

Stelara® (ustekinumab) (Intravenous/Subcutaneous)

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I. Length of Authorization

Crohn's Disease and Ulcerative Colitis:

Coverage will be provided for 8 weeks initially and may be renewed in 6 month intervals thereafter.

All other indications:

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Subcutaneous

- Stelara 45 mg vial/prefilled syringe:
 - Loading: 1 syringe at weeks 0 & 4
 - Maintenance: 1 syringe every 12 weeks
- Stelara 90 mg prefilled syringe:
 - Loading: 1 syringe at weeks 0 & 4
 - Maintenance: 1 syringe every 8 weeks

Intravenous

- Stelara 130 mg (5 mg/mL) single-dose vial: 4 vials

B. Max Units (per dose and over time) [HCPCS Unit]:

Indication	Max Units
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	<u>Subcutaneous Loading (J3357):</u> <ul style="list-style-type: none">• 90 billable units at weeks 0 & 4; maintenance dosing 12 weeks later <u>Subcutaneous Maintenance (J3357):</u> <ul style="list-style-type: none">• 90 billable units every 12 weeks
Psoriatic Arthritis	<u>Subcutaneous Loading (J3357):</u> <ul style="list-style-type: none">• 45 billable units at weeks 0 & 4; maintenance dosing 12 weeks later

Indication	Max Units
	<u>Subcutaneous Maintenance (J3357):</u> <ul style="list-style-type: none"> 45 billable units every 12 weeks
Crohn's Disease & Ulcerative Colitis	<u>Intravenous Induction (J3358):</u> <ul style="list-style-type: none"> 520 billable units <u>Subcutaneous Maintenance (J3357):</u> <ul style="list-style-type: none"> 90 billable units 8 weeks after induction & every 8 weeks thereafter

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria ¹

- Patient has been evaluated and screened for the presence of latent (tuberculosis) TB infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**

Plaque Psoriasis (PsO) † ^{1-5,25,26,30}

- Patient is at least 6 years of age; **AND**
- Patient has moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
 - Involvement of at least 3% of body surface area (BSA); **OR**
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
- Patient did not respond adequately (or is not a candidate) to a 4 week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least one non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**

- Patient did not respond adequately (or is not a candidate*) to a 3 month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)

Psoriatic Arthritis (PsA) † 1,6-9,15,16,17,27,33

- Patient has documented moderate to severe active disease; **AND**
 - For patients with predominantly axial disease OR active enthesitis, a trial and failure of at least a 4 week trial of ONE (1) non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**
 - For patients with peripheral arthritis or dactylitis, a trial and failure of at least a 3 month trial of ONE (1) oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc.

Crohn's Disease † 1,10-12,14,18,24

- Documented moderate to severely active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g., adalimumab, certolizumab, or infliximab)

Ulcerative Colitis † 1,13,19-23,29

- Documented moderate to severe active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g., adalimumab, golimumab, or infliximab)

*Examples of contraindications to phototherapy (PUVA or UVB) include the following: 31,32

- Xeroderma pigmentosum
- Pregnancy or lactation (PUVA only)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, malignancy, severe hypersensitivity reactions, posterior reversible encephalopathy syndrome (PRES) or reversible posterior leukoencephalopathy syndrome (RPLS), non-infectious pneumonia, etc.; **AND**

Plaque Psoriasis (PsO) ^{15,16}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement $\leq 1\%$), and/or an improvement on a disease activity scoring tool [e.g., a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four-point reduction in the DLQI from when treatment started].

Psoriatic Arthritis (PsA) ¹⁴

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g., defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria].

Crohn's Disease ¹³

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

Ulcerative Colitis ¹⁹⁻²³

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

V. Dosage/Administration

Indication	Dose
Plaque Psoriasis & Psoriatic Arthritis with Co-existent Moderate-Severe Plaque Psoriasis	<u>Adult Subcutaneous Loading Dose:</u> <ul style="list-style-type: none"> <100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <u>Adult Subcutaneous Maintenance Dose:</u> <ul style="list-style-type: none"> <100 kg: 45 mg every 12 weeks >100 kg: 90 mg every 12 weeks
	<u>Pediatric Subcutaneous Loading Dose:</u> <ul style="list-style-type: none"> <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later 60 – 100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <u>Pediatric Subcutaneous Maintenance Dose:</u> <ul style="list-style-type: none"> <60 kg: 0.75 mg/kg every 12 weeks 60 – 100 kg: 45 mg every 12 weeks >100 kg: 90 mg every 12 weeks
	<u>Subcutaneous Loading Dose:</u> <ul style="list-style-type: none"> 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <u>Subcutaneous Maintenance Dose:</u> <ul style="list-style-type: none"> 45 mg every 12 weeks
Crohn's Disease & Ulcerative Colitis	<u>Intravenous Induction Dose (one-time only):</u> <ul style="list-style-type: none"> ≤ 55 kg: 260 mg > 55 kg to 85 kg: 390 mg > 85 kg: 520 mg <u>Subcutaneous Maintenance Dose:</u> <ul style="list-style-type: none"> 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter

VI. Billing Code/Availability Information

HCPCS Code:

- J3357 – Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg
- J3358 – Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg

NDC:

- Subcutaneous
 - Stelara 45 mg single-dose vial (SDV) and prefilled (PF) syringe: 57894-0060-xx
 - Stelara 90 mg prefilled (PF) syringe: 57894-0061-xx
- Intravenous
 - Stelara 130 mg (5 mg/mL) single-dose vial (SDV): 57894-0054-xx

VII. References

- Stelara [package insert]. Horsham, PA; Janssen Biotech, Inc; December 2020. Accessed September 2021.

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Appendix 1 – Covered Diagnosis Codes

Subcutaneous (J3357)

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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
L40.0	Psoriasis vulgaris

ICD-10	ICD-10 Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
R19.7	Diarrhea, unspecified

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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC