Stelara® (ustekinumab)
for subcutaneous administration

FDA INDICATIONS AND USAGE[1]

STELARA® is a human interleukin-12 and -23 antagonist indicated for the treatment of:

- Adult patients with:
  - moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
  - active psoriatic arthritis (PsA).
  - moderately to severely active Crohn's disease (CD).
  - moderately to severely active ulcerative colitis.
- Pediatric patients 6 years and older with:
  - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
  - active psoriatic arthritis (PsA).

APPROVAL CRITERIA[1,2,3,4,5,6]

1. Initial Authorization Request must include:
   - Monitoring plan
   - Previous therapies trialed and the nature of the failure
   - Current weight
   - Complete medication regimen
   - Confirmation patient is **not** receiving concurrent phototherapy
   - Requested dosing which conforms to an FDA approved regimen based on indication

   Plaque psoriasis (Ps)
   1. Patient meets FDA labeled age; **AND**
   2. Has moderate to severe Ps; **AND**
   3. Has a Psoriasis Area and Severity Index (PASI) score ≥ 12 (or equivalent); **AND**
   4. Has trialed and failed a TNF blocker and at least one other therapy to include at least one topical agent.

   Psoriatic Arthritis (PsA)
   1. Patient meets FDA labeled age; **AND**
   2. Has active PsA; **AND**
   3. Has a Health Assessment Questionnaire-Disability Index (HAQ-DI) score ≥ 2 (or equivalent); **AND**
   4. Has trialed and failed a TNF blocker and at least one other therapy.

   Crohn's disease (CD)
   1. Patient meets FDA labeled age; **AND**
   2. Has moderate to severe active CD; **AND**
   3. Baseline Crohn's Disease Activity Score (CDAI) has been submitted; **AND**

4. Has trialed and failed a TNF blocker and at least one other therapy (e.g. mesalamine, sulfasalazine, corticosteroid, etc.).

Ulcerative Colitis (UC)

1. Patient meets FDA labeled age; **AND**
2. Has moderate to severely active UC; **AND**
3. Baseline Mayo score (or equivalent) has been submitted; **AND**
4. Has trialed and failed a TNF blocker and at least one other therapy (e.g. azathioprine, cyclosporine, mesalamine, etc.).

2. Reauthorization Request for use beyond 4 weeks must include:
   - A letter of medical necessity with chart notes demonstrating therapeutic benefit.
     - Baseline and current PASI score (or equivalent, for Ps).
     - Baseline and current number of tender and/or swollen joints, Health Assessment Questionnaire Disability Index (HAQ-DI) or equivalent, CRP, etc. (for PsA)
     - Baseline Crohn's Disease Activity Score (CADI) has been submitted at baseline and at 6 months of therapy.
   - Documentation of tolerance and absence of adverse events.

DENIAL CRITERIA

1. Known hypersensitivity to ustekinumab or any of its excipients.
2. Current active severe infection.
3. Concurrent therapy with an integrin antagonist or TNF blocker.
4. Concurrent phototherapy.
5. For patients initiating on therapy, PASI score < 12 (or equivalent).
6. Latex allergy (for the prefilled syringe; needle cover contains latex).

CAUTIONS[1,2]

- While approved for subcutaneous administration, initial ustekinumab doses should only be administered under the supervision of a physician. Subsequent administrations may be performed by the patient provided the physician determines that it is appropriate and the patient has received training and demonstrated competency in self-administration. Close monitoring and adequate follow-up is required in both circumstances for the safety of the patient.
- Patients must be monitored for new or worsening neurological issues due to the risk of reversible posterior leukoencephalopathy syndrome (RPLS).
- Live vaccines should not be administered while patients are receiving ustekinumab unless determined that the benefit outweighs the risk.
- Patients should be advised to avoid excessive exposure to ultraviolet light and should be monitored for new skin growths.
- Patients on other therapies that are metabolized through the CYP450 pathway, especially those therapies with a narrow therapeutic index, should be monitored for therapeutic effect while taking ustekinumab.
- Refer to the prescribing information and medication guide for complete information.

DURATION OF APPROVAL

- Initial Approval: 4 weeks (Injections at 0 and 4 weeks)
- Reauthorization Approval: up to 12 months (Injections at week 16 and beyond at twelve week intervals)

QUANTITY LIMIT

- 45 mg per dose; weight up to 100 kg
- 90 mg per dose; weight greater than 100 kg for Plaque Psoriasis indications
- 90 mg per dose; Crohn's Disease and Ulcerative Colitis after initial IV infusion.

NOTES[1,2,3]

Ustekinumab is a human IgG1 antibody which acts as an interleukin antagonist to IL-12 and IL-23. The binding of the p40 subunit used by IL-12 may increase a patient's malignancy risk.

REFERENCES / FOOTNOTES:

1. Stelara® [package insert]. Horsham, PA; Janssen Biotech, Inc., March 2024.
2. Certolizumab pegol (Cimzia) and ustekinumab (Stelara) for psoriatic arthritis. *Med Lett Drugs Ther*. 2014;56(1435):10.
3. Ustekinumab (Stelara) for psoriasis. *Med Lett Drugs Ther*. 2014;52(1330):7-8.
4. Ustekinumab for the treatment of adults with moderate to severe psoriasis. NICE technology appraisal guidance 180. Issued September 2009. Available at www.nice.org.uk/guidance/ta180.
5. Menter A, Gottlieb A, Feldman SR et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008;58:826-850. doi:10.1016/j.jaad.2008.02.039.
6. Gottlieb A, Korman NJ, Gordon KB *et al*. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on biologics. *J Am Acad Dermatol*. 2008;58:851-864. doi: 10.1016/j.jaad.2008.02.040.