Effective Date: 08/09/2018

Stelara® (ustekinumab)

FDA approval: Subcutaneous – September 25, 2009; Intravenous - September 26, 2016
HCPCS: Subcutaneous – J3357; Intravenous – J3358, C9487
Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

I. Coverage is provided for the following diagnoses:
   A. For treatment of psoriasis, ALL of the following criteria must be met:
      1) Chart notes support a diagnosis of chronic plaque psoriasis involving at least 10% of the body surface area or causes significant functional disability
      2) Prescribed by or in consultation with a dermatologist
      3) Treatment with phototherapy or photochemotherapy was ineffective, contraindicated, or not tolerated
      4) Treatment with at least one oral systemic agent for psoriasis was ineffective or not tolerated, unless all are contraindicated. Examples of systemic agents include, but are not limited to, cyclosporine, methotrexate, and acitretin
      5) Patient may not use Stelara in combination with other biologics (eg. Enbrel, Humira, Cimzia, Simponi, Remicade, Kineret)

   B. Psoriatic arthritis: treatment of adult patients with active psoriatic arthritis when the all of the following criteria is met:
      1) Prescribed by or in consultation with a dermatologist or rheumatologist
      2) Treatment with one nonbiologic DMARD is not tolerated or is ineffective after at least 12 weeks treatment at a target therapeutic dose. Examples of DMARDs include: sulfasalazine, methotrexate, cyclosporine, and leflunomide.

   AND

   C. Crohn’s Disease: treatment of adult patients with active Crohn’s disease when the following criteria is met:
      1) Medication is prescribed by, or in consultation with a gastroenterologist
      2) Conventional therapy (examples: corticosteroids, immunomodulator) has been ineffective, contraindicated or not tolerated based on clinical documentation
      3) Must start therapy with appropriate dose of intravenous Stelara based on body weight

II. Approval Lengths and Quantity Limits:
   1) Plaque Psoriasis/Psoriatic arthritis Quantity Limit:
      a. If prior authorization is approved, coverage of Stelara will be authorized for 3 months initially as follows:

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Therapeutic considerations:

2) Crohn’s Disease Quantity Limit:
   a. Intravenous: FDA approved dosing based on patient’s weight
      i. Authorization will be a one-time approval for one month duration to allow the patient to receive
         the infusion
   b. Subcutaneous (SC): FDA approved dosing
      ii. To be started 8 weeks after intravenous dosing
         iii. 90 mg SC every 8 weeks

3) Plaque Psoriasis Continuation Criteria:
   a. Continuation of coverage requires documentation of beneficial clinical response to Stelara defined
      as achieving a PASI 75 response or equivalent response such as greater than 50% reduction in
      Body Surface Area (BSA) covered by psoriasis compared to baseline
   b. Authorization will cover 1 syringe every 84 days

4) Psoriatic arthritis Continuation Criteria:
   a. Authorization may be reviewed at least annually to confirm that current medical necessity criteria
      are met and that the medication is effective

5) Crohn’s Disease Continuation Criteria:
   A. Subcutaneous: Authorization will be reviewed annually thereafter to assess treatment response:
      a. Achieves clinical response to symptoms
      b. Achieves remission

III. Stelara is considered investigational for all other clinical conditions including, but not limited to:
   1) Ankylosing Spondylitis
   2) Multiple Sclerosis
   3) Ulcerative Colitis

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage
Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid
Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based
on medically accepted indications which have supported citations included or approved for inclusion determined by CMS
approved compendia

Therapeutic considerations:

A. FDA approved indication / Diagnosis
   a. Treatment of adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic
      therapy
   b. Treatment of adults with active psoriatic arthritis (as monotherapy or in combination with methotrexate).
   c. For the treatment of moderately to severely active Crohn’s disease in adults (18 years or older) who have failed
      or were intolerant to treatment with immunomodulators or corticosteroids but never failed treatment with a tumor
      necrosis factor (TNF) blocker, or who failed or were intolerant to treatment with one or more TNF blockers.

*Please refer to most recent prescribing information.

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intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.
B. Background Information
Stelara® is a monoclonal antibody that inhibits interleukin (IL)-12 and IL-23. It has shown to be safe and effective for the treatment of psoriasis, psoriatic arthritis, and Crohn's disease.

C. Efficacy

*Please refer to most recent prescribing information.

D. Medication Safety Considerations
Box Warning: No

*Please refer to most recent prescribing information.

E. Dosing and administration

*Please refer to most recent prescribing information.

F. How supplied
a. 45 ml single use prefilled syringe
b. 90 ml single use prefilled syringe
c. 130 mg/26 mL (5 mg/mL) solution in a single-dose vial

References:
1) Stelara ® [prescribing information]. Horsham, PA: Centocor Ortho Biotech Inc.; September, 2016
Policy History

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<tr>
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<th>Change Description</th>
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<tr>
<td>1.0</td>
<td>Effective: 10/2010</td>
<td>New Policy</td>
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<tr>
<td>1.1</td>
<td>Effective: 7/10/2012</td>
<td>Criteria Updates</td>
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<td>1.3</td>
<td>Effective: 8/8/2013</td>
<td>Criteria updates, include self-injectable</td>
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<td>1.4</td>
<td>Effective 02/06/2014</td>
<td>criteria update to include psoriatic arthritis</td>
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<td>1.5</td>
<td>Effective 01/01/2016</td>
<td>Document updated with specified drugs required</td>
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<tr>
<td>1.6</td>
<td>Effective Date: 9/26/16</td>
<td>FDA approval Stelara Intravenous/Crohns</td>
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<td>1.7</td>
<td>Effective Date: 02/09/2017</td>
<td>FDA approval Stelara Intravenous/Crohns</td>
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<td>1.8</td>
<td>Effective Date: 03/23/2017</td>
<td>Criteria updated for preferred biologics based on current contracting</td>
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<td>1.9</td>
<td>Effective Date: 08/10/2017</td>
<td>Take off steps for medical only and annual review</td>
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<tr>
<td>2.0</td>
<td>Effective Date: 08/09/2018</td>
<td>Annual Review of Medical Policy</td>
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<tr>
<td>2.1</td>
<td>Effective Date: 08/28/18</td>
<td>Updated the QL for psoriasis/psoriatic arthritis indication in patients weighing &gt;100kg to reflect prescribing information recommendations; did not take to P&amp;T since we are being less restrictive</td>
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm)