UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1097-17
Program	Prior Authorization/Notification
Medication	*Ustekinumab: **Otulfi® (ustekinumab-aauz), **Pyzchiva® (ustekinumab-ttwe), **Selarsdi™ (ustekinumab-aekn), **Stelara® (ustekinumab), Steqeyma® (ustekinumab-stba), **Ustekinumab-ttwe, Wezlana™ (ustekinumab-auub), and Yesintek™ (ustekinumab-kfce) *This program applies to the subcutaneous formulation of ustekinumab. **Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-aekn), Stelara® (ustekinumab), and Ustekinumab-ttwe are excluded from coverage for the majority of our benefits.
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, 9/2022, 7/2023, 10/2024, 3/2025, 5/2025
Effective Date	9/15/2025

1. Background:

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

2. Coverage Criteria[a]:

A. <u>Plaque Psoriasis</u>

1. **<u>Initial Authorization</u>**

   a. Ustekinumab 45 mg/0.5 mL will be approved based on **<u>both</u>** of the following criteria:

      (1) Diagnosis of moderate to severe plaque psoriasis

      -AND-

      (2) Patient is not receiving the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

b. Ustekinumab 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 the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Ustekinumab 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 the requested ustekinumab therapy

-AND-

(2) Patient is not receiving the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. Ustekinumab 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 the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

b. Ustekinumab 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 the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Ustekinumab 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 the requested ustekinumab therapy

-AND-

(2) Patient is not receiving the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Crohn's Disease (CD)

1. **Initial Authorization for Maintenance Dosing**

   a. Ustekinumab 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 the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

   Authorization will be issued for 12 months.

2. **Reauthorization**

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

      (1) Documentation of positive clinical response to the requested ustekinumab therapy

      -AND-

      (2) Patient is not receiving the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

   Authorization will be issued for 12 months.

D. Ulcerative Colitis

1. **Initial Authorization**

   a. Ustekinumab 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 the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab,

Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to the requested ustekinumab therapy

-AND-

(2) Patient is not receiving the requested ustekinumab product in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

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.

**Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-aekn), Stelara (ustekinumab), and Ustekinumab-ttwe, are excluded from coverage for the majority of our benefits.

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 Ustekinumab.

4. Reference:

1. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; March 2024.
2. Steqeyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; December 2024.
3. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
4. Selarsdi [package insert], Boston, MA: argenx US, Inc.; June 2025.
5. Otulfi [package insert], Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2024.
6. Pyzchiva [package insert], Princeton, NJ: Sandoz Inc.; December 2024.
7. Wezlana [package insert]. Thousand Oaks, CA: Amgen Inc. for Nuvaila; January 2025.

Program	Prior Authorization/Notification - Ustekinumab: **Otulfi (ustekinumab-aauz), **Pyzchiva (ustekinumab-ttwe), **Selarsdi (ustekinumab-aekn), **Stelara (ustekinumab), Steqeyma (ustekinumab-stba), **Ustekinumab-ttwe, Wezlana (ustekinumab-auub), and Yesintek (ustekinumab-kfce)
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.
9/2022	Updated background to include patients 6 years and older with active psoriatic arthritis. Added state mandate footnote. Updated reference.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Annual review with no changes to clinical coverage criteria. Updated reference.
3/2025	Added Steqeyma and Yesintek to all coverage criteria in parity with Stelara. Updated background and reference.
5/2025	Renamed program to Ustekinumab. Added Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), Selarsdi (ustekinumab-aekn), Ustekinumab-ttwe, and Wezlana (ustekinumab-auub) to the program. Added notation stating some products are excluded from coverage for the majority of our benefits. Updated Stelara, Steqeyma, or Yesintek to Ustekinumab throughout the program. Updated references.
9/5/2025	Administrative change to add Wezlana into coverage.