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 ≥ 12 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.

Crohn’s disease (CD)
1. Patient is ≥ 18 years of age; **AND**
2. Has moderate to severe active CD; **AND**
3. Baseline Crohn’s Disease Activity Score (CADI) has been submitted at baseline; **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>Weight</th>
<th>≤ 100 kg (&lt;220 lbs)</th>
<th>&gt; 100 kg (&gt;220 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plaque Psoriasis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(moderate to severe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weeks 0, 4</td>
<td>45 mg</td>
<td>90 mg</td>
</tr>
<tr>
<td>Every 12 weeks</td>
<td>45 mg</td>
<td>90 mg</td>
</tr>
<tr>
<td><strong>Psoriatic Arthritis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ Plaque Psoriasis (co-existent moderate to severe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weeks 0, 4</td>
<td>45 mg</td>
<td>90 mg</td>
</tr>
<tr>
<td>Every 12 weeks</td>
<td>45 mg</td>
<td>90 mg</td>
</tr>
<tr>
<td><strong>Psoriatic Arthritis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weeks 0, 4</td>
<td>45 mg</td>
<td>45 mg</td>
</tr>
<tr>
<td>Every 12 weeks</td>
<td>45 mg</td>
<td>45 mg</td>
</tr>
<tr>
<td><strong>Crohn’s Disease</strong></td>
<td>&lt;55kg</td>
<td>55-85kg</td>
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<tr>
<td>Week 0</td>
<td>260 mg IV</td>
<td>390 mg IV</td>
</tr>
<tr>
<td>Every 8 Weeks</td>
<td>90 mg</td>
<td>90 mg</td>
</tr>
</tbody>
</table>

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. Age < 18 years for Psoriatic Arthritis and Crohn’s Disease and < 12 years for Plaque Psoriasis.
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\(^\circledast\) 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
- 90 mg per dose; Crohn’s Disease 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:

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