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
HyrimozTM (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. HyrimozTM is a biosimilar to Humira® (adalimumab). HyrimozTM 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) and has been designated by the FDA as interchangeable for Humira®. 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](http://www.crohnscolitisfoundation.org/clinical-trials-community)

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