Stelara (ustekinumab)

Line(s) of Business: HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date:
10/01/2015

Current Effective Date:
01/01/201805/01/2019

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Active psoriatic arthritis (PsA)
- Moderate to severe plaque psoriasis (PsO)
- Moderately to severely active Crohn’s disease (CD)

Stelara for intravenous administration is FDA-approved for the treatment of Crohn’s disease and will only be authorized for this condition.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:

- For psoriasis, the following documentation is required:
  - Initial authorization of therapy
    - Documentation supporting a history of plaque psoriasis for longer than six months
    - Percent of body surface area involvement
    - Documentation supporting if there are crucial body areas affected (e.g. hands, feet, face, neck, scalp, etc.)
    - Results of treatment with methotrexate such as ineffective treatment or intolerance, or documentation that methotrexate is contraindicated
  - For Continuation of therapy
    - Documentation in member’s chart or medical record supporting a decrease in percent of body surface area involvement when compared to baseline

- For Crohn’s disease, prescribers will be asked to fill in the member’s Crohn’s Disease Activity Index (CDAI) at baseline and after 6 months of therapy

C. CRITERIA FOR INITIAL APPROVAL

1. Active psoriatic arthritis (PsA)
   Initial authorization of 6 months may be granted for members who are 18 years of age or older who meet the following criteria:
   i. Member has been diagnosed with active PsA, and meets ANY of the following:
2. **Moderate to severe chronic plaque psoriasis**
   Initial authorization of 6 months may be granted for members who are 12 years of age or older who meet ALL of the following criteria:
   i. Treatment with Stelara was recommended by a dermatologist
   ii. Member has been diagnosed with moderate to severe chronic plaque psoriasis defined as the following
      o At least 10% of body surface area (BSA) is affected, or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected, and
      o History of psoriasis 6 months or longer
   iii. Plaque psoriasis is characterized by well-defined patches of red and raised skin
   iv. Member has tried methotrexate for at least 3 months at a therapeutic dose and found it to be ineffective, or the member exhibited intolerance or allergy, or the use of methotrexate is contraindicated.
      o Ineffective treatment is defined as symptoms and/or signs that are not resolved after completion of treatment at the recommended therapeutic dose and duration. If there is no recommended treatment time, the member must have had a meaningful trial.
      o Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.
      o Allergy is defined as a state of hypersensitivity produced by exposure to a particular antigen resulting in harmful immunologic reactions on subsequent exposures. The most common symptoms are skin rash or anaphylaxis.

3. **Moderately to severely active Crohn’s disease (CD)**
   Initial authorization of 6 months may be granted for members who are 18 years of age or older who meet the following criteria:
   i. Member has been diagnosed with moderately to severely active Crohn’s disease (CD)
   ii. Member has a pre-treatment Crohn’s Disease Activity Index (CDAI) score ≥ 220 or member has fistulizing disease
   iii. Member meets ANY of the following:
      a) Member experienced an inadequate response to a tumor necrosis factor (TNF) blocker
      b) Member has a history of intolerance to a TNF blocker
      c) Member experienced an inadequate response to immunomodulators or corticosteroids
      d) Member has a history of intolerance to immunomodulators or corticosteroids

D. **RE-AUTHORIZATION/CONTINUATION OF THERAPY**
1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
2. Reauthorization:
   a. Authorization may be granted to members requesting authorization for continuation of therapy if Stelara was previously authorized by HMSA/CVS and the criteria below are met.
   b. Chronic plaque psoriasis
To receive Authorization for an additional 6 months, may be granted to members requesting authorization for continuation of therapy who are benefitting from Stelara therapy as evidenced by therapy for chronic plaque psoriasis, documentation supporting a decrease in percent of body surface area involvement when compared to baseline, and were previously authorized by HMSA/CVS. Thereafter, authorization of an additional 12 months may be granted.

d.  

Psoriatic arthritis
Authorization of an additional 12 months may be granted to members requesting authorization for continuation of therapy who are benefitting from Stelara therapy as evidenced by decrease in percent of body surface area involvement when compared to baseline, and were previously authorized by HMSA/CVS.

e.  

Crohn’s disease
Authorization of an additional 12 months may be granted to members requesting authorization for continuation of therapy who have received treatment with Stelara, a positive clinical response to treatment and are benefitting from Stelara therapy as evidenced by a decreased or stable CDAI score severity of condition compared with baseline, and were previously authorized by HMSA/CVS. Thereafter, authorization of an additional 12 months may be granted.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the HMSA medical policy website for the fax form.

G. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’ determination as to medical necessity in a given case, the physician may request that CVS/caremark/HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
H. REFERENCES


<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/2015</td>
<td>Original effective date</td>
</tr>
<tr>
<td>10/01/2016</td>
<td>Revision effective date (PsA criteria)</td>
</tr>
<tr>
<td>11/09/2016</td>
<td>Added new indication, Crohn’s disease</td>
</tr>
<tr>
<td>04/14/2017</td>
<td>Revision effective date</td>
</tr>
<tr>
<td>06/2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>01/01/2018</td>
<td>Revision effective date</td>
</tr>
<tr>
<td>03/2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>05/01/2019</td>
<td>Revision effective date</td>
</tr>
</tbody>
</table>