Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Stelara® (Ustekinumab)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***October 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: December *2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Stelara® (ustekinumab).

Stelara® (ustekinumab) is indicated for the treatment of adult patients (18 years or older) with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis, alone or in combination with methotrexate
- Moderately to severely active Crohn's disease who have:
  - Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker
  - Failed or were intolerant to treatment with one or more TNF blockers

DEFINITIONS

Dactylitis – a painful inflammation of the fingers or toes; a sausage shaped digit associated with psoriatic arthritis

Enthesitis – inflammation of sites where tendons or ligaments insert into the bone. It is also called enthesopathy, or any pathologic condition involving the enthuses. The

enthuses are any point of attachment of skeletal muscles to the bone, where recurring stress or inflammatory autoimmune disease can cause inflammation or occasionally fibrosis and calcification.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Stelara® (ustekinumab), is subject to the prior authorization process.

PROCEDURE

*****Please Note: When coverage of Stelara is requested through the pharmacy benefit, please refer to policy RX.PA.125.1.E. This policy, RX.PA.125.2.E (B), is for requests for Stelara on the Medical Benefit only.*****

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Stelara® are subject to the preferred medical drug list program. This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for these products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products*
Preferred	• Remicade® (infliximab) • Simponi Aria® (golimumab, intravenous)
Non-preferred	• Actemra® (tocilizumab) • Cimzia® (certolizumab pegol) • Entyvio® (vedolizumab) • Ilumya® **(tildrakizumab-asmn)** • Inflectra® (infliximab-dyyb) • Renflexis® (infliximab-abda) • Stelara® (ustekinumab) • Orencia® (abatacept)

*If applicable for approved indication

Requests for Stelara® on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

I. *EXCEPTION CRITERIA (Use for Non-Preferred Requests Only)*

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product(s) (as applicable).

Coverage for a non-preferred product is provided when ANY of the following criteria are met:

A. Actemra, Cimzia, Entyvio, Ilumya, Orencia and Stelara
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
   2. Member has a documented inadequate response or intolerable adverse event with all of the preferred product(s) indicated for the condition being treated, unless there is a documented clinical reason to avoid TNF inhibitors
      i. History of demyelinating disorder
      ii. History of congestive heart failure
      iii. History of hepatitis B virus infection
      iv. Autoantibody formation/lupus-like syndrome
      v. Risk of lymphoma
   3. Requested product is Cimzia and member is currently pregnant or breastfeeding

B. Inflectra and Renflexis
   1. Member has a documented intolerable adverse event with the preferred product, Remicade

III. CLINICAL CRITERIA (*Use for ALL Drug Requests on the Medical Benefit*)

Must meet criteria for all diagnoses in addition to that listed under the respective diagnosis:

For all diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with Stelara
- Must have no evidence of infection
- Must have first Stelara dose administered in a physician office by a healthcare professional

1. Plaque psoriasis:

- Must be prescribed by a dermatologist
- Must be age 12 or older
- Must have a diagnosis of moderate-to-severe plaque psoriasis
- Must have a minimum body surface area involvement of >10% (members with plaque psoriasis of palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (e.g., methotrexate, cyclosporine, or acitretin) with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies

2. Psoriatic arthritis:

- Must be prescribed by a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis
- For peripheral disease and dactylitis:

  - Must have an adequate trial (of at least 4 weeks) with a non-steroidal anti-inflammatory drug (NSAID) at an anti-inflammatory dose, with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
  - Must have an adequate trial (of at least 3 months), of a conventional systemic therapy (e.g., methotrexate, sulfasalazine, or leflunomide) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- For axial disease and enthesitis:
  - Must have an adequate trial (of at least 4 weeks each) with TWO NSAIDs at anti-inflammatory doses with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- For skin and nail disease:
  - Must have an adequate trial of topical treatments, phototherapy, or photochemotherapy with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
  - Must have an adequate trial (of at least 3 months) of a conventional systemic therapy (e.g., methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

3. Crohn's Disease

- Must be prescribed by a gastroenterologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active Crohn's disease
- Must have tried ONE of the following conventional therapies:
  - Corticosteroids with an inadequate response, loss of response, or intolerance as defined as one of the following:
    - Persistent active disease despite a history of at least one 4-week induction regimen that included a dose equivalent to prednisone 30mg daily orally for two weeks or intravenous corticosteroid for 1 week
    - 2 failed attempts to taper corticosteroids to below a dose equivalent to prednisone 10mg orally daily on 2 separate occasions
    - History of intolerance to corticosteroids (including, but not limited to, Cushing's syndrome, osteopenia/osteoporosis, hyperglycemia, insomnia, and infection). If intolerant to corticosteroids, member must try an immunomodulator.

- Immunomodulator with an inadequate response, loss of response, or intolerance as defined as one of the following:
  - Persistently active disease despite an adequate trial (of at least 2 months) of oral azathioprine, 6-mercaptorpurine, or methotrexate
  - History of intolerance to one or more immunomodulators (including, but not limited to, nausea/vomiting, abdominal pain, pancreatitis, liver function test abnormalities, lymphopenia, thiopurine methyltransferase genetic mutation, and infection). If intolerant to immunosuppressants, member must try corticosteroids.

Reauthorization Criteria:
All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and there is no evidence of infection.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Up to 1 year • Plaque psoriasis: Stelara is covered according to the following weight-based doses: o Patients weighing ≤ 100kg (220 lbs): 45mg o Patients weighing > 100kg (220 lbs): 90mg • Crohn's Disease: an initial starting dose for IV administration lasting 8 weeks is approved according to the following weight-based doses: o Patients weighing ≤ 55kg (121 lbs): 260mg (2 vials) o Patients weighing > 55kg (121 lbs) and ≤ 85kg (187 lbs): 390 mg (3 vials) o Patients weighing > 85 kg (187 lbs): 520mg (4 vials) o Maintenance dose of one 90mg syringe every 8 weeks is approved
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

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RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 12/16, 04/17, 01/18*
Preferred Product Update (effective 4/1/18)	*02/18*
Added procedural clarification	*6/18*
Preferred Product Update (effective 1/1/19)	*12/18*