ustekinumab

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: IL-12 and 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 request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

For members enrolled in our Blue Shield Select (PPO) and Blue Shield Medicare (PPO) plans:
Wezlana, Yesintek, Otulfi, Selarsdi, Steqeyma, Pyzchiva, and Imuldosa requires step therapy. Step therapy requires you to try other drug(s) first before a drug can be covered. The BSC preferred step

drug is Stelara. Stelara will need to be tried for members newly initiating Wezlana, Yesintek, Otulfi, Selarsdi, Steqeyma, Pyzchiva, or Imuldosa therapy.

J3357 USTEKINUMAB, FOR SUBCUTANEOUS INJECTION, **Q5137** USTEKINUMAB-AUUB (WEZLANA), BIOSIMILAR, SUBCUTANEOUS, INJECTION, **Q5098** USTEKINUMAB-SRLF (IMULDOSA), BIOSIMILAR , **Q5099** INJECTION, USTEKINUMAB-STBA (STEQEYMA), BIOSIMILAR, **Q5100** INJECTION, USTEKINUMAB-KFCE (YESINTEK), BIOSIMILAR, **Q9996** INJECTION, USTEKINUMAB-TTWE (PYZCHIVA), SUBCUTANEOUS, **Q9989** INJECTION, USTEKINUMAB-AEKN (SELARSDI), BIOSIMILAR, and **Q9999** INJECTION, USTEKINUMAB-AAUZ (OTULFI), BIOSIMILAR: These self-administered products are on Noridian's Self-Administered Drug Exclusion list and only covered under Part D.

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. Patient is 18 years or older
2. Not being used in combination with other targeted immunomodulators
3. For PPO request for Wezlana, Yesintek, Otulfi, Selarsdi, Steqeyma, Pyzchiva, or Imuldosa: Intolerable side effect or contraindication with preferred ustekinumab product (e.g. Stelara) that is not expected with the requested ustekinumab drug

Covered Doses:

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)

Coverage Period:

One-time

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. Patient is 18 years or older
2. Not used in combination with a targeted immunomodulator
3. For PPO request for Wezlana, Yesintek, Otulfi, Selarsdi, Steqeyma, Pyzchiva, or Imuldosa: Intolerable side effect or contraindication with preferred ustekinumab product (e.g. Stelara) that is not expected with the requested ustekinumab drug

Covered Doses:

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)

Coverage Period:
One-time

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

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Stelara, Wezlana, Yesintek, Otulfi, Selarsdi, Steqeyma, Pyzchiva, and Imuldosa
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
3. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Beginning January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) provided Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs to lower costs and improve the quality of care for Medicare beneficiaries.
- Support for using biosimilars as step requirement is found in Noridian Health Care Solutions and supported by the FDA. Noridian will accept a biosimilar drug on the same criteria as the drug to which it is a biosimilar unless an article is published to the contrary. Per the FDA, a biosimilar is highly similar to and has no clinically meaningful difference from an existing FDA approved biologic reference drug.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at http://www.lexi.com
5. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
6. Imuldosa (ustekinumab) [prescribing information]. Raleigh, NC: Accord BioPharma Inc; October 2024.

7. Otulfi (ustekinumab) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA LLC; March 2025.
8. Pyzchiva (ustekinumab) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2025.
9. Selarsdi (ustekinumab) [prescribing information]. Leesburg, VA: Alvotech USA Inc; February 2025.
10. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; November 2024.
11. Steqeyma (ustekinumab) [prescribing information]. Jersey City, NJ: Celltrion USA Inc; February 2025.
12. Wezlana (ustekinumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2025.
13. Yesintek (ustekinumab) [prescribing information]. Cambridge, MA: Biocon Biologics Inc; November 2024.
14. Feuerstein JD, Isaacs KL, Schneider Y et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020; 158:1450-1461AHFS. Available by subscription at http://www.lexi.com
15. 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.
16. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
17. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.
18. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-alpha biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology 2013; 145:1459-63.

Review History

Date of Last Annual Review: 1Q2025
Changes from previous policy version:
Added additional biosimilars

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