Stelara (ustekinumab)

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<th>Line(s) of Business:</th>
<th>Original Effective Date:</th>
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<td>10/01/2015</td>
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<td>Current Effective Date:</td>
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### 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)

#### B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
- For psoriasis, the following documentation is required:
  - For new starts on therapy
    - Documentation supporting a history of plaque psoriasis for longer than six months
    - Percent of body surface area involvement
    - Results of treatment with methotrexate (MTX) such as ineffective treatment or intolerance, or documentation that MTX 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 must be submitted

#### 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:
   - Member has been diagnosed with active PsA, and meets ANY of the following:
     a) Member has tried at least 2 of the following drugs for PsA: MTX, sulfasalazine, and leflunomide and experienced an inadequate response to MTX.
     b) Member has a history of intolerance to MTX, sulfasalazine, or leflunomide.
     c) Member has a contraindication to MTX, sulfasalazine AND leflunomide.
2. **Moderate to severe chronic plaque psoriasis**
   Initial authorization of 6 months may be granted for members who are 18 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 MTX 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 MTX 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.

D. **RE-AUTHORIZATION/CONTINUATION OF THERAPY**
   Members who have had Stelara previously authorized by HMSA/CVS are subject to the continuation criteria below for approval. Members without previous authorization are required to meet criteria for initial authorization in section C. above.

   **Chronic plaque psoriasis**
   To receive authorization for an additional 6 months of therapy for chronic plaque psoriasis, documentation supporting a decrease in percent of body surface area involvement when compared to baseline must be submitted. Thereafter, authorization of 12 months may be granted.

   **Psoriatic arthritis**
   Authorization of 12 months may be granted for members who achieve or maintain positive clinical response as evidenced by low disease activity, improvement in signs and symptoms or maintenance of improvement in signs and symptoms.

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. **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’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES


Revised: December 2015April 2016.