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.

FDA-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)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines
Approval may be granted for members who meet the following diagnosis specific criteria:

Psoriatic arthritis (PsA):
1. Member is at least 18 years of age AND
2. Member has a diagnosis of PsA AND
3. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
   b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication AND
4. Dosing is appropriate (see appendix A)

**Moderate-severe plaque psoriasis:**
1. Member has a diagnosis of moderate-severe plaque psoriasis AND
2. Member is at least 12 years of age AND
3. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
      i. 1 topical agent + 1 systemic agent
      ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
      iii. 1 systemic agent + 1 phototherapy
      iv. 2 systemic agents
   b. Contraindication to ALL conventional therapies
      i. Topical agents
      ii. Phototherapy
      iii. Systemic agents
   c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis AND
4. Dosing is appropriate (see appendix A)

**Moderate-severe Crohn’s disease:**
1. Member is at least 18 years of age AND
2. Member has a diagnosis of moderate-severe Crohn’s disease AND
3. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
      i. Aminosalicylate
      ii. Antibiotic
      iii. Corticosteroid
      iv. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate AND
4. Prescriber has provided documentation of ONE of the following:
   a. 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
5. Dosing is appropriate (see appendix A)

*If a request documents severe disease, a trial of an oral immunomodulator may be bypassed*

**Ulcerative colitis**
1. Member is at least 18 years of age AND
2. Member has a diagnosis of Ulcerative Colitis AND
3. Member has had an adverse reaction to one biologic DMARD that is FDA-approved for ulcerative colitis; OR
4. Member has had an inadequate response, adverse reaction, or contraindication to all of the following:
   a. an aminosalicylate; AND
b. a corticosteroid; **AND**
c. an immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate).

**Continuation of Therapy**
Reauthorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

**Limitations**
1. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
   a. Note: Members who have received Stelara or any other biologic DMARD or targeted synthetic DMARD (e.g. Xeljanz) are exempt from requirements related to TB screening in this Policy.
2. Stelara for intravenous administration is FDA-approved for the treatment of Crohn’s disease and Ulcerative and will only be authorized for one loading dose for this condition

**Appendix A:**

<table>
<thead>
<tr>
<th>Stelara® (ustekinumab)</th>
<th><strong>Crohn’s Disease:</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Patients ≤ 55 kg</strong></td>
<td>260 mg (2 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks</td>
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<tr>
<td><strong>Patients 55-85 kg</strong></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><strong>Patients &gt; 85 kg</strong></td>
<td>520 mg (4 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks</td>
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</tbody>
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<tr>
<th><strong>Plaque Psoriasis:</strong></th>
<th><strong>Patients ≤ 100 kg (220 lbs.)</strong></th>
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</thead>
<tbody>
<tr>
<td>45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Patients &gt; 100 kg (220 lbs.)</strong></td>
<td>90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks</td>
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</table>

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

| **Co-existent 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).
Followed by a subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then 90mg every 8 weeks thereafter

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
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.