Royal United Hospitals Bath
NHS Foundation Trust

COVID-19 Vaccination FAQs

For Adult Rheumatology patients

Updated 21.09.2022 including:

Autumn booster vaccine

Previous updates: 23.09.2021, 14.09.2021, 05.07.2021 , 22.04.2021, 03.03.2021, 14.02.202, 05.01.2021, 28.09.2021

There are currently 5 COVID-19 vaccines approved for use in the UK developed by Pfizer/BioNTech (given approval by the MHRA on 2nd December 2020), Oxford/AstraZeneca (given approval by the MHRA late December 2020), Moderna vaccine (given approval by MHRA January 2021), Janssen vaccines (MHRA approval May 2021) and Nuvaxovid/Novavax (MHRA approval February 2022). The MHRA is the Medicines and Healthcare products Regulatory Agency, who, after months of rigorous clinical trials and a thorough analysis of the data by experts, have concluded that the vaccines have met its strict standards of safety, quality and effectiveness (gov, 2020a). Benefits of the vaccine are described here.

The rheumatology department has put together some frequently asked questions (FAQs) regarding the MHRA approved COVID-19 vaccinations.

The information below contains some general information but also details that are specifically relevant to patients with autoimmune/inflammatory rheumatic disease. Information is changing rapidly and we endeavour to keep this page updated with the latest details as and when more information becomes available from the wider teams at the RUH trust and the government. In the meantime, we thank you for your interest in the vaccine and patience.

This document does not contain information about managing COVID-19 infection. If you think you have COVID-19 infection, please follow government advice (information found here).

Is this a live vaccine?

The vaccines are **not** live vaccines and cannot give you COVID-19 infection. There are some potential side effects to the vaccines including the potential to cause a

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mild fever which usually resolves within 48 hours of the vaccination. Further information about what to expect after COVID-19 vaccination can be found here.

I am taking medications that suppress my immune system – can I have the vaccine?

There are some drugs used to treat rheumatology related conditions which suppress the immune system such as:

- Steroids
- Methotrexate
- Leflunomide
- Mycophenolate
- Azathioprine
- Ciclosporin
- Tacrolimus
- Cyclophosphamide
- Biologic medications including:
    - Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab,
    - Sarilumab, Tocilizumab
    - Abatacept
    - Apremilast
    - Ixekizumab, Secukinumab
    - Ustekinumab
    - Anakinra
    - Belimumab
    - Rituximab
- JAK inhibitors: Baracitinib, Tofacitinib, Upadacitinib, Filgotinib

As the vaccine is not a live vaccine, it **can** be given if you are taking the medications listed above. When taking these medications it is possible that your response to the vaccine may be dampened. As such, you should continue to follow government guidance on reducing your risk of infection.

People who have recently had Rituximab (also known as Truxima, Rixathon, MabThera) may be less likely to make an immune response to the COVID-19 vaccine. This means the vaccine *may be* less effective if you have had Rituximab within 6 months before or 4 weeks after the vaccine is given. However, it is still safe to have the vaccine if you have recently had Rituximab and you may get some benefit from it. For Rheumatology patients receiving Rituximab we would advise the following with respect to the *first 2 vaccine doses*:

- If you are offered the COVID-19 vaccine and your last Rituximab infusion was more than 8 weeks ago, please have the vaccination when you are offered it - **do not delay the vaccine**.
- If you are offered the COVID-19 vaccine less than 8 weeks *after* your Rituximab infusion please call the Rheumatology advice line to discuss the best timing of your COVID-19 vaccination. You will be advised depending on your personal circumstances.
- If you are due your next Rituximab infusion and have a planned date for a COVID-19 vaccination please contact us by email or telephone (detailed

below) to discuss if it is appropriate to delay your Rituximab infusion by a few weeks in order to get the best response to the vaccine dose.
- For information on the *3rd primary vaccine or booster* dose please see below.

Consultant	Email address
Dr E Korendowych	debra.morris3@nhs.net
Dr A Allard	sarahcotton1@nhs.net
Dr S Hardcastle / Dr W Tillett	gay.tulyholowycz@nhs.net
Dr R Sengupta / Dr T Ahmed	julie.anscombe1@nhs.net
Dr C Lapraik	glynis.vincent@nhs.net
Dr S Skeoch / Dr V Flower / Dr V Rogers	beverleysatchell@nhs.net

Advice line 01225 428823

Will I be offered the vaccine?

First courses of the vaccinations have been performed in order of priority as outlined by the Joint Committee of vaccination and Immunisation (JCVI). Phases of the vaccination programme can be found here.

The vaccine should not be given if you:

- have had a confirmed anaphylactic reaction to a previous dose of the same COVID-19 vaccine,
- have had an anaphylactic reaction to any of the components of the vaccine.
- If you cannot receive an mRNA vaccine then Novavax will usually be offered.

Please see the GOV.UK website for further information on vaccination in children (click here).

COVID-19 vaccine and blood clots (information from Greenbook Chapter 14a)

There have been a small number of reports of rare blood clots occurring after receiving the Astrazeneca vaccine. The numbers of reports are very low. These are rare types of blood clots (e.g. cerebral venous sinus thrombosis, portal vein thrombosis) and occurs with other clinical features including low platelets in the blood. This is a rare and specific problem and is different from a blood clot occurring on in a vein on its own.

Currently the advice from the MHRA is **not** to receive the Astrazeneca vaccine if you have previously had a blood clot that occurred with low platelets in the blood, including conditions such as:

- Heparin-induced thrombocytopaenia with thrombosis (a.k.a. HITT or HIT type 2)
- Antiphospholipid syndrome with a history of blood clots with low platelets.
- These people should receive an alternative vaccine

- If you have been told that you have antiphospholipid antibodies/syndrome but have not had a blood clot that occurred with low platelets at the same time, then you are advised to have a COVID-19 vaccine from any approved

manufacturer that is offered to you. All adults aged 18-39 years will be offered an alternative to the Astrazeneca vaccine. Adults aged 40 years and over can receive a COVID-19 vaccine from any manufacturer providing that you are not allergic to any of the components.

If you have already received your first dose of the Astrazeneca vaccine and did not develop a blood clot with low platelets then the MHRA advise that you receive the second vaccine as planned.

If you have antiphospholipid syndrome and would like to discuss this further please contact your Rheumatology Consultant using the details on the page above.

COVID-19 vaccination in pregnancy and breastfeeding

Clinical trials have not been performed using these vaccines in pregnant or breastfeeding women and therefore their safety in pregnancy or breastfeeding in humans is unknown. However, non-clinical studies from Pfizer, AstraZeneca and Moderna vaccines in animals do not demonstrate any safety concerns. Post marketing data for Pfizer and Moderna do not raise any safety concerns in pregnancy. More information can be found here. Women who are pregnant will be offered the vaccine. Pfizer and Moderna vaccines are currently the preferred vaccine in pregnant women of any age due to more extensive experience of use during pregnancy.

There are no data on the safety of COVID-19 vaccines in breastfeeding or on the breastfed infant. Despite this, COVID-19 vaccines are not thought to be a risk to the breastfeeding infant, and the benefits of breast-feeding are well known. Because of this, the JCVI has recommended that women can receive the COVID-19 vaccine whilst breastfeeding. This is in line with recommendations in the USA and from the World Health Organisation.

How will the vaccine be administered?

The vaccine is administered as an injection into the muscle into the upper arm or thigh. Most vaccines are administered in this way. The Pzifer/BioNTech COVID-19 vaccine is administered in two doses, a minimum of 21 days apart. The Oxford/AstraZeneca and Moderna vaccines are administered as two doses, a minimum of 28 days apart. Janssen is administered as a single dose for the primary vaccine schedule. Novavax is given as 2 dose a minimum of 3 weeks apart.

There is evidence that a longer interval between the first doses of vaccine provides longer protection and therefore the timing of the second vaccine doses may be given after longer intervals (minimum 8 weeks) in line with Government guidance (for more information click here). One exception to this is where patients are due to receive new immunosuppressive treatment. In these patients the first 2 vaccine doses should be given at the minimum respective intervals described above.

Who will receive a third dose of the vaccine for their primary vaccine course?

In August 2021 the JCVI recommended that patients who were significantly immunosuppressed at the time of their first two vaccination doses (i.e. their primary vaccination course), should receive a third dose soon. This is not a "booster" vaccine, but instead aims to improve the initial vaccine response in those who may not have mounted a full response to the first course. The full list of eligible patients is listed in the Green book here. This will include rheumatology patients who were receiving any of the following at the time of their previous vaccination **or** if you started these medications within 2 weeks after their vaccination was administered:

- Biologic medications within the previous 3 months
    - Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab,
    - Sarilumab, Tocilizumab
    - Abatacept
    - Apremilast
    - Ixekizumab, Secukinumab
    - Ustekinumab
    - Anakinra
    - Belimumab
- Rituximab within the previous 6 months
- JAK inhibitors within the previous 3 months
    - Baracitinib, Tofacitinib, Upadacitinib, Filgotinib
- Cyclophosphamide within the previous 6 months
- Prednisolone >40mg per day for more than 1 week in the previous month
- Prednisolone ≥20mg for more than 10 days in the previous month
- Prednisolone ≥10mg for more than 4 weeks in the previous 3 months
- Methotrexate ≥20mg per week (by tablets or injections)
- Azathioprine
- 6-mercaptopurine >1.5mg/kg/day
- Mycophenolate
- Combination treatment of Methotrexate and Leflunomide at any dose within the previous 3 months
- Combination treatment with prednisolone ≥7.5mg and one or more of the following at any dose:
    - Methotrexate
    - Leflunomide
    - Azathioprine
    - Mycophenolate
    - 6-mercaptopurine

The third dose should be ideally given *at least 8 weeks* after the second dose. If you receive Rituximab therapy you should have the 3rd primary dose of the vaccine when you are offered it. If you are due a Rituximab infusion in the near future please liaise with the Rheumatology team to discuss if it is appropriate to delay your Rituximab infusion until 2-4 weeks after your 3rd vaccine. You should not stop or delay any other medications for your Rheumatic condition unless this has been suggested by your Rheumatology team.

Vaccinations are being delivered through vaccination centres. When you attend for the vaccine, you should inform the vaccine centre that this is your 3rd primary dose

of the vaccine. We are aware that in some circumstances the dose may be documented on your record as a "booster" rather than a "3rd primary dose". However, on a practical level this is not a problem and patients who were immunosuppressed at the time of their 1st and 2nd vaccines will be invited for a booster dose at a later date based on separate coding linked with their health record.

Who will be offered a "booster" vaccine?

An Autumn 2022 "booster" vaccine will be offered to people who are in priority groups 1-9 as described in the Green book here. This includes:

- those living in residential care homes for older adults
- all adults aged 50 years or over
- frontline health and social care workers
- all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19
- adult carers (>16 years old)
- household contacts of immunosuppressed individuals (aged 5-49 years).

Current advice from the JCVI is that the booster can be given 3 months after the last dose.

If you are due a Rituximab infusion in the near future please liaise with the Rheumatology team to discuss if it is appropriate to delay your Rituximab infusion until 2-4 weeks after your booster vaccine. You should not stop or delay any other medications for your Rheumatic condition unless this has been suggested by your Rheumatology team.

Can I get a test to check if I have responded to the vaccine?

Blood tests are available through the NHS under some circumstances to check antibody responses to COVID-19 vaccines and infection. However, we do not know what level of antibodies offer protection against COVID-19. There are also other parts of the immune system that respond to a vaccine that we cannot test. Testing your antibody levels therefore does not *currently* tell us whether you have responded fully to the vaccine. These tests are therefore only being performed in patients who are severely immunosuppressed and where the result may change their treatment. Your Rheumatologist will discuss this with you if it is appropriate. Please do not call the Rheumatology advice line to discuss antibody testing.

Can I receive the COVID-19 vaccine and the 'Flu vaccine at the same time?

Yes you can. There is no evidence to suggest that receiving two non-live vaccines at the same time is harmful.

Timing of 'Flu vaccine in Rituximab patients during the COVID-19 pandemic

Patients receiving Rituximab infusions are usually advised to have their annual 'Flu (influenza) vaccine either 6 months after or 4 weeks before their Rituximab infusion.

During the COVID-19 pandemic, it is more important than ever to protect yourself from viruses and reduce the risk of needing hospital admission. If you are due a Rituximab infusion then please contact the department to see if it is appropriate to delay your treatment until (minimum 2 weeks) ideally 4 weeks after your 'Flu vaccine has been given. If you have recently had a Rituximab infusion then we would still suggest that you still receive your 'Flu vaccine this winter, and do not delay it by a full 6 months. You may make a better response to the vaccine if it is given 4-8 weeks after your Rituximab infusion.

What treatments are available if you develop COVID-19 infection?

Adult Rheumatology patients who receive the following medications at the time of active COVID-19 infection *may be* eligible for anti-viral treatments if they are not getting better from COVID-19 infection within the first 5 days of symptoms starting:

- Biologic medications
  - Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab,
  - Sarilumab, Tocilizumab
  - Abatacept
  - Apremilast
  - Ixekizumab, Secukinumab
  - Ustekinumab
  - Anakinra
  - Belimumab
- Rituximab within the previous 6-12 months
- JAK inhibitors
  - Baracitinib, Tofacitinib, Upadacitinib, Filgotinib
- Rituximab in the last year
- steroids
- Cyclophosphamide
- Tacrolimus
- Cyclosporine
- Mycophenolate
- Downs, HIV/AIDS, Solid organ transplant, multiple sclerosis, myasthenia gravis, huntingtons, Motor neurons, primary immune deficiency
- Decompensated liver disease, liver disease on immunosuppression, Downs, Sickle cell, solid cancer, chemotherapy within a year, radiotherapy within 6 months, haematological malignancy, CKD4/5, renal disease with significant immunosuppression such as rituximab or alemtuzumab)

Patients with a positive lateral flow test should register their result on the GOV.uk website. Patients who have been on these medications pre-dating November 2021 should then be contacted automatically by their local COVID treatment centre to be assessed over the telephone for possible anti-viral treatments. Those who have started medications since November 2021 may need to call their Rheumatology team for assessment, but should still register their positive swab result via GOV.uk.

Evusheld is an anti-COVID-19 antibody treatment. This is not available in the UK.

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Links to external websites you may find helpful:

Booking a vaccine
https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/who-can-get-the-vaccine/

NHS website information on COVID-19 vaccination
https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/

Priority groups for COVID-19 vaccination (Gov 2020a)
https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020

Information on COVID-19 infection
https://www.gov.uk/coronavirus

COVID-19 vaccine: a guide for older adults (GOV.UK)
https://www.gov.uk/government/publications/covid-19-vaccination-guide-for-older-adults

COVID-19 vaccine: what to expect after vaccination (GOV.UK)
https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination

COVID-19 vaccination in pregnancy and breastfeeding
https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a-pregnancy-or-breastfeeding

Lateral flow testing
https://www.gov.uk/order-coronavirus-rapid-lateral-flow-tests

Advice for people who are clinically extremely vulnerable
www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19

Versus Arthritis
www.versusarthritis.org/

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Please contact the Patient Advice and Liaison Service (PALS) if you require this leaflet in a different format, or would like to feedback your experience of the hospital. Email ruh-tr.pals@nhs.net or telephone 01225 825656.

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