



The LAM Foundation COVID-19 Vaccine Statement

Revised on **12.20.2020** – Please read carefully.

Since our last vaccine update of 11/30/2020, there have been some exciting new developments in the field, chief among them being the release of data regarding the safety and efficacy of two COVID-19 vaccines that have been granted Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA). The following is an updated guide aimed at providing answers to some of the most commonly asked questions pertaining to COVID-19 vaccination. We are closely monitoring developments in this field and will update this page as new information becomes available.

What vaccines have been granted EUA by the FDA?

Two vaccines have been granted EUA by the FDA. The Pfizer/BioNTech vaccine was the first to receive EUA by the FDA on December 11, 2020, followed by the Moderna vaccine that received EUA on December 18, 2020.

How do these vaccines work?

Both the Pfizer/BioNTech and the Moderna vaccines use messenger RNA (mRNA) technology. The vaccines do not contain viruses or protein, instead they contain a small piece of viral genetic material that instruct our cells to produce a portion of the spike protein of the virus that causes COVID-19. This protein primes the immune system to be ready to better protect us when faced with the real virus.

What is the vaccine dosing schedule?

Both vaccines require two doses to obtain maximal benefit. The Pfizer/BioNTech vaccine requires a second dose 21 days after the first dose and the Moderna vaccine requires a second dose 28 days after the first dose.

Can I skip the second dose of the vaccine?

Although even one dose of these vaccine confers some protection against COVID-19, both doses are needed to obtain maximal sustained protection. As such, it is imperative that patients take both doses of the vaccine.

Can I acquire COVID-19 from these vaccines?

Neither of the two vaccines are live vaccines. As such, there is no risk of acquiring COVID-19 infection from vaccination.

What is the efficacy of these vaccines?

Both vaccines have a greater than 90% efficacy in providing protection against COVID-19. In the Pfizer/BioNTech study, of tens of thousands of enrolled subjects, there were a total of 170 confirmed cases of COVID-19 following two doses of the vaccine - 162 in the placebo group and 8 in the vaccine group, for an overall efficacy of 95%. In the Moderna study, with roughly similar enrollment, there were a total of 196 confirmed cases of COVID-19, 185 in the placebo group and 11 in the vaccine group, for an overall efficacy of 94%.

What are the side effects of these vaccines?

The most common side effects from the COVID-19 vaccines were local reactions such as injection site soreness, pain and swelling. These were seen in >85% of the vaccine recipients. Other common side effects from the COVID-19 vaccines include fatigue and headache seen in over half of the subjects, followed by chills and joint pains in about one-third, and fever in roughly 15% of the vaccine recipients. These reactions were generally worse after the second dose than the first dose, and worse in younger subjects as opposed to people ≥ 55 years of age. The majority of these side effects were mild-to-moderate in nature and self-limited with a resolution time of 1-2 days. Over-the-counter medications such as Tylenol (acetaminophen) and NSAIDs (e.g., ibuprofen) may be needed for symptom relief in some cases and are OK to use. Patients with history of serious allergic reactions should discuss the safety of this vaccine with their healthcare providers. It is possible that with more widespread vaccination, some other unexpected side effects or serious adverse reactions to the COVID-19 vaccines may occur, however, we expect these to be infrequent. Overall, the COVID-19 vaccines appear to be both safe and effective for the vast majority of recipients.

When can I expect to receive vaccination?

The COVID-19 vaccination is being rolled out in a staggered fashion with the initial supplies being provided to healthcare personnel and people residing in long-term care facilities. The next group of people to be prioritized for vaccination will likely include teachers, first responders, other essential workers outside of health care, people ≥ 65 years of age and people at risk of serious complications from COVID-19 such as people with underlying health conditions. LAM patients, by virtue of their lung disease, will fall in this category. While the exact timelines for vaccine availability for this group are not clear at this time, it is likely to be available for most LAM patients by spring 2021.

Can I take the COVID-19 vaccination if I am on mTOR inhibitors (sirolimus/everolimus)?

The safety and efficacy of COVID-19 vaccination has not been well studied in patients taking immunosuppressive medications such as mTOR inhibitors. Although there is no direct evidence, there is no reason to think that the side effect profile from vaccination will be different in patients taking mTOR inhibitors versus patients not on these drugs. The major concern with vaccination in patients on mTOR inhibitors pertains to their efficacy, i.e., will the mTOR inhibitors impair the immune response to the vaccination leading to suboptimal protection? While the exact answer to this question is not known, it is likely that patients on mTOR inhibitors will mount at least some response to vaccination and derive at least partial immunity from COVID-19 as opposed to the prospect of no protection without vaccination. As such, we recommend that LAM patients should take the COVID-19 vaccine regardless of their use of mTOR inhibitors.

Should I get vaccinated if I have previously had COVID-19?

Previous infection with COVID-19 provides you some natural immunity against re-infection. However, the efficacy and duration of natural immunity to prevent COVID-19 reinfection is not well understood. At the present time, we suggest getting vaccinated for COVID-19 even if you have previously been infected, similar to the recommendation for Shingles.

Do I need to continue to social distance and wear mask after I have received the COVID-19 vaccine?

Yes. While the availability of COVID-19 vaccination represents a landmark moment in our quest to quell the pandemic, the staggered roll out of the vaccine and the time it will take to mount an effective response to vaccination (~2 weeks following the second dose) implies that we need to continue to take all the necessary precautions such as hand hygiene, social distancing, and mask use in order to maximize our chances of staying safe and controlling community spread.

The LAM Foundation's recommendation regarding vaccination

Considering the severity of illness that patients with COVID-19 may experience, the increased risk of disease-related complications in patients with underlying lung disease, and the overall favorable safety and efficacy profile of the vaccines, we strongly recommend LAM patients to get vaccinated against COVID-19 at the earliest opportunity available to them.

Additional Resources

Centers for Disease Control and Prevention (CDC): <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>