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: online.ccfa.org/brochures

**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-qbtz) – 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.

**RENFLIXIS® (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**
Stelara® (ustekinumab) is a biologic therapy indicated for the treatment of adults with moderately to severely active Crohn’s disease 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 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**
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.

**HUMIRA® (Adalimumab) – September 25, 2014**
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.

**ENTITYVIO™ (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.