UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Stelara

Program	Prior Authorization
Medication	Stelara (ustekinumab)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	1/2020
Effective Date	4/2020

NOTE: This program applies to the subcutaneous formulations of Stelara

1. Background:

Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. It is also indicated for active psoriatic arthritis, alone or in combination with methotrexate. In addition, it is also indicated for moderately to severely active Crohn's disease and for moderately to severely active ulcerative colitis.

2. Coverage Criteria:

A. <u>Plaque Psoriasis</u>

1. <u>Initial Authorization</u>

a. Stelara will be approved based on one of the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting **<u>all</u>** of the following:

(a) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(b) Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

-AND-

(c) **<u>Both</u>** of the following:

i. History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

-AND-

ii. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

(d) History of failure, contraindication, or intolerance to **two** of the following preferred biologic products (document drug, date, and duration of trial):

i. Humira (adalimumab)
ii. Enbrel (etanercept)
iii. Cimzia (certolizumab)
iv. Ilumya (tildrakizumab)

-AND-

(e) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

(f) Patient is not receiving Stelara in combination with **any** of the following:

i. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(g) **One** of the following:

i. Requested medication is Stelara 45 mg/0.5 mL

-OR-

ii. **Both** of the following:

a. Requested medication is Stelara 90 mg/1 mL

-AND-

b. Patient's weight is > 100 kg (220 lbs)

-AND-

(h) Prescribed by or in consultation with a dermatologist

-OR-

(2) **All** of the following:

(a) Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

(b) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(c) Patient is not receiving Stelara in combination with **any** of the following:

i. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(d) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Stelara therapy

-AND-

b. Patient is not receiving Stelara in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. **One** of the following:

(1) **Both** of the following:

(a) Requested medication is Stelara 45 mg/0.5 mL

-AND-

(b) Diagnosis of active psoriatic arthritis

-OR-

(2) **All** of the following:

(a) Requested medication is Stelara 90 mg/1 mL

-AND-

(b) Patient's weight is > 100 kg (220 lbs)

-AND-

(c) Diagnosis of active psoriatic arthritis

-AND-

(d) Diagnosis of co-existent moderate to severe plaque psoriasis

-AND-

b. Patient is not receiving Stelara in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

d. **Both** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)

-AND-

(2) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

e. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of active psoriatic arthritis

-AND-

c. Patient is not receiving Stelara in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Stelara therapy

-AND-

b. Patient is not receiving Stelara in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab),

Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

C. Crohn's Disease (CD)

1. Initial Authorization for Maintenance Dosing

a. Stelara 90 mg/1 mL will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. History of failure to **one** of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

-AND-

ii. History of failure, contraindication or intolerance to Humira (adalimumab) and Cimzia (certolizumab)

-OR-

(b) Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

(3) Patient is not receiving Stelara in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

2. Reauthorization

(1) Documentation of positive clinical response to Stelara therapy

-AND-

(2) Patient is not receiving Stelara in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

D. Ulcerative Colitis

1. Initial Authorization

a. Stelara 90 mg/1 mL will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. History of failure to **one** of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

(1) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(2) 6-mercaptopurine (Purinethol)
(3) Azathioprine (Imuran)
(4) Aminosalicylates (e.g., mesalamine, sulfasalazine)

-AND-

ii. History of failure, contraindication or intolerance to Humira (adalimumab)

-OR-

(b) Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

(3) Patient is not receiving Stelara in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Stelara will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Stelara therapy

-AND-

(2) Patient is not receiving Stelara in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc., October 2019.
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.

6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
7. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.

Program	Program type – Prior Authorization
Change Control	
Date	Change
12/2013	New Criteria
3/2015	▪ For plaque psoriasis, removed requirement to try conventional therapies, including phototherapy (one of the following: ultraviolet light B [UVB] used alone or in combination with topical or systemic treatments, pulsed dye laser, psoralen and exposure to ultraviolet light A [PUVA], photochemotherapy) and systemic therapy (one of the following: methotrexate, cyclosporine, acitretin, hydroxyurea, sulfasalazine, 6-thioguanine, mycophenolate). ▪ For plaque psoriasis, changed requirement of trial of Humira and Enbrel to trial of Humira only due to Enbrel PDL deletion ▪ The examples of biologic DMARDs in the concomitant therapy criterion have been revised to list the most commonly utilized products: Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab). ▪ Reauthorization criteria revised to include concomitant therapy criteria (biologic DMARD or janus kinase inhibitor). ▪ For psoriatic arthritis (initial authorization), added rheumatologist as a prescriber. ▪ For psoriatic arthritis changed requirement of trial of Humira and Enbrel to trial of Humira and Cimzia due to Enbrel PDL deletion and Cimzia PDL addition
3/2016	Added Enbrel to prerequisite therapy requirement for both psoriasis and psoriatic arthritis initial therapy sections Removed all “notes to prescriber” Updated policy template

10/2016	Updated background. Added Phosphodiesterase 4 (PDE4) inhibitor to combination therapy requirements. Added criteria section for Crohn's disease.
2/2017	Added statement that Stelara IV is not a pharmacy benefit. Updated policy template.
9/2017	Added Otezla to preferred products for diagnoses of psoriatic arthritis and plaque psoriasis
2/2018	Removed Otezla as a step therapy medication. Added step through Cosentyx for psoriasis section.
2/2019	Revised psoriasis section to match criteria for other non-preferred psoriasis biologics. Removed prescriber check from all sections for consistency among biologic products. Updated background and references.
3/2019	Added step through Cosentyx for psoriatic arthritis section. Revised biologic examples to align for each section.
11/2019	Added prerequisite therapy for psoriatic arthritis. Updated references.
12/2019	Added review criteria for ulcerative colitis. Revised additional prerequisite therapies and added documentation of drug, date, and duration of trials. Separated continuation of therapy requirements for current users. Updated background and references.
1/2020	Revised psoriasis step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.