

Fact Sheet

News from the IBD Help Center

BIOLOGICS

Medical treatment for Crohn's disease and ulcerative colitis has two main goals: achieving remission and then maintaining remission. **Biologics** are antibodies created in the laboratory and are available for the treatment of inflammatory bowel disease (IBD) and other inflammatory diseases. Biologic medications target the specific proteins in the body that may be involved with the inflammation that occurs in IBD. While it is not possible to determine which biologic will work best for an individual patient, your physician will recommend different options and work with you on a goal of achieving remission.

Biosimilars are biologic medications that are nearly identical copies of other already approved biologic therapies. There are no meaningful differences between the biosimilar and the originally approved biologic. They are just as safe and effective and are taken in the same form and dose.

For more information on biosimilars visit: <https://www.crohnscolitisfoundation.org/what-is-ibd/medication/biosimilars>

In the next few sections, we will review brief information about the different types of biologic therapies. It is important to note that these treatments are not a cure for IBD, but are used to manage symptoms and inflammation, and help you work together with your doctor towards a goal of remission.

All IBD medications listed below are FDA approved. Information about market availability of these current medications may not be reflected in this educational resource. For more information about each medication, including other medications for IBD, please view our IBD Medication Guide at www.ibdmedicationguide.org.

Anti-Tumor Necrosis Factor Agents

Biologics known as anti-tumor necrosis factor (anti-TNF) agents, bind and block a small protein that promotes inflammation in both the intestine and other organs or tissues. All anti-TNF medications have been shown not only to reduce the symptoms of IBD, but also result in healing of the inflamed intestine. While anti-TNF medications are not effective for every individual, many patients benefit from this type of medication. It may take up to eight weeks after starting an anti-TNF to notice an improvement in symptoms, though many experience more immediate improvement. Examples of anti-TNF medications include:

- **Adalimumab (Humira®)** is a prescription medicine shown to bring about and maintain clinical remission in patients with moderate to severe Crohn's disease and ulcerative colitis. It is also available in a citrate-free formulation. Adalimumab is given as an injection under the skin of the abdomen or thigh.

Biosimilars to adalimumab include:

- **Adalimumab-afzb (Abrilada®)** – citrate free
- **Adalimumab-atto (Amjevita™)** – citrate free
- **Adalimumab-adbm (Cyltezo™)** – citrate free

- **Adalimumab-bwwd (Hadlima™)** – available in citrate free and citrate containing formulations
 - **Adalimumab-fkjp (Hulio®)** – citrate free
 - **Adalimumab-adaz (Hymiroz™)** – citrate free
 - **Adalimumab-aacf (Idacio®)** – citrate free
 - **Adalimumab-ryvk (Simlandi®)** – citrate free
 - **Adalimumab-aaty (Yuflyma®)** – citrate free
 - **Adalimumab-aqvh (Yusimry™)** – citrate free
- **Certolizumab pegol (Cimzia®)** is another anti-TNF used in the treatment of moderate to severe Crohn's disease. Certolizumab pegol is given as an injection under the skin of the abdomen or thigh.
 - **Golimumab (Simponi®)** is used for the treatment of patients with moderate to severe ulcerative colitis. Golimumab is given as an injection under the skin of the abdomen or thigh.
 - **Infliximab (Remicade®)** has been approved for the treatment and maintenance of remission of moderate to severe Crohn's disease and ulcerative colitis. It is also effective in healing certain fistulas (tunnels formed between intestine and other organs) and maintaining fistula closure in adult patients with fistulizing disease. It is given by an intravenous (through the veins) infusion. Biosimilars of infliximab are currently available.
 - **Infliximab-dyyb (Zymfentra®)** is a subcutaneous (given as an injection under the skin) formulation of infliximab approved for the maintenance treatment of adult patients with moderate to severe Crohn's disease and ulcerative colitis.

Biosimilars to infliximab include:

- **Infliximab-axxq (Avsola™)**
- **Infliximab-dyyb (Inflectra™)**
- **Infliximab-qbtx (IXIFI™)**
- **Infliximab-abda (Renflexis®)**

An unbranded biologic of Infliximab is also available in the market. This specific unbranded Infliximab is an exact copy of Remicade®, but not considered a biosimilar.

Integrin Receptor Antagonists

These biologics also prevent inflammation from occurring in the body, but they target different proteins in the body. Examples of this type of medication include:

- **Natalizumab (Tysabri®)** has been approved for patients with moderate to severe Crohn's disease. Natalizumab users who get an infection called John Cunningham (JC) virus, have an increased risk of a severe brain condition called progressive multifocal leukoencephalopathy (PML). It is important to be tested for JC virus prior to starting natalizumab; patients who are negative for JC virus have a much lower risk of developing PML. This drug is given by an intravenous (IV) infusion.

Biosimilars to natalizumab include:

- **Natalizumab-sztn (Tyruko®)**
- **Vedolizumab (Entyvio™)** has been approved for patients with moderate to severe Crohn's disease and ulcerative colitis. In large clinical trials, it was not associated with (PML) that is rarely observed in those using natalizumab (Tysabri®). This drug given by an intravenous (IV) infusion or subcutaneous injection for maintenance therapy following induction.

Interleukin-12 and -23 Antagonists

These biologics target specific proteins (interleukin-12 and interleukin-23) that play a key role in inflammation. Examples of this type of medication include:

IL-12/23

- **Ustekinumab (Stelara®)** has been approved for the treatment of patients with moderately to severely active Crohn's disease and ulcerative colitis. The first dose is a one-time intravenous (IV) infusion based on body weight that is given under the supervision of a health care professional. The following doses are given as an injection under the skin.

Biosimilars to ustekinumab include:

- **Ustekinumab-ttwe (Pyzchiva®)**
- **Ustekinumab-auub (Wezlana™)**
- **Ustekinumab-aekn (Selarsdi™)**
- **Ustekinumab-srlf (Imuldosa™)**

IL- 23

- **Guselkumab (Tremfya®)** is a biologic treatment approved for patients with moderate to severely active ulcerative colitis. The first doses are given by an intravenous infusion, and then can be taken as an injection under the skin.
- **Risankizumab-rzaa (Skyrizi®)** is a biologic treatment approved for patients with moderately to severely active Crohn's disease and ulcerative colitis. The first doses are given by an intravenous infusion, and then can be taken as an injection under the skin.
- **Mirikizumab-mrkz (Omvo™)** is a biologic treatment approved for patients with moderately to severely active ulcerative colitis. The first doses are given by an intravenous infusion, and then can be taken as an injection under the skin.

Risks and Special Considerations

While the benefits often far outweigh the risks of biologic medications in people with IBD, it is important to consider the following when using biologics:

- **Side effects & intolerance.** Because biologics are given by intravenous infusions or subcutaneous injections, they may produce redness, itching, bruising, pain, or swelling at the location on your body where the medication was injected. Other side effects may include: headache, fever, chills, hives and other rashes. Occasional severe allergic reactions may occur.
- **Infections.** Because biologics affect the immune system to help control IBD, this class of medication can impact your ability to fight infections and therefore, they can increase the risk of developing less common infections. While the majority of patients using biologics never experience an infection related to the medication, it is important to discuss this with your IBD specialist. To help prevent infections, patients should be up-to-date on appropriate vaccinations, including yearly influenza vaccinations, COVID-19, pneumonia vaccine, and hepatitis vaccines. If you develop any signs of infection while taking these medications, such as fever, new cough, or the flu, inform your doctor immediately.
- **Cancer Risk.** Anti-TNF medications have been associated with a small increase in the incidence of lymphoma, an uncommon cancer. The overall risk of lymphoma is very low, and this risk is also noted in patients using anti-TNF medications together with another immunosuppressant medication.

- **Liver Problems.** Biologic therapies have been rarely connected with changes in the liver. If you develop jaundice (yellowing of skin and eyes) while using biologics, inform your doctor immediately. Your liver may be checked by your doctor through laboratory tests.
- **Arthritis.** While anti-TNF medications often are effective treatments for inflammatory arthritis (joint pain), in some situations they may cause new joint pain. Notify your doctor if you are experiencing new joint discomfort while using anti-TNF medications.
- **Lupus-like reaction.** Rarely, an anti-TNF medication can cause a lupus-like reaction (LLR) which may present with symptoms such as a rash, joint pain, muscle ache, and/or fever. Talk to your doctor if these symptoms appear.
- **Skin reactions.** Rashes and anti-TNF–induced psoriasis (a condition in the skin) have been reported.
- **Other considerations.** Tell your doctor if you have any other health problems such as heart failure, hepatitis, or multiple sclerosis before taking these treatments. Your doctor will help determine if the benefits of biologics outweigh the risks in your individual situation.

On rare occasions, nervous system disorders also have been reported. Let your doctor know if you have or have had a disease that affects the nervous system, or if you experience any numbness, weakness, tingling, or visual changes while using anti-TNF medications.

Combination Therapy

In some circumstances, a health care provider may recommend adding an additional therapy that will work in combination with the initial therapy to increase its effectiveness. For example, combination therapy could include the addition of an immunomodulator to a biologic. As with all therapy, there are risks and benefits of combination therapy. Combining therapies can increase the effectiveness of IBD treatment, but there may also be an increased risk of additional side effects.. Your health care provider will identify the treatment option that is most effective for your individual health care needs.

Drug Interactions

People taking several different medicines, whether prescription or over-the-counter, should always be on the lookout for interactions between drugs. Drug interactions may affect the way it works in your body, and/or cause unexpected side effects. Before taking any medication, be sure to talk to your doctor about other medications you may be taking. Don't forget to include any over-the-counter medicines, and complementary therapies (supplements, herbals, vitamins, etc.).

Take Medications as Prescribed

The best way to control IBD is by taking medications in the dose and frequency that your doctor has prescribed it. Even during times of remission, it is important to continue taking your medications as prescribed to prevent inflammation and future flare-ups. Sticking to your medications as prescribed can also help so that the medications do not lose their effectiveness. If you are experiencing unpleasant side effects or continue to have IBD symptoms, do not stop taking your medications until speaking with your doctor. Do not make your own changes to the amount of medication or how frequently you take it, without seeking the advice of your doctor.

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October 2024