

## Stelara® (ustekinumab) – Expanded indication

- On July 30, 2020, [Janssen announced the FDA approval of Stelara \(ustekinumab\)](#), for the treatment of patients 6 years or older with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
  - Previously, Stelara was approved for this same indication in patients 12 years and older.
- Stelara is also indicated for the treatment of adult patients with active psoriatic arthritis, alone or in combination with methotrexate; moderately to severely active Crohn’s disease, and moderately to severely active ulcerative colitis.
- PsO is the most common form of psoriasis in adults and children. It is an inflammatory, immune-mediated disease resulting in overproduction of skin cells which causes raised, red, scaly plaques that may be itchy or painful.
  - It is estimated that more than 8 million Americans live with the disease. About one-third of people with psoriasis first have symptoms before the age of 20 years and approximately 20,000 children under the age of 10 are diagnosed with psoriasis.
- Use of Stelara in children 6 to 11 years with moderate to severe PsO is supported by evidence from an open-label, single-arm, efficacy, safety and pharmacokinetics study in 44 subjects.
- The recommended dose of Stelara in pediatric patients (6 – 17 years old) is administered subcutaneously at weeks 0 and 4, then every 12 weeks thereafter.

Body weight of patient at the time of dosing	Recommended dose
< 60 kg	0.75 mg/kg*
60 kg to 100 kg	45 mg
> 100 kg	90 mg
* For pediatric patients weighing < 60 kg, refer to Stelara’s drug label for the administration volume for the recommended dose.	

- Refer to Stelara’s drug label for dosing recommendations for all its other indications.