

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

ZEPOSIA® (ozanimod) - May 2021

Zeposia® is an oral medication indicated for adult patients with moderately to severely 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).

Abrilada™ (Adalimumab-afzb) – Nov 2019

Abrilada™ (adalimumab-afzb) 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. Abrilada™ is a biosimilar to Humira® (adalimumab). Abrilada™ is not yet available to patients.

HADLIMA (Adalimumab-bwwd) – July 2019

HADLIMA (adalimumab-bwwd) 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. HADLIMA is a biosimilar to Humira® (adalimumab). HADLIMA is not yet available to patients.

Hyrimoz (Adalimumab-adaz) - October, 2018

Hyrimoz™ (adalimumab-adaz) 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. Hyrimoz™ is a biosimilar to Humira® (adalimumab). Hyrimoz™ is not yet available to patients.

Xeljanz® (Tofacitinib) - May 30, 2018

Xeljanz® is an oral therapy, and an inhibitor of Janus kinases (JAK's) indicated for the treatment of adult patients with moderately to severely active ulcerative colitis. Use of Xeljanz® in combination with biological therapies for ulcerative colitis or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

IXIFI™ (Infliximab-qbtx) – December 13, 2017

IXIFI™ 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. IXIFI™ is biosimilar to Remicade® (infliximab).

CYLTEZO™ (Adalimumab-adbm) – August 29, 2017

Cyltezo™ (adalimumab-adbm) 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. Cyltezo™ is a biosimilar to Humira® (adalimumab). Cyltezo™ is not yet available to patients.

RENFLEXIS® (Infliximab-abda) – April 21, 2017

Renflexis® 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. Renflexis® is biosimilar to Remicade® (infliximab).

STELARA® (Ustekinumab) – September 26, 2016, update 2019

Stelara® (ustekinumab) is a biologic therapy indicated for the treatment of adults with moderately to severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. It targets interleukin (IL)-12 and IL-23.

AMJEVITA™ (Adalimumab-atto) – September 23, 2016

Amjevita™ (adalimumab-atto) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adults with moderately to severely active Crohn's disease and ulcerative colitis. Amjevita™ is a biosimilar to Humira® (adalimumab). Amjevita™ is not yet available to patients and will likely be available in the US market in 2023.

MESALAMINE DR 800mg – August 1, 2016

Mesalamine delayed-release tablets are indicated for the treatment of moderately active ulcerative colitis in adults. Safety and effectiveness of mesalamine delayed-release tablets beyond 6 weeks have not been established. Mesalamine DR 800mg is an authorized generic drug for Asacol®HD.

INFLECTRA™ (Infliximab-dyyb) – April 5, 2016

Inflectra™ (infliximab-dyyb) 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. Inflectra™ is biosimilar to Remicade® (infliximab).

UCERIS® (Budesonide) 2mg Rectal Foam – October 7, 2014

UCERIS® (Budesonide) rectal foam is a glucocorticosteroid indicated for the induction of remission in patients with active mild or moderate distal ulcerative colitis extending up to 40 cm for the anal verge.

ENTYVIO™ (Vedolizumab) – May 20, 2014

Entyvio™ (vedolizumab) is an integrin receptor antagonist indicated for the treatment of adult patients with moderately to severely active ulcerative colitis and Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

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

Disclaimer: *The Crohn's & Colitis Foundation provides information for educational purposes only. We encourage you to review this educational material with your health care professional. The Foundation does not provide medical or other health care opinions or services. The inclusion of another organization's resources or referral to another organization does not represent an endorsement of a particular individual, group, company or product.*

June 2021