



8737 Colesville Road, Suite 400 | Silver Spring, MD 20910
800-225-6872 | info@tscalliance.org | tscalliance.org

TSC Alliance COVID-19 Vaccine Position Statement - Update November 16, 2021

COVID-19 Vaccination Addendum:

The FDA has authorized the use of Pfizer's COVID-19 vaccine, under an Emergency Use Authorization (EUA), in individuals 5 years of age and older. In addition, for those 18 years and older, the CDC has approved an individual's choice of COVID-19 vaccine as a booster. Some people may prefer the same vaccine type originally received, whereas others may choose a different booster.

FAQ: New eligibility of COVID-19 vaccine for individuals 5 years of age and older.

Does my child need to stop taking any medication prior to the vaccine?

No. Ongoing research provides no evidence to alter or stop any medication including mTOR inhibitors prior to the vaccine. We strongly defer recommendations to the prescribing providers preference.

Will my child's seizures worsen with the vaccine?

It is possible to have a breakthrough febrile (fever) associated seizure due to any vaccination. However, there is still no evidence that any of the COVID-19 vaccines lower seizure threshold. Always defer to your seizure action plan defined by your current provider.

Do I need to get my child's antibodies tested after vaccination series has been completed?

Currently there is no evidence that support antibody level testing after completion of the vaccination series. At the time of this addendum, there is no consensus on antibody levels required for a protective response. We strongly defer recommendations to the prescribing providers preference.

Can my child receive the vaccine at the same time of their other childhood vaccinations including the seasonal influenza vaccine?

Yes. The American Academy of Pediatrics confirms that COVID-19 vaccines can be co-administered on the same day as other routine vaccinations – or within 14 days – of other vaccines. If your child is on an altered schedule of vaccinations or there are additional concerns, we strongly recommend discussing this with your local pediatrician and pediatric neurologist.



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When my child receives the vaccine will they be immune from contracting the virus?

No. To be considered “fully protected” you must complete the vaccination series. Two weeks following the last (2nd) vaccine injection, you are considered “fully vaccinated.” Remember, vaccines reduce transmission; however, those vaccinated can still become infected. In fully vaccinated individuals (completed vaccine series and 2 weeks post-last injection) the associated infections are milder and prevent serious illness. The goal of vaccination is to decrease the severity of complications associated with the illness.

If my child had COVID-19, should they still get vaccinated?

Yes. Studies in adults have provided evidence that detectable antibodies levels are variable following “natural” COVID-19 infection, where some have protection for only a few weeks. Furthermore, the risk of reinfection after natural infection is 2 to 5 times more likely, which raises the need to consider vaccination.

How is the Pfizer vaccine different for ages 5– 11 than the other available vaccines?

Currently, Pfizer has the only approved vaccine for this age group. The dose is one-third of the dose for the 12+ age group (10 micrograms vs 30 micrograms) and is safe and effective.

If my child is currently 11 but will turn 12 before the second dose, what should I do?

If your child received the smaller dose, you should complete with the smaller dose to complete the series. Unlike other medications, this vaccine is not weight dependent. The dose is based on immune system maturity. Furthermore, do not wait until your child is 12 before starting the vaccination series

What are most common side effects of the vaccine for ages 5-11?

Compared to adults and children age 12+, children ages 5-11 showed similar side effects such as, fatigue, headache, muscle pain and soreness at the injection site. Fever and chills were not as common as compared to the other age group trials. The most common adverse events are lymphadenopathy (swelling of the lymph nodes) or hypersensitivity (rash/dermatitis). In the event these occur we recommend contacting your local health care provider.

You can also self-report any adverse event through the vaccine adverse event reporting system (VAERS) at <https://vaers.hhs.gov/index>. If your child is experiencing a medical emergency, you need to seek immediate assistance from a healthcare provider or call 911. VAERS is for data tracking purposes and does NOT provide medical treatment.



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Given TSC cardiac manifestations, is my child at higher risk of vaccine induced myocarditis?

Myocarditis is inflammation of the heart caused by viral and other pathogens. Myocarditis due to COVID-19 vaccine is milder as compared to classic myocarditis, covid 19 virus, or MIS-C myocarditis. In continuing clinical studies in children 5–11-year-old with the Pfizer vaccine, there has been no reported cases of myocarditis. Given the uniqueness of TSC, personal concerns and other health related issues, we strongly recommend discussing this with your local pediatrician and TSC providers.

FAQ: Individuals 18 years of age and older boosters and mixing of boosters

Does TSC qualify me to receive a booster?

We strongly encourage you to have further discussion with your prescribing provider as qualification due to TSC, is dependent on the individual manifestations. Currently, boosters are approved for people 18+ years of age with an underlying health condition, particularly those with severe immunosuppression (e.g., certain cancers, organ transplant, HIV). Those who take mTOR inhibitors for TSC/LAM specific indications could have a lower immune response. Ongoing studies provide some evidence that individuals with TSC/LAM on a single therapy mTOR inhibitor exhibit an appropriate response for the 2-dose mRNA COVID-19 vaccination series, or the 1 dose of Johnson & Johnson shot.

When should I get a booster?

It is encouraged that you receive a booster vaccine when available (6 months after mRNA series or 2 months after Johnson & Johnson shot). This is due to waning antibodies over time and risk for complications associated to those with underlying health conditions associated with TSC. For those who have severe immunosuppression (such as certain cancers, organ transplant, and HIV), 3 shots were required to generate a desired antibody response to complete their primary series and will require an additional booster 6 months for the time of the last shot. This is also being referred to as “4th booster.” We strongly encourage further discussion with your prescribing provider preference.

What booster is recommended for those with TSC?

All booster vaccines are shown to provide protection. Those who had an mRNA-based vaccine should continue with an mRNA-based booster if available locally. Ideally, if you tolerated the Pfizer vaccine for your first series, it is reasonable to continue with that manufactured vaccine. However,



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if locally Moderna is only mRNA vaccine available, it is safe and effective to mix from your primary series to your booster.

For those who took Johnson & Johnson adenovirus-based vaccine, there is evidence to support wider protection from an mRNA-based booster. If Johnson & Johnson is the only vaccine booster available, it is completely fine receiving this booster shot. Either mRNA-based vaccine can be used. We strongly defer recommendations to provider preference and encourage discussion on the options with your local or TSC/LAM expert providers.

Are there any differences to the booster shots than the primary series vaccines?

Pfizer and Johnson & Johnson both are utilizing the same dose for their booster shots and the primary vaccines. Moderna booster dose is reduced by 50%.

What are the most common side effects associated with the booster shot?

Fever, headache, fatigue, and pain at the injection site of the shot. These symptoms usually resolve within 24 to 48 hours and are normal response to a vaccine. Most common adverse events are lymphadenopathy (swelling of the lymph nodes) or hypersensitivity (rash/dermatitis). In the event these occur, we recommend you reaching out to your local health care provider. You can also self-report any adverse event through the vaccine adverse event reporting system (VAERS) at <https://vaers.hhs.gov/index>. If you are experiencing a medical emergency, you need to seek immediate assistance from a healthcare provider or call 911. VAERS is for data tracking purposes, and you will not receive individualized medical treatment.

Can I/my adult child receive the vaccine at the same time of the seasonal influenza vaccine?

Yes. The CDC confirms that COVID-19 vaccines can be co-administered on the same day as other routine vaccinations – or within 14 days – of other vaccines.



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Medical Review Note

This information was reviewed and approved by:

- Peter B. Crino, MD, PhD, Chair, TSC Alliance Board of Directors
- Darcy A. Krueger, MD, PhD, Chair, TSC Alliance Professional Advisory Board
- Mustafa Sahin, MD, PhD, Chair, TSC Alliance International Scientific Advisory Board and Co-Chair, TSC Alliance Science and Medical Committee
- John J. Bissler, MD, TSC Alliance Professional Advisory Board
- Nishant Gupta, MD, Director of LAM Clinic Network
- Joel Moss, MD, PhD, TSC Alliance Professional Advisory Board
- Elizabeth Petri Henske, MD, TSC Alliance Professional Advisory Board

For additional questions or concerns please reach out to Ashley Pounders MSN, FNP-C, TSC Alliance Director, Medical Affairs at apounders@tscalliance.org or 240-472-4302.

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