Stelara™ (ustekinumab) – New Indication

- On September 26, 2016, Janssen announced the FDA approval of Stelara (ustekinumab) for the treatment of adult patients with moderately to severely active Crohn's disease (CD) who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker; or failed or were intolerant to treatment with one or more TNF blockers.

- Stelara is also FDA approved for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, and for the treatment of adult patients with active psoriatic arthritis (PsA).

    - Stelara can be used alone or in combination with methotrexate (MTX) for PsA.

- The approval of Stelara's new indication was based on data from three clinical studies of 1,756 adults with moderately to severely active CD. Two studies were 8-week intravenous (IV) induction studies followed by a 44-week subcutaneous (SC) maintenance study representing 52 weeks of therapy.

    - In the induction studies, a greater proportion of patients treated with Stelara achieved clinical response at week 6 vs. placebo [34% vs. 21% ($p < 0.01$) and 56% vs. 29% ($p < 0.001$)] and clinical remission at week 8 vs. placebo [21% vs. 7% ($p < 0.001$) and 40% vs. 20% ($p < 0.001$)].
    - In the maintenance study, a greater proportion of patients treated with Stelara achieved clinical response vs. placebo (59% vs. 44%, $p < 0.05$) and clinical remission vs. placebo (53% vs. 36%, $p < 0.01$).

- The most common adverse reaction (≥ 3%) with Stelara for induction use in patients with CD was vomiting.

- The most common adverse reactions (≥ 3%) with Stelara for maintenance use in patients with CD were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.

- The recommended IV induction dose of Stelara for CD is based on the patient's body weight. Refer to the Stelara prescribing information for details. The recommended maintenance regimen of Stelara is 90 mg SC administered 8 weeks after the initial IV dose, then every 8 weeks thereafter.

- Refer to the Stelara prescribing information for the recommended dosage regimens for all other FDA approved indications.