

Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health



Clinical Guidance on COVID- 19 Vaccines for Persons with Autoimmune Rheumatic Diseases

This guidance is intended for health-care providers and is based on known evidence as of April 18, 2023.

The majority of adults and children with autoimmune rheumatic diseases (ARD) require immune modulating therapies for disease control. These therapies put people with ARD at higher risk for infections, particularly viral infections.¹ Immunosuppressed persons have a higher risk of poor outcomes with infections.^{1, 2} Although there is limited information about outcomes for people with ARD who develop COVID-19, one international study demonstrated that prednisone and an underlying diagnosis of lupus could be associated with worse outcomes and higher mortality.³

Is COVID-19 immunization recommended for people with autoimmune rheumatic diseases?

COVID-19 vaccines should be encouraged for people with autoimmune rheumatic diseases and are not contraindicated, including those who have had a COVID-19 infection.

- Although the majority of patients with ARD who are immunosuppressed were excluded from clinical trials of the COVID-19 vaccines, the Canadian Rheumatology Association,⁴ American College of Rheumatology⁵ and British Rheumatology Association⁶ have all released position statements strongly supporting the use of COVID-19 immunization in this population.
- Experts agree that the potential benefits and anticipated desirable effects of COVID-19 immunization outweigh the potential harms in persons with ARD.⁴⁻⁶

While data specific to the safety and efficacy of the COVID-19 vaccines in people who take immunosuppressant or immunomodulating therapies is currently limited, there are data to suggest that the currently available COVID-19 vaccines have efficacy.⁷ The authors of this guidance agree that the benefits of COVID-19 immunization with these vaccines outweigh any theoretical risks of immunization.



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If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.



Is the COVID-19 vaccine efficacious and safe in patients with autoimmune rheumatic diseases?

Adults and children with ARD who take immunosuppressant/immunomodulating therapy were excluded in all of the trials for the COVID-19 vaccines currently approved in Canada. As per NACI, safety data in immunocompromised individuals, including those receiving immunosuppressive therapy, were available from observational studies in people who were taking immunosuppressive therapies. The frequency and severity of adverse events following vaccination with an mRNA COVID-19 vaccine were comparable to that of non-immunocompromised individuals in these studies and what was reported in clinical trials. Safety data in these populations following vaccination with a viral vector vaccine is not available.

There is one study that suggests that a third dose of COVID-19 vaccine in immunocompromised patients can increase antibody levels.⁸ Small studies on third doses of the mRNA COVID-19 vaccines have shown that immunogenicity (immunity measured in the blood) may increase with a third dose. The safety of a third dose is unknown at this time for ARD, but in these small studies reactions were found to be similar to that of prior doses. The impact of additional doses on the worsening of underlying disease or on rare adverse events, including the risk of myocarditis and/or pericarditis, is unknown at this time.⁹

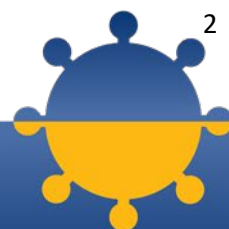
Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines, as well as a discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. The recommendations in this clinical guidance are based on these small observational studies, extrapolation of data from other viral infections, immunology of immunizations and from expert opinion.

When infected, people with ARD can exhibit high variability with respect to clinical presentation, organ involvement, disease severity, comorbidities and medications. If a patient has complicated disease or multiple medical conditions and health-care providers have questions, they are encouraged to reach out to the patient's rheumatologist for specific guidance.

As the majority of patients with ARD are on immune suppressing medications, there may be blunting of the magnitude and duration of vaccine response compared to the general population.^{4,6,10} Regardless, the benefits of immunization are considered to outweigh the potential risks.

Are there any specific contraindications or exceptions for people with autoimmune rheumatic diseases?

Individuals who have had a severe allergic reaction to an ingredient of one type of COVID-19 vaccine are still able to receive future doses of the other type of vaccine.¹¹ BCCDC has a list of the individual components and their purpose in



the vaccines. For a complete list of components in the vaccine, consult the vaccine monographs found at: www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccines-for-covid-19.

People with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to revaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccination is going ahead, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination.

Health Canada continues to monitor any adverse events following immunization through their post-authorization surveillance [process](#).

Other than allergy, there are no specific contradictions or exceptions for people with ARD apart from the efficacy and safety considerations outlined above.

COVID-19 vaccines can be given concomitantly with, or any time before or after any other indicated vaccine including the seasonal influenza vaccine.¹²⁻¹⁵

Are there specific recommendations or considerations for safe and/or most effective administration?

Guidance from the Canadian Rheumatology Association⁴ is to continue underlying immunosuppression and disease modifying agents without adjustment around COVID-19 immunization with the exception of Rituximab/Ocrelizumab, and high-dose prednisone as indicated below. Clinical advice to adjust Mycophenolate Mofetil around COVID-19 immunization (when the condition is stable) is derived from the American College of Rheumatology guidelines.⁵

For patients on the following medications, there is **no need to adjust or delay the medication**:

- Adalimumab
- Anakinra
- Anifrolumab
- Azathioprine
- Belimumab
- Canakinumab
- Certolizumab
- Cyclosporin
- Etanercept
- Golimumab
- Gusulkumab
- Hydroxychloroquine



- **Infliximab**
- **Intravenous immunoglobulin (IVIG)**
- **Ixekizumab**
- **Leflunomide**
- **Methotrexate***
- **Oral cyclophosphamide**
- **Prednisone less than 20mg/day (or equivalent)***
- **Sarilumab**
- **Secukinumab**
- **Sulfasalazine**
- **Tacrolimus**
- **Tocilizumab**
- **Ustekinumab**

*For patients on **weekly methotrexate**, hold (stop) the medication for 2 weeks following COVID-19 vaccination.¹⁶

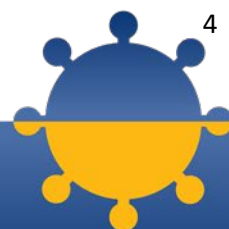
For patients on **rituximab** or **ocrelizumab**, the COVID-19 immunization should ideally be timed four to five months after their last infusion and two to four weeks prior to their next infusion, when possible, in order to optimize vaccine response. However, in patients who require immediate infusion or who are unable to optimize timing of infusion product and vaccine, it is likely more important to have the COVID-19 vaccine earlier than to delay based on timing of B-cell therapy.

For patients on **mycophenolate mofetil**, if the disease is stable, hold the medication for one week following a COVID-19 dose.⁶

*For patients on **prednisone** 20mg/day or higher (or equivalent), consider waiting until the prednisone dose is tapered to below 20mg/d to receive both vaccine doses. Pediatric patients on high-dose steroids should consult with their pediatric rheumatologist to decide on the best time to receive the vaccine.¹⁷

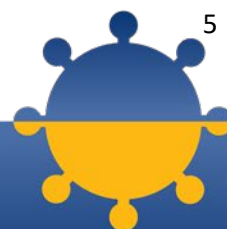
NOTE: The American College of Rheumatology⁵ differs from the Canadian Rheumatology Association with adjustment recommendations for the medications as follows. The authors of this guidance document are aligned with the Canadian Rheumatology Association's recommendations, with the exception of mycophenolate mofetil as described above. However, the American College's recommendations are available [here](#) and provided below for reference:

- *For patients on weekly **methotrexate (MTX)**, an option is to skip the MTX dose the following week after each vaccine dose.*
- *For patients on **tofacitinib, baricitinib, upadacitinib**, an option is to skip the medication for one week following each vaccine dose.*
- *For patients on **abatacept** weekly injections, an option is to skip the abatacept one week before and one week after the first dose of vaccine. Continue abatacept through the second dose of vaccine. For IV **abatacept**, consider timing the first dose of vaccine four weeks post-dose and postpone next infusion by one week. No IV Abatacept adjustments are needed for the second vaccine dose.*
- *For patients on **intravenous cyclophosphamide**, an option is to take each vaccine dose at least one week prior to the next cyclophosphamide infusion.*



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