

COVID-19 VACCINES AND MYOSITIS FAQs

Now that the first COVID-19 vaccine is here, what does that mean for those living with myositis? Together with some of the myositis experts, we have created this FAQ to help answer some of the questions you may have.

It is generally recommended that people with Myositis conditions receive the vaccine. However, we recommend talking with your health care team about the vaccine and your treatment plan, since it can vary from person to person.

How soon will be any vaccine be available for me to take?

The U.S. Food and Drug Administration (FDA) has approved an Emergency Use Authorization (EUA) for two vaccine to prevent COVID-19 (the illness caused by SARS-CoV-2, a type of coronavirus). The vaccines were developed and is manufactured by Pfizer, Inc and Moderna. Both are given in two doses at least three weeks apart. **You must receive both doses to get the full benefit from the vaccine.**

The FDA is responsible for authorizing and approving all vaccines in the U.S. Pfizer is the first company to have a vaccine approved in the U.S. In addition, Moderna, Inc. submission was approved on December 18th by the FDA panel of experts. AstraZeneca also has a leading vaccine candidate, and several other companies are also working to develop vaccines.

The FDA will continue to review safety and effectiveness data for all COVID-19 vaccines that are in use or waiting for authorization.

Even with the EUA, the vaccine may not be available to most people until spring or summer of 2021. Because of the limited supply of the vaccines, people at very high risk, such as health care providers and people who live in nursing homes or assisted living facilities, will get a vaccine before people whose risk of illness is lower.

Other vaccines are being developed around the world and should be approved by regulators in the first quarter of 2021. Different technologies have been deployed to develop, some of those include viral vector vaccines, inactivated whole virus or protein sub-units. You can check those and the countries developing them here <https://www.gavi.org/vaccineswork/there-are-four-types-covid-19-vaccines-heres-how-they-work>.

Do the RNA vaccines use live virus? How do they work?

Neither the Pfizer vaccine (which has received an EUA) nor the Moderna vaccine contain live virus. Both vaccines use a new technology that relies on [messenger RNA \(mRNA\)](#) from the virus to teach the body how to respond to COVID-19 exposure.

Other vaccines that are under development may use different ways to protect the body from the virus that causes COVID-19. We will know more about how those vaccines work as the companies release more information.

These vaccines were studied in thousands of people before they are given approval by FDA. It isn't possible, however, to study each vaccine in every type of person before it is approved. The FDA, the Centers for Disease Control and Prevention (CDC), and the companies that make the vaccines will continue to study their [safety](#) and effectiveness even after they are approved.

The following CDC vaccine pages are a great place to learn more about how COVID-19 vaccines are being developed and how they work in the body:

- [Facts about COVID-19 Vaccines \(cdc.gov\)](#)
- [Understanding How COVID-19 Vaccines Work \(cdc.gov\)](#)

The video below is a brief overview of how the mRNA vaccine works. The speaker in this ['viral video'](#) is a Biochemistry PhD candidate at Cornell University, and brings to life mRNA vaccines for non-scientists in an easy-to-understand classroom presentation:

What type of side effects will I get? Are they serious?

Many people in the clinical trials had some short-term side effects from taking the COVID-19 vaccine. The side effects are usually not serious -- one of the most common is a sore or achy arm. Some people develop low-grade fevers or chills and feel tired. This is because the vaccine is working and causing a response from the immune system, you will not get COVID from it. The Pfizer vaccine is given in two doses, three weeks apart. It is more common to have side effects from the second dose than the first. You must receive **both doses** to get the full benefit from the vaccine.

In most cases these side effects are not dangerous and will go away on their own within a short time. Please call your doctor if these side effects last for more than two days or if you have side effects that are more severe.

Most side effects are minor after 12 million people have received at least one dose of either the Pfizer or the Moderna vaccine. You may have some side effects, which are normal signs that your body is building protection. These side effects may affect your ability to do daily activities, but they should go away in a few days. For a quick reference to side effect see the [CDC brochure](#).

Will my myositis medicines affect how the vaccines work?

In general, myositis medications will not affect how the vaccine works, that includes commonly used IVIG infusions. In some cases, particularly for those who take powerful immunosuppressant drugs like steroids, your doctor may have special instructions for you so that you can get the greatest possible benefit from the vaccine. **Please check with your doctor if you are concerned about how the vaccine fits into your treatment plan.** See Dr. Aggarwal's video discussing this topic in his series on [Autoimmunity and COVID vaccines](#).

Were myositis patients included in the vaccine trials?

It is unlikely that many people with myositis were included in the clinical trials for the vaccine. There is no evidence that people with myositis should not receive the vaccine. There is strong evidence from the clinical trials, however, that taking the vaccine greatly reduces the chance that a person will get COVID-19, which can be a serious or even fatal illness.

For this reason, it is generally recommended that people with Myositis conditions receive the vaccine.

We will have more information as more research studies are conducted and analyzed over time. **We recommend talking with your health care team about the vaccine and your treatment plan, since it can vary from person to person.**

Will people with Myositis be among the first to receive the vaccine?

The CDC has an [Advisory Committee on Immunization Practices \(ACIP\)](#) that makes recommendations on who should receive the vaccine when there is a limited supply. ACIP has recommended that health care providers and people who live in nursing homes or assisted living facilities receive the vaccine before others. Those at high risk for severe COVID-19 illness due to underlying medical conditions and people aged 65 years and older may also be given priority. Many of the IBM patients might be in that group due to their age.

Your state may have their own guidance on how they are implementing the CDC guidelines and their plans for administering the vaccines. [Here is a directory of US local health departments](#).

It may be spring or summer of 2021 before the vaccine becomes available to you, your family, or caregivers. It is important that you continue to follow [public health guidelines](#) to protect yourself and your family:

- Stay at home as much as you can. Avoid high-risk activities such as travel, indoor gatherings with people outside of your household, and large gatherings even if they are outdoors.
- When you do go out, wear a mask, avoid crowds, wash your hands often, and sanitize surfaces.

- Stay in touch with your health care team and continue to follow your myositis treatment plan.
- Take care of your **mental and emotional health**.
- Get Support! Join Myositis Support and Understanding for online and video patient and caregiver support. Learn more at [Understandingmyositis.org/support](https://www.understandingmyositis.org/support).

I am an older patient with IBM Myositis, should I also consider the vaccine?

Yes, you should. The vaccines trials included older patients and showed protection in those individuals as well. The CDC are planning to further assess how well COVID-19 vaccines protect against developing COVID-19 among older adults, including those living in nursing homes and long-term care facilities.

Disease complications and risk of death increase dramatically with age and underlying conditions such as diabetes, heart problems, obesity and many others. People in their 60s or 70s are, in general, at higher risk for severe illness than people in their 50s. The greatest risk for severe illness from COVID-19 is among those aged 85 or older. **Severe illness** means that a person with COVID-19 may require hospitalization, intensive care or a ventilator to breathe, or they may even die.

Here are some importance recommendations from the CDC for older patients:

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>

Are the Pfizer and Moderna considered live vaccines? Can the vaccine cause a flare of my myositis?

Currently, neither the Pfizer nor Moderna vaccines contain any live virus particles, only RNA within a lipid bubble. There is no reason to assume that those vaccines should cause flares in your myositis condition. However, COVID-19 does increase the risk of worsening autoimmune diseases.

Patients with autoimmune disease may have increased susceptibility to COVID-19 due to the underlying disorder, increased comorbidity, and ongoing therapy with immunosuppressive, immunomodulating, and/or glucocorticoid agents.

In adults, if the immune system is weak due to medications that suppress the immune system, live vaccines might cause symptoms of active infection. Examples of live vaccines include the nasal spray vaccine for the flu, the yellow fever vaccine, chicken pox and shingles vaccines, and the measles, mumps and rubella vaccine. **It's a good idea to talk to your doctor about any vaccines you may need, as well as the risks and benefits of each.**

Vaccines such as Astra Zeneca, approved in England, uses a replication-deficient chimpanzee viral vector based on a weakened version of a common cold virus (adenovirus) and contains the genetic material of the SARS-CoV-2 spike protein.

Should I get the vaccine even if I got COVID earlier in the year?

Due to the severe health risks associated with COVID-19 and the fact that reinfection with COVID-19 is possible, you may be advised to get a COVID-19 vaccine even if they have been sick or tested positive for COVID-19 before.

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Natural immunity may not last very long according to earlier data, but it's too early to tell.

We won't know how long immunity produced by vaccination will last until we gather more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

Also, keep in mind that neither of the vaccines in the US will cause you to test positive on [viral tests](#), which are used to see if you have a **current infection**.

Can I get an allergic reaction to a vaccine?

As with all vaccines, it is possible to get an allergic reaction due to a vaccine, which may be light or severe depending on the patient response.

Currently, information is fluid. In the US, the Centers for Disease Control and Prevention stated on December 13th that people who have experienced severe reactions to food or drugs can still get the Pfizer vaccine for COVID-19 but **should discuss the risks with their doctors and be monitored for 30 minutes afterward**. As more patients are vaccinated, we will know more about additional precautions.

In England, the regulatory body for medicines (MHRA) issued a recommendation to health care professionals stating that any person with a significant allergic reaction to a vaccine, medicine or food -- such as previous history of anaphylactoid reaction, or those who have been advised to carry an adrenaline autoinjector -- should not receive the vaccine at this time. This may change as more patients are vaccinated.

I believe a vaccine caused my myositis, should I take this vaccine?

Vaccines in the US are voluntary, it's your decision to take any type of vaccine. As prevention, you are not curing a disease in the present but preventing one in the future. Each of us is our own best health advocate.

Many times, our loved ones depend on us for information and protection too. With so much information – and sometimes incorrect information – available today, learning the facts before making health decisions is very important.

For a historical perspective on vaccine safety concerns please see the information from the [CDC](#).

Should I worry about which vaccine to get?

Depending on your immune response status your doctor may recommend that you take a specific type of vaccine depending on your previous history. As of this winter, there are only two vaccines available in the US, both of them are RNA vaccines.

Currently the vaccines developed include are four categories of vaccines in clinical trials: [WHOLE VIRUS](#), [PROTEIN SUBUNIT](#), [VIRAL VECTOR](#) and [NUCLEIC ACID \(RNA AND DNA\)](#).

Is there more of one variant of the COVID virus at this time?

Yes, Multiple SARS-CoV-2 variants are circulating globally. Several new variants emerged in late of 2020, most notably:

- In the United Kingdom (UK), a new variant of SARS-CoV-2 (known as 20I/501Y.V1, VOC 202012/01, or B.1.1.7) emerged with an unusually large number of mutations. This variant has since been detected in numerous countries around the world, including the United States (US) and Canada.
- In South Africa, another variant of SARS-CoV-2 (known as 20H/501Y.V2 or B.1.351) emerged independently of B.1.1.7. This variant shares some mutations with B.1.1.7. Cases attributed to this variant have been detected outside of South Africa.
- In Brazil, a variant of SARS-CoV-2 (known as P.1) emerged and was identified in four travelers from Brazil. This variant has 17 unique mutations.

Scientists are working to learn more about these variants to better understand how easily they might be transmitted. At this time, there is no evidence that these variants cause more severe illness or increased risk of death. New information about the virologic, epidemiologic, and clinical characteristics of these variants is rapidly emerging.

Does the COVID vaccine work on all variants?

Because people usually make more than one type of antibody against a virus, experts say it's unlikely such a mutation would render the virus completely resistant to a vaccine. However, experts aren't so sure of the overall impact of the new strains.

UPDATED 1/20/2021