

Coronavirus Disease 2019 (COVID-19): Frequently Asked Questions for Transplant Candidates, Recipients, and Care Givers

Last updated January 12, 2023

Information regarding COVID-19 continues to change rapidly. This document will be updated with new information whenever possible. Please contact your transplant center with specific questions or concerns.

Human coronaviruses are common viruses that cause the common cold, and do not usually cause serious symptoms. A novel coronavirus named SARS-CoV-2 causes the disease called Coronavirus disease 2019 (COVID-19). This coronavirus appeared in December 2019 and quickly spread all over the world. COVID-19 spreads from person to person through close contact, most often by respiratory droplets that are spread when an infected person coughs, sneezes or talks. People are thought to be most contagious when they have symptoms, but even those who are not experiencing symptoms or have mild symptoms can spread the virus.

Like many other viruses, mutations (changes in the virus) are common with SARS-CoV-2 and several important variants (different versions of the virus) have been reported since December 2019. In late 2021, Omicron emerged and became the dominant variant around the world within a few weeks largely because its mutations allowed the virus to evade immune responses and spread more easily. While prior immunity still decreases disease severity, breakthrough infection, particularly with Omicron, can occur.

Over the course of 2022, several Omicron subvariants emerged, including BA.4.6, BA.5, BQ.1, BQ.1.1 and XBB, causing new outbreaks and limiting options to treat and prevent infection. Many of these Omicron subvariants, particularly BA.4.6 and BA.5, were found to be significantly less susceptible to tixagevimab/cilgavimab (Evusheld). In addition, the subvariants BQ.1 and BQ.1.1 were not only also resistant to Evusheld but also to bebtelovimab, the only monoclonal antibody therapy available at the time, causing the US FDA to withdraw Emergency Use Authorization for bebtelovimab on 11/30/2022.

What are the symptoms of COVID-19?

This list is not all-inclusive. If you develop symptoms concerning for COVID-19, contact your transplant center right away. Common symptoms include:

- Fever
- Cough
- Shortness of breath or difficulty breathing
- Chills/repeated shaking
- Muscle pains
- Headache
- Sore throat
- Fatigue
- Nausea, diarrhea, abdominal pain
- New loss of smell and/or taste
- Rash

How is COVID-19 treated?

Most people with COVID-19 who have mild to moderate symptoms will recover on their own with supportive care. However, some people with risk factors, such as being a transplant recipient, are at risk for more severe disease. Letting your primary care provider or transplant team know about your symptoms right away is critical so they can provide further guidance on the best treatment, especially since some of these treatments are time sensitive and work best when given early. Along with supportive care, below are some treatments currently being used for COVID-19. Because new strains of the virus are frequently emerging, therapies for COVID-19 are constantly changing so it is important to check with your transplant team to learn what is available to you.

Oral Antiviral Therapy

The US FDA has given Emergency Use Authorization (EUA) for two oral antivirals nirmatrelvir/ritonavir (Paxlovid; Pfizer; for ages ≥ 12 years of age and ≥ 40 kg)) and molnupiravir (Lagevrio; Merck;≥ 18 years of age) for treatment of COVID-19. Both nirmatrelvir/ritonavir and molnupiravir are meant to be used as outpatient therapy for COVID-19, for high-risk patients early in disease (within 5 days of symptom onset). Nirmatrelvir/ritonavir can be challenging to use in many transplant patients due to significant drug interactions and the difficulty with checking drug levels in outpatients with active COVID-19 infection. Let your transplant team know right away if you are prescribed nirmatrelvir/ritonavir because your immunosuppression

will probably need immediate adjustment if you are going to take this medication. **Do not start** this medication or change your immunosuppression until you have received specific instructions from your transplant team. There are usually no adjustments required when taking molnupiravir but you should review all new medications, including molnupiravir, with your transplant team before you start taking them.

Monoclonal Antibodies

Up until December 2022, anti-SARS-CoV-2 monoclonal antibodies were used to treat mild to moderate COVID-19 infections in patients who are at high risk of clinical progression. As newer versions of the virus emerged (particularly Omicron and subvariants), different monoclonal antibodies have lost their effectiveness. These have included bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab and bebtelovimab. **As of 1/2023**, there are **no** monoclonal antibody therapies authorized for treatment of COVID-19 in the United States.

Remdesivir

Remdesivir is an intravenous antiviral medication that has been FDA approved for the treatment of COVID-19. Initially, it was used only in hospitalized patients with moderate to severe COVID-19. More recently a shorter 3-day course may be given in the outpatient setting as early treatment of patients including children with mild to moderate disease.

Corticosteroids

Dexamethasone (a steroid) is used for patients with severe disease who are hospitalized with COVID-19 and are requiring oxygen support due to hypoxia.

<u>Immunomodulatory Drugs</u> (Medications that affect your immune system)

For hospitalized patients on dexamethasone who have rapidly increasing oxygen needs and signs of systemic inflammation, a second immunomodulatory drug (e.g., tocilizumab, baricitinib or anakinra) may be used. Published data on these medications in COVID-19 have demonstrated mixed results. Nonetheless, the FDA has given Emergency Use Authorization (EUA) for the use of these two drugs in hospitalized patients on corticosteroids who meet certain EUA criteria.

• For more information on COVID-19 treatment, visit: https://www.covid19treatmentquidelines.nih.gov/whats-new/

Prevention

Are the COVID-19 vaccines safe and effective in transplant candidates and recipients?

Vaccination

Yes, vaccination against COVID-19 is an important thing you can do to protect yourself and others. We strongly recommend all transplant candidates, patients and contacts receive COVID-19 vaccines. COVID-19 vaccines are safe. Although they may be less effective in transplant patients, vaccinated transplant patients are still less likely to develop severe disease or be hospitalized or die from COVID-19 when compared to transplant patients who are not vaccinated.

Everyone 6 months of age and above should get a COVID-19 vaccine and booster as soon as they can. Widespread vaccination is critical to stopping the pandemic. Vaccination is recommended even if you have had COVID-19 infection.

You can receive an mRNA vaccine (Pfizer-BioNTech or Moderna) or the Janssen/Johnson & Johnson (Adenovirus vector vaccine), or the Novavax COVID-19 Vaccine (protein subunit vaccine). The mRNA vaccines are preferred, and the new bivalent booster vaccines (approved September 2022) are only available as mRNA vaccines. All COVID-19 vaccines are safe but it is normal to have some side effects after receiving these vaccines. These generally resolve in 24-48 hrs.

The mRNA vaccines are approved by the U.S. FDA and are more effective in transplant patients. When possible, please request either the Pfizer-BioNTech or Moderna vaccine, although the other vaccines are also effective and safe options. The response to a vaccine may vary from person to person. It is important that you receive 3 doses (Pfizer-BioNTech or Moderna) or 2 doses (one dose Janssen/Johnson & Johnson plus one dose of either Pfizer-BioNTech or Moderna; or two doses of Novavax) of a vaccine followed by the bivalent booster.

The FDA has authorized bivalent formulations of the <u>Pfizer-BioNTech</u> and <u>Moderna</u> COVID-19 vaccines for use as a single dose at least <u>two months</u> after completing primary or booster vaccination for individuals aged 5 years and older. Even if you received a booster with the original version of the vaccine, you should update your boosters with one of the bivalent vaccines. The new updated bivalent COVID-19 vaccine boosters (approved September 2022) are formulated to better protect against newer variants (Omicron) and can help restore waning protection since prior vaccination.

The AST COVID-19 Task Force has provided updated and helpful information about vaccines here. See AST Vaccine FAQ here for more info.

Monoclonal Antibodies for Prevention

A long-acting monoclonal antibody called Evusheld was authorized by the FDA on 12/8/2021 for patients who were vaccinated but immunocompromised or did not receive the vaccine due to severe allergies and had not been exposed to COVID-19 recently. Unfortunately, Evusheld was found to be significantly less protective against several of the new Omicron subvariants that emerged in 2022, including BA4.6, BA.5, BQ.1 and BQ.1.1. Because of this, most transplant centers have stopped recommending Evusheld at this time.

What can I do to protect myself and others from COVID-19?

There are several things you can do to protect yourself in addition to vaccination.

Best practices include:

- Wash your hands or use hand sanitizer frequently
- Avoid touching your eyes, mouth, and nose
- Avoid large crowds when COVID-19 is circulating in your community
- Wear a well-fitting mask if you are going to be in crowded areas indoors
- Practice social distancing by staying at least six feet from other people and groups when COVID-19 is circulating in your community
- Stay at home if you are sick and encourage others to do so if they are sick
- Make sure that your family, friends, and other close contacts get vaccinated too.

Can I get the COVID-19 booster and Influenza vaccine at the same time?

You can receive the Influenza and COVID-19 boosters at the same visit. Getting both vaccines at the same visit increases your chances of being up to date with vaccinations. The updated COVID-19 vaccine booster and seasonal flu vaccines are available at most pharmacies, doctor's offices and health care clinics.

I had COVID-19. When can I get the booster vaccine?

The CDC's clinical guidance states that if you recently had COVID-19, you **may** consider delaying your booster by up to <u>3 months</u> from when your symptoms started or 3 months from the positive COVID-19 test if you had no symptoms. However, certain factors, such as the personal risk of severe disease, local COVID-19 community level, and a change in the most common COVID-19 variant currently causing illness, could be reasons to get a booster sooner rather than later. If you have not completed your primary set of vaccines, you should complete those as soon as you have resolved your symptoms and are out of quarantine. Talk to your transplant team about the right time to get your vaccines.

Is it safe for me to go outside without a mask? When can I resume normal activities?

In most areas of the country, it is safe to be outdoors without a mask, provided that you follow basic safety guidelines. Local and state public health authorities will determine many of these, so it is important to stay up to date.

The CDC maintains <u>guidelines</u> for the use of masks that vary based on local community levels. However, even if you are fully vaccinated, **transplant recipients should continue wearing a well-fitting mask**, **such as a surgical mask or KN95 or a N95 respirator**, indoors when surrounded by other people. Transplant candidates and recipients should wash or sanitize their hands often. The CDC also does not recommend the use of face shields. You should still wear a mask even if you use a face shield.

You can resume domestic travel (within the U.S.) safely. You should wear a mask on planes, buses, trains, and other public transportation, even if others are not. For international travel, please follow the U.S. Department of State <u>guidance</u>. Please monitor for an increase in COVID-19 cases at your travel destination and avoid traveling to places with high rates of COVID-19.

It is safe to return to work and/or school once you have been fully vaccinated and follow precautions.

What are the outcomes of COVID-19 in transplant recipients?

Transplant recipients are at higher risk of severe COVID-19. Initial reports in 2020 showed that adult transplant recipients experienced higher rates of hospitalization (up to 77% of patients) and mortality (up to 19% of patients) when compared to the general population. As more effective treatments became available, such as remdesivir, dexamethasone and monoclonal antibodies, these outcomes <u>steadily improved</u> for most people, including transplant recipients. In addition, getting vaccinated against COVID-19 also decreases the risk for severe disease and

death from COVID-19. Even though vaccinated transplant recipients may develop breakthrough infections, studies have shown that COVID-19 is <u>milder</u> in those who are vaccinated (80% reduction in COVID-19 symptoms).

Despite these improvements, transplant recipients still have higher rates of hospitalization. The severity of illness may be <u>reduced</u> with the Omicron variant when compared to previous variants.

What should I do if I have COVID symptoms or am diagnosed with COVID-19?

The first step is to isolate and separate yourself from others. Although there are many different causes for fever, cough, shortness of breath, stomach upset, and flu-like symptoms, COVID-19 is still a concern in most parts of the world. Testing for COVID-19 early is important because treatment is most effective if given early. If your symptoms are mild, you should then contact your transplant center or primary care provider to arrange for COVID-19 testing. This can be done using home testing kits or in a laboratory. However, if you notice chest pain, confusion, difficult breathing, or other severe symptoms, please call 911 (or emergency services).

Letting your primary care provider or transplant team know about your symptoms **right away** is critical so they can provide further guidance on the best treatment, especially since most treatments are time sensitive and work best if given early in the infection. It is important to remember that most people, including transplant candidates and recipients, experience only mild to moderate symptoms and recover from COVID-19 without problems. Many do not need hospitalization but are able to stay at home in isolation.

You can also refer to the AST COVID-19 Resources for Transplant Recipients and candidates for specific instructions and home monitoring guides: https://www.myast.org/covid-19-transplant-handouts-recipients-and-candidates.

I had COVID-19. When can I stop self-isolating?

The CDC <u>recommends</u> that transplant recipients recovering from COVID-19 stay home longer than 10 days and up to 20 days counting from the first day of symptoms and/or diagnosis. The CDC also recommends that immunosuppressed patients (including transplant patients) should undergo testing or discuss with an infectious disease specialist before they end their isolation period. Consequently, some medical centers may require that transplant patients repeat COVID-19 testing to further determine when to stop isolation. These extended recommendations are because transplant recipients with COVID-19 may be infectious for a longer period than those who are not immunosuppressed.

I had COVID-19 and recovered. Can I get reinfected?

Yes, reinfection with COVID-19 has been a common issue, particularly with newer Omicron variants. A variant strain has one or more mutations in its viral structure that make it different from the virus circulating in the community. Some variants may be more infectious. For now, the new bivalent COVID-19 booster offers protection against severe disease from the original and Omicron variants. The CDC continues to monitor emerging variants and its implications on current treatment guidelines and vaccines.

I am awaiting a transplant. Could I get COVID-19 from my donor?

The risk of acquiring COVID-19 from organ donation is very low. The rare cases reported in the literature thus far involve lung transplant recipients only. Organ procurement organizations are screening all potential donors for COVID-19 symptoms and exposure history. All potential donors are also tested for COVID-19 prior to transplant. Given the low risk of transmission outside of lung transplant, some centers may accept carefully selected donors with positive PCRs.

Transplant centers have also taken careful steps to screen living donors, including checking for symptoms, exposures, and viral testing. At some centers, living donors are being asked to avoid travel to high-risk areas and to isolate themselves before donation and monitor symptoms.

I had COVID-19. When can I be cleared for transplant?

If you have had COVID-19 and recovered, please contact your transplant center once you are symptom free so they can assess you and determine when you would be ready for transplant.

Resources for Patients

1. Get the latest public health information from CDC or WHO:

https://www.coronavirus.gov

https://www.who.int/emergencies/diseases/novel-coronavirus-2019

2. Get the latest research information from NIH:

https://www.nih.gov/coronavirus

3. For information on COVID-19 Treatment: https://www.covid19treatmentquidelines.nih.gov/whats-new/

4. For information on specific clinical trials underway for treatment of patients with COVID-19 infection:

clinicaltrials.gov

5. Information from the American Society of Transplantation: https://www.myast.org/covid-19-information

6. CDC information for COVID-19 and children:

Caring for Children

7. COVID-19 information for parents from Pediatric Infectious Disease Society: <u>COVID-19 Resources</u>

8. AST COVID-19 resources for transplant recipients and candidates: https://www.myast.org/covid-19-transplant-handouts-recipients-and-candidates