ALASKA MEDICAID
Prior Authorization Criteria

Stelara® (ustekinumab)
for subcutaneous administration

FDA INDICATIONS AND USAGE

- 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 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:

<table>
<thead>
<tr>
<th></th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 100 kg (220 lbs)</td>
</tr>
<tr>
<td><strong>Plaque Psoriasis</strong></td>
<td></td>
</tr>
<tr>
<td>(moderate to severe)</td>
<td></td>
</tr>
<tr>
<td>Weeks 0, 4</td>
<td>45 mg</td>
</tr>
<tr>
<td>Every 12 weeks</td>
<td>45 mg</td>
</tr>
</tbody>
</table>

| **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             |                   |
| Every 12 weeks           | 45 mg             | 45 mg             |

Stelara® Criteria
Version: 2
Original: 11/14/2014
Approval: 11/21/2014
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. 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.
2. Patients must be monitored for new or worsening neurological issues due to the risk of reversible posterior leukoencephalopathy syndrome (RPLS).
3. Live vaccines should not be administered while patients are receiving ustekinumab unless determined that the benefit outweighs the risk.
4. Patients should be advised to avoid excessive exposure to ultraviolet light and should be monitored for new skin growths.
5. 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.
6. Refer to the prescribing information and medication guide for complete information.
7. REMS information on serious infection, malignancy, and RPLS risks associated with Stelara® is available at: www.stelararems.com

DURATION OF APPROVAL
1. Initial Approval: 4 weeks (Injections at 0 and 4 weeks)
2. Reauthorization Approval: up to 12 months (Injections at week 16 and beyond at twelve week intervals)

QUANTITY LIMIT
1. 45 mg per dose; weight up to 100 kg
2. 90 mg per dose; weight greater than 100 kg for Plaque Psoriasis indications
NOTES\textsuperscript{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:

2. Certolizumab pegol (Cimzia) and ustekinumab (Stelara) for psoriatic arthritis. Med Lett Drugs Ther. 2014;56(1435):10.