ustekinumab intravenous

Medical Benefit Drug Policy

ustekinumab (Stelara)
ustekinumab-aekn (Selarsdi)
ustekinumab-aauz (Otulfi)
ustekinumab-auub (Wezlana)
ustekinumab-hmny (Starjemza)
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:
J3357:Ustekinumab, for subcutaneous injection, 1 mg
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
Q5137:Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138:Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q5164:Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q9996:Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 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.,

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off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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 (2 years and older)
2. 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, Starjemza, 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	Up to 260 mg (2 vials)
Greater than 55 kg to 85 kg	Up to 390 mg (3 vials)
Greater than 85 kg	Up to 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:

One-time intravenous dose

ICD-10:

K50-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. Prescribed by or in consultation with a gastroenterologist
3. Not used in combination with a targeted immunomodulator
4. Request for Imuldosa, Otulfi, Pyzchiva, Starjemza, 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	Up to 260 mg (2 vials)
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Greater than 85 kg	Up to 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:
One-time intravenous dose

ICD-10:
K51.0-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. Starjemza (ustekinumab-hmny) Prescribing Information. Hikma Pharmaceuticals USA Inc., Berkeley Heights, NJ: 5/2025.
6. Stelara (ustekinumab) Prescribing Information. Janssen Biotech, Inc., Horsham, PA: 7/2020.
7. Steqeyma (ustekinumab-stba) Prescribing Information. CELLTRION USA, Inc., Jersey City, NJ: 12/2024.
8. Wezlana (ustekinumab-auub) Prescribing Information. Amgen Inc., Thousand Oaks, CA: 1/2025.

9. 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 HCPCS Q5164 for Starjemza, effective 7/1/2026

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