Overview
Ustekinumab is a monoclonal antibody that binds to and interferes with proinflammatory cytokines, interleukin (IL)-12 and IL-23. Ustekinumab also interferes with the expression of monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor-alpha, interferon-inducible protein-10 and interleukin (IL)-8 resulting in reduction of these proinflammatory signalers.

Approved Indications
1. Moderate to severe plaque psoriasis
2. Active psoriatic arthritis
3. Moderately to severely active Crohn’s disease
4. Moderately to severely active Ulcerative colitis (UC)
5. Moderate to severe hidradenitis suppurativa (HS) – off label indication

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Stelara excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Psoriatic Arthritis (PsA)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
   b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
3. Appropriate dosing

**NOTE:** DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs

**Moderate to Severe Plaque Psoriasis**

Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B)
      i. topical agent
      ii. phototherapy
      iii. systemic agent
   b. Contraindication to **ALL** conventional therapies:
      i. topical agents
      ii. phototherapy
      iii. systemic agents
   c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

**Moderate to Severe Crohn’s disease**

Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for Crohn’s disease
   b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for Crohn’s disease
3. Appropriate dosing

**Moderate-to-severe Ulcerative colitis**

Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for ulcerative colitis
   b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for ulcerative colitis
3. Appropriate dosing

**Continuation of Therapy**

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, an approved indication and appropriate dosing.
Limitations
1. Initial approvals will be granted for:
   a. Plaque Psoriasis: 3 months.
   b. All other diagnosis: 6 months.
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stelara Inj 5mg/mL</td>
<td>4 vials per 56 days</td>
</tr>
<tr>
<td>Stelara Inj 45mg/0.5mL</td>
<td>1 unit per 12 weeks</td>
</tr>
<tr>
<td>Stelara Inj 90mg/mL</td>
<td>1 unit per 8 weeks</td>
</tr>
</tbody>
</table>

Appendix:
Appendix A: Dosing

<table>
<thead>
<tr>
<th>Stelara® (ustekinumab)</th>
<th>Crohn’s Disease:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Patients ≤ 55 kg</strong></td>
</tr>
<tr>
<td></td>
<td>260 mg (2 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks</td>
</tr>
<tr>
<td></td>
<td><strong>Patients 55-85 kg</strong></td>
</tr>
<tr>
<td></td>
<td>390 mg (3 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks</td>
</tr>
<tr>
<td></td>
<td><strong>Patients &gt; 85 kg</strong></td>
</tr>
<tr>
<td></td>
<td>520 mg (4 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks</td>
</tr>
</tbody>
</table>

| Plaque Psoriasis:       | **Patients ≤ 100 kg (220 lbs.)**                               |
|                        | 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks |
|                        | **Patients > 100 kg (220 lbs.)**                               |
|                        | 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks |

| Psoriatic Arthritis:    | 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks |

| Plaque Psoriasis AND Psoriatic Arthritis in Patient >100 kg (220 lbs.): | 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks |

| Ulcerative Colitis:     | **A single intravenous infusion using weight-based dosing:** Weight Range (kilogram) |
|                        | **Recommended Dosage for patients up to 55 kg 260 mg (2 vials)** |
|                        | **Patients greater than 55 kg to 85 kg 390 mg (3 vials)** |
|                        | **Patients greater than 85 kg 520 mg (4 vials)** |
Appendix B. Conventional Therapies for Plaque Psoriasis

<table>
<thead>
<tr>
<th>Conventional Treatment Lines</th>
<th>Agents Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical Agents</td>
<td>emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors</td>
</tr>
<tr>
<td>Systemic Agents</td>
<td>Traditional DMARDs: methotrexate, apremilast, acitretin,</td>
</tr>
<tr>
<td>Phototherapy</td>
<td>ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)</td>
</tr>
</tbody>
</table>

Appendix C: Off-Label Indications

Moderate to severe hidradenitis suppurativa (HS)

Prescriber provides documentation of ALL of the following:

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)
2. Paid claims or physician documented inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
4. Dosing of Stelara: 45 to 90mg every 12 weeks

References


Review History
04/05/10 – Implemented
02/22/10 – Reviewed
02/28/11 – Reviewed
02/27/12 – Reviewed
02/25/13 – Reviewed
02/24/14 – Reviewed
02/23/15 – Reviewed
02/22/16 – Reviewed
02/27/17 – Updated (adopted SGM & Step)
02/26/18 – Updated
03/01/18 – Updated (Adopted MH RS)
02/20/19 – Updated
11/20/19 – Updated (added new UC indication)

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.