ALASKA MEDICAID
Prior Authorization Criteria

Stelara® (ustekinumab)
for subcutaneous administration

FDA INDICATIONS AND USAGE[1]

- Moderate to severe plaque psoriasis (Ps):
  - For adult patients who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis (PsA):
  - For adult patients used alone or in combination with methotrexate.

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

   Plaque psoriasis (Ps)
   1. Patient is ≥ 18 years of 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 is ≥ 18 years of 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.

   Dosing requested conforms with the following FDA approved regimens based on indication:

	Weight	
	≤ 100 kg (220 lbs)	**> 100 kg (220 lbs)**
Plaque Psoriasis *(moderate to severe)*		
Weeks 0, 4	45 mg	90 mg
Every 12 weeks	45 mg	90 mg
Psoriatic Arthritis + Plaque Psoriasis *(co-existent moderate to severe)*		
Weeks 0, 4	45 mg	90 mg
Every 12 weeks	45 mg	90 mg
Psoriatic Arthritis		
Weeks 0, 4	45 mg	45 mg
Every 12 weeks	45 mg	45 mg

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)
   - Documentation of tolerance and absence of adverse events.

DENIAL CRITERIA

1. Known hypersensitivity to ustekinumab or any of its excipients.
2. Age < 18 years.
3. Current active severe infection.
4. Concurrent therapy with an integrin antagonist or TNF blocker.
5. Concurrent phototherapy.
6. For patients initiating on therapy, PASI score < 12 (or equivalent).
7. 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.
- REMS information on serious infection, malignancy, and RPLS risks associated with Stelara® is available at: www.stelararems.com

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

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 2014.
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.