

Ustekinumab:
Stelara®; Wezlana™
(Intravenous)

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I. Additional Information:

FOR SUBCUTANEOUS (SC) DOSAGE FORMS, USE NAVITUS 'STELARA SC' PA FORM TO MAKE REQUESTS FOR AUTHORIZATION.

FOR INTRAVENOUS DOSAGE FORMS, Please provide PA request to the Plan Pharmacy Services.

After IV induction dose, if continuation of therapy is needed with the SC product, a separate request for the SC dosage form is required. Please use the Navitus 'STELARA' PA form and note in the request that Stelara IV had been previously approved and that the provider requests continuing therapy with the SC product. The IV dosage form is available only through the medical benefit with prior authorization through the Plan Pharmacy Services and is not covered through the pharmacy benefit. The SC dosage form is available only through the pharmacy benefit with prior authorization through Navitus using the STELARA SC PA form.

II. Length of Authorization ¹⁻¹¹

Crohn's Disease and Ulcerative Colitis and Immune Checkpoint Inhibitor Related Diarrhea/Colitis:

Coverage will be approved for one (1) dose within 3 months

III. Dosing Limits

Stelara/Wezlana 130 mg (5 mg/mL) single-dose vial: 4 vials (total 520 billable units) x 1 dose

Requested dose should be indicated along with weight of patient

- 260 mg (two of the 130mg vials) - <= 55kg
- 390 mg (three of the 130mg vials) - >55kg and <=85kg
- 520 mg (four of the 130mg vials) - >85kg

IV. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

Crohn's Disease † ^{1,2,12-17} /Ulcerative Colitis † ^{1,2,18-25}

- Documented diagnosis of moderate to severe Crohn's disease or ulcerative colitis; **AND**
- Prescribed by a gastroenterology specialist; **AND**
- Not currently established on ustekinumab (Stelara); **AND**

Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis ‡ ^{3,26}

- Patient is at least 18 years of age; **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, tremelimumab, dostarlimab, retifanlimab, etc.); **AND**
 - Patient has mild (G1) diarrhea or colitis with persistent or progressive symptoms and is lactoferrin/calprotectin positive; **OR**
 - Patient has moderate (G2) to severe (G3-4) diarrhea or colitis that is refractory to infliximab and/or vedolizumab

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

NOTE: Stelara (ustekinumab) may NOT be approved for an individual with ANY of the following:

- Concurrent treatment with another TNF-inhibitor, IL-inhibitor, biologic response modifier or other non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib, deucravacitinib, etc.)
- Tuberculosis, invasive fungal infection, or other active serious infections
- Receiving live vaccines during therapy
- Treatment of all other indications, including but not limited to ankylosing spondylitis, relapsing-remitting multiple sclerosis, and rheumatoid arthritis.

V. Renewal Criteria ^{1,2}

- **NOTE:** After IV induction dose, if continuation of therapy is needed with the SC product, a separate request for the SC dosage form is required. Please use the Navitus 'STELARA SC' PA form.

VI. Billing Code/Availability Information

HCPCS Code:

- J3358 – Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg
- J3590 – Unclassified biologics (Wezlana only)

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NDC:

- Intravenous
 - Stelara 130 mg (5 mg/mL) single-dose vial (SDV): 57894-0054-xx
 - Wezlana 130 mg/26mL (5 mg/mL) single-dose vial: 55513-0066-xx

VII. References

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26. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ustekinumab. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2023.

Appendix 1 – Covered Diagnosis Codes

Intravenous (J3358)

ICD-10	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula

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ICD-10	ICD-10 Description
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction

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ICD-10	ICD-10 Description
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
R19.7	Diarrhea, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC