



Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Stelara	Drug Generic Name:	Ustekinumab
J Code:	J3357 (SUBQ) [†]	1 billable unit =	1 mg
Original Date of Review:	12/7/2022	Last Reviewed:	6/12/2024
Revision Date History	12/7/2022, 8/30/2023, 6/12/2024		

[†]Prior authorization is only required for SUBQ formulations (J3357). IV formulation (J3358) does not require a prior authorization.

Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation.

Criteria:

- **Length of authorization (LOA):**
 - **Crohn's Disease and Ulcerative Colitis:** 8 weeks (initial); 6 months (renewal)
 - **Immune Checkpoint Inhibitor Related Diarrhea/Colitis:** up to 3 maintenance SUBQ doses total following IV induction dose. May not be renewed.
 - **All other indications:** 6 months (initial); 6 months renewal
- **Age: see below for product specific requirements**
- **Diagnoses:**
 - Plaque Psoriasis (Moderate to Severe)
 - Psoriatic Arthritis, Active
 - Chron's Disease (Moderate to Severe)
 - Ulcerative Colitis (Moderate to Severe)
 - Immune Checkpoint Inhibitor Related Diarrhea/colitis
- **Quantity Limit:**
 - 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

- **Maximum Units:**

Indication	Billable Units	Per Number of Days
Plaque psoriasis (Moderate to Severe) & Psoriatic Arthritis with co- existent moderate-severe Plaque Psoriasis	90	<u>Initiation:</u> 0 and 4 weeks <u>Maintenance:</u> starting 12 weeks after last initiation dose; every 12 weeks
Psoriatic Arthritis, Active (without co-existent Plaque Psoriasis)	45	<u>Initiation:</u> 0 and 4 weeks <u>Maintenance:</u> starting 12 weeks after last initiation dose; every 12 weeks
Crohn's Disease & Ulcerative Colitis	90	<u>Maintenance:</u> ** Starting 8 weeks after IV induction therapy; every 8 weeks (may be given as frequently as every 4 weeks if criteria for dose escalation is met; see Dosage/Administration)
Immune Checkpoint Inhibitor Related Diarrhea/Colitis	90	<u>Maintenance:</u> Starting 8 weeks after IV induction therapy; every 8 weeks for up to 3 maintenance doses

- **Initial Approval Criteria**

- **Universal Criteria**

- 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**
- 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**
- Provider attests that the patient will be screened for active infection, including clinically important localized infections, prior to each administration of this medication; **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**

- **Indication Specific Criteria**

- **Plaque Psoriasis**

- 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 at least TWO (2) therapeutically different 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 (1) 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**
 - 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**
 - 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**
 - 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); **OR**
 - 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)

- **Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); **AND**
 - Patient has mild (grade 1) diarrhea or colitis with persistent or progressive symptoms and is lactoferrin/calprotectin positive; **OR**
 - Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy and is refractory to infliximab and/or vedolizumab

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

- 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*)

- **Renewal Criteria**

- **Universal Renewal 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**

- **Indication Specific Renewal Criteria**

- **Plaque Psoriasis**

- 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**

- 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**

- 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**

- 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].

- **Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**

- May not be renewed

- **Dosage/Administration**

Stelara (SUBQ)	
Indication	Dose (Subcutaneous administration)
Plaque Psoriasis (Moderate to Severe) & Psoriatic Arthritis with Co-existent Moderate-Severe Plaque Psoriasis	<u>Adult Loading Dose:</u> - Weight ≤100 kg: ○ 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later - Weight >100 kg: ○ 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <u>Adult Maintenance Dose:</u> - Weight ≤100 kg: 45 mg every 12 weeks - Weight >100 kg: 90 mg every 12 weeks
Indication	Dose (Subcutaneous administration)
Plaque Psoriasis (Moderate to Severe) & Psoriatic Arthritis with Co-existent Moderate-Severe Plaque Psoriasis (Continued)	<u>Pediatric Loading Dose:</u> - Weight <60 kg:

	<ul style="list-style-type: none"> ○ 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later - Weight 60 – 100 kg: <ul style="list-style-type: none"> ○ 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later - Weight >100 kg: <ul style="list-style-type: none"> ○ 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <p><u>Pediatric Maintenance Dose:</u></p> <ul style="list-style-type: none"> - Weight <60 kg: 0.75 mg/kg every 12 weeks - Weight 60 – 100 kg: 45 mg every 12 weeks - Weight >100 kg: 90 mg every 12 weeks
Psoriatic Arthritis, Active (without co-existent Plaque Psoriasis)	<p><u>Loading Dose:</u></p> <ul style="list-style-type: none"> - 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <p><u>Maintenance Dose:</u></p> <ul style="list-style-type: none"> - 45 mg every 12 weeks
Crohn's Disease & Ulcerative Colitis	<p><u>Maintenance dose:</u> **</p> <ul style="list-style-type: none"> - Begin 8 weeks after IV induction dose - 90 mg every 8 weeks (may be given up to every 4 weeks if criteria for dose escalation is met; see below)
<p>**Criteria for Crohn's Disease & Ulcerative Colitis dose escalation:</p> <ul style="list-style-type: none"> - may occur upon clinical review on a case-by-case basis provided that the patient has: <ul style="list-style-type: none"> ○ Shown an initial response to therapy; AND ○ Received an initial intravenous loading dose; AND ○ Received a minimum of one subcutaneous maintenance dose as specified above; AND ○ Responded to therapy (by treatment week 16[¥]) with subsequent loss of response; AND ○ Has a ustekinumab trough of <4.5 mcg/ml ○ Dose escalation must not exceed the following limits: <ul style="list-style-type: none"> ▪ <u>90 mg every 4 weeks</u> (certain patients may benefit from a smaller reduction in interval if they become symptomatic 5, 6, or 7 weeks after the prior administration) <ul style="list-style-type: none"> • <u>Initial coverage</u> at escalated dosing will be provided for <u>3 months</u> with continued approval contingent upon demonstration of clinical improvement (as specified under LOA and renewal criteria) and ustekinumab levels. <ul style="list-style-type: none"> ○ Patients who do <u>not</u> regain response at a 4-week interval should discontinue therapy ○ Patients who are responding to therapy may continue with their current dosing or consider frequency adjustment as defined below: <ul style="list-style-type: none"> ▪ Patients who are well-controlled with a trough ≥4.5 micrograms/mL on the 4-week dosing interval may be candidates to increase the interval between administrations from 4 weeks to 6 weeks. Response should be assessed after 3 months at this every 6-week interval. Those patients demonstrating loss of response may decrease the interval back to 90 mg every 4 weeks. • <u>Renewal coverage</u> at escalated dosing will follow indication-specific renewal criteria and duration. ○ Some patients may benefit from one additional IV loading dose in conjunction with this more frequent maintenance dosing interval. 	

^y Requests for dose escalation prior to week 16: <ul style="list-style-type: none"> ○ Request for dose escalation prior to week 16 will be evaluated considering the patient’s clinical picture regarding severity of inflammation, factors which may result in subtherapeutic response to standard dosing (e.g., hypoalbuminemia, prior TNF-I failure), timing of response and breakthrough/loss of response, presence of perianal fistula; AND ○ ustekinumab trough is <4.5 micrograms/mL 	
Immune Checkpoint Inhibitor- Related Diarrhea/Colitis	<u>Maintenance Dose:</u> <ul style="list-style-type: none"> - Begin 8 weeks after IV induction dose - 90 mg every 8 weeks for up to 3 maintenance doses only

NDC:

- Stelara 45 mg single-dose vial (SDV) and prefilled (PF) syringe: 57894-0060-xx
- Stelara 90 mg prefilled (PF) syringe: 57894-0061-xx

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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
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
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
K51.20	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
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
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
L40.8	Other Psoriasis
L40.9	Psoriasis, unspecified
L73.2	Hidradentis suppurativa