CCFA 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 CCFA's *Understanding IBD Medications & Side Effects* brochure by visiting: online.ccfa.org/brochures

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). Amejevita™ is not yet available to patients and will likely be available in the US market in mid-2017.

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.

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.

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

SIMPONI® (Golimumab) – May 15, 2013
Simponi® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adults with moderately to severely active ulcerative colitis when certain other medicines have not worked well enough or cannot be tolerated.

DELZICOL™ (Mesalamine) – February 1, 2013
Delzicol™ (mesalamine) delayed-release capsules are indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis.

UCERIS™ (Budesonide) – January 14, 2013
UCERIS™ (budesonide) is a glucocorticosteroid indicated for the induction of remission in patients with mildly to moderately active ulcerative colitis.

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: http://www.ccfa.org/resources/clinical-trials-101.html

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