These fact sheets include dosing instructions, potential side effects, drug interactions and information about who can and cannot take Molnupiravir.

Are there people who should not take Lagevrio (Molnupiravir)?

- People who are allergic to Lagevrio (Molnupiravir) or its ingredients.
- Lagevrio (Molnupiravir) is not recommended for use in pregnant people. It may affect the unborn baby.

Other Treatments, Including for Hospitalized Patients

In patients with severe COVID-19, the body's immune system may overreact to the threat of the virus, worsening the disease. This can cause damage to the body's organs and tissues. Some treatments can help reduce this overactive immune response.

- Antivirals administered through an IV infusion (Remdesivir) may be recommended by their doctor for patients who are hospitalized.
- Convalescent plasma, plasma from patients who have recovered from COVID-19, can contain antibodies (fighting cells) to the virus. This could help the immune system recognize and respond more effectively to the virus, but currently, the NIH only recommends the use of convalescent plasma for select individuals who are hospitalized and are severely immunocompromised.
- COVID-19 can damage the heart, blood vessels, kidneys, brain, skin, eyes, and gastrointestinal organs. It also can cause other complications. Depending on the complications, additional treatments might be used for severely ill hospitalized patients, such as steroids to control inflammation and blood thinners to prevent or treat blood clots.

Test to Treat

Federal Test to Treat Initiative

- In March 2022, the federal government launched a nationwide Test to Treat initiative to give people a new way to rapidly access free treatment for COVID-19.
- In this program, people are able to get tested. If they are positive and treatments are appropriate, they receive a prescription from a healthcare provider and have their prescription filled — all in one location.
- Individuals who receive COVID-19 test results through at-home tests or another testing site can also utilize a Test to Treat location to receive a prescription from a qualified healthcare provider and treatment on the spot, if eligible.
- These "One-Stop Test to Treat" sites are available nationwide, including pharmacy-based clinics, federally qualified community health centers (FQHCs), and long-term care facilities.
- People will continue to be able to be tested and treated by their own healthcare provider, as well.
- Some of the nation's largest pharmacy chains are participating and locations have clinics inside their stores where healthcare providers can prescribe COVID-19 therapies to eligible people. There are also hundreds of FQHCs already participating with additional long-term care facilities that serve high-risk residents also coming on board.
- Pharmacy-based clinics participating in the initiative are eligible to receive oral antiviral pills from Merck (Molnupiravir) and Pfizer (Paxlovid).
- A federal Test to Treat website has been developed where people can go to find a Test to Treat site near them.

Additional Resources

- HHS Test to Treat website
- HHS Test to Treat fact sheet
- HHS Test to Treat FAQs
- HHS Test to treat infographic: https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/print-resources/Test-Soon-Treat-Early.pdf

Frequently Asked Questions

Q: Are these treatments (monoclonal antibodies, oral antiviral pills) effective against the Omicron variant?

A: Some of these treatments may not be effective against the Omicron variant or subvariants. Your healthcare provider will decide which, if any, of these treatments are appropriate to treat your illness.

Q: Should I still quarantine/wear a mask after taking this medication?

A: Patients treated with monoclonal antibody therapies should continue to follow measures to reduce their risk of infection, including wearing masks, practicing social distancing, cleaning and disinfecting surfaces and washing hands frequently according to current CDC guidelines.

Q: How soon can I get vaccinated after taking this medication?

A: COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma. People who previously received antibody products (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment or prophylaxis (PrEP or PEP) can be vaccinated with a COVID-19 vaccine at any time.

In the past, a 90-day waiting period was recommended between receiving these products and getting vaccinated because of the concern for interference between the two. However, this is no longer the case.

- **Exception:** People who have received a COVID-19 vaccine should wait at least two weeks prior to receiving Evushield for pre-exposure prophylaxis.

Source: https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf

Q: What about other treatments like hydroxychloroquine, ivermectin, supplements, etc.? Are those authorized or approved by the FDA?

A: Hydroxychloroquine is a medication used to treat malaria. Current research suggests hydroxychloroquine is not safe or effective for treating patients with COVID-19 disease.

Ivermectin is neither authorized nor approved for use in preventing or treating COVID-19 disease in humans or animals.

- Ivermectin is a medication approved by the FDA to treat humans infected with parasites (worms), head lice etc. Animal ivermectin products are very different from those approved for humans.
- Available data from ongoing research studies show ivermectin is not effective against COVID-19 disease, nor is it safe.
- Taking large doses of ivermectin is dangerous and can lead to serious side effects including seizures, coma or even death.
- It is very dangerous to use animal ivermectin products for preventing or treating COVID-19 disease in humans.

The FDA and the NIH continue to study medications for use in preventing and treating COVID-19 disease and caution the public to avoid using drugs as emergency treatments that have not been studied in clinical trials or authorized/approved for that use by the FDA and NIH.

Sources:

- https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/)
- https://www.covid19treatmentguidelines.nih.gov/therapies/supplements/summary-recommendations/
- https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19

Social Media Posts

Talking points, like those above, are meant for just that — talking. They shouldn't be used verbatim in print, email or social media.

Talking points are most effective when you use your own language to share the basic information found in said content, sharing messages in a style of speech that is both expected and best understood by your audiences. For social media, making content meaningful requires keeping it short, conversational and not trying to tackle too much information at once. Stick to the most important details, and don't try to explain too much in a single post.

You wouldn't read Shakespeare to a fifth-grade class; instead, you would talk about the general themes of Shakespeare's stories and avoid the complicated language. We suggest a similar approach to sharing critical vaccine information on social media. For example:

Twitter (limited to 280 characters with spaces):

If you or someone you know is sick with #COVID19 you may qualify for monoclonal antibodies to prevent severe illness and avoid hospitalization.

Monoclonal antibodies can help people sick with #COVID19, but #COVID19 vaccines provide the best protection against becoming infected with COVID-19.

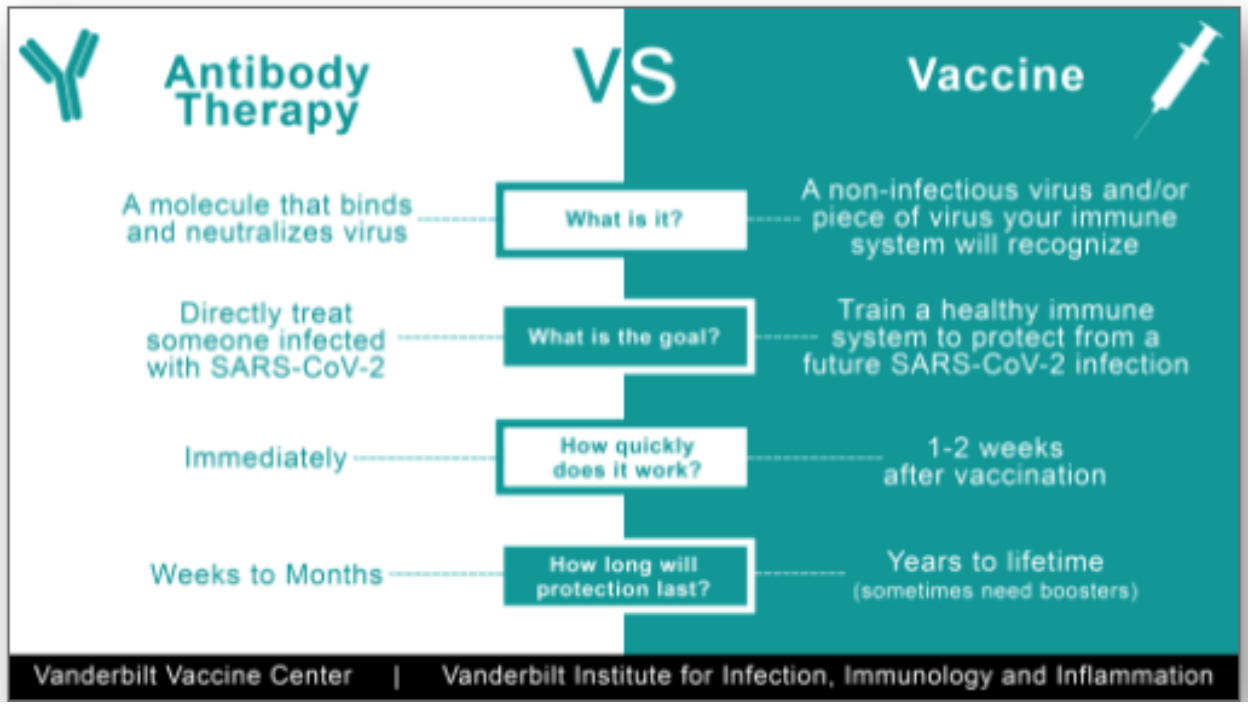
Facebook

If you or someone you know is sick with COVID-19 you may qualify for monoclonal antibodies to prevent severe illness and keep you out of the hospital. Talk to your doctor to see if you are a candidate for monoclonal antibodies.

Monoclonal antibodies can help people sick with COVID-19, but COVID-19 vaccines provide the best protection against becoming infected with COVID-19. Monoclonal antibodies are meant to be used as treatment for COVID-19 infection to prevent severe illness.

Resources

Infographic from Vanderbilt Institute for Infection, Immunology and Inflammation, May 2020



- FDA Press Announcement: Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19
- Paxlovid EUA Letter of Authorization
- Frequently Asked Questions on the Emergency Use Authorization for Paxlovid
- Emergency Use Authorization: Drugs and Non-Vaccine Biological Products
- Coronavirus Disease (COVID-19)
- Coronavirus Treatment Acceleration Program (CTAP)

FDA Know your treatment options for COVID-19: https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19

HHS Combat COVID: https://combatcovid.hhs.gov

NIH COVID-19 Treatment Guidelines with monoclonal antibodies: https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/

NIH COVID-19 Treatment guidelines with convalescent plasma: https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/convalescent-plasma/

CDC: Interim Clinical Considerations for use of COVID-19 vaccines: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/molnupiravir/

Update from NIH COVID-19 Treatment Guidelines, Antiviral therapy: https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/

https://combatcovid.hhs.gov/possible-treatment-options-covid-19