



## **The LAM Foundation Statement on additional dose of COVID-19 vaccine**

August 17, 2021

On August 12, 2021, the United States Food and Drug Administration (FDA) modified the Emergency Use Authorizations (EUAs) for the mRNA COVID-19 vaccines (Pfizer and Moderna) to allow for the administration of an additional dose (i.e., a third dose) after an initial two-dose primary mRNA COVID-19 vaccine series for certain immunocompromised people. This amendment was subsequently endorsed by the Centers for Disease Control and Prevention (CDC) on August 13, 2021.

### **Who is eligible to receive the additional vaccination dose now?**

Per the CDC recommendations, the additional dose should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e.,  $\geq 20$ mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

### **Are these recommendations applicable to LAM patients?**

These recommendations are relevant to the subset of LAM patients who take sirolimus or everolimus for treatment. Sirolimus and everolimus belong to a class of medications called mTOR (mechanistic target of rapamycin) inhibitors. mTOR inhibitors are commonly prescribed along with other immunosuppressive medications to prevent rejection in patients with organ transplantation. While it is clear that some patients who have had organ transplants and who are on combination immunosuppressive medications do not mount an effective response following COVID-19 vaccination, it is unclear if that is also the case for LAM patients on monotherapy with mTOR inhibitors. Preliminary data indicates that patients with LAM who received the COVID-19 vaccination while on sirolimus are able to mount a good response following vaccination; however, this data requires further validation.

### **I have LAM but am not on sirolimus. Do I qualify for an additional dose?**

It is likely that in the near future an additional dose of the COVID-19 vaccine will be recommended for all individuals to boost our defenses against the virus. However, the current recommendations are only applicable to patients with LAM who are on sirolimus or everolimus, or qualify under one of the other above-mentioned CDC criteria.

**Can I use antibody titers to decide if I need the additional dose?**

At this time, there is no known blood SARS-CoV2 antibody titer that corresponds to protection from COVID-19 infection. As such, it is currently unclear how the blood-based antibody measurement should be used in making decisions regarding additional doses of the COVID-19 vaccine.

**What is the safety and efficacy of the additional dose of vaccination?**

Although the clinical benefit of an additional vaccination dose is not yet precisely known, it has been shown to enhance the antibody response, thus potentially providing superior protection against COVID-19.

Both mRNA vaccines (Pfizer and Moderna) have a robust safety profile. The major side effects include local reactions such as injection site soreness, pain and swelling. Other side effects include fatigue, headache, chills, joint pains and fever. These side effects typically last for 1-2 days and respond well to over-the-counter medications such as Tylenol (acetaminophen) and NSAIDs (e.g., ibuprofen). Additional information regarding the COVID-19 vaccines is available [here](#).

**Which vaccine should I take?**

For the additional dose, individuals should receive the same vaccine product as was used in their initial two-dose mRNA COVID-19 primary vaccine series (Pfizer or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered.

**I took the Johnson and Johnson vaccine previously. Am I eligible for an additional vaccination dose?**

Individuals who received the Johnson & Johnson COVID-19 vaccine as their primary vaccine are not eligible for an additional dose at this time due to insufficient data. Ongoing research is being conducted to ensure optimal vaccine protection for those who received the Johnson & Johnson vaccine.

**How long after the second dose can I receive the additional dose?**

The additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series.

**How do I get the additional vaccination dose?**

Contact your local pharmacies and vaccination centers to schedule your additional dose. You do not need a prescription to receive the additional dose.

**What is The LAM Foundation's recommendation regarding additional vaccination dose for patients on mTOR inhibitors?**

Given the uncertainty regarding the degree of antibody response generated following vaccination on the background of mTOR inhibitors, the potential for severe complications in patients with LAM following COVID-19 infection, and the overall safety and efficacy of the mRNA vaccines, the consensus recommendation from The LAM Foundation is for LAM patients on mTOR inhibitors to receive the additional dose of mRNA COVID-19 vaccination.

**Disclaimer**

This content was created for general informational purposes only. The content is not intended to be a substitute for professional medical advice. The risk profile for each individual is unique and immunity

from COVID-19 may be affected by factors such as age, chronic health conditions, and other medications. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding these recommendations.

**Additional Resources**

[Centers for Disease Control and Prevention](#)

[TSC Alliance COVID-19 Vaccine Position Statement](#)