Stelara® (ustekinumab)

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Date of Origin: 02/15/2011

I. Length of Authorization

**Crohn’s Disease:**
Coverage will be provided for 8 weeks initially and may be renewed in 6 month intervals thereafter.

**All other indications:**
Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. **Quantity Limit (max daily dose) [Pharmacy Benefit]:**
   - Stelara 45 mg vial/prefilled syringe:
     - Loading: 1 syringe at weeks 0 & 4
     - Maintenance: 1 syringe every 12 weeks
   - Stelara 90 mg prefilled syringe:
     - Loading: 1 syringe at weeks 0 & 4
     - Maintenance: 1 syringe every 8 weeks
   - Stelara 130 mg (5 mg/mL) single-dose vial: 4 vials

B. **Max Units (per dose and over time) [Medical Benefit]:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Max Units</th>
</tr>
</thead>
</table>
| Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis | **Subcutaneous Loading (J3357):**
- 90 billable units at weeks 0 & 4; maintenance dosing 12 weeks later
**Subcutaneous Maintenance (J3357):**
- 90 billable units every 12 weeks              |
| Psoriatic Arthritis                             | **Subcutaneous Loading (J3357):**
- 45 billable units at weeks 0 & 4; maintenance dosing 12 weeks later
**Subcutaneous Maintenance (J3357):**
- 45 billable units every 12 weeks              |
| Crohn’s Disease                                | **Intravenous Induction (Q9989):**
- 520 billable units (520 mg)                    |
**Subcutaneous Maintenance (J3357):**
- 90 billable units 8 weeks after induction & every 8 weeks thereafter |
III. Initial Approval Criteria

- Self-administered injectable medications are not covered when supplied in a provider’s office, clinic or facility.

Coverage is provided in the following conditions:

- Adult patient (18 years or older); AND
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
- Patient is free of any clinically important active infections; AND
- Stelara will not be administered concurrently with live vaccines; AND
- Patient is not on concurrent treatment with any other biological response modifier or biologic DMARD; AND

Plaque Psoriasis †

- Patient has Moderate to severe plaque psoriasis for at least 6 months with at least 1 of the following:
  - Involvement of at least 10% of body surface area (BSA); OR
  - Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR
  - Incapacitation due to plaque location (i.e. head and neck, palms, soles or genitalia); AND
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial to topical agents (i.e. anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues); AND
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least 1 systemic agent (i.e. immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (i.e. psoralens with UVA light (PUVA) or UVB with coal tar or dithranol)

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Enbrel AND Humira; OR
- Patient is continuing treatment

Psoriatic Arthritis (PsA) †

- Documented moderate to severe active disease; AND
  - For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
  - For patients with peripheral arthritis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Enbrel AND Humira: OR
• Patient is continuing treatment

**Crohn’s Disease †**

• Documented moderate to severely active disease: AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate): AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, certolizumab, or infliximab)

• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Humira: OR
• Patient is continuing treatment

† FDA Approved Indication(s)

**IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:

• Patient continues to meet criteria identified in section III: AND
• Absence of unacceptable toxicity from the drug: Examples of unacceptable toxicity include the following: serious infections, reversible posterior leukoencephalopathy syndrome (RPLS), etc: AND
• Patient is receiving ongoing monitoring for presence of TB or other active infections: AND

**Plaque Psoriasis**

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement.

**Psoriatic Arthritis (PsA)**

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts.

**Crohn’s Disease**

• Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extraintestinal complications, and use of anti-diarrheal drugs.
V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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</table>
| Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis | **Subcutaneous Loading Dose:**  
  • <100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later  
  • >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later  

<table>
<thead>
<tr>
<th></th>
<th><strong>Subcutaneous Maintenance Dose:</strong></th>
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<tbody>
<tr>
<td></td>
<td>• &lt;100 kg: 45 mg every 12 weeks</td>
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<td>• &gt;100 kg: 90 mg every 12 weeks</td>
</tr>
</tbody>
</table>

| Psoriatic Arthritis                     | **Subcutaneous Loading Dose:**  
  • 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later  

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<th><strong>Subcutaneous Maintenance Dose:</strong></th>
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<tr>
<td></td>
<td>• 45 mg every 12 weeks</td>
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| Crohn’s Disease                        | **Intravenous Induction Dose:**  
  • ≤ 55 kg: 260 mg  
  • > 55 kg to 85 kg: 390 mg  
  • > 85 kg: 520 mg  

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<th><strong>Subcutaneous Maintenance Dose:</strong></th>
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<tr>
<td></td>
<td>• 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter</td>
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VI. Billing Code/Availability Information

Jcode:
- J3357 – Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg
- Q9989 – Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg

NDC:
- Stelara 45 mg vial and prefilled syringe: 57894-0060-xx
- Stelara 90 mg prefilled syringe: 57894-0061-xx
- Stelara 130 mg (5 mg/mL) single-dose vial: 57894-0054-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>K50.00</td>
<td>Crohn’s disease of small intestine without complications</td>
</tr>
<tr>
<td>K50.011</td>
<td>Crohn’s disease of small intestine with rectal bleeding</td>
</tr>
<tr>
<td>K50.012</td>
<td>Crohn’s disease of small intestine with intestinal obstruction</td>
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<tr>
<td>K50.013</td>
<td>Crohn’s disease of small intestine with fistula</td>
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<tr>
<td>K50.014</td>
<td>Crohn’s disease of small intestine with abscess</td>
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<tr>
<td>K50.018</td>
<td>Crohn’s disease of small intestine with other complication</td>
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<td>K50.019</td>
<td>Crohn’s disease of small intestine with unspecified complications</td>
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<td>K50.10</td>
<td>Crohn’s disease of large intestine without complications</td>
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<td>K50.111</td>
<td>Crohn’s disease of large intestine with rectal bleeding</td>
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<tr>
<td>K50.112</td>
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<tr>
<td>K50.113</td>
<td>Crohn’s disease of large intestine with fistula</td>
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<tr>
<td>K50.114</td>
<td>Crohn’s disease of large intestine with abscess</td>
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<td>ICD-10</td>
<td>ICD-10 Description</td>
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<tr>
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<tr>
<td>K50.118</td>
<td>Crohn’s disease of large intestine with other complication</td>
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<td>K50.119</td>
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<td>K50.80</td>
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<td>K50.811</td>
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<td>K50.812</td>
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<tr>
<td>K50.814</td>
<td>Crohn’s disease of both small and large intestine with abscess</td>
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<td>K50.818</td>
<td>Crohn’s disease of both small and large intestine with other complication</td>
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<td>K50.819</td>
<td>Crohn’s disease of both small and large intestine with unspecified complications</td>
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<tr>
<td>K50.90</td>
<td>Crohn’s disease, unspecified, without complications</td>
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<td>K50.911</td>
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<tr>
<td>K50.912</td>
<td>Crohn’s disease, unspecified, with intestinal obstruction</td>
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<td>K50.913</td>
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<td>L40.0</td>
<td>Psoriasis vulgaris</td>
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<td>L40.50</td>
<td>Arthropathic psoriasis, unspecified</td>
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<td>Psoriatic arthritis mutilans</td>
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<td>Psoriatic spondylitis</td>
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<td>L40.59</td>
<td>Other psoriatic arthropathy</td>
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**Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

**Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A**

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<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
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<td>Jurisdiction</td>
<td>Applicable State/US Territory</td>
<td>Contractor</td>
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<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Cahaba Government Benefit Administrators, LLC</td>
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<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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</tbody>
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