

# **Clinical Guidance**

# COVID-19 Testing, Diagnosis and Treatment for Patients at Higher Risk

## **Background**

Family physicians and care teams play a critical role in ensuring that patients are vaccinated against COVID-19 and educating them about other preventive measures to mitigate the spread of the virus. These steps are especially important for those who are at high risk of complications from SARS-CoV-2 infection. Seeking testing, diagnosis and treatment in a timely manner is also vital.

The American Academy of Family Physicians has developed clinical guidance to help family medicine practices provide the right care for patients with underlying medical conditions who are at higher risk of severe COVID-19 outcomes. This guidance provides an overview of COVID-19 vaccination recommendations, testing and diagnosis, treatment options and recommendations, and counseling techniques.

# Primary Risk Factors for Severe COVID-19 Outcomes

The Centers for Disease Control and Prevention defines severe outcomes of COVID-19 as hospitalization, admission to the intensive care unit, intubation or mechanical ventilation, or death.1 Knowing the primary risk factors for these outcomes helps family physicians and care teams make informed decisions about patient care and increase awareness among their patients who are at high risk. The CDC has identified the following risk factors:

- Age Older age is the strongest risk factor for severe COVID-19 outcomes.¹ According to data from the National Vital Statistics System, co mpared with the risk for adults ages 18 to 29, the risk of death from COVID-19 is 25 times higher for adults ages 50 to 64, 60 times higher in adults ages 65 to 74 and 140 times higher for adults ages 75 to 84.
- Race and Ethnicity The CDC points out that "inequities in living, working, health, and social conditions that have persisted across generations" lead to health differences between racial and ethnic groups.<sup>2</sup> For example, some racial and ethnic minority groups are more likely to encounter barriers to accessing health care, including

COVID-19 vaccination and treatment options.3 These may include structural barriers related to socioeconomic status (e.g., inadequate insurance, lack of transportation, inability to take time off work), cultural and language differences between patients and clinicians, and long-standing systemic inequities. Age-adjusted data from the CDC has shown that Black, Hispanic or Latino and American Indian or Alaska Native people are at higher risk of being infected with SARS-CoV-2 and experiencing severe health outcomes from COVID-19 compared with white people.2,4 In addition, estimates of U.S. COVID-19 deaths have shown a disproportionately high rate of death among people from racial and ethnic minority groups.1

- Medical Conditions People with certain underlying medical conditions, including those shown in Table 1, are at higher risk of severe health outcomes from COVID-19 that include hospitalization and death. Key findings from a study of more than 540,000 adults hospitalized with COVID-19 included the following<sup>5</sup>:
  - A number of underlying medical conditions were associated with an increased risk of severe COVID-19 illness in adults.
  - Having more medical conditions was associated with more severe COVID-19 illness and a higher risk of death
  - Obesity, diabetes with complications, and anxiety and fear-related disorders had the strongest association with death in adults with COVID-19.

The CDC defines a condition as "higher risk" if conclusive findings from the CDC systematic review process or a published meta-analysis or systemic review show that the condition increases the risk of one or more severe COVID-19 outcomes.<sup>1</sup>

Table 1. Underlying Medical Conditions Associated With Higher Risk for Severe COVID-191

Asthma	Cancer	Cerebrovascular disease	
Chronic kidney disease	Chronic lung disease	Chronic liver disease	
Cystic fibrosis	Diabetes mellitus, types 1 & 2	Heart conditions	
HIV	Obesity	Pregnancy and recent pregnancy	

Note: This list of underlying medical conditions is not exhaustive.

# **COVID-19 Vaccination Recommendations**

The most effective measure family physicians can take to reduce the severity of COVID-19 infection and prevent hospitalization and death is to strongly recommend COVID-19 vaccination for all eligible patients, particularly those who are at higher risk.

**RECOMMENDATION**<sup>6</sup>: People ages 6 months and older should receive the updated COVID-19 vaccine. You can access <u>current recommendations</u> on the CDC's COVID-19 vaccines webpage.

The CDC's COVID-19 vaccine schedule for people who are moderately or severely immunocompromised provides detailed, age-specific information to help your family medicine practice recommend and administer COVID-19 vaccines to your patients.

# **COVID-19 Testing and Diagnosis**

COVID-19 testing and diagnosis are powerful tools for clinicians to use with patient populations that are at higher risk of severe health outcomes. A person who has COVID-19 symptoms or has been exposed to someone with COVID-19 should be tested in a timely manner. This will help you determine appropriate preventive measures and medical care for your patient.

## **Diagnostic Tests**

Viral tests are recommended to detect current SARS-CoV-2 infection and diagnose COVID-19.7

**Nucleic acid amplification tests,** or NAATs, are highly sensitive and highly specific tests that detect viral RNA genes. Polymerase chain reaction, or PCR, tests are the most common type of NAAT used for COVID-19 testing. Most NAATs are conducted in a laboratory and produce positive or negative results. They should not be used on someone who has tested positive for COVID-19 within the past 90 days.

Antigen tests detect the presence of specific viral proteins (i.e., antigens) that indicate current infection. They can be conducted at home, at the point of care or in a laboratory. Antigen tests have high specificity that is similar to NAATs. However, they are less sensitive, so the FDA recommends repeat testing to confirm a negative result.<sup>8</sup> People who have COVID-19 symptoms should test again 48 hours after the first negative test. Asymptomatic people should repeat the test 48 hours after the first negative test and then test again 48 hours after the second negative test, for a total of at least three tests.

When testing a patient for COVID-19, provide clear, concise information, including the following<sup>7</sup>:

- · Reason for the test
- Type of test to be performed (e.g., PCR test or antigen test)
- Difference between diagnostic testing and screening testing
- How the test will be performed
- Next steps, depending on whether the test results are positive or negative

Detailed information on COVID-19 testing considerations and options is available on the CDC's website.

· Consequences of declining to be tested

#### **Preventive Measures**

In addition to testing and diagnosis, preventive measures are vital for reducing the spread of COVID-19. They are especially important for people who are at higher risk of severe health outcomes. Key ways you can help your patients protect themselves, their family and their community include the following:

- Continue strongly recommending that your patients stay up to date with COVID-19 vaccination. If your practice does not offer COVID-19 vaccination for any reason, point your patients to <a href="https://www.vaccines.gov">www.vaccines.gov</a> or recommend another resource to help them find COVID-19 vaccines in your area.
- Inform your patients about measures that have been shown to mitigate the spread of the virus, such as moving activities outdoors when possible and following the CDC's recommendations for what to do if they have been exposed to COVID-19.

 Be sure your patients are aware of common COVID-19 symptoms (e.g., cough, shortness of breath, congestion, sore throat, fatigue, headache) so they know when to seek testing and medical care.

The CDC's patient education resources for <u>people with certain</u> <u>medical conditions</u> and <u>people who are immunocompromised</u> can help guide conversations with your patients who are at higher risk of severe COVID-19 outcomes.

# **COVID-19 Treatment Options and Recommendations**

Therapeutics are an option when treating COVID-19 (*Table 2*). For optimal effectiveness, these medications must be given during a certain time frame. Early treatment is important to reduce the severity of COVID-19.

Table 2. COVID-19 Therapeutics

Therapeutic	Туре	Population	Background	Use in Specific Populations	Recommendations
Nirmatrelvir packaged with ritonavir for coadministration (Paxlovid)	Oral antiviral	Adults and children ages 12 years and older who weigh at least 40 kg	On December 22, 2021, the FDA issued an EUA for the use of Paxlovid to treat mild-to-moderate COVID-19 in adults and certain eligible pediatric patients who are at high risk for progression to severe COVID-19.  On May 25, 2023, the FDA approved Paxlovid for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.	Do not use Paxlovid for the following: Patients who have severe kidney disease Patients who are on dialysis Patients who have severe liver disease  Drug levels can become too high in these patients, causing increased side effects.	Initiate Paxlovid treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.  The FDA's <u>Paxlovid fact sheet</u> provides additional dosage and administration recommendations for health care professionals.  When Paxlovid can be used, the NIH COVID-19 Treatment Guidelines Panel recommends it as the primary option for nonhospitalized adults and adolescents with mild to moderate COVID-19 who are at high risk of progressing to severe illness.
Remdesivir (Veklury)	IV antiviral	Adults and pediatric patients ages 28 days and older who weigh at least 3 kg	On April 25, 2022, the FDA approved Veklury for the treatment of COVID-19 in the following:  • Adults and certain eligible pediatric patients who are hospitalized  • Adults and certain eligible pediatric patients who are not hospitalized, have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death	Do not use Veklury for the following: Patients who have liver or kidney problems	HOSPITALIZED PATIENTS: Initiate treatment course as soon as possible after diagnosis of symptomatic COVID-19. Veklury is given by IV infusion one time each day for up to 10 days.  NONHOSPITALIZED PATIENTS: Initiate treatment as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset. Veklury is given by IV infusion one time each day for 3 days.  The FDA's Veklury prescribing information provides additional dosage and administration recommendations for health care professionals.
Molnupiravir (Lagevrio)	Oral antiviral	People ages 18 years or older	On December 23, 2021, the FDA issued an EUA for the use of Lagevrio to treat mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.	Do not use Lagevrio for the following: Patients who are pregnant Patients who are trying to get pregnant Patients who are breastfeeding	Initiate Lagevrio treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. Four capsules are taken twice per day for 5 days.  The FDA's <u>Lagevrio fact sheet</u> provides additional dosage and administration recommendations for health care professionals.

EUA = emergency use authorization; FDA = U.S. Food and Drug Administration; IV = intravenous; NIH = National Intstitutes of Health. Information from references 9-18.

#### COVID-19 Rebound

COVID-19 rebound is defined as "experiencing recurrence of symptoms and/or SARS-CoV-2 antigen positivity after initial resolution." It can occur in patients treated with COVID-19 therapeutics, including Lagevrio and Paxlovid. However, it is important to note that patients who have not received any treatment can also experience rebound. Evidence has shown that patients experiencing rebound have an extremely low probability of developing severe COVID-19, and additional studies to investigate rebound occurrences are being conducted.

The CDC has issued a health advisory with information and guidance to help clinicians manage COVID-19 rebound.

# Counseling Patients About COVID-19 Testing, Diagnosis and Treatment

Family physicians are well equipped to counsel patients about available COVID-19 vaccines, tests and therapeutics. They also have opportunities to emphasize the importance of being tested, diagnosed and treated early and in a timely manner to reduce the severity of infection and the risk of hospitalization and death. When you have conversations with patients who have certain underlying medical conditions or other risk factors for severe COVID-19 outcomes, you may find it helpful to apply counseling steps that include use of motivational interviewing techniques.<sup>19</sup>

#### Step 1: Embrace an understanding and collaborative approach

- Provide clear, detailed information about the different COVID-19 tests and therapeutics available.
- Encourage your patient to participate in the conversation and give feedback. Express interest in understanding their perspective.
- Consider cultural factors and family dynamics when discussing COVID-19 infection, testing and therapeutics.

## Step 2: Discuss underlying medical conditions and increased risk of severe COVID-19 outcomes

- Explain how COVID-19 infection in people at higher risk has the potential to cause severe illness and can lead to hospitalization or death.
- Describe the specific risk factors and underlying medical conditions that apply to your patient.
- Stress the evidence-based benefits of getting tested for COVID-19, diagnosed and treated as early as possible.
- Explain the importance of managing COVID-19 symptoms and taking preventive measures (e.g., wearing a high-quality mask) in settings that pose a higher risk of infection.

#### Step 3: Use motivational interviewing techniques

- Address myths, misinformation and disinformation about COVID-19 therapeutics.
- If your patient is hesitant to get tested for COVID-19, diagnosed and treated in a timely manner, ask questions to identify the reasons for their hesitancy and help move them toward the desired outcome.
- Look for common ground with your patient, and try to understand their reasoning and motivation if they disagree with your recommendations. Be curious, compassionate and empathetic.
- Show support for your patient by incorporating their personal values and health needs into conversations about COVID-19 testing and treatment options.

#### Step 4: Respond to questions and concerns about health and/or mental health

- Address your patient's concerns and questions about health and/or mental health issues by providing appropriate scientific information or referring them to a reputable source.
- Explain how essential it is for your patient to be up to date on COVID-19 vaccinations and take preventive health measures to protect themself, their family and their community.

As a family physician, you are the most valued and trusted source of health information and advice for your patients. The use of effective counseling techniques may help persuade your patients, especially those who are at higher risk of severe health outcomes from COVID-19, to decrease their risk by taking preventive measures and seeking testing and medical care as early as possible.

## References

- Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. Underlying medical conditions
  associated with higher risk for severe COVID-19: information for healthcare professionals. February 9, 2023. Accessed September 12, 2023.
  https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html
- 2. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. COVID-19 in racial and ethnic minority groups. June 25, 2020. Accessed September 12, 2023. https://stacks.cdc.gov/view/cdc/89820
- 3. Centers for Disease Control and Prevention, Office of Health Equity. What is health equity? July 1, 2022. Accessed September 12, 2023. https://www.cdc.gov/healthequity/whatis/index.html
- 4. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. Risk for COVID-19 infection, hospitalization, and death by race/ethnicity. November 8, 2022. Accessed September 12, 2023. https://stacks.cdc.gov/view/cdc/122265
- 5. Kompaniyets L, Pennington AF, Goodman AB, et al. Underlying medical conditions and severe illness among 540,667 adults hospitalized with COVID-19, March 2020-March 2021. Prev Chronic Dis. 2021;18:E66.
- Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. Interim clinical considerations for use of COVID-19 vaccines in the United States. September 15, 2023. Accessed September 15, 2023. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- 7. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. Overview of testing for SARS-CoV-2, the virus that causes COVID-19. August 8, 2023. Accessed September 12, 2023. https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
- 8. U.S. Food and Drug Administration. In vitro diagnostics EUAs antigen diagnostic tests for SARS-CoV-2. September 8, 2023. Accessed September 12, 2023. https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2
- 9. U.S. Food and Drug Administration. RE: Emergency Use Authorization 105 [letter]. May 25, 2023. Accessed September 12, 2023. https://www.fda.gov/media/155049/download
- 10. U.S. Food and Drug Administration. FDA approves first oral antiviral for treatment of COVID-19 in adults [news release]. May 25, 2023. Accessed September 12, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-antiviral-treatment-covid-19-adults
- 11. Katella K. 13 things to know about Paxlovid, the latest COVID-19 pill. September 5, 2023. Accessed September 12, 2023. https://www.yalemedicine.org/news/13-things-to-know-paxlovid-covid-19
- 12. U.S. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for Paxlovid™. May 2023. Accessed September 12, 2023. https://www.fda.gov/media/155050/download
- 13. U.S. Food and Drug Administration. Coronavirus (COVID-19) update: FDA approves first COVID-19 treatment for young children [news release]. April 25, 2022. Accessed September 12, 2023. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-approves-first-covid-19-treatment-young-children
- 14. U.S. Food and Drug Administration. Veklury® (remdesivir) for injection, for intravenous use. 2020. Accessed September 12, 2023. https://www.accessdata.fda.gov/drugsatfda\_docs/label/2022/2147870rig1s020lbl.pdf
- 15. U.S. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for Lagrevio™ (molnupiravir) capsules. July 2023. Accessed September 12, 2023. https://www.fda.gov/media/155054/download
- 16. Administration for Strategic Preparedness & Response. Paxlovid (nirmatrelvir co-packaged with ritonavir). Accessed September 12, 2023. https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Pages/default.aspx
- 17. Administration for Strategic Preparedness & Response. Lagevrio (molnupiravir). Accessed September 12, 2023. https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Lagevrio/Pages/default.aspx
- 18. Administration for Strategic Preparedness & Response. Veklury (remdesivir). Accessed September 12, 2023. https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Veklury/Pages/default.aspx
- 19. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. Talking with patients about COVID-19 vaccination. November 3, 2021. Accessed September 12, 2023. https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

© 2024 American Academy of Family Physicians. All rights reserved.