Inflectra® (infliximab-dyyb) – Expanded indication

- On June 18, 2019, the FDA approved Celltrion/Pfizer's Inflectra (infliximab-dyyb), for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy.
    - Previously, Inflectra was approved for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active UC who have had an inadequate response to conventional therapy.
- Inflectra is also approved to treat Crohn's disease in adult and pediatric patients, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.
- Inflectra is a biosimilar to Janssen's Remicade® (infliximab).
- Similar to Remicade, Inflectra carries a boxed warning for serious infections and malignancy.
- The recommended dose of Inflectra for pediatric patients 6 years and older with moderately to severely active UC is 5 mg/kg given as an intravenous induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks.
- Consult the Inflectra drug label for dosing information for all other indications.

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