UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2204-4
Program	Prior Authorization/Medical Necessity
Medication	*Stelara™ (ustekinumab) *This program applies to the subcutaneous formulation of ustekinumab.
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

1. Background:

Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of adult and pediatric 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 adults for active psoriatic arthritis, alone or in combination with methotrexate. In addition, it is also indicated in adults for moderately to severely active Crohn's disease and for moderately to severely active ulcerative colitis.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. Initial Authorization

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

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

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

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

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

ii. 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):

a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
c. Tazarotene
d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
e. Anthralin
f. Coal tar

-AND-

iii. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)].

-OR-

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

i. Patient is currently on Stelara therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Janssen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Stelara*

-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 dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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) **One** of the following:

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

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

ii. 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):

a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
c. Tazarotene
d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
e. Anthralin
f. Coal tar

-AND-

iii. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)].

-OR-

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

i. Patient is currently on Stelara therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Janssen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Stelara*

-AND-

(4) 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-

(5) Prescribed by or in consultation with a dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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 **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)]

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 **all** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

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

(a) History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab), Tremfya (guselkumab) Xeljanz (tofacitinib), Otezla (apremilast)].

-OR-

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

i. Patient is currently on Stelara therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Janssen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Stelara*

-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 **one** of the following:

(a) Rheumatologist
(b) Dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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) **One** of the following:

(a) History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast)].

-OR-

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

i. Patient is currently on Stelara therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Janssen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a

pharmacy for a free supply of medication) as a means to establish as a current user of Stelara*

-AND-

(4) 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-

(5) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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

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

-OR-

(b) Patient has been previously treated with a biologic DMARD FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab)].

-OR-

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

i. Patient is currently on Stelara therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Janssen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Stelara*

-AND-

(3) 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)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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., 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 **all** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

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

(a) Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

-OR-

(b) Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of ulcerative colitis as

documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Humira (adalimumab), Simponi (golimumab), Xeljanz (tofacitinib)].

-OR-

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

i. Patient is currently on Stelara therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Janssen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Stelara*

-AND-

(3) 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)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Janssen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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 **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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut business, only a 60-day trial will be required. For Kentucky business only a 30-day trial will be required.

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.
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.
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.
9. Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517.
10. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.

Program	Prior Authorization/Medical Necessity - Stelara (ustekinumab)
Change Control	
5/2020	New program
5/2021	Annual review. Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Updated UC coverage criteria to align with other Med Nec programs. Removed drug documentation where only one drug is required. References and background updated.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting previous or current therapy with a biologic DMARD in order to bypass step through non-biologic therapies if claim history not available.
12/2021	Updated conventional DMARD bypass language for psoriasis, psoriatic arthritis and ulcerative colitis with no change to clinical intent. Updated initial authorization duration to 12 months for ulcerative colitis. Updated CT/KY footnote.