

Group Education Biologics

The Dudley Group of
Hospitals
NHS Foundation Trust



05/11/2020

For rheumatology patients

COVID-19 information

- We are currently living through a pandemic, which has changed everyone's lives and how we in Rheumatology work.
- Immunosuppressive treatment such as biologic medication *may* increase your risk of severe COVID-19 infection.
- Being prescribed a biologic treatment at this time may also have consequences on your daily life and how/where you work. It has recently meant that most patients on biologic drugs were advised that they were in the 'shielding' category.
- As we learn more about COVID-19 infection, guidance is updated
- We are aiming to continue to treat our patients in the safest possible way and this means balancing the risks and benefits of any treatment for your rheumatological disease

COVID-19 information

- Your rheumatology doctor should have discussed with you the risks and benefits of starting a biological drug at this time
- If your doctor has not discussed this with you please contact us on the helpline number 01384 244789
- You should be clear that this is the right treatment for you at this time
- If you are already taking a biologic drug and you develop symptoms of Coronavirus you should stop the drug and follow national guidelines.

Here are some other links and sources of advice that can be of help in relation to COVID 19:

Our own website will be updated regularly and has useful links

<https://www.dgft.nhs.uk/services-and-wards/rheumatology/>

<https://www.gov.uk/government/topical-events/coronavirus-covid-19-uk-government-response>

<https://www.nhs.uk/conditions/coronavirus-covid-19/>

<https://111.nhs.uk/covid-19/> or call NHS111

<https://www.nras.org.uk/news/coronavirus-what-we-know-so-far>

<https://www.versusarthritis.org/news/2020/march/coronavirus-covid-19-what-is-it-and-where-to-go-for-information/>

Biologic therapy and Targeted Synthetic Small molecules

What types of biologics are there?

There are many types of biologic drugs and they target different pathways of your immune system

- **Anti-IL6 drugs** - Tocilizumab, Sarilumab
- **Anti-TNF drugs** – Adalimumab, Etanercept, Golimumab, Certolizumab, Infliximab
- **Anti-CD20 (B cell depletion)** - Rituximab
- **Anti-CD40 drugs** - Abatacept
- **Anti-IL17 drugs** – Secukinumab, Ixekizumab
- **Anti-IL12/23 drugs** – Ustekinumab
- **JAK inhibitors** – Baricitinib, Tofacitinib (tablet form) (these drugs are not strictly biologic drugs but targeted synthetic small molecules. Essentially we shall consider them in this presentation as biologic treatments)

Why am I being started on a biologic?

- Most people are starting a biologic because they have active arthritis which has not been controlled with Disease Modifying Anti- Rheumatic Drugs (DMARDs) such as Methotrexate
- Some people will start a biologic because they have been unable to take DMARDs due to side effects.
- Your doctor has referred you to the virtual biologics clinic (VBC) who will check that you are eligible for the drug, the most appropriate drug has been chosen and it is safe for you to use it.

Next steps!

Once your drug is approved by the VBC team what happens next?

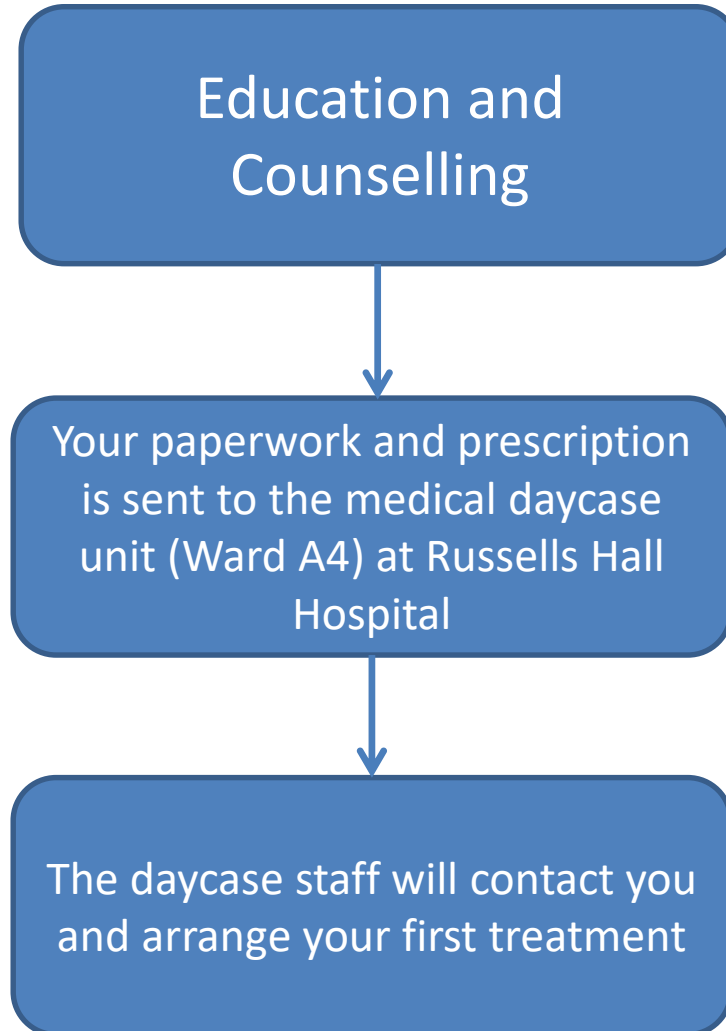
- The biologic coordinator will have arranged for you to have this presentation so you can learn more about the process, the drugs and some safety guidance.
- What happened next depends on:

Whether the drug you are to receive is something you take orally or inject yourself

OR

A drug that is given as an infusion in the hospital

What happens now: For treatment that you have as an infusion in the hospital?



Rheumatology Day Case

- There is a waiting list for treatment and times can vary. **Treatments will take place on A4 Medical Daycase Unit, Ground floor, Russells Hall Hospital**
- The rheumatology day case staff will contact you with the date/time of first infusion.
- You may be in the Day case anywhere from an hour up to a full day.
- If you are unable to attend, then you must let the Day case staff know ASAP (**not the rheumatology nurses**).
- It's your responsibility to ensure your next infusion is arranged before you leave.

Common Questions

How often do I have my infusion?

Orencia (Abatacept)	Monthly infusion, after loading dose at 0, 2 and 4 weeks (or alternatively as a weekly injection that can do yourself at home)
RoActemra (Tocilizumab)	Monthly infusion (or alternatively as a weekly injection that can do yourself at home)
MabThera/ Truxima (Rituximab)	According to your doctor Given as 1 or 2 infusions 2 weeks apart.
Remsima (Infliximab)	Every 8 weeks, after loading dose at 0, 2 and 6 weeks (or alternatively as a weekly injection that can do yourself at home)

Next steps if you are to be treated with a drug you inject yourself at home or as a tablet!

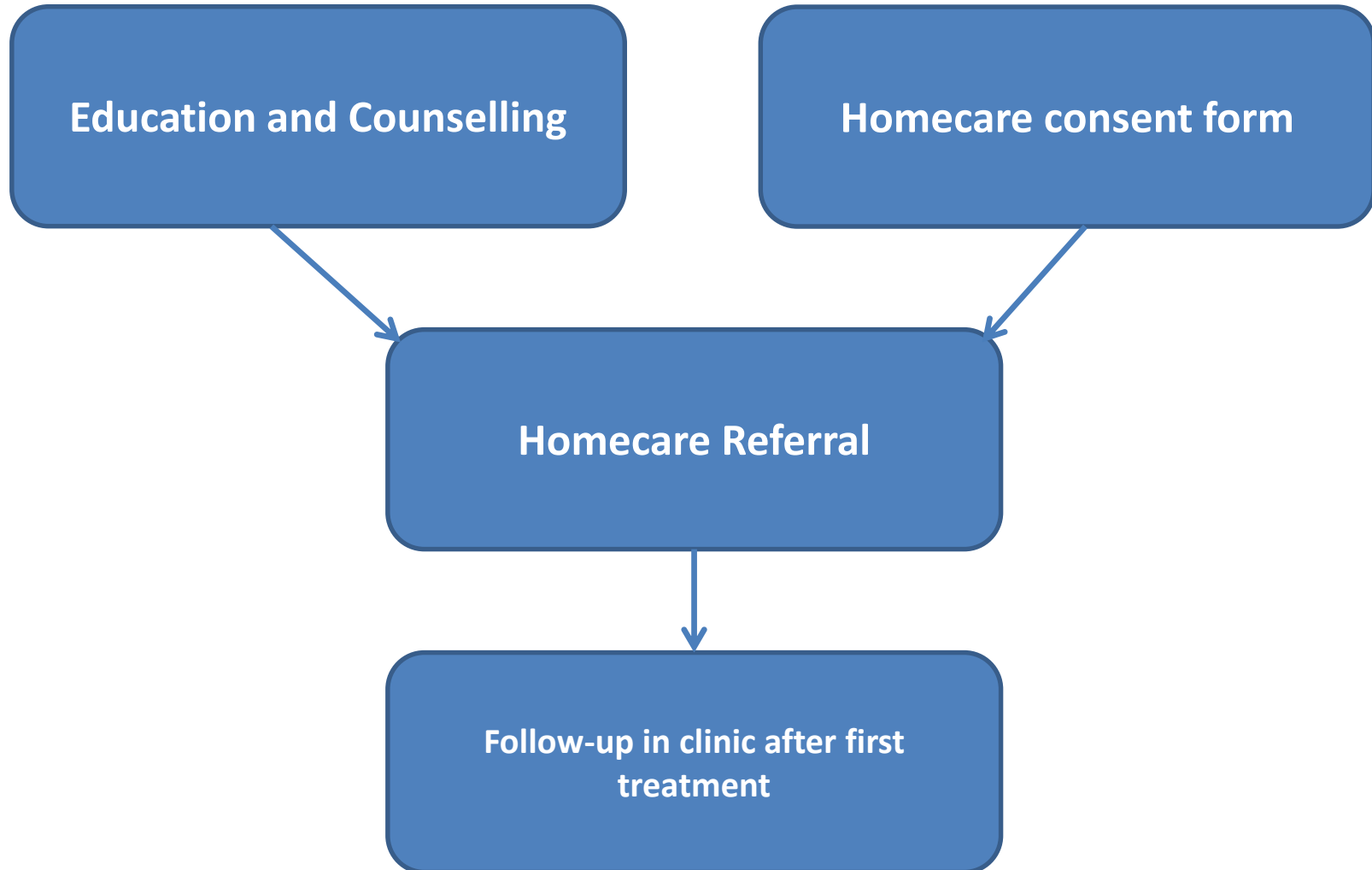
- We will be registering you with a healthcare provider, (such as Health Care @Home) to deliver your drugs, usually to your own home, and provide you with education on giving the injection
- As we need to provide these companies with some of your private details, we will need to have your **consent** to give them some of your details e.g your phone number and address
- You should have received a consent form for us to share your information.
- Assuming you are happy with this, contact us on 01384 244297 to confirm. Could the form please be signed and posted/ emailed back to us?

Rheumatology Biologics Co-ordinator (BC)

- Once we know you have understood the content of this presentation and we have your consent to do so, we will send the paperwork off to pharmacy and the homecare provider.
- Unfortunately this can up to 6 weeks to fully process.
- You will be contacted directly by the homecare provider to arrange delivery of the drug and training.
- The Rheumatology BC will co-ordinate all repeat prescriptions with the Rheumatology team.
- Contact the Rheumatology BC 01384 456111 ext 4297 for prescription queries only please



What happens now for treatment that you inject at home?



How do I get my medication?

- Initially a 3 month supply will be delivered via a Homecare provider (such as HealthCare@ Home).
- A nurse will contact you once this has been delivered
- Any problems– ring OUR team in pharmacy or the Rheumatology help line 01384 244789



Common Questions

How do I store the drug?

- Cool and away from light i.e in a fridge

Do not freeze!

- Tablets do not need any specific conditions
 - just a safe place



How long can it be out of the fridge?

Drug	Time it is stable outside the fridge
Humira (Adalimumab)	Up to 14 days outside of the fridge
Benepali (Etanercept)	Up to 4 weeks outside of the fridge
Simponi (Golimumab)	Up to 24 hours outside of the fridge
RoActemra (Tocilizumab)	Up to 8 hours outside of the fridge
Stelara (Ustekinumab)	Up to 4 hours outside of the fridge
Cosentyx (Secukinumab)	Up to 4 days outside of the fridge
Orencia (Abatacept)	Up to 8 hours outside the fridge.
Taltz (Ixekizumab)	Up to 5 days outside of fridge
Certolizumab pegol (Cimzia)	Up to 10 days outside of fridge
Kevzara (Sarilumab)	Up to 14 days outside of fridge

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

Common Questions

How often do I have my biologic injection?

Orencia (Abatacept)	Weekly injection or monthly drip
Humira (Adalimumab)	Fortnightly injection
Cimzia (Certolizumab)	Fortnightly injection after loading dose
Benepali (Etanercept)	Weekly injection
Simponi (Golimumab)	Monthly injection
Remsina (Infliximab)	Fortnightly injection
Cosentyx (Secukinumab)	Loading dose weekly for 5 weeks, then monthly injection.
RoActemra (Tocilizumab)	Weekly injection or monthly drip
Kevzara (Sarilumab)	Fortnightly injection
Ixekizumab	The initial loading doses depend on your condition but then every 4 weeks
Ustekinumab	The 1 st injection is followed by a 2 nd after 4 weeks then every 12 weeks. The dose may be adjusted for those >100KGS

Common Questions

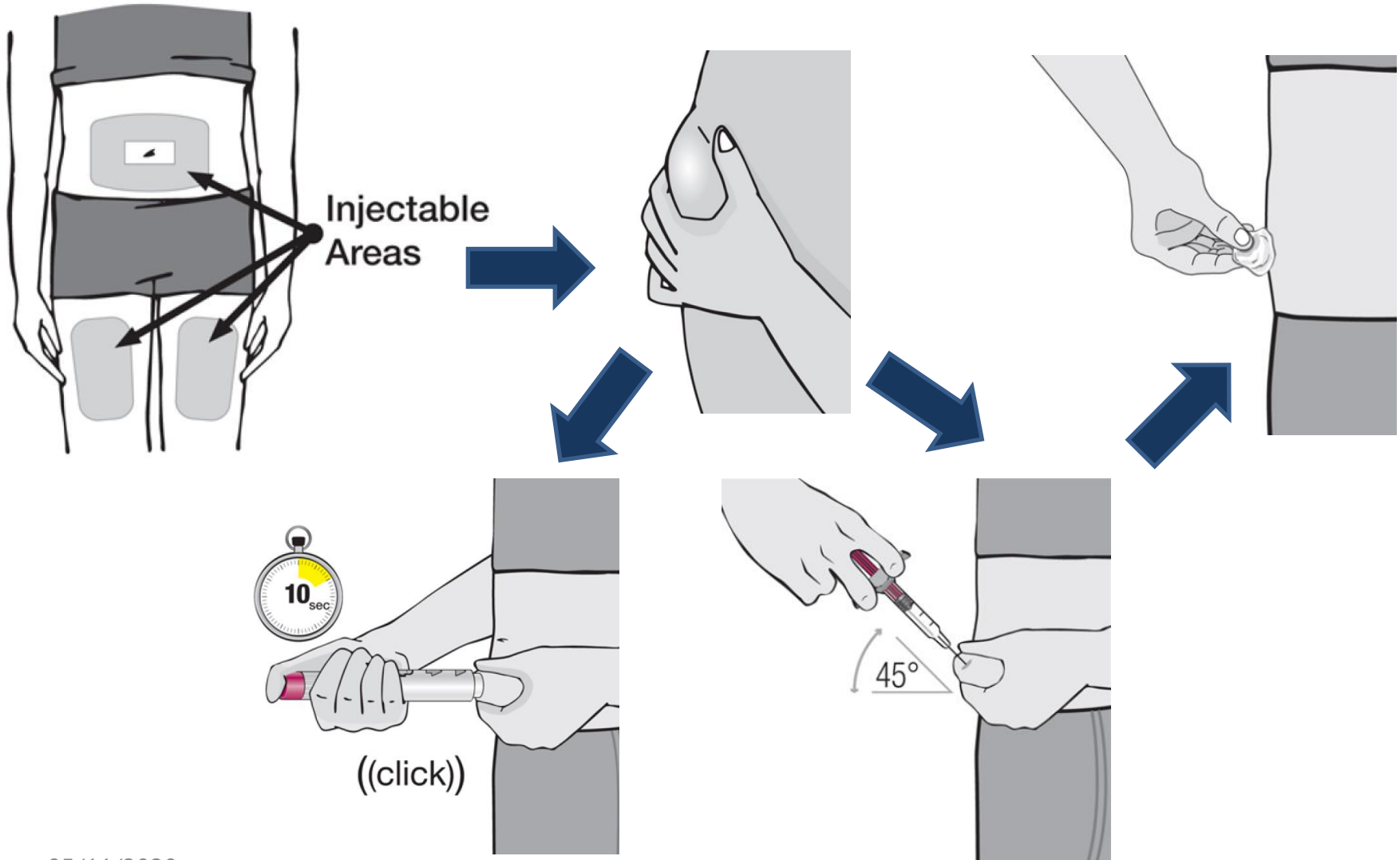
How do I take my medication?



A nurse will contact you, and if you are having an injectable treatment, teach you to inject yourself, once you have had a delivery of the medication

The nurse will be from the homecare company

How do I inject myself?



05/11/2020

Adapted from <http://www.humira.com/global/injecting-humira-pen.aspx> and <http://www.humira.com/global/injecting-humira-syringe.aspx>

Common Questions

How often will I need to attend the Rheumatology clinic?

- 3 months after your first treatment.
- Then after 3 months.
- Then every further six months for the duration of your treatment
- **We are exploring new ways of running clinics and these may in the future be over the phone or via video-links**

If you don't attend for your appointments or blood tests, your prescription may be put on hold!



Common Questions

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 also require a 3 monthly lipid (cholesterol) test until stable

Please be warned as we check these every time we sign a prescription. So, if you haven't had a blood test done, your prescription will not be completed and treatment may be delayed



Common Questions

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

- Depending on which biologic you are prescribed, you may start to experience improvement in your arthritis within a few days to weeks. Some of these drugs take a bit longer to work but we would hope you would start to feel better within 3 months.
- Unfortunately, not all patients will respond to biologics. We currently think about 30% may not have a good response. You will be monitored closely for your response over the first few months on treatment and decision to continue or change will be made between 3 and 6 months after starting.

Common Questions

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 injection site or sites. This usually goes away with time.
- Some patients have reported headaches, rashes or an increase in the frequency of coughs and cold and other minor infections.

What are the serious side effects?

- Serious side effects are very rare and most patients will not experience one.
- Occasionally, severe rash and more severe infections which have required hospitalisation have been reported.
- 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.



Questions & Answers

Are there any other more potential but less common serious risks?

- As with all new medications which suppress the immune system, there is a concern whether this could lead to an increase risk of cancers.
- Data on thousands of patients around the world have now been analysed, including almost 16000 UK patients, and to date there does not appear to be an increased risk of cancer in patients receiving these drugs. However, if you are investigated / treated for cancer, please stop your drug and inform the department.
- There has been a question if these drugs could increase the risk of skin cancer. Data from the UK study does not suggest this, but evidence suggests that all patients on immunosuppressive drugs may have a heightened risk of skin cancer and therefore, take care in the sun – If you have had PUVA, please discuss with your Doctor

Questions & Answers

- Biologic drugs can reactivate an infection called **Tuberculosis** (TB) in patients who may have been exposed to the infection in the past.
- At The Dudley Group NHS FT, all patients are now being screened for TB using a chest x-ray and a blood test called T-SPOT.
- If we think you are at increased risk for TB, you will have been assessed and had appropriate treatment from the respiratory team.
- If you think you might have been in contact with TB or be at increased risk, please inform the Rheumatology department.
- If you experience night sweats , weight loss or cough once on treatment, please inform the Rheumatology department.

Questions & Answers

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 well.
- If you are not sure, please ask or contact the helpline



Chickenpox & Shingles

Chickenpox and shingles

If you have never had chickenpox and develop it as an adult on immunosuppressive drug, you can be very ill.

We test everybody to make sure they are immune to Chickenpox before you start your biologics.

What if I have immunity but come in contact with chicken pox or shingles?

If you have had chickenpox, you will have your own immunity and you don't need to worry. If you have not had chickenpox, you need to get in touch with us.

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

1. Avoid on-going contact if possible
2. Stop biologic
3. Contact rheum/GP urgently for advise and possible blood testing
4. You may need some treatment
5. Contact department regardless before re-starting biologic



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 can happen at any time, but is more likely to happen when someone's immunity is suppressed.
- **Stop your biologic medication.** If you are on methotrexate, sulphasalazine, azathioprine or mycophenolate you should also stop this.
- **You need to see your GP to start antiviral medication (aciclovir)** and you will only restart your medication when the spots have dried up and you are feeling better.

Questions & Answers



What do I do if I get an infection?

- You will need to stop your biologic medication straight away and contact your GP.
- If you develop symptoms of COVID-19 stop your drug and follow current national guidelines (see slide 2). Remember to mention your biologic drug!
- Only restart it when you are feeling better and have finished your antibiotics (if prescribed).

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

- You will have been given an alert card with your drug information pack. Ensure that you show it to any health professional.
- Your GP should know you are on a biologic, but it may not be recorded in your medication list, as it will be prescribed by the hospital.

Questions & Answers

What do I do if I need surgery?

- Tell your surgeon all your 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 2-4 weeks prior to surgery.
- Your surgeon /rheumatologist should advise when to restart but usually this is after evidence of good wound healing and no signs of infection.
- Most important fact is to tell your surgeon you are on a biologic medication.
- If it is emergency surgery don't worry, just inform the surgeon what medication you are on.



Questions & Answers

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 or adalimumab but there is little information on the other drugs. No special precautions are needed 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 or adalimumab. It appears that very little drug enters breast milk and likely even less absorbed by the baby.

Vaccinations

What do I need to know about vaccinations?



- You should have the yearly flu vaccine. A one-off pneumonia vaccine is also advised. Your GP surgery will arrange this for you.
- You should NOT have live vaccines. If it is essential that you need a live vaccine, please discuss with your rheumatologist.
- 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.
- The current shingles vaccine is live and this should not be given if you are already on a biologic drug.
 - If you wish to have the shingles vaccine (anyone over 50 years)
 - Have it at your GP surgery
 - Wait 2 weeks after vaccine before starting 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.

Vaccinations

Below is a table of vaccines, you should avoid while on biologics.

	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 Vaccine	Varilrix [®] , Varivax [®] , Zostavax [®]
Yellow Fever	Arilvax [®] , Stamaril [®]

Travel advice

- Take your biologic drug in your Hand luggage ONLY
- 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!



Special Situations

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)



PML (Progressive multifocal leukoencephalopathy)

- For patients starting Rituximab, there have been a handful of cases of a serious brain inflammation/infection (Progressive Multifocal Leucoencephalopathy, PML). Millions of patients world wide have received Rituximab and there have only been a few cases.
- There have also been cases of this infection in patients not receiving Rituximab, but it is important that you tell your doctor if you experience any unusual neurological symptoms. Chances are it is not related to your medication but should be discussed.

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

Health Psychology



We are fortunate to have a health psychologist within our department

We believe that well-being comes from a balance of good physical and psychological health

Long term conditions can have an impact on psychological health – it's very common to feel low or anxious, or hate tablets and needles!

If you want to have a chat with someone, ask one of the Rheumatology doctors or nurse to refer you to Dr Liz Hale

Questions & Answers

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

Yes! You should have an alert card with your drug information pack

- ✓ Ensure that you show it to any health professional.
- ✓ Your GP will be alerted that you are starting a biologic by us.
- ✓ As the drug will not be on your regular prescription list from your GP, please tell any nurse or doctor that you are on a biologic drug as well.
- ✓ 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.

Thank you for your attention

Any questions?