

Fact Sheet

News from the IBD Help Center

RECENTLY APPROVED TREATMENTS

The following medications recently received approval from the Food & Drug Administration (FDA). Please note that new treatments may have been approved since this document was created. Speak with your health care provider regarding these and other treatments. For descriptions of previously approved treatments, view the Crohn's & Colitis Foundation's *Understanding IBD Medications & Side Effects* brochure by visiting: www.crohnscolitisfoundation.org/brochures

SKYRIZI® (risankizumab-rzaa) June 2022

Skyrizi® is an injection medication indicated for adults with moderate to severe Crohn's disease. It is the first specific anti-interleukin 23 (IL-23) monoclonal antibody used to treat Crohn's disease.

RINVOQ® (Upadacitinib)- March 2022

Rinvoq® is an oral medication, and an inhibitor of Janus kinases (JAK's), indicated for adult patients with moderate to severe ulcerative colitis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.

Unbranded Infliximab (Infliximab) – 2022

Unbranded Infliximab is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult and pediatric patients with moderately to severely active Crohn's disease or ulcerative colitis. Unbranded Infliximab is the approved brand-name biologic (Remicade®) that is now being marketed under its approved biologics license without the brand name.

Yusimry™ (Adalimumab-aqvh) – December 2021

Yusimry™ (adalimumab-aqvh) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active Crohn's disease or ulcerative colitis. Yusimry™ is a biosimilar to Humira® and is not yet available to patients.

ZEPOSIA® (ozanimod) - May 2021

Zeposia® is an oral medication indicated for adult patients with moderate to severe active ulcerative colitis. It is the first and only oral sphingosine 1-phosphate (S1P) receptor modulator approved for ulcerative colitis.

HUMIRA® (Adalimumab) – February 2021

Humira® (adalimumab) is a tumor necrosis factor (TNF) blocker. In addition to an indication for adults, recent major changes include indications and usage for pediatric Crohn's Disease. Humira is the first and only subcutaneous biologic treatment option for patients ages five and up with moderately to severely active ulcerative colitis.

Hulio® (Adalimumab-fkjp) – July 2020

Hulio® (adalimumab-fkjp) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active Crohn's disease or ulcerative colitis who have had an inadequate response to conventional therapy. Hulio® is a biosimilar to Humira® (adalimumab). Hulio® is not yet available to patients.

Avsola™ (Infliximab-axxq) – July 2020

Avsola™ is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult and pediatric patients with moderately to severely active Crohn's disease, as well as adults with moderately to severely active ulcerative colitis, who have had an inadequate response to conventional therapy. Avsola™ is biosimilar to Remicade® (infliximab).

The advances in current IBD treatment are possible only because people before you offered to participate in clinical trials. To find out about clinical trials visit: www.crohnscolitisfoundation.org/clinical-trials-community

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