

# July 2021 Newsletter



## MS and COVID-19 Vaccines

Three COVID-19 vaccines have emergency use authorization from the Food & Drug Administration in the United States. Two [mRNA vaccines](#), made by [Pfizer-BioNTech](#) and [Moderna](#), require two doses for maximum protection. A third [viral vector vaccine](#), made by [Johnson & Johnson](#) (J&J) requires a single dose. According to the National MS Society, “Whether you receive the Pfizer BioNTech, Moderna or J&J vaccine, it takes two weeks after being fully vaccinated before you are considered protected.”



The National MS Society’s [COVID-19 vaccine guidance](#) for people with MS was updated in June 2021 to say, “The science has shown us that the COVID-19 vaccines are safe and effective. Like other medical decisions, the decision to get a vaccine is best made in partnership with your healthcare provider. Most people with relapsing and progressive forms of MS should be vaccinated. The risks of COVID-19 outweigh any potential risks from the vaccine. In addition, members of the same household and close contacts should also be vaccinated against COVID-19 when available to decrease the impact of the virus.” According to the guidance, the COVID vaccines are safe to use with MS medications. These recommendations are based on clinical trials of the general population and studies of other vaccines administered to people with MS. It’s unclear how many subjects with MS or those on disease modifying therapy (DMT) were included in the COVID-19 vaccine clinical trials. This may leave people with MS wondering whether or not

it's safe to get vaccinated and if it will be effective in light of their MS treatment. These are hot topics in MS research and numerous studies are underway to provide clarity.



A [recent study](#) concluded that the Pfizer vaccine is safe and effective in people with MS. As part of this research, over 500 adults with MS received the Pfizer vaccine between December 2020 and January 2021 (555 MS subjects received the first dose and 435 received the second dose in that timeframe). The most common adverse events from the vaccine were the same as reported in the general population (pain at the injection site, fatigue, and headache). These symptoms were more common after the second dose than after the first dose. Results show the vaccine does not increase the risk of MS relapse activity and it is highly effective over the short term. Investigators state that longer follow-up is necessary to better evaluate its protection over time.

As discussed in our [January 2021 newsletter](#), vaccines help develop immunity by imitating an infection. The immune system recognizes the “vaccine germs” as foreign invaders just as it would the “disease germs” and responds by making proteins called antibodies. Antibodies help resolve an infection by destroying the germs. They also provide protection from future infections by remaining in the bloodstream. If the same germs attack again, they are destroyed before they cause illness. Some MS DMTs act by suppressing this immune response and this could reduce the effectiveness of the COVID-19 vaccines in people taking these medications. Two recent studies explored this important subject, with very interesting findings. [Researchers](#) in the Netherlands looked at SARS-CoV-2 antibody levels (the virus that causes COVID-19) in 546 subjects with MS, 405 of which were on a DMT. They found antibodies were less prevalent in subjects taking beta interferon drugs (Avonex, Rebif, Betaseron, Extavia and Plegridy), glatiramer acetate (Copaxone) and ocrelizumab (Ocrevus). These data imply that B-cell depletion could influence SARS-CoV-2 antibody production in people with MS. [Investigators](#) in Israel evaluated the immune response in 125 MS subjects and healthy control subjects one month after the second dose of the Pfizer vaccine. MS subjects were either untreated or under treatment with fingolimod (Gilenya), cladribine (Mavenclad), or ocrelizumab (Ocrevus). Results show that healthy subjects and MS subjects that were untreated or treated with cladribine had high antibody titers for SARS-CoV-2. Only 22 percent of MS subjects treated with ocrelizumab developed a protective immune response. Most fingolimod-treated MS subjects failed to develop SARS-CoV-2 antibodies.





A number of clinical trials are underway to better understand the immune response in people with MS after COVID infection and COVID vaccination in the context of MS treatments.

## **Current COVID-19 clinical trials in people with MS**

[Researchers](#) in Switzerland are studying the immune response after COVID-19 infection in subjects with MS treated with various DMTs and subjects with MS not on treatment.

A [clinical study](#) is underway in Oregon to determine whether DMTs affect the ability to mount and sustain an immune response following COVID vaccination in people with MS.

[Investigators](#) at Saint Barnabas Medical Center in New Jersey are evaluating the effect of MS DMTs on antibody responses to the Moderna vaccine in subjects with MS.

The [VIOLA study](#) (Vaccine-generated Immunity in Ocrelizumab-treated Patients) will shed light on the immune response in MS subjects on ocrelizumab (Ocrevus) receiving the Pfizer and Moderna vaccines.

[Researchers](#) in Massachusetts are evaluating whether or not subjects with MS currently receiving treatment with ocrelizumab (Ocrevus) or natalizumab (Tysabri) produce antibodies following COVID-19 vaccination.

Investigators from Novartis in Germany are conducting the [KYRIOS study](#) to evaluate the immune response following COVID vaccination in subjects with relapsing remitting MS taking ofatumumab (Kesimpta) and the [AMA-VACC study](#) to better understand the immune response following COVID vaccination in subjects with secondary progressive MS taking siponimod (Mayzent).

[Investigators](#) in France are conducting a multicenter study of immunocompromised people, including people with MS, to better understand their immune response after receiving the Pfizer vaccine with respect to the UK and South African variants and any other COVID variants that may emerge.



In collaboration with researchers at Case Western Reserve University and Massachusetts General Hospital, and with funding support from the National MS Society, the research team at iConquerMS is conducting the [COVER-MS study](#) (COVID-19 Vaccine Response in MS) to collect information from iConquerMS members related to their experiences with COVID-19

vaccines. Participants are asked to complete surveys on the [iConquerMS portal](#) at different timepoints. These surveys contain questions about demographics, MS characteristics, COVID-19 infection, any COVID-19 vaccines received, reactions to them, and any MS symptoms experienced before and after vaccination. According to the July 6 [status report](#), over 1,250 network members have enrolled in COVER-MS, 84% of whom are female. The vast majority of participants are white (92%), 68% have relapsing remitting MS, 29% have progressive MS and the remaining 2% have clinically isolated syndrome. With regard to COVID vaccines, 57% of subjects received the Pfizer vaccine, 35% received the Moderna vaccine and 5% received the Johnson & Johnson vaccine. 955 participants received their first COVID-19 vaccine with 61% experiencing side effects. 640 subjects received their second dose with 71% reporting side effects. The majority of side effects were reported to be mild or moderate, with injection site pain, fatigue and headache being the most common. Regarding DMT use, 23% of respondents had not taken any DMT in the year prior to participation in the study, 28% had been on B-cell depleting therapies and 49% had taken other DMTs in the same time period. The initial data analyses are underway, focusing on factors that affect who experiences side effects and how severe they are. Stay tuned for these real-world results, which will provide a better understanding of the effects of these vaccines in the MS population! If you are an iConquerMS member who has received a COVID-19 vaccine and you haven't participated in COVER-MS, please login today and share your experience by clicking on "Participate in the COVID-19 Vaccination Study." Not yet a member? Please [join](#) iConquerMS and power research with your data!

## BREAKING NEWS:

COVID-19 mRNA  
**VACCINE GUIDANCE**  
for People Living with MS



The Society recently issued [guidance](#) on dosing modifications for DMTs in people with stable MS receiving a COVID-19 vaccine. As stated in the guidance, "Based on expert consensus and available data, we offer the following guidance regarding COVID-19 vaccination for people on MS disease modifying therapies (DMTs). This guidance applies to people with MS ages 12 and older and only for the vaccines authorized for use for their

age in the United States. This guidance will be updated as new data are available... **The Pfizer BioNTech, Moderna and Janssen/J&J vaccines are safe for people with MS, and they are safe to use with MS DMTs.** The vaccines are not likely to trigger an MS relapse or have any impact on long-term disease progression. The risks of COVID infection far outweigh any potential vaccine risk, and persons with MS are encouraged to get the vaccine as soon as possible. Most DMTs are not expected to affect the responses to these vaccines, though some may make the vaccines less effective. Coordinating the timing of vaccine administration with these DMTs may provide the best vaccine response.” Please see the [full guidance](#) for details.

According to recent [guidelines](#) issued by the Centers for Disease Control and Prevention (CDC), most healthy people who are fully vaccinated can get back to normal activities without wearing a mask or social distancing. Because researchers are still learning how the vaccines work in people with weakened immune systems, the CDC warns that people with certain health conditions, like MS, or who are taking immune-suppressing medications may not be fully protected against COVID-19 even if they’re fully vaccinated. As a result, these individuals may need to continue wearing a mask for the foreseeable future. The Society [echoes](#) this recommendation, stating, “For people with MS, especially those in high-risk groups and those taking a DMT that might reduce the effectiveness of the vaccines, the safest approach is to continue wearing masks, practicing social distancing, and performing regular hand-washing.”



It’s important for people with MS to consult with their healthcare providers on COVID-19 vaccine questions, and to coordinate vaccination with their MS treatment. Researchers around the world, including ACP through the COVER-MS study, are gathering data specific to the safety and effectiveness of these vaccines in the MS population that will provide clarity in these decisions. The core of ACP’s mission is to facilitate research efforts like these, that significantly impact the MS community.

