Stelara® (ustekinumab) – Expanded indication

- On July 29, 2022, the FDA approved Janssen's Stelara (ustekinumab), for the treatment of patients 6 years or older with active psoriatic arthritis (PsA).
    - Stelara was previously approved for this indication in adults only.
- Stelara is also approved for the treatment of patients 6 years or older with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy; for the treatment of adult patients with moderately to severely active Crohn's disease; and for the treatment of adult patients with moderately to severely active ulcerative colitis.
- The approval of Stelara for the expanded use was based on evidence from adequate and well controlled studies of Stelara in adults with psoriasis and PsA, pharmacokinetic data from adult patients with psoriasis, adult patients with PsA and pediatric patients with psoriasis, and safety data from two clinical studies in 44 pediatric patients 6 to 11 years old with psoriasis and 110 pediatric patients 12 to 17 years old with psoriasis.
    - The observed pre-dose (trough) concentrations are generally comparable between adult patients with psoriasis, adult patients with PsA and pediatric patients with psoriasis, and the pharmacokinetic exposure is expected to be comparable between adult and pediatric patients with PsA
- The recommended dose of Stelara for the treatment of patients 6 years or older with active PsA is based on body weight as shown below and administered subcutaneously at weeks 0 and 4, then every 12 weeks thereafter:

Body weight of patient at the time of dosing	Recommended dose
less than 60 kg	0.75 mg/kg
60 kg or more	45 mg
greater than 100 kg with co-existent moderate-to-severe PsO	90 mg

- Refer to the Stelara drug label for dosing for all its other indications.