RXADVANCE
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Stelara (ustekinumab) Injection
Clinical Update

Clinical Update: Patient Population Altered- FDA Approves Stelara (ustekinumab) for treatment of pediatric patients with moderate to severe plaque psoriasis.
FDA approval date: July 30, 2020

Stelara (ustekinumab), is the first and only biologic treatment in this patient population to target the interleukin (IL) 12/IL-23 pathways, an important therapeutic target for the condition. Stelara is now the only IL-12/IL-23 inhibitor approved in the United States for the treatment of:

1) adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

2) adult patients (18 years or older) with active psoriatic arthritis, used alone or in combination with methotrexate (MTX).

3) adult patients (18 years and older) with moderately to severely active Crohn's disease 4) adult patients (18 years and older) with moderately to severely active ulcerative colitis.

Stelara is a prescription medicine used to treat:

- adults and children 6 years and older with moderate or severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults 18 years and older with active psoriatic arthritis. Stelara can be used alone or with the medicine methotrexate.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to Stelara.

The FDA approval of Stelara for pediatric use is based on results from the CADMUS Junior study, an open-label, single-arm, multicenter phase 3 clinical trial, of 44 patients with moderate to severe plaque psoriasis in which 77 percent of patients achieved clear or almost clear skin, at week 12 after two doses. Secondary endpoints included the proportion of patients achieving 75 percent or 90 percent improvement in their Psoriasis Area and Severity Index (PASI) score at week 12 compared to baseline. Study results showed 84 percent and 64 percent of patients achieved a PASI 75 response and PASI 90 response, respectively.