UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1097-11
Program	Prior Authorization/Notification
Medication	*Stelara™ (ustekinumab) *This program applies to the subcutaneous formulation of ustekinumab.
P&T Approval Date	1/2007, 6/2008, 4/2009, 6/2009, 12/2009, 7/2010, 11/2010, 7/2011, 11/2011, 7/2012, 11/2012, 2/2013, 11/2013, 2/2014, 2/2015, 3/2016, 11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 12/2021
Effective Date	3/1/2022; Oxford only: N/A

1. Background:

Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of patients 6 years of age or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. It is also indicated in adult patients with active psoriatic arthritis, alone or in combination with methotrexate. In addition, Stelara is indicated in adult patients with moderately to severely active Crohn's disease and for moderately to severely active ulcerative colitis.

2. Coverage Criteria:

A. Plaque Psoriasis

1. Initial Authorization

a. Stelara 45 mg/0.5 mL will be approved based on **both** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

-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)]

Authorization will be issued for 12 months.

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

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

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

-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)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Stelara 45 mg/0.5 mL or 90 mg/mL will be approved based on **both** 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)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. Stelara 45 mg/0.5 mL will be approved based on **both** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-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)]

Authorization will be issued for 12 months.

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

(1) Diagnosis of active psoriatic arthritis

-AND-

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

-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)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Stelara 45 mg/0.5 mL or 90 mg/mL will be approved based on **both** 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)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

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 **both** of the following criteria:

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

-AND-

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

(a) Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

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., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

Authorization will be issued for 12 months.

D. Ulcerative Colitis

1. Initial Authorization

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

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) Patient is not receiving Stelara in combination with **either** of the following:
(a) Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Stelara therapy

-AND-

(2) Patient is not receiving Stelara in combination with **either** of the following:
(a) Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

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.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the UnitedHealthcare Drug Policy for Stelara.

4. Reference:

1. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; December 2020.

Program	Prior Authorization/Notification - Stelara (ustekinumab)
Change Control	
11/2013	Added criteria for psoriatic arthritis. Extended reauthorization duration to 24 months.
2/2014	Concomitant therapy criterion revised to list most commonly utilized biologic DMARDs. Reauthorization criteria revised to include concomitant therapy criterion.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated background and references.
3/2016	Annual review. Added Otezla (apremilast) to the combination criteria. Removed co-existent moderate to severe plaque psoriasis from criteria to align with the indication section of the prescribing information. Updated statement regarding scope of the program. Added reference to UHC drug policy for intravenous infusions. Updated references.
11/2016	Added criteria for Crohn's disease. Updated formatting, background and references.
11/2017	Annual review. No changes to program.
11/2018	Annual review. No changes to clinical coverage criteria. Updated background and reference.
11/2019	Updated criteria for Crohn's disease and new indication for ulcerative colitis. Updated reference.
11/2020	Annual review. Changed reauthorization durations to 12 months. Updated background and reference.
11/2021	Annual review with no changes to clinical coverage criteria. Updated background and reference.
12/2021	Updated initial authorization for UC to 12 months.