ustekinumab intravenous

Commercial Medical Benefit Drug Policy

ustekinumab (Stelara)
ustekinumab-aekn (Selarsdi)
ustekinumab-aauz (Otulfi)
ustekinumab-auub (Wezlana)
ustekinumab-kfce (Yesintek)
ustekinumab-stba (Steqeyma)
ustekinumab-srlf (Imuldosa)
ustekinumab-ttwe (Pyzchiva)

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Interleukin (IL)-12/IL-23 Inhibitor
HCPCS:
J3358:Ustekinumab, for intravenous injection, 1 mg
Q5098:Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q5099:Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100:Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg
Q5138:Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9997:Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9998:Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg
Q9999:Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg
How Supplied:
130 mg single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Crohn's Disease, Moderate to Severe
- Ulcerative Colitis, Moderate to Severe

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

The 130 mg vial given intravenously is administered by a healthcare provider and managed under the Medical Benefit. For the 45 mg/ 90 mg prefilled syringe and 45 mg vial that can be self-administered in the home, please refer to the "Self-Administered Drugs" Medical Benefit drug policy.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first dose of this drug or is being re-initiated on this drug after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Crohn's Disease, Moderate to Severe

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (18 years and older)
2. ***Effective 2/1/2026 and after, will require*** Prescribed by or in consultation with a gastroenterologist
3. Not being used in combination with other targeted immunomodulators

4. Request for Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, or Wezlana: Intolerable side effect or contraindication with preferred ustekinumab product (e.g. Yesintek) that is not expected with the requested ustekinumab drug

Covered Doses:
Initial dosing: A single intravenous infusion using weight-based dosing

Weight Range (kg)	Recommended Dosage
Up to 55 kg	260 mg (2 vials)
Greater than 55 kg to 85 kg	390 mg (3 vials)
Greater than 85 kg	520 mg (4 vials)

Maintenance dosing: Drug is available as a 45 mg/90 mg prefilled syringe and a 45 mg vial that can be self-administered subcutaneously for maintenance. Self-administered products can be requested from your Pharmacy Benefit.

Coverage Period:
Initial dosing: One-time intravenous dose

ICD-10:
K50.00-K50.119, K50.80-K50.919

Ulcerative Colitis, Moderate to Severe
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA-approved indication (18 years and older)
2. ***Effective 2/1/2026 and after, will require*** Prescribed by or in consultation with a gastroenterologist
3. Not used in combination with a targeted immunomodulator
4. Request for Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, or Wezlana: Intolerable side effect or contraindication with preferred ustekinumab product (e.g. Yesintek) that is not expected with the requested ustekinumab drug

Covered Doses:
Initial dosing: A single intravenous infusion using weight-based dosing

Weight Range (kg)	Recommended Dosage
Up to 55 kg	260 mg (2 vials)
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Greater than 85 kg	520 mg (4 vials)

Maintenance dosing: Drug is available as a 45 mg/90 mg prefilled syringe and a 45 mg vial that can be self-administered subcutaneously for maintenance. Self-administered products can be requested from your Pharmacy Benefit.

Coverage Period:
Initial dosing: One-time intravenous dose

ICD-10:
K51.0-K51.319, K51.5-K51.519, K51.80-K51.919

References

1. Imuldosa (ustekinumab-srlf) Prescribing Information. Accord BioPharma Inc., Raleigh, NC: 10/2024.
2. Otulfi (ustekinumab-aauz) Prescribing Information. Fresenius Kabi USA, LLC, Lake Zurich, IL: 9/2025.
3. Pyzchiva (ustekinumab-ttwe) Prescribing Information. Sandoz Inc. Princeton, NJ: 12/2024.
4. Selarsdi (ustekinumab-aekn) Prescribing Information. Teva Pharmaceuticals, Parsippany, NJ: 2/2025.
5. Stelara (ustekinumab) Prescribing Information. Janssen Biotech, Inc., Horsham, PA: 7/2020.
6. Steqeyma (ustekinumab-stba) Prescribing Information. CELLTRION USA, Inc., Jersey City, NJ: 12/2024.
7. Wezlana (ustekinumab-auub) Prescribing Information. Amgen Inc., Thousand Oaks, CA: 1/2025.
8. Yesintek (ustekinumab-kfce) Prescribing Information. Biocon Biologics Inc., Cambridge, MA: 11/2024.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Added specialist requirement for patients with Crohn's disease and patients with ulcerative colitis (UC).

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee