CVS caremark

Reference number(s)
2393-A

Standard Medicare Part B Management Stelara and Biosimilars Intravenous (IV)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Stelara	ustekinumab	intravenous (IV)
Imuldosa	ustekinumab-srlf	intravenous (IV)
Otulfi	ustekinumab-aauz	intravenous (IV)
Pyzchiva	ustekinumab-ttwe	intravenous (IV)
Selarsdi	ustekinumab-aekn	intravenous (IV)
Starjemza	ustekinumab-hmny	intravenous (IV)
Steqeyma	ustekinumab-stba	intravenous (IV)
Wezlana	ustekinumab-auub	intravenous (IV)
Yesintek	ustekinumab-kfce	intravenous (IV)
ustekinumab (unbranded Stelara)	ustekinumab	intravenous (IV)
ustekinumab-aauz (unbranded Otulfi)	ustekinumab-aauz	intravenous (IV)
ustekinumab-aekn (unbranded Selarsdi)	ustekinumab-aekn	intravenous (IV)
ustekinumab-stba (unbranded Steqeyma)	ustekinumab-stba	intravenous (IV)
ustekinumab-ttwe (unbranded Pyzchiva)	ustekinumab-ttwe	intravenous (IV)

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Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, the member has no exclusions to the prescribed therapy, and the drug or biological is usually not self-administered. The criteria outlined in this policy is only applicable to drugs not usually self-administered and are furnished incident to a physician's service. Requests for drugs on a region's self-administered drug list are not covered. Members enrolled in Medicare Part D may seek coverage under their Medicare Part D plan.

FDA-approved Indications[1-13]

- Treatment of adult patients with moderately to severely active Crohn's disease (CD)
- Treatment of adult patients with moderately to severely active ulcerative colitis (UC)

The following indications are FDA-approved but the drug approved to treat the indication is usually self-administered and thus not covered by this policy.

- Treatment of patients 6 years or older with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Treatment of patients 6 years or older with active psoriatic arthritis (PsA)

Compendial Uses[14,15]

Immune checkpoint inhibitor-related toxicity

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

Immune checkpoint inhibitor-related toxicity

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

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Coverage Criteria

Crohn's disease (CD)[1-13]

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Ulcerative colitis (UC)[1-13]

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Immune checkpoint inhibitor-related toxicity[14,15]

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related diarrhea or colitis when the member has had an inadequate response, intolerance, or has a contraindication to infliximab or vedolizumab.

Summary of Evidence

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

- The prescribing information for Stelara and its biosimilars.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Management of immunotherapy-related toxicities
- An evidence-based systematic review on medical therapies for inflammatory bowel disease
- ACG Clinical Guideline: Management of Crohn's Disease in Adults
- 2025 ACG Clinical Guideline: Ulcerative Colitis in Adults
- AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis
- AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Stelara and its biosimilars are covered in addition to immune checkpoint inhibitor-related toxicity.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using ustekinumab to manage immune checkpoint inhibitor-related toxicity can be found in the National Comprehensive Cancer Network's guideline for the management of immunotherapy-related toxicities. The NCCN Guideline for the management of immunotherapy-related toxicities supports the use of adding ustekinumab for mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin. Additionally, consider ustekinumab for infliximab- and/or vedolizumab-refractory moderate (G2) or severe (G3-4) diarrhea or colitis.

References

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2. Imuldosa [package insert]. Raleigh, NC: Accord BioPharma Inc.; October 2024.
3. Otulfi [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2024.
4. Pyzchiva [package insert]. Princeton, NJ: Sandoz Inc.; December 2024.
5. Selarsdi [package insert]. Leesburg, VA: Alvotech USA Inc.; October 2024.
6. Starjemza [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2025.
7. Steqeyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; June 2025.
8. ustekinumab [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
9. ustekinumab-aauz [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; April 2025.
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11. ustekinumab-stba [package insert]. Jersey City, NJ: Celltrion USA, Inc.; April 2025.
12. ustekinumab-ttwe [package insert]. Grand Cayman, Cayman Islands: Quallent Pharmaceuticals Health LLC; March 2025.
13. Wezlana [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2024.
14. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
15. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 21, 2025.
16. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immunotherapy-Related Toxicities. Version 1.2025. Available at: www.nccn.org. Accessed January 21, 2025.
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