

Biologics and other targeted medicines

Biologics and other targeted medicines are types of treatment for <u>Crohn's</u> and <u>Colitis</u>. In general, they are prescribed for people with moderate to severe Crohn's or Colitis.

This information provides an overview of biologics and other targeted medicines. It is for people who may be starting treatment with one, or considering it as an option.

It looks at:

- The different biologics and targeted medicines available for <u>Crohn's Disease</u> and <u>Ulcerative Colitis</u>
- Starting treatment with a biologic or other targeted medicine
- Changing treatment or switching brands
- Stopping treatment

If you are considering different options, our <u>Medicine Tool</u> could help you decide what's important to you and compare the different treatments.

We have separate, detailed information about each of the individual <u>medicines used to</u> <u>treat Crohn's and Colitis</u>.

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Key facts about biologics and other targeted medicines

- Biologics and other targeted medicines are treatments that block particular proteins or chemical pathways involved in inflammation. They are more precise than immunosuppressant medicines.
- They may be an option for some people with moderate to severe Crohn's Disease or Ulcerative Colitis.
- They can help get Crohn's or Colitis under control and keep them under control. But they also alter your immune system, so you might not fight off infections as well as other people.
- Deciding to take a biologic or other targeted medicine can feel like a big step. Your
 IBD team should discuss your options with you so you can make the decision together.
- You have biologics through a drip in your arm, or as an injection under your skin.
 Other targeted medicines are tablets that you take by mouth.
- It can be hard to predict which treatment is likely to work best for you. You may
 need to change to a different biologic or other targeted medicine if treatment does
 not work well, stops working or you get side effects that are serious or hard to
 manage.
- Your IBD team should review your treatment at least once a year to check that it is still the right option for you.

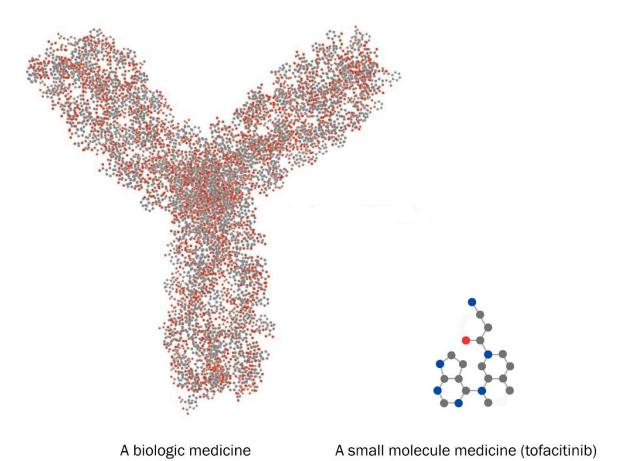


What are biologics and other targeted medicines?

<u>Crohn's Disease</u> and <u>Ulcerative Colitis</u> cause inflammation in your gut, and sometimes other parts of your body. Biologics and other targeted medicines are treatments that block particular proteins or chemical pathways involved in inflammation. This reduces inflammation. They are more precise than immunosuppressant medicines.

- Biologic medicines are antibodies that are made by living cells in a lab. Antibodies
 are proteins that recognise and stick to specific targets. They are large, complex
 molecules. Biologics have been used to treat Crohn's or Colitis for over 20 years.
- Other targeted medicines are made by chemical processes. They are smaller and less complex than biologics. They are sometimes called 'small molecule' medicines. The first targeted small molecule medicine became available for Colitis in the UK in 2018.





The pathways that biologics and other targeted medicines block are part of your immune system. So these medicines can affect the way your immune system works. This means your body might not fight off infections as well as other people. You might get more infections than you used to, or they might last longer or be more serious than usual.



Who might have them?

Biologics and other targeted medicines may be an option for people with moderate to severe Crohn's Disease or Ulcerative Colitis:

They are often considered:

- When other medicines such as immunosuppressants (<u>azathioprine</u>, <u>mercaptopurine</u>, and <u>methotrexate</u>) or <u>steroids</u> have not worked well or have stopped working
- When other medicines have had bad side effects
- In combination with other medicines

They might also be used as a first medicine if your IBD team feel they are the best option for you. They may be especially useful in people with severe Crohn's or Colitis or people who also have non-gut symptoms or fistulas.

Biologics and other targeted medicines used to treat Crohn's and Colitis

Lots of biologics and other targeted medicines are available in the UK to treat Crohn's and Colitis. Some are used to treat Crohn's, some to treat Colitis, and some to treat both. Sometimes they can only be used in particular circumstances, like when other options have not worked. Not all medicines are suitable for everyone.

To compare medicines that might be an option for you, have a look at our <u>Medicine</u>

Tool.

Sometimes, your IBD team might suggest using medicines outside their licensed indications if they appear to be the best available option for you.



Biologics

Below, we give an overview of biologics that are currently available in the UK. More are being developed and could be available in the future.

We also have separate detailed information on individual medicines.

Adalimumab

Brand names: Amgevita, Hyrimoz, Idacio, Imraldi, Humira, Yuflyma.

Used to treat: Crohn's Disease or Ulcerative Colitis in adults and children over 6.

How it works: It is a type of medicine called an anti-TNF. It sticks to a protein called TNF-alpha. Your immune system naturally makes TNF to help you fight infections, but it can also cause inflammation. Adalimumab blocks the effects of TNF-alpha, which helps reduce inflammation.

Full drug information available at: Adalimumab

Golimumab

Brand names: Simponi, Gobivaz.

Used to treat: Ulcerative Colitis in adults.

How it works: It is a type of medicine called an anti-TNF. It sticks to a protein called TNF-alpha. Your immune system naturally makes TNF to help you fight infections, but it can also cause inflammation. Golimumab blocks the effects of TNF-alpha, which helps reduce inflammation.

Full drug information available at: Golimumab



Infliximab

Brand names: Flixabi, Inflectra, Remicade, Remsima, Zessly.

Used to treat: Crohn's Disease (including <u>fistulas</u>) or Ulcerative Colitis in adults and children over 6.

How it works: It is a type of medicine called an anti-TNF. It sticks to a protein called TNF-alpha. Your immune system naturally makes TNF to help you fight infections, but it can also cause inflammation. Infliximab blocks the effects of TNF-alpha, which helps reduce inflammation.

Full drug information available at: Infliximab

Mirikizumab

Brand names: Omvoh.

Used to treat: Ulcerative Colitis in adults.

How it works: It is a type of medicine called an IL-23 inhibitor. It sticks to a protein called interleukin-23, or IL-23. Your immune system naturally makes IL-23 to help you fight infections, but it can also cause inflammation. Mirikizumab blocks the effects of IL-23, which helps reduce inflammation.

Full drug information available at: Mirikizumab

Risankizumab

Brand names: Skyrizi.

Used to treat: Crohn's Disease in people over 16.

How it works: It is a type of medicine called an IL-23 inhibitor. It sticks to a protein called interleukin-23, or IL-23. Your immune system naturally makes IL-23 to help you fight infections, but it can also cause inflammation. Risankizumab blocks the effects of IL-23, which helps reduce inflammation.

Full drug information available at: Risankizumab





Ustekinumab

Brand names: Imuldosa, Otulfi, Pyzchiva, Stelara, Steqeyma, Uzprovo, Wenzela.

Used to treat: Crohn's Disease or Ulcerative Colitis in adults.

How it works: It is a type of medicine called an IL-12/23 inhibitor. It sticks to two different proteins, called interleukin 12 and interleukin 23, or IL-12 and IL-23. Your immune system naturally makes these to help you fight infections, but they can also cause inflammation. Ustekinumab blocks the effects of IL-12 and IL-23, which helps reduce inflammation.

Full drug information available at: <u>Ustekinumab</u>

Vedolizumab

Brand names: Entyvio.

Used to treat: Crohn's Disease or Ulcerative Colitis in adults.

How it works: It is a type of medicine called a gut-selective integrin blocker. It sticks to a protein called integrin on the surface of the white blood cells. This stops the white blood cells entering your gut, where they can cause inflammation.

Full drug information available at: Vedolizumab



Other targeted medicines

Below, we give an overview of other targeted medicines that are currently available in the UK. More are being developed and could be available in the future.

We also have separate detailed information on individual medicines.

Filgotinib

Brand names: Jyseleca.

Used to treat: Ulcerative Colitis in adults.

How it works: It is a type of medicine called a JAK inhibitor. It blocks the effects of proteins called janus kinases, or JAKs. JAKs activate your immune system and help you fight infection, but they also cause inflammation. Blocking the effects of JAKs helps reduce gut inflammation.

Full drug information available at: Filgotinib

Ozanimod

Brand names: Zeposia.

Used to treat: Ulcerative Colitis in adults.

How it works: It is a type of medicine called an S1P receptor modulator. It sticks to a protein called sphingosine-1-phosphate (S1P) on some white blood cells. This stops them from travelling into your gut and causing inflammation.

Full drug information available at: Ozanimod





Tofacitinib

Brand names: Xeljanz.

Used to treat: Ulcerative Colitis in adults.

How it works: It is a type of medicine called a JAK inhibitor. It blocks the effects of proteins called janus kinases, or JAKs. JAKs activate your immune system and help you fight infection, but they also cause inflammation. Blocking the effects of JAKs helps reduce gut inflammation.

Full drug information available at: Tofacitinib

Upadacitinib

Brand names: Rinvoq.

Used to treat: Crohn's Disease or Ulcerative Colitis in adults.

How it works: It is a type of medicine called a JAK inhibitor. It blocks the effects of proteins called janus kinases, or JAKs. JAKs activate your immune system and help you fight infection, but they also cause inflammation. Blocking the effects of JAKs helps reduce gut inflammation.

Full drug information available at: Upadacitinib



Starting treatment with a biologic or other targeted medicine

Deciding to take a new medicine can feel like a big step. There are lots of things to think about. Your IBD team should discuss your options with you.

Some people worry about having injections or blood tests, taking time off work for treatment, or having a lowered immune system. But biologics and other targeted medicines can help get Crohn's or Colitis under control and keep them under control.

- If you're worried about starting treatment with a biologic or other targeted medicine, you're not alone. Our <u>Helpline</u> takes many calls from people in the same situation.
 We cannot offer advice, but we can help you talk through your concerns.
- We also have a <u>Guide for employees</u> and <u>Guide for employers</u>, which includes information about taking time off for medical appointments.

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

Living with Crohn's Colitis

There are many different treatments available, and it can be difficult to predict which one will work best for you. Your IBD team might give you a choice of different treatments. You should consider the potential benefits, possible risks, and the goals of your treatment together.





Things to consider include:

- How you take it
- How often you take it
- How effective it is
- What effect it might have on other symptoms, like joint or skin problems
- How quickly it's likely to work
- · How long it's likely to keep working
- Side effects you might get
- Whether you need ongoing tests or checks
- Other medicines you're on

Our <u>Appointment guide</u> includes a list of questions you might want to ask. It can help you focus on what matters most to you.

Before you start a biologic or other targeted medicine, your IBD team will ask you some questions and do some blood tests to make sure it's suitable for you. They will also make sure your vaccinations are up to date. They may do a chest X-ray.

How to take biologics or other targeted medicines

How you take your medicine depends on the type of medicine you are on.

Biologics

You cannot take biologics by mouth because they are broken down in the gut, which stops them working. Instead you either have them as an infusion (a drip in your arm), or as an injection under your skin.





Depending on which medicine you are on, you might:

- Have all your doses as infusions
- Have all your doses as injections
- Start off having infusions and then swap to injections

You could think about whether a hospital infusion or an injection at home would work best for you. It might be helpful to look at our <u>Guide for employees</u> and <u>Guide for employees</u>. These include information about taking time off for medical appointments.

Infusions

Watch the video to find out what happens when you have an infusion.

Biologics Infusion Therapy - YouTube

Injections

You have some biologics as injections under your skin. This is called a subcutaneous injection.

Once you've got used to your medicine, your doctor or nurse will usually teach you how to give yourself the injection at home. This could be through an injection pen, a pre-filled syringe, or an injector that you stick to your skin (called an on-body injector).

A pre-filled syringe





An injection pen



An on-body injector



Injecting yourself might sound daunting at first, but most people find it a lot easier than they expected. If you're not comfortable injecting yourself, your doctor or nurse might be able to teach a friend or family member to do it for you.





When I was first told I needed to inject myself at home, I was worried about doing it wrong. However, you have the support of a nurse to begin with to build up your confidence. Now my fortnightly injections feel like part of my routine - like brushing my teeth.

Sophie

Living with Crohn's

If you have home injections, you usually have them sent straight to you by a homecare delivery service. You have to store biologic medicines in the fridge.

Other targeted medicines

Other targeted medicines are tablets that you take by mouth. Depending on which medicine you are on, you take them once or twice a day.

Changing treatment

If the first biologic or targeted treatment you try is not right for you, you may need to change to a different one. The decision about which treatment to try next depends on several factors. Your IBD team should discuss this with you and make the decision together.

There are a few reasons you may need to change treatment.

Treatment does not work well

Biologics and other targeted medicines don't work for everyone. Some people find that treatment does not help them feel better. Your IBD team will monitor how well your treatment is working.

If your symptoms do not improve within a few months, your IBD are likely to suggest stopping the medicine and trying a different option. Switching to a medicine that works in a different way could be an option.



Treatment stops working well

For some people, treatment works well at first but stops working over time.

For biologic medicines, this can happen because your immune system recognises the drug as a foreign substance and thinks it is harmful. It then produces proteins called antibodies against the biologic drug, which stop it working as well.

If this happens there may be a few options:

- Increase the dose
- Shorten the time between doses
- Add an immunosuppressant, if you are not already taking one, to help lower your antibody levels
- Change to a different medicine that works the same way
- Change to a medicine that works in a different way

Side effects are serious or hard to manage

Tell your IBD team if you are getting side effects. If you have side effects that are serious or hard to manage, they might suggest stopping treatment and trying a different option.

Washout period

When you change to a different medicine, your IBD team might recommend taking a break from treatment for a few weeks. This is to make sure all the first medicine is out of your system before you start the next one. It is called a washout period. The idea behind it is to keep your risk of infection as low as possible, but the evidence on whether or not it is needed is unclear.

A recent study found no difference in infection risk in people who had a washout period of less than 30 days compared to people who had a washout period of more than 30 days. So you might not need to stop treatment for long. Your IBD team will tell you what they recommend.



Switching brands

Sometimes, your IBD team might suggest switching to a different brand of the same medicine. This could happen for a few reasons, such as:

- A cheaper brand is available that works just as well
- There are shortages of the brand of medicine you are on
- The manufacturer stops making the brand of medicine you are on
- A different brand has an injection device or formulation that might suit you better

Your IBD team will let you know if they are considering switching you to a different brand of medicine. This could be by letter, text, email, or at an appointment.

You should have a chance to discuss the switch and make the decision together. This should consider your needs, preferences and values as well as the clinical evidence.

Biosimilars

For biologic medicines, different brands are slightly different from each other. This is because biologics are very complex medicines made by living cells, so it is not possible to make an exact copy. These slightly different brands are called biosimilars. They are very similar to the original medicine.

Biosimilars are thoroughly tested to make sure they are just as safe and effective as the original brand.

Biosimilars are much cheaper for the NHS than the original brand. The money saved means more people can access treatment. There is no evidence that switching to a biosimilar makes your Crohn's or Colitis get worse or flare up.

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

Injection device: If you switch brands, the injection device is likely to be different.
 Your doctor or nurse will teach you how to use the new device and support you to become confident using it.



- Homecare delivery service: If you change to a different brand, you may need to have it delivered by a different homecare delivery service.
- Side effects: Biosimilars are no more likely to cause side effects than the original brand. But because different brands are not exactly the same, some people who switch products may get different side effects. Tell your IBD team if this happens.
- Ingredients or materials: The active ingredient of different brands is always very similar to the original brand. But some of the other ingredients, like preservatives, might be different. Different brands might also use different materials to make the injection devices. This means some brands may not be suitable for people with allergies to certain ingredients or materials.

The Patients Association has more information on <u>switching to biosimilars</u>. This includes a <u>video about biosimilars</u>, and a <u>biosimilars leaflet to download</u>.

If you have any problems after switching brands, tell your IBD team.

Together you can agree the best way forward. Depending on your experience, they may suggest switching back to your original brand, or trying a different medicine.

Stopping treatment

Your IBD team should review your treatment at least once a year. If it is working and you are not getting serious side effects, they are likely to recommend that you carry on taking it. If you're finding side effects hard to manage, or you want to have a break from treatment, tell your IBD team. They can help you consider your options.

If your Crohn's or Colitis stays under control for a long time, your IBD team might suggest stopping your biologic or other targeted medicine. They should discuss it with you so you can make the decision together. You can tell them if you have any concerns about stopping. If you do stop treatment, your team will monitor you. If your symptoms come back, you should have the option to start treatment again.





If you've been taking a biologic or other targeted medicine with an immunosuppressant such as <u>azathioprine</u>, your IBD team might suggest taking the immunosuppressant alone.

Help and support from Crohn's & Colitis UK

We're here for you whenever you need us. Our award-winning information 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 and employment. We'll help you find answers, access support and take control.

All information is available on our website: crohnsandcolitis.org.uk/information

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
- Help you understand and access disability benefits
- Be there to listen if you need someone to talk to
- Help you to find support from others living with the condition

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

Members of Crohn's & Colitis UK get benefits including a Can't Wait Card and a RADAR key to unlock accessible toilets. This card shows that you have a medical condition, and will help when you need urgent access to the toilet when you are out. See crohnsandcolitis.org.uk/membership for more information, or call the Membership Team on 01727 734465.

Crohn's & Colitis UK information is research-based and produced with patients, medical advisers and other professionals. They are prepared as general information and are not intended to replace advice from your own doctor or other professional. We do not endorse any products mentioned.

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 information 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 <u>crohnsandcolitis.org.uk</u>.

About our information

Crohn's & Colitis UK information is research-based and produced with patients, medical advisers and other professionals. They are prepared as general information and are not



intended to replace advice from your own doctor or other professional. We do not endorse any products mentioned.

We hope that you've found this information helpful. You can email the Knowledge and Information Team at evidence@crohnsandcolitis.org.uk if:

- · You have any comments or suggestions for improvements
- You would like more information about the research on which the information is based
- You would like details of any conflicts of interest

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.

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