Education pack for patients with Rheumatoid Arthritis treated with Biologics and Targeted synthetic DMARDs at Dudley Group NHS FT

Dudley Rheumatology RA VBC Patient Education Version 1.2 11th June 2024

NHS
The Dudley Group
NHS Foundation Trust

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Contents

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Section 1

Introduction to enhanced therapies

Biologics and Targeted Synthetic DMARD Treatments

- The first treatments prescribed for patients with Rheumatoid Arthritis (RA) nationally are usually conventional DMARDs e.g. Methotrexate or Hydroxychloroquine, DMARDs stands for Disease Modifying Anti-Rheumatic Drugs
- DMARDs should control RA individually or in combination.
- If at least 2 of these drugs have not sufficiently controlled the disease after taking the maximum tolerated doses & a review with rheumatology team, the next step is often to consider escalation to an enhanced therapies in the form of a Biologic or Targeted Synthetic DMARDs (tsDMARDs)
- These high costing treatments have been scientifically designed to target specific parts of the inflammation path involved in RA
- Rheumatologists worldwide have been using these treatments for over 20 years

Biologics and Targeted Synthetic DMARDS

- Biologic and tsDMARDs have been proven to be very effective and safe in the treatment of RA
- To work these drugs will dampen a part of your immune system so they are called **immunosuppressive** drugs
- Biologic drugs are given by injection or infusion
- Targeted synthetic DMARDs are tablets

For more information about RA treatments, please visit Versus Arthritis & National Rheumatoid Arthritis Society websites:

Rheumatoid arthritis | Causes, symptoms, treatments (versusarthritis.org)

Biologics For Rheumatoid Arthritis (RA) | NRAS

Types of Biologics and Targeted Synthetic DMARDS

Biologics & tsDMARDs have a generic name and a brand name, e.g Ibuprofen = generic name & Nurofen® = brand name

When better value brands become available Dudley Group Hospitals will assess and aim to switch patients to the better value brands, this supports sustainability for DGH & the NHS.

Below is a list of the treatments available & their generic names.

Biologics

- Anti-TNF class: **Adalimumab, Etanercept, Certolizumab & Golimumab** (all are INJECTIONS) **Infliximab** (available as INJECTION & hospital INFUSION)
- B cell depletion class : **Rituximab** (INFUSION)
- Anti-IL6 class: **Tocilizumab, Sarilumab** (both are INJECTIONS)
- Anti-CD40 class: **Abatacept** (INJECTION)

Target Synthetic DMARDs

- JAK inhibitors**: Baricitinib, Tofacitinib, Upadacitinib & Filgotinib** (all are TABLETS)

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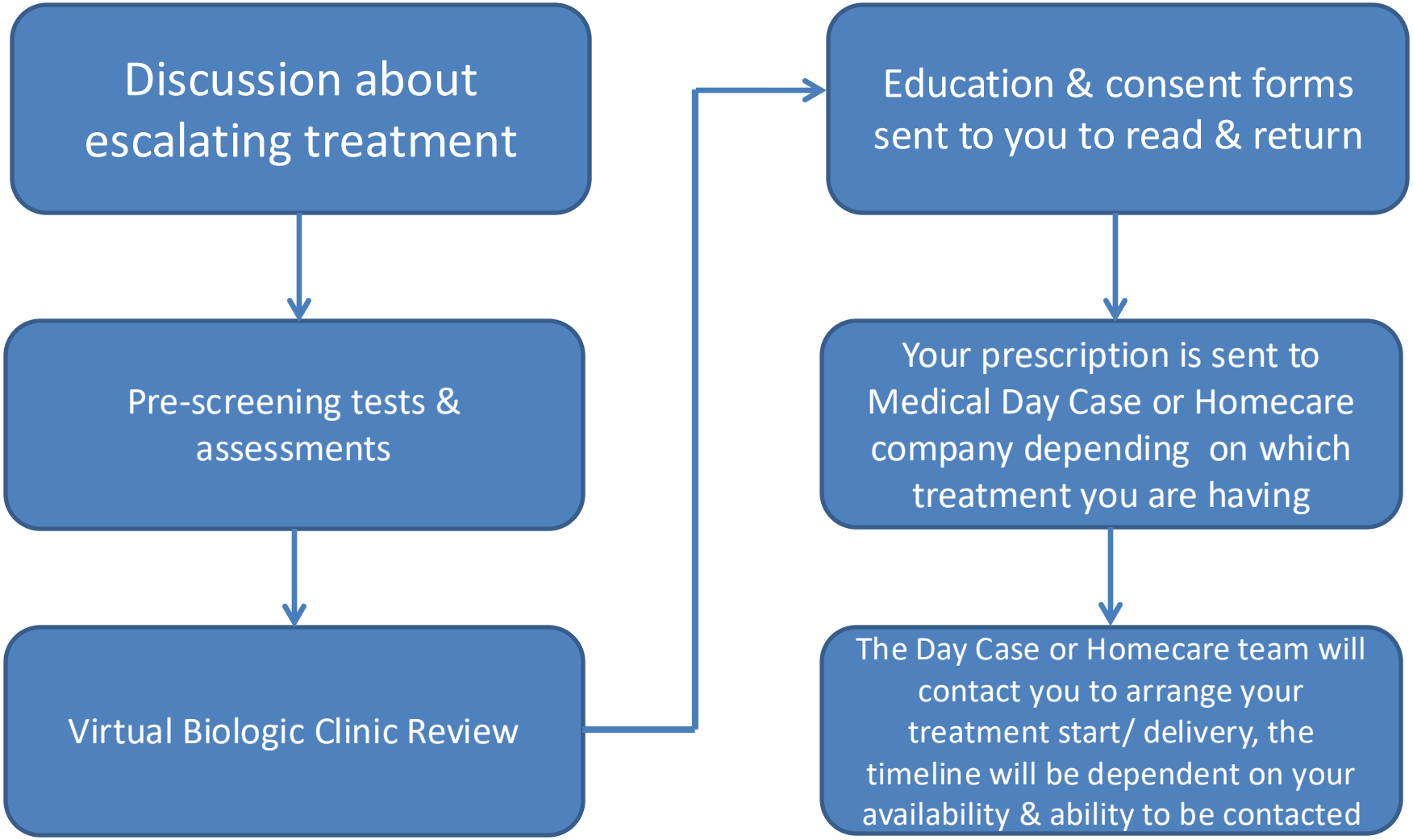
Section 2: Timeline for starting enhanced therapies

The time it takes to initiate your treatment can vary



Pre-treatment screening & starting treatment

- Biologic and TsDMARDs can dampen down the immune system more than conventional DMARDs. Therefore, before starting one of these drugs, we routinely undertake checks including a set of blood tests and a Chest Xray to make sure you have no underlying risks.
- When starting one of these drugs it is also important to take into consideration any other health problems that you may have.
- Biologics and TsDMARDs are high-cost treatments that are commissioned by NHSE & other NHS commissioners. We, therefore, for each patient, must seek commissioning by providing initial & continued recorded tests & assessments to show that you meet the national criteria to have treatment. It is therefore mandatory to attend all appointments & undertake all blood tests that the rheumatology invite you to.
- DGH undertake a Virtual Biologics Clinic (VBC) prior to commencing your treatment which includes a Multidisciplinary team: Rheumatologists, Clinical Nurse Specialist, Specialist Pharmacist and Administrative support. The VBC will ensure your proposed treatment is safe, effective, appropriate, sustainable & available for you.
- Once VBC approve & gain funding for your proposed treatment, a prescription will be generated.

Once your drug is approved by the Virtual Biologic Clinic what happens next?

- The biologic admin team will have sent you this presentation so you can learn more about the process, the drugs and some guidance about using the drug safely.

What happens next depends on whether the drug you are to have, is one that is:

- A **TABLET**
- An **INJECTION** that you can do yourself at home

OR

- Given as a **HOSPITAL INFUSION** as a day case. This is the case for Rituximab and infliximab, but in rare cases tocilizumab or abatacept can be given by infusion.

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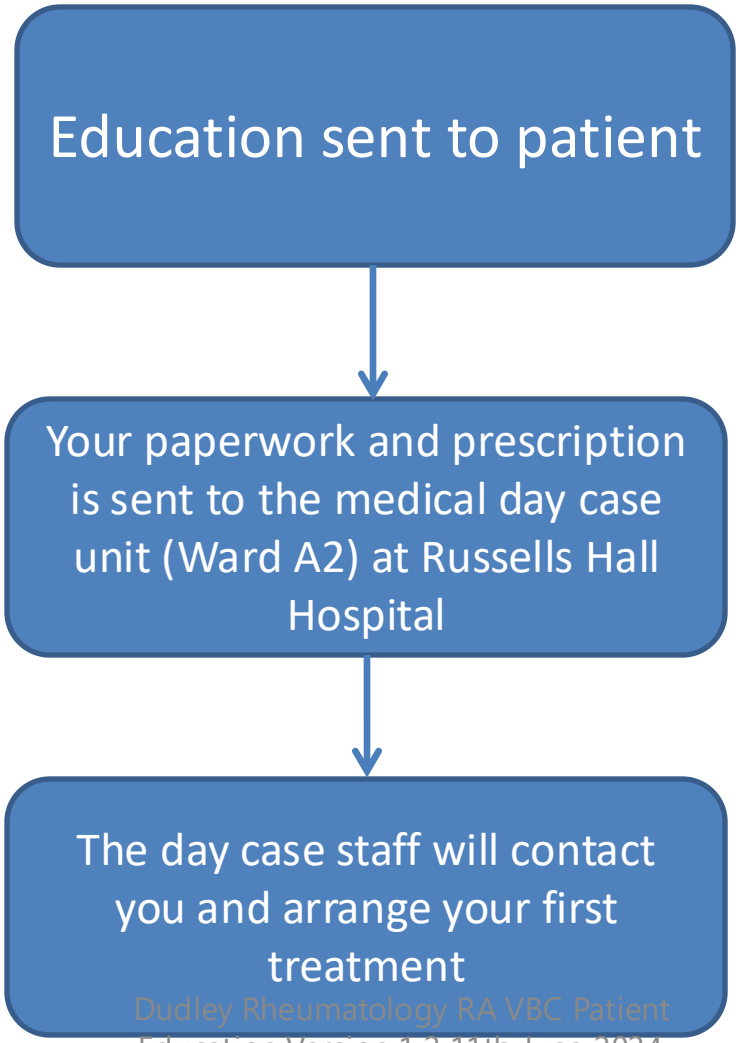
Section 3

Biologics given as a hospital infusion

Skip to section 4 if you are having a TABLET or INJECTION

For treatments that you have as an **infusion** in the hospital?



Medical Daycase Unit

- **Treatments given by infusion will take place on A2 Medical Day Case Unit, Ground floor, Russells Hall Hospital**
- The lead nurse is Sister Cole and she and her team have many years of experience treating patients with RA.
- There is a waiting list for treatment, but the day case team will arrange a convenient time as quickly as possible
- You may be in the day case unit just a few hours or for rituximab it may be a full day and simple refreshments will be available.
- If you are unable to attend, then you must let the day case staff know ASAP (not the rheumatology nurses).
- If relevant you must book your next infusion with the day case staff before you leave.
- Medical day case phone number: 01384 456111 ext 3365 or 2096

How often do I have my infusion?

Rituximab	Given as 2 infusions 2 weeks apart initially, then as a single infusion when needed at least 6 months later
Infliximab	One infusion every 8 weeks after loading doses at 0, 2 and 6 weeks
Tocilizumab	Monthly infusion
Abatacept	Monthly infusion, after loading doses at 0, 2 and 4 weeks

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Section 4

Treatments given by TABLET or Home INJECTION

Homecare consent and referral

- Like most Hospitals across nationally, we use Homecare companies that prepare and deliver enhanced therapies.
- As we need to provide these companies with some of your private details, e.g. your phone number and address we will need to have your consent to share this.
- The link to the electronic consent form is:
- https://forms.office.com/e/S764F5qaar or you can access it via using the QR code on the next slide.
- For a document format of the consent form see:
- Dudley-Homecare-Service-Consent-Form.pdf (dgft.nhs.uk)
- Or contact dgft.biologics.admin@nhs.net
- Please complete and sign the form either electronically or on paper and return by post/ email back to the above address asap
- **We cannot proceed with your prescription until we have your consent**

QR code for Homecare consent

Your smartphone has a built-in QR code reader

1.Point your camera at the code. ...

2.When your camera scans the QR code, you'll see an icon or web address on your screen near the code. ...

3.You'll go to the associated website via your phone's web browser, which should launch automatically.

Dudley Rheumatology Homecare Service - Consent Form

Homecare companies

We currently use the companies listed below to provide enhanced treatments to your own home, or at another agreed address.

- Sciensus contact number 0333 1039 499
- Lloyds contact number 01279 456 789
- HealthNet contact number 08000 833 060
- Alcura contact number 01604 433 510
- Fresenius contact number 01623 518 919
- Pharmaxo contact number 01225 302 188
- Calea contact number 0800 0902 461

Once you have returned your consent form, we will forward your prescription to the relevant company.

It is important to note the company will call on a withheld number so please ensure your phones accept withheld numbers & please ensure you provide up to date contact details to your clinic team when you consent for treatment.

Ongoing prescriptions

Future prescriptions will be requested by the homecare provider; a prescription is created by the rheumatology admin team. A rheumatology doctor or CNS reviews blood tests and clinical details and if safe the prescription is signed and sent from pharmacy to the homecare provider.

For prescription queries please **first contact your Homecare Provider**, if they do not have a prescription or there is an issue with the prescription, please then contact:

- The Rheumatology biologic admin team on 01384 456111 ext 4297 or email dgft.biologics.admin@nhs.net
- The Rheumatology advice line 01384 244789

It is important to chase prescriptions at least 2 weeks before you are due your last dose

How often do I have my biologic injection?

Adalimumab	Fortnightly injection
Etanercept	Weekly injection
Golimumab	Monthly injection
Certolizumab	Fortnightly injection after loading dose
Tocilizumab	Weekly injection or monthly drip
Sarilumab	Fortnightly injection
Abatacept	Weekly injection

How do I store the drug?

- Your injections must be stored in a refrigerator (2° C – 8° C).
- Do not freeze injections.
- The information leaflet will tell you how long the injections can be left out the fridge until it is no longer safe to use.
- Tablets do not require any special temperature storage conditions.
- Store tablets in the original packaging in order to protect from moisture & light

How long can it be out of the fridge

Drug	Time it is stable outside the fridge
Adalimumab	Up to 14 days outside of the fridge
Etanercept	Up to 4 weeks outside of the fridge
Golimumab	Up to 24 hours outside of the fridge
Certolizumab	Up to 10 days outside of fridge
Tocilizumab	Up to 8 hours outside of the fridge
Sarilumab	Up to 14 days outside of fridge
Abatacept	Up to 8 hours outside the fridge.

Please Contact the Rheumatology advice line, should you have any concerns about your medications.

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Section 5

Frequently Asked Questions

What can I expect to happen after I start taking my biologic?

- You may start to experience improvement in your arthritis within a few days to weeks. Sometimes, it may take a bit longer to work but we would hope you would start to feel better within 3 months.
- Most patients will respond to treatment.
- You will be monitored for your response.
- If you do not respond, we will stop the drug and consider swapping it to another agent.

How often will I need to attend the Rheumatology clinic?

- We will see you ideally 3-4 months after you start treatment to check it is working well, that there are no side effects and arrange regular monitoring
- Even when your condition is under controlled, you must come back at least for annual review
- If your disease in not under control, contact the advice line as you would do normally.
- If you have not had an appointment and you think you should have one, please contact us.
- **If you don't attend for your appointments or blood tests, your prescription may be stopped!**

How often will I need to have blood tests done?

- Most drugs require blood test at least every 3 months
- Tocilizumab & sarilumab - Blood tests monthly until stable then every three months
- Tocilizumab, sarilumab, baricitinib, tofacitinib, upadacitinib and filgotinib also require a 3-month cholesterol test after treatment starts. Your doctor may want to keep a check of this
- Please be warned: we check blood results every time when we sign a prescription. So, if you haven't had a blood test done, we cannot safely sign your prescription and your treatment may be delayed

What are the most common side effects?

- Most people tolerate these medications well and do not have any side effects.
- Some patients can experience redness and soreness at the site of the injection. This usually goes away with time. If not let us know!
- Some patients report:
  - headaches, rashes or mood changes
  - more coughs, cold and other minor infections
- If you have concerns, contact the rheumatology team or your own doctor

What are the serious side effects?

- Serious side effects are rare.
- Occasionally, severe rash and more severe infections which required hospitalisation have been reported. We will discuss infection in more detail.
- If you get any of these, do not take any more of your biologic and seek emergency medical advice.
- If you ever have concerns about your medication, do discuss these with your nurse or rheumatologist.

Do I need to tell other medical professionals that I am on a biologic?

- Show your alert card (in your drug information pack) to any health professional.
- We will inform your GP once you are started on biologic therapy, but we would recommend that you let them know also and if possible, add it to your GPs electronic list of medications.
- Don’t assume that non-rheumatology medical professionals understand the drug or how it is given as it is a specialist drug rarely used outside rheumatology

What do I do if I miss a dose?

- If it is because you have forgotten, then take it as soon as you remember, but keep in mind that the next dose must be taken when it is due and not too early/late.
- If you have had a gap in treatment due to an infection, then restart it when you are well again.
- If you are not sure, please ask or contact the advice line

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Section 6

Vaccinations, Infections & Travel

Vaccinations - 1

- Inform your GP before you start your biologic therapy, preferably for arrangements of vaccinations as below:
  - Yearly flu vaccine.
  - A pneumonia vaccine
  - For COVID vaccine, follow the current national guidelines.
  - For shingles vaccination in patients over 50 years old, two doses of Shingrex, recombinant vaccine, should be given
  - Chickenpox vaccine before biologic treatment if low antibody level is noted on screening

Vaccinations - 2

- You should NOT have live vaccines. If it is essential that you need a live vaccine, please discuss with your rheumatologist
- Patients on rituximab should time any vaccination around treatment to get the best response to the vaccine, ie 3 months after treatment.
- Certification of yellow fever vaccine is an entry requirement to some African countries. If you intend to travel to an exotic location in the future, it may be worthwhile considering a yellow fever vaccine before you start your biologic drug.
- Those with children, remember to be aware that the kids nasal flu vaccine, MMR and Rotavirus (avoid nappies for 3 weeks) are all live vaccines
- There is currently a local Measles outbreak. If you are on a biologic drug, you should not have an MMR vaccine. If you are in contact with measles you should contact your GP.

Avoid Live Vaccinations

Below is a table of vaccines, you should avoid while on a biologic or Ts DMARDs.

If a live vaccine is required, you should consider having this before starting the biologic or you will have to come off the drug for a period of time before you have a live vaccine .

	Brand Name
BCG	Bacillus Calmette-Guerin Vaccine
Measles, Mumps and Rubella combined vaccine (MMR)	MMRvaxPRO®, Priorix®
Poliomyelitis (Live oral vaccine)	Poliomyeltis Vaccine, live (oral) GSK OPV
Rotavirus (Live oral vaccine)	Rotarix®
Typhoid (Live oral vaccine)	Vivotif®
Varicella-Zoster, Chickenpox and shingles live Vaccine	Varilrix®, Varivax®, Zostavax®
Yellow Fever	Arilvax®, Stamaril®

What do I do if I get an infection?

- Stop your biologic medication straight away and contact your GP.
- If you are hospitalized, remember to tell the medical team about your biologic or TsDMARD drug.
- Only restart it when you are feeling better and have finished antibiotics (if prescribed).

Any special type of infection more commonly seen when using biologics?

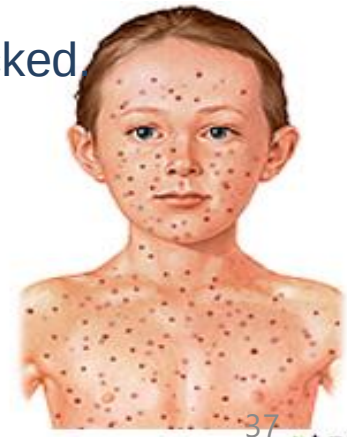
- Biologic drugs can reactivate an infection called **Tuberculosis** (TB) in patients who may have been exposed to the infection in the past.
- All our patients are now being screened for TB using a chest x-ray and a T-SPOT blood test.
- Patients with increased risk for TB will have been assessed and had appropriate treatment from the respiratory team.
- If you have been in contact with TB or experience night sweats, weight loss or cough once on treatment, please inform your GP or the rheumatology department.

Chickenpox & Shingles

We do a blood test to make sure you have immunity (ie you have had Chickenpox and made antibodies against the virus) before you start your biologics. Most people are immune. If you are not immune we will probably already been in contact.

If you come into contact with Chickenpox or shingles and you are not sure if you are immune, we would advise:

- Avoid on-going contact if possible
- Do not take another dose of your drug until you have been checked
- Contact your GP or rheumatology urgently for advice
- Possible blood testing to check that you are still immune
- You may need some treatment
- Contact department regardless before re-starting biologics



What do I do if I get shingles?

- Shingles is caused by the reactivation of the chicken pox virus in someone who has previously had chicken pox. It is more likely to happen when someone's immunity is suppressed.
- **Stop your biologic medication**. If you are on methotrexate or leflunomide you should also stop this.
- **You need to see your GP to start antiviral medication** (aciclovir) and restart your medication when the spots have dried up and you are feeling better.

Travel Advice

- Try not to start a new medication just before holiday travel as monitoring is needed
- Take your biologic drug in your Hand luggage ONLY
  - (see slide 21 for how long is it stable out of the fridge)
- Request a travel letter from us in good time
- Carry your alert card
- Be sensible when you are away
  - Hand washing
  - Watch what you eat and drink to avoid tummy bugs
  - Remember good sun protection
  - Safe sex too

Other considerations

Avoid food susceptible to transmit listeria or salmonella

- Raw eggs (fresh mayonnaise)
- Pâtés
- Uncooked meats/ fish
- Unpasteurised milk
- Unpasteurized cheese (e.g. Blue and goat cheese, Brie – check the label as UK Bries are usually pasteurised))

PML (Progressive multifocal leukoencephalopathy)

- This is a viral infection that can affect the brain.
- A handful of cases internationally have occurred in patients on rituximab
- It may evolve over the course of several weeks to months
- The most prominent symptoms are:
  - Clumsiness
  - Progressive weakness
  - Visual, speech, and sometimes personality changes
- It is important that you tell your doctor if you experience any unusual neurological symptoms

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Section 7

Surgery and Pregnancy

What do I do if I need surgery?

- Tell your surgeon and preoperative assessment team all the medications you are on including your biologic drugs, even if these are only by infusion.
- Depending on the surgery you are having, you may be advised to stop these medications prior to surgery
  - For rituximab: operation is ideally 3-6 months after last infusion
  - For JAK inhibitors: stop 4 days before operation
  - For anti-TNF, anti-IL 6 and anti-CD40, skip one dose and have operation one week after the skip dose (see the table on the next slide).
- If you need emergency surgery inform the surgeon what medication you are on and omit it until advised to restart
- Your surgeon /rheumatologist should advise when to restart but usually this is after evidence of good wound healing, stitches have been removed and no signs of infection (usually around 2 weeks after operation).

A guide to when to stop Biologic or TsDMARD before having elective orthopaedic surgery ?

Drug	Mode of action and disease it is used in	Dosing interval	Recommended timing for surgery since last medication dose
Etanercept	Anti TNF inhibitors	Weekly (sc)	2 weeks
Adalimumab		2 weekly (sc)	3 weeks
Golimumab		4 weekly (sc)	5 weeks
Certolizumab		2 weekly (sc)	3 weeks
Infliximab		2 weekly (sc) 8 weekly (iv)	3 weeks 9 weeks
Tocilizumab	IL-6 inhibitors	Weekly (sc) 4 weekly (iv)	2 weeks 4 weeks
Sarilumab		2 weekly (sc)	3weeks
Rituximab	B cell depletion	Adhoc iv typically 6 monthly	3-6 months post treatment (consider which is the priority)
Abatacept	Inhibits T cell activation	Weekly (sc) Monthly (iv)	2weeks 5 weeks
Baricitinib	JAK inhibitors	Daily oral	4 days
Upadacitinib		Daily oral	
Filgotiinib		Daily oral	
Tofacitinib		Daily oral	

What do I do if I am planning a baby?

Women:

- If you are planning a pregnancy, discuss this early on with your rheumatology team, ideally before you conceive.
- We would normally take into consideration potential of pregnancy when planning for biologic treatment
- With some biologic drugs, it is safe to continue at least part way into pregnancy, but other drugs you need to stop before considering getting pregnant.

Men:

- For men wishing to father children, there does not appear to be a risk with infliximab, etanercept, adalimumab, certolizumab and golimumab but there is little information on the other drugs. No special precautions are needed as recent evidence suggests methotrexate does not need to be stopped in men. Please just check with us.

Pregnancy

What if I unexpectedly find out I am pregnant?

- Don’t worry! But contact your rheumatology team who will be able to advise you further. Most pregnancies in women who received a biologic at conception have had normal outcomes with no increased risk of birth defects.

Can I breastfeed on biologics?

- Based on limiting but reassuring evidence women should not be discouraged from breastfeeding on infliximab, etanercept, adalimumab, certolizumab and goliumumab. It appears that very little drug enters breast milk and likely even less absorbed by the baby.

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Section 8

Cancer consideration

Cancer and biologic drugs?

- Data on thousands of patients around the world have now been analysed, including thousands of patients in the UK. There does not appear to be an increased risk of cancer in patients receiving biologic drugs with the exception of some skin cancers. So, you should be careful with sun protection.
- If you have had a cancer, we will need to take this into consideration when choosing the right drug for you
- If you are now or in the future being investigated / treated for cancer, we would ask you to stop your drug and inform the department.

Cancer and tsDMARDS ie JAK inhibitors drugs?

- JAK inhibitors (tofacitinib, baricitinib, filgotinib and upadacitinib).
  - A small increase in cancers has been seen in patients using tofacitinib. An increase in cancer has not to date been seen the other drugs which are being intensively studied.
- As a precaution, we are advised to avoid using these drugs unless there is not a good alternative in patients over 65 years of age or who have a history of cancer or a pre-cancerous problem
- If you are to start one of these drugs, please let us know asap if you are concerned that you are in an at-risk group.
- Here is a link to the government advice:
  - Janus kinase (JAK) inhibitors: new measures to reduce risks of major cardiovascular events, malignancy, venous thromboembolism, serious infections and increased mortality - GOV.UK (www.gov.uk)

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Section 9

Research & Psychology

Research

We are a department that regularly undertakes research and would be grateful if you could support any active research studies if approached. Full details of any active research studies will be discussed with you separately.

We are most often recruiting patients into national registries to monitor long term side effects from drugs

You do not have to participate, and it will not affect your treatment if you choose not to

Thank you for your attention

If you have any question please contact us via the advice line

We hope your new drug works well and without any side effects!
The Virtual Biologic team

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