

Stelara® (ustekinumab) - Expanded indication

- On October 13, 2017, <u>Janssen announced</u> the FDA approval of <u>Stelara (ustekinumab)</u> for adolescent patients (12 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
 - Previously, Stelara was indicated only for adult patients for this indication.
- Stelara is also indicated for adult patients with active psoriatic arthritis, alone or in combination with
 methotrexate; and moderately to severely active Crohn's disease who have failed or were intolerant
 to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor
 (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers.
- The expanded indication for Stelara was based on a placebo-controlled study conducted in 110 adolescent patients aged 12 17 years with plaque psoriasis, who were candidates for phototherapy or systemic therapy and whose disease was inadequately controlled by topical therapy. The endpoints were the proportion of patients who achieved a Physician's Global Assessment (PGA) score of cleared (0) or minimal (1), Psoriasis Area and Severity Index (PASI) 75, and PASI 90 at week 12.
 - The PGA score was achieved in 69.4% of Stelara-treated patients vs. 5.4% of placebotreated patients.
 - The PASI 75 was achieved in 80.6% of Stelara-treated patients vs. 10.8% of placebotreated patients.
 - The PASI 90 responders were 61% of Stelara-treated patients vs. 5.4% of placebo-treated patients.
- The recommended dosage of Stelara in adolescent patients for plaque psoriasis is weight based dosing given subcutaneously at weeks 0 and 4, then every 12 weeks thereafter as follows:

Body Weight at Time of Dosing	Dose
< 60 kg	0.75 mg/kg
60 kg – 100 kg	45 mg
> 100 kg	90 mg

- Consult Stelara's drug label for injection volumes of Stelara 45 mg/0.5mL single-dose vials for adolescent patients weighing < 60 kg and for dosing for adult patients for all indications.
- In adolescent patients, it is recommended that Stelara be administered by a health care provider.



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