## **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 a listing of previously approved treatments, visit: <u>http://www.ccfa.org/assets/pdfs/understanding-ibd-meds-nov.pdf</u>

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

Indication: UCERIS® 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.

Indication: Reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

ENTYVIO<sup>™</sup> (Vedolizumab) – May 20, 2014

Indication: Entyvio  $^{TM}$  (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

Indication: Simponi<sup>®</sup> (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of adults with moderately to severely active ulcerative colitis (UC) when certain other UC medicines have not worked well enough or cannot be tolerated,

DELZICOL™ (Mesalamine) - February 1, 2013

Indication:  $Delzicol^{\mathcal{M}}$  (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

Indication: UCERIS<sup>TM</sup> (budesonide) is a glucocorticosteroid indicated for the induction of remission in patients with mildly to moderately active ulcerative colitis.

GATTEX KIT® (Teduglutide Recombinant) – December 21, 2012

Indication: GATTEX (teduglutide [rDNA origin]) is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adult patients with with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

## **GIAZO**<sup>™</sup> (Balsalazide) – November, 2012

Indication: GIAZO® (balsalazide) is indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older.

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

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