STELARA (USTEKinumAb)

Products Affected

- STELARA SUBCUTANEOUS SOLUTION
  PREFILLED SYRINGE

<table>
<thead>
<tr>
<th>PA Criteria</th>
<th>Criteria Details</th>
</tr>
</thead>
</table>
| **Covered Uses**| *Treatment of adult patients with moderate to severe plaque psoriasis (PP) who are candidates for phototherapy or systemic therapy.  
   *Active psoriatic arthritis (PsA), alone or in combination with methotrexate.  
   *Treatment of adult patients with active moderate to severe Crohn’s disease who have failed/ intolerant to treatment with immunomodulators, corticosteroids, but never failed treatment with a tumor necrosis factor blocker.  
   *Treatment of adult patients with active moderate to severe Crohn’s disease who failed or were intolerant to treatment with 1 or more tumor necrosis factor blockers. |
| **Exclusion Criteria** | N/A                                                                                                                                               |
| **Required Medical Information** | *Patient must have a negative tuberculosis test or received treatment if tested positive.  
   *Crohn’s disease:  
   *Clinically diagnosed with Crohn’s disease.  
   *Failed, intolerant or contraindicated to at least one of the following: a DMARD (such as azathioprine, methotrexate, 6-mercaptopurine, cyclosporine, corticosteroids) OR an aminosalicylate (such as sulfasalazine, mesalamine, olsalazine, balsalazide)  
   *Failed, intolerant or contraindicated to Humira  
   *Plaque Psoriasis:  
   *Clinically diagnosed with plaque psoriasis involving greater than 10% of body surface area.  
   *Failed, intolerant or contraindicated to at least one of the following: phototherapy, methotrexate, cyclosporine, or acitretin.  
   *Psoriatic Arthritis:  
   *Clinically diagnosed with psoriatic arthritis.  
   *Failed, intolerant or contraindicated to at least one DMARD (such as methotrexate, leflunomide, azathioprine).  
   *Rheumatoid Arthritis:  
   *Clinically diagnosed with rheumatoid arthritis.  
   *Failed, intolerant or contraindicated to at least one DMARD (such as methotrexate, leflunomide, azathioprine). |
<table>
<thead>
<tr>
<th><strong>PA Criteria</strong></th>
<th><strong>Criteria Details</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>hydroxychloroquine, sulfasalazine, methotrexate, leflunomide).</td>
<td></td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>*Must be 18 years of age and older</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>*Must be prescribed by a rheumatologist, gastroenterologist or dermatologist.</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>*1 year</td>
</tr>
</tbody>
</table>
| **Other Criteria** | Approved dosing for Psoriatic Arthritis  
| | *Stelara 45mg prefilled syringe:  
| | *Loading: 1 syringe at weeks 0 & 4  
| | *Maintenance: 1 syringe every 12 weeks  
| | *Stelara 90mg (for patients with moderate to severe psoriatic arthritis & weighing over 100kg) prefilled syringe:  
| | *Loading: 1 syringe at weeks 0 & 4  
| | *Maintenance: 1 syringe every 12 weeks  
| | *Approved dosing for Psoriasis:  
| | * Stelara 45mg(patients weighing 100kg or less) prefilled syringe:  
| | *Loading: 1 syringe at weeks 0 & 4  
| | *Maintenance: 1 syringe every 12 weeks  
| | *Stelara 90mg (patients weighing 100kg or more) prefilled syringe:  
| | *Loading: 1 syringe at weeks 0 & 4  
| | *Maintenance: 1 syringe every 12 weeks  
| | *Approved dosing for Crohn’s disease:  
| | * Stelara: IV  
| | *Loading (single infusion at week 0):  
| | *260mg (for patients weighing 55 kg or less)  
| | *390mg (for patients weighing 55kg-85kg)  
| | *520mg (for patients weighing more than 85kg)  
| | *Stelara PFS:  
| | *Maintenance: 90mg (prefilled syringe) every 8 weeks continuation of therapy criteria:  
| | *Patient is tolerating treatment.  
| | *Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient's condition).  
| | *Dosing must be consistent with approved FDA dosing for Psoriasis, Psoriatic Arthritis and Crohn’s disease.  
| | *Benefit Type: Pharmacy/Medical  
| | *Adopted: 03/10/10  
<p>| | *Reviewed:6/14/17: updated FDA indications, criteria for use, |</p>
<table>
<thead>
<tr>
<th>PA Criteria</th>
<th>Criteria Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>continuation of therapy, added approval duration &amp; benefit type, removed contraindications, cautions and special considerations; 9/13/17: added dermatologist for plaque psoriasis prescriber, added involving BSA requirement for psoriatic arthritis; added FDA approved dosing; 2/14/18: removed failure of Humira and Enbrel from PP &amp; PSA.</td>
</tr>
</tbody>
</table>