

Policy: MBP 75.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Stelara (ustekinumab)

I. Policy:

Stelara (ustekinumab)

II. Purpose/Objective:

To provide a policy of coverage regarding Stelara (ustekinumab)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:

Stelara (ustekinumab) is a fully humanized immunoglobulin G1 monoclonal antibody that targets the p40 subunit of human IL-12 and IL-23.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Stelara (ustekinumab) will be considered medically necessary when all of the following criteria are met:

1. Adult Plaque Psoriasis

- Prescription must be written by a dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
- Medical record documentation of moderate to severe plaque psoriasis characterized by $\geq 5\%$ of body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx*

*Requires Prior Authorization

2. Pediatric Plaque Psoriasis

- Prescription must be written by a dermatologist **AND**
- Member must be at least 6 years of age **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by $\geq 5\%$ of body surface area involved or disease affecting crucial body areas such as hands, feet, face, or genitals **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on at least two topical corticosteroids **AND**
- Medical record documentation that the prescribed dose is appropriate for the patient's weight **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

Dosing for plaque psoriasis:

- Patients weighing over 100kg should receive 90 mg every 12 weeks (GPI 9025058500E540)
- Patients weighing $\geq 60\text{kg}$ to $\leq 100\text{kg}$ should receive 45 mg every 12 weeks (GPI 90250585002020 or 9025058500E520)
- Patients weighing less than 60kg should receive 0.75mg/kg every 12 weeks (via single dose vial – GPI 90250585002020)

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Stelara therapy.

Quantity Limit (for plaque psoriasis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
Less than 60 kg	Facets RX Count: 135 Darwin QL: One-time, one week authorization: 0.5 mL per 28 days by GPI 14 Remainder of 6 month authorization: 0.5 mL per 84 days by GPI 14	Facets RX Count: 225 Darwin QL: 0.5 mL per 84 days by GPI 14
Greater than or equal to 60 kg to 100 kg or less	Facets RX Count: 135 Darwin QL: One-time, one week authorization: 0.5 mL per 28 days by GPI 14 Remainder of 6 month authorization: 0.5 mL per 84 days by GPI 14	Facets RX Count: 225 Darwin QL: 0.5 mL per 84 days by GPI 14
Greater than 100 kg	Facets RX Count: 270 Darwin QL: One-time, one week authorization: 1 mL per 28 days by GPI 14 Remainder of 6 month authorization: 1 mL per 84 days by GPI 14	Facets RX Count: 450 Darwin QL: 1 mL per 84 days by GPI 14

3. Psoriatic Arthritis

- Prescription must be written by a rheumatologist or a dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patient has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weighs > 100 kg. **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx*

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Stelara therapy.

Quantity Limit (for psoriatic arthritis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
100 kg or less	Facets RX Count: 135 Darwin QL: One-time, one week authorization: 0.5 mL per 28 days by GPI 14 Remainder of 6 month authorization: 0.5 mL per 84 days by GPI 14	Facets RX Count: 225 Darwin QL: 0.5 mL per 84 days by GPI 14
Greater than 100 kg	Facets RX Count: 270 Darwin QL: One-time, one week authorization: 1 mL per 28 days by GPI 14 Remainder of 6 month authorization: 1 mL per 84 days by GPI 14	Facets RX Count: 450 Darwin QL: 1 mL per 84 days by GPI 14

4. Crohn's Disease (CD)

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab (or biosimilar) *, or Tysabri* **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) OR Stelara 90mg syringes (for maintenance therapy) being prescribed.

*Requires Prior Authorization

Note to reviewer: Stelara 45mg syringe is not indicated for use in Crohn's disease.

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of **six (6) months**. After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of **twelve (12) months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Stelara therapy.

Quantity limit (for Crohn's disease):

Initial Authorization:

- One-time authorization:
 - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
 - Darwin Quantity Limit: 104 mL per 56 days GPI 14 for Stelara 130 mg vial
- Remainder of initial authorization:
 - Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])
 - Darwin Quantity limit: 1mL per 56 days GPI 14 for Stelara 90mg Syringe

Subsequent Authorizations:

- Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])
- Darwin Quantity limit: 1 mL per 56 days GPI 14 for Stelara 90mg Syringe

5. Ulcerative Colitis

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira*, Entyvio*, and infliximab (or biosimilar) * **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) OR Stelara 90mg syringes (for maintenance therapy) being prescribed.

*Requires Prior Authorization

Note to reviewer: Stelara 45mg syringe is not indicated for use in ulcerative colitis.

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of **six (6) months**. After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of **twelve (12) months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Stelara therapy.

Quantity limit (for ulcerative colitis):

Initial Authorization:

- One-time authorization:
 - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
 - Darwin Quantity Limit: 104 mL per 56 days GPI 14 for Stelara 130 mg vial
- Remainder of initial authorization:
 - Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])
 - Darwin Quantity limit: 1mL per 56 days GPI 14 for Stelara 90mg Syringe

Subsequent Authorizations:

- Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])
- Darwin Quantity limit: 1 mL per 56 days GPI 14 for Stelara 90mg Syringe

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 03/10/10

Revised: 09/13; 02/14 (add indication); 09/16/14; 12/30/14 (updated formulary alternatives criteria), 09/15/15 (joint counts removed), 7/19/16 (dosing criteria added), 3/21/17 (Crohn's disease), 3/20/18 (form alt, duplicate therapy), 4/24/18 (per DHS, grandfather), 5/15/18 (peds plaque psoriasis), 4/15/20 (ulcerative colitis, updated QLs), 1/19/21 (pediatric age)

Reviewed: 02/12, 4/22/19, 2/1/20, 1/18/22 (Updated Darwin QLs)