

Stelara® (ustekinumab) – Expanded indication

- On July 30, 2020, <u>Janssen announced</u> the <u>FDA approval</u> of <u>Stelara (ustekinumab)</u>, 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, immunemediated 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.



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