



INFORMATION SHEET

BIOLOGIC MEDICINES

INTRODUCTION

Deciding to take a biologic medicine can feel like a big step. But if you're not well and other treatments aren't working, they can make a huge difference to your quality of life.

Whether you've been prescribed a biologic for Crohn's or Colitis or you're considering it as an option, this information sheet is for you.

It looks at:

- the different biologics available for Crohn's Disease and Ulcerative Colitis
- how the medicines work
- stopping or changing treatment
- biosimilars.

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My main concern with starting infliximab was the safety of the drug, both in the short and long term. Knowing that it had undergone rigorous clinical trials helped give me the confidence to go ahead with it. Five years on it's still allowing me to enjoy a normal quality of life.

”

Rebecca, age 32
Diagnosed with Crohn's Disease in 2007

CONTENTS

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WHAT IS A BIOLOGIC MEDICINE?	2
WHAT BIOLOGIC MEDICINES ARE USED TO TREAT CROHN'S AND COLITIS?	2
• CROHN'S DISEASE	2
• ULCERATIVE COLITIS	3
HOW DO BIOLOGIC MEDICINES WORK?	4
WHAT CAN I EXPECT FROM TREATMENT?	4
HOW DO I TAKE BIOLOGIC MEDICINES?	4
MAKING TREATMENT CHOICES	5
STOPPING OR CHANGING TREATMENT	5
• TREATMENT DOESN'T WORK OR STOPS WORKING	5
• SIDE EFFECTS ARE SEVERE OR DIFFICULT TO MANAGE	6
• STABLE REMISSION	6
WHAT IS A BIOSIMILAR?	6
QUESTIONS YOU MAY HAVE ABOUT BIOSIMILARS	7
STARTING TREATMENT WITH A BIOLOGIC MEDICINE	8
HELP AND SUPPORT FROM CROHN'S & COLITIS UK	9

WHAT IS A BIOLOGIC MEDICINE?

Biologic medicines are treatments for people with moderate to severe Crohn's Disease or Ulcerative Colitis. They may be an option when other drugs such as immunosuppressants (azathioprine, mercaptopurine, methotrexate) or steroids haven't been effective, or side effects have been hard to manage.

Biologic medicines are produced by biological rather than chemical processes. Living organisms, such as living cells, produce the active substance which is made of proteins.

WHAT BIOLOGIC MEDICINES ARE USED TO TREAT CROHN'S AND COLITIS?

There are five different biologic medicines available to treat moderate to severe Crohn's Disease or Ulcerative Colitis. These are infliximab, adalimumab, golimumab, vedolizumab and ustekinumab.

Not all drugs are available to treat both conditions - find out more in our individual **Drug Treatment Information Sheets**.

CROHN'S DISEASE

Drug	Adalimumab	Infliximab	Ustekinumab	Vedolizumab
Brand name	Humira Amgevita Hulio Imraldi Hyrimoz	Remicade Remsima Inflextra Flixabi Zessly	Stelera	Entyvio
Available for	Adults and children over age 6	Adults and children over age 6	Adults	Adults

Infliximab is available to treat active fistulising Crohn's Disease that hasn't responded to treatment. Adalimumab has also been used successfully to treat fistulas in people with Crohn's who also have active inflammation. Find out more in **Living with a Fistula**.

Vedolizumab is a treatment option only when infliximab or adalimumab (anti-TNF drugs) haven't been effective or there is a reason why you shouldn't take these.

Ustekinumab may be used where immunosuppressants or steroids haven't worked, or an anti-TNF drug hasn't been effective or has stopped working.

ULCERATIVE COLITIS

Drug	Adalimumab	Infliximab	Golimumab	Ustekinumab	Vedolizumab
Brand name	Humira Amgevita Hulio Imraldi Hyrimoz	Remicade Remsima Inflextra Flixabi Zessly	Simponi	Stelera	Entyvio
Available for	Adults and children over age 6	Adults and children over age 6	Adults	Adults	Adults

Vedolizumab may be an option if other treatments such as steroids or immunosuppressants haven't helped your condition. Vedolizumab and ustekinumab may also be an option if infliximab, adalimumab or golimumab (anti-TNF drugs) haven't worked for you, have stopped working or you have had side effects that are difficult to manage.

HOW DO BIOLOGIC MEDICINES WORK?

Gut inflammation in Crohn's and Colitis is caused by over-activity of the immune system. Biologic medicines act to block some parts of this, reduce the inflammation and so improve symptoms.

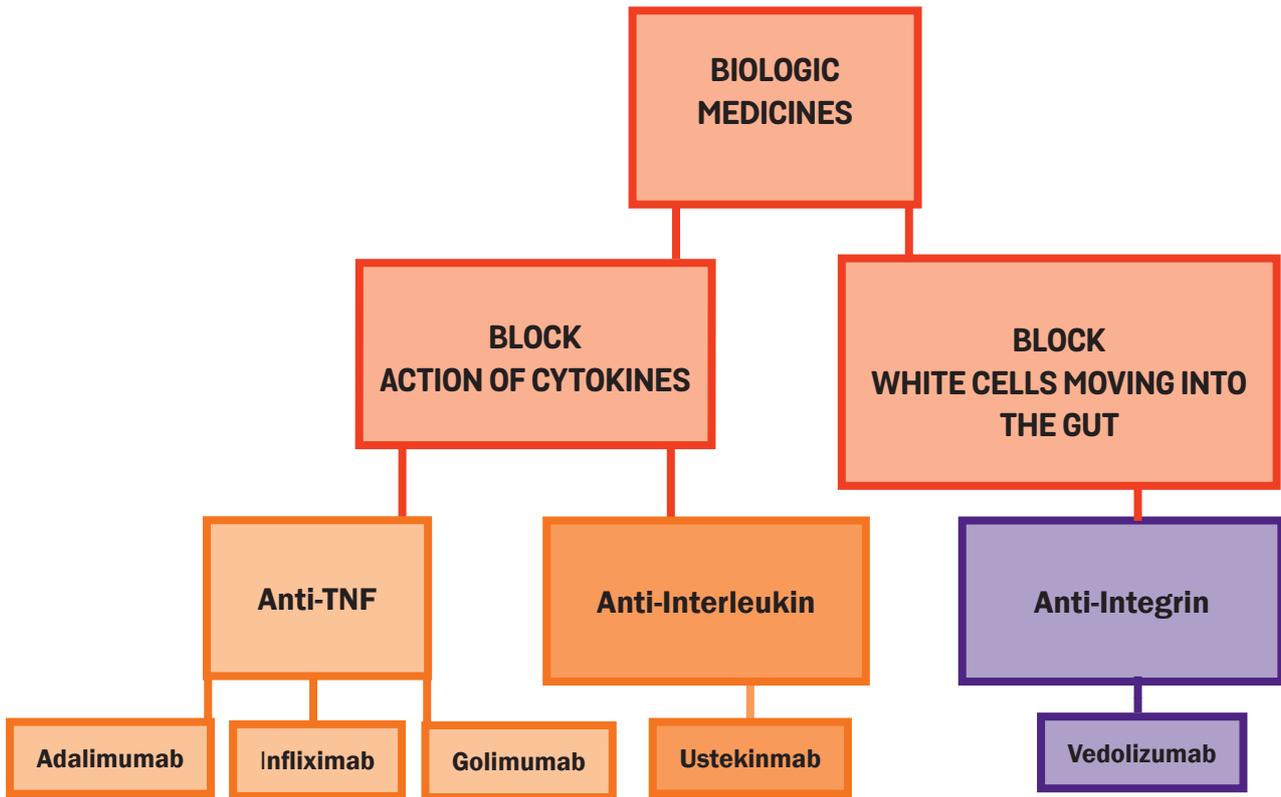
They work in different ways:

Blocking the activity of cytokines (TNF alpha or interleukins). Cytokines are specific proteins usually produced as a response to infection or injury. In Crohn's and Colitis overproduction of these proteins is thought to be partly responsible for the inflammation in the gut.

- **Infliximab, adalimumab, golimumab – Anti-TNF.** These drugs work by targeting a protein in the body called tumour necrosis factor-alpha (TNF-alpha). They bind to the TNF-alpha, this reduces the inflammation and helps to relieve symptoms. They are known as anti-TNF drugs.
- **Ustekinumab – Anti-interleukin.** Ustekinumab targets the proteins interleukin-12 (IL-12) and interleukin-23 (IL-23) which contribute to ongoing inflammation in the gut. Ustekinumab binds to both these proteins and prevents them from working, helping to reduce inflammation and improve symptoms.

Blocking white cells moving into the gut – Gut-selective integrin blocker. White blood cells are made by the immune system to fight infection, but in Crohn's and Colitis, overproduction of these cells leads to gut inflammation.

- **Vedolizumab – Anti-integrin.** This works by stopping the white blood cells from entering the lining of the gut and causing inflammation. The drug only targets the immune system of the gut and because the action is local, it may cause fewer immunosuppressive side effects.



This can mean that if one type of treatment hasn't worked for you, trying a drug that works in a different way could be an option. The decision about which treatment to try next depends on several factors which you could discuss with your IBD team.

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My experience of having been on Humira, Remicade and Remsima are only positive, all can be life changing, and when they work it is like you no longer have IBD. Ensure you keep in contact with your IBD team and let them know how you are doing – remember they have lots of experience of IBD and are the best people to talk to.

”

Barry, age 41
Diagnosed with Crohn's Colitis in 2006

WHAT CAN I EXPECT FROM TREATMENT?

Biologic drugs have all been shown to be effective in improving gut symptoms, bringing about and maintaining remission (preventing flares) in people with moderate to severe Crohn's or Colitis. They can also reduce the need for hospitalisation or surgery. But they don't work for everyone, and for some people they stop working after some time.

Because they suppress parts of the immune system, all biologics carry an increased risk of infections, which in rare cases can be serious. Find out more in our individual **Drug treatment information sheets**.

Symptoms outside the gut

Some biologic medicines (infliximab, adalimumab) have been shown to be effective in improving symptoms outside the gut related to Crohn's or Colitis. These are also known as extra intestinal manifestations (EIMs) and can include problems with:

- Joints – pain (arthralgia), pain and swelling (arthritis). Find out more in **Joints**.
- Skin – erythema nodosum, this is swollen fat under the skin causing red bumps and patches.
- Eyes – uveitis, this is inflammation of the eyes that causes redness and soreness.

HOW DO I TAKE BIOLOGIC MEDICINES?

All these drugs are taken either by injection under the skin or through a drip in the arm (IV infusion). You can't take biologics by mouth because the digestive system would break down and destroy the drug.

Drug	Adalimumab	Infliximab	Golimumab	Ustekinumab	Vedolizumab
How it is taken	Injection under the skin	Infusion through a drip in the arm (IV infusion)	Injection under the skin	Infusion through a drip in the arm (IV infusion) followed by injection under the skin	Infusion through a drip in the arm (IV infusion)
How often	Every 1 or 2 weeks	Every 8 weeks	Every 4 weeks	Every 8 or 12 weeks	Every 4 or 8 weeks
Where	Self-inject at home	Hospital outpatients	Self-inject at home	Single, initial infusion in hospital outpatients followed by self-inject at home	Hospital outpatients

MAKING TREATMENT CHOICES

The decision about your treatment should be made after full discussion between you and your IBD team. You should consider the potential benefits, possible risks, and the goals of your treatment together.

This will include how active the condition is, how the medicine doses are taken and the impact on other symptoms you may have such as joint or skin problems. You might like to think about whether a hospital infusion or an injection at home would work best for you: Will you be able to arrange time off for infusions with your employer? Do you have a reliable fridge at home?

The first biologic medicines that are often tried are infliximab or adalimumab. This is because they have been used for a long time and are shown to be effective. But, if they don't work well for you, there may be other biologics you can try.

“ I was moved from Remicade to a biosimilar in February 2015, when the patent expired. I have found the biosimilar to be no more different in effect from infliximab: I have had no side effects and it is just as an effective a treatment for me.

”

Claire, age 64
Diagnosed with Ulcerative Colitis in 2009

STOPPING OR CHANGING TREATMENT

Treatment doesn't work or stops working

Treatment isn't effective from the start. Biologic medicines don't work for everyone. Some people find that treatment doesn't make them feel better. Your IBD team will monitor how treatment is working for you in the first three months.

If your symptoms haven't improved treatment will be stopped, and another approach tried. Some people may not respond to the way one biologic works, so switching to a biologic that acts in a different way can be helpful.

Treatment loses effect over time. Some people find treatment is effective to begin with, but this becomes less over time. This often happens because the immune system recognises the drug as a foreign substance and thinks it is harmful. It then produces proteins called antibodies against the biologic drug and these stop it from working as well.

If this happens there may be a few options:

- Increase the dose.
- Add an immunosuppressant so that you would be taking a combination of medicines. There is evidence that this can reduce the levels of antibodies.
- Change to a biologic that works in a different way.
- Change to a different biologic that works in the same way.

Side effects are severe or difficult to manage

Treatment may be stopped if you experience side effects that are difficult to manage.

Stable remission

If you are in stable remission after one year of treatment, your IBD team may decide that you can stop taking your biologic. Stable remission means that your symptoms have gone away, and you haven't had any flares in that time. You'll continue to be monitored and if a relapse happens you should be able to start treatment again.

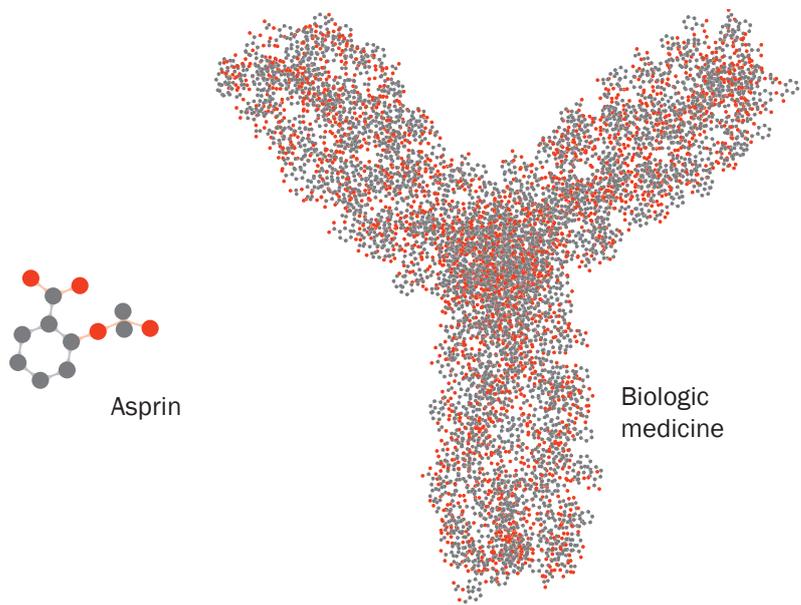
If you've been taking the biologic together with an immunosuppressant such as azathioprine, your IBD team may suggest you continue treatment with the immunosuppressant alone.

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WHAT IS A BIOSIMILAR?

It isn't possible to produce an exact copy of a biological drug because they are complex medicines made from living cells,

You can see aspirin is a small molecule so it's easy to replicate compared to a complex biologic medicine.



A biosimilar is a biological medicine which is highly similar to the original drug. The first brand produced is known as the “originator”, other brands of the same medicine are known as “biosimilars”.

Infliximab and adalimumab have biosimilars. Both these medicines should always be prescribed by the brand name so there is no uncertainty about which one is being used.

Infliximab - The originator product is Remicade. Biosimilar versions are Inflectra, Remsima and Flixabi which became available from February 2015. Zessly is a biosimilar available from 2018.

Adalimumab - The originator product is Humira. Biosimilar versions are Amgevita, Hulio, Imraldi and Hyrimoz. These became available in 2018.

What are the advantages of biosimilar medicines?

Biosimilars are much cheaper for the NHS to use than the originator medicine. The money saved can be reinvested in new drugs and treatments.

What differences might there be?

Biosimilars are thoroughly tested. They meet strict standards to show they are as safe, effective and have no clinically meaningful differences from the originator. Where NICE has recommended the use of a biological medicine, they state that the same guidance applies to the biosimilar.

However, there are likely to be some small differences including:

- **Injection device** – Injection devices for all the different products vary. If you have changed brand, this is likely to be different from the one you have been used to using. You will receive full training until you are confident to use the new one.
- **Homecare delivery service** - If you change to a different product you are likely to have this delivered by a different homecare delivery service.
- **Side effects** - Because the formulations are not the same, some people who switch products may experience new injection site reactions. Your IBD team can help you with tips to reduce these.

Some people may be sensitive to latex, which is used as a needle cover in some of some types of biosimilars, or citrate which is sometimes included as one of the ingredients.

Some types of adalimumab are available without citrate or latex, and you can ask to try one of these.

QUESTIONS YOU MAY HAVE ABOUT BIOSIMILAR MEDICINES

How will my hospital tell me if it wants to use a new biosimilar medicine?

Your IBD team will contact you by letter.

Do I have to change to the biosimilar or can I stay on the originator product?

Talk to your IBD team about any concerns you have. Each hospital should have alternative versions of adalimumab available. But you can say if you are happy with your medication and don't want to change brand.

What are my rights when it comes to changing to a new medicine?

Switching to any new medicine should involve a discussion between you and your IBD team. This should consider your needs, preferences and values as well as all the available clinical evidence.

Can I change back if I don't feel as well on the biosimilar?

Your IBD team will discuss any problems you're experiencing with you and together you can agree the best way forward. A new side effect may be a good reason to change back. But if you feel your condition is not as well controlled on the biosimilar it could be that you are losing response to the medication and a completely different biologic could be tried.

Find out more about adalimumab biosimilars: www.adalimumab-faq

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STARTING TREATMENT WITH A BIOLOGIC MEDICINE

It can feel daunting starting a new medicine. You've probably never had to inject yourself before or you might be worried about taking time off to go for an infusion. But it's all done with the aim of getting you better, and you'll probably find you get used to it faster than you thought.

Our Helpline takes many calls on these issues so you're not alone. We can't advise but it may help to talk through your worries. We can also provide you with more information about the individual biologics.

- Infiximab
 - Adalimumab
 - Golimumab
 - Vedolizumab
 - Ustekinumab
-

HELP AND SUPPORT FROM CROHN'S & COLITIS UK

We're here for you whenever you need us. Our award-winning publications on Crohn's Disease, Ulcerative Colitis, and other forms of Inflammatory Bowel Disease have the information you need to help you manage your condition.

We have information on a wide range of topics, from individual medicines to coping with symptoms and concerns about relationships, school and employment. We'll help you find answers, access support and take control.

All publications are available to download from our website:
crohnsandcolitis.org.uk/publications

Health professionals can order some publications in bulk by using our online ordering system, available from the webpage above. If you would like a printed copy of a booklet or information sheet, please contact our helpline.

Our helpline is a confidential service providing information and support to anyone affected by Crohn's or Colitis.

Our team can:

- help you understand more about Crohn's and Colitis, diagnosis and treatment options
- provide information to help you live well with your condition
- be there to listen if you need someone to talk to.
- help you understand and access disability benefits.
- put you in touch with a trained support volunteer who has personal experience of Crohn's or Colitis.

Call us on **0300 222 5700** or email **helpline@crohnsandcolitis.org.uk**. See our website for LiveChat: **crohnsandcolitis.org.uk/livechat**

Crohn's & Colitis UK Forum

This closed-group community on Facebook is for everyone affected by Crohn's or Colitis. You can share your experiences and receive support from others at: **facebook.com/groups/CCUKforum**

Help with toilet access when out and about

If you become a member of Crohn's & Colitis UK, you will get benefits including a **Can't Wait Card** and a **Radar key** to unlock disabled toilets. This card shows that you have a medical condition and combined with the Radar key will help when you need urgent access to the toilet when you are out and about. See our website for further information: **crohnsandcolitis.org.uk/membership** or call the membership team on **01727 734465**.

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We hope that you have found this leaflet helpful and relevant. If you would like more information about the sources of evidence on which it is based, or details of any conflicts of interest, or if you have any comments or suggestions for improvements, please email the Publications Team at publications@crohnsandcolitis.org.uk. You can also write to us at Crohn's & Colitis UK, 1 Bishops Square, Hatfield, Herts, AL10 9NE or contact us through the **Helpline: 0300 222 5700**.

ABOUT CROHN'S & COLITIS UK

We are Crohn's & Colitis UK, a national charity fighting for improved lives today – and a world free from Crohn's and Colitis tomorrow. To improve diagnosis and treatment, and to fund research into a cure; to raise awareness and to give people hope, comfort and confidence to live freer, fuller lives. We're here for everyone affected by Crohn's and Colitis.

This publication is available for free thanks to the generosity of our supporters and members. Find out how you can join the fight against Crohn's and Colitis: call **01727 734465** or visit crohnsandcolitis.org.uk.