Medical Policy:

Ustekinumab IV solution and SC injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.106	May 30, 2025	April 1, 2019

Definitions

Ustekinumab is a human IgG1-kappa monoclonal antibody that binds to the p40 subunits of IL-12 and IL-23 cytokines and interferes with inflammatory and immune responses.

Length of Authorization

Crohn's Disease and Ulcerative Colitis:

Initial coverage will be provided for 8 weeks and may be renewed annually thereafter.

- Dose escalation requests for Crohn's Disease and Ulcerative Colitis: will be provided for 3 months with continued renewal annually thereafter (See Section V for continuation details).

All other indications:

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [Medical Benefit]:

Indication	Max Units
Crohn's Disease, Ulcerative Colitis	Intravenous Induction (J3358): • 520 billable units x 1 dose Subcutaneous Maintenance (J3357): • 90 billable units (90 mg) 8 weeks after induction & every 4 weeks thereafter
Psoriatic Arthritis	Subcutaneous Loading (J3357): • 45 billable units (45mg) at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance (J3357): • 45 billable units (45 mg) every 12 weeks
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	Subcutaneous Loading (J3357): • 90 billable units (90 mg) at weeks 0 & 4; maintenance dosing 12 weeks later Subcutaneous Maintenance (J3357): • 90 billable units (90 mg) every 12 weeks

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

- Patient is 18 years or older (unless otherwise specified); **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient is free of any clinically important active infections; **AND**
- Therapy will not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

Intravenous Induction Criteria:

1. Crohn's Disease † (intravenous induction)

A. Documented moderate to severely active disease; **AND**

i. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of ONE corticosteroid or immunomodulator (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **OR**

ii. 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) **OR**

iii. Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary; **OR**

iv. Patient is already established on biologic or targeted synthetic therapy for the treatment of CD

2. Moderately to severely active ulcerative colitis † (intravenous induction)

A. Documented moderate to severely active disease; **AND**

i. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of ONE corticosteroid or immunomodulator (e.g. azathioprine, 6-mercaptopurine); **OR**

ii. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, or infliximab)

Subcutaneous Formulation

1. Adult Plaque Psoriasis (PsO) Subcutaneous

A. Documented moderate to severe plaque psoriasis for at least 6 months with at least **ONE** of the following:
   i. Involvement of at least 3% of body surface area (BSA); **OR**
   ii. Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
   iii. Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**

B. 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**

C. 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**

D. 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)

2. Pediatric Plaque Psoriasis (PsO) Subcutaneous

A. Patient is at least 6 years of age; **AND**

B. Documented moderate to severe plaque psoriasis for at least 6 months with at least **ONE** of the following:
   i. Involvement of at least 3% of body surface area (BSA); **OR**
   ii. Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
   iii. Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; AND

C. 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**

D. 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**

E. 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

3. Adult Psoriatic Arthritis (PsA) Subcutaneous

A. Documented moderate to severe active disease; **AND**
   i. 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**

ii. 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.

4. Juvenile Psoriatic Arthritis (PsA) Subcutaneous

A. Patient is at least 6 years of age; **AND**
B. Documented moderate to severe active polyarticular disease**; AND**
C. May be used as a single agent or in combination with methotrexate; **AND**
D. Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) **OR** an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

5. Crohn's Disease Subcutaneous

A. Documented moderate to severely active disease; **AND**
B. 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**
C. 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)

6. Ulcerative Colitis Subcutaneous

A. Documented moderate to severe active disease; **AND**
    i. 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**
    ii. 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)

† FDA Approved Indication(s)

Limitations/Exclusions

Stelara (ustekinumab) is not considered medically necessary for indications other those listed above due to insufficient evidence of therapeutic value.

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

1. Patient continues to meet the universal and other indication-specific relevant criteria identified in initial criteria; **AND**
2. Duration of authorization has not been exceeded (refer to initial criteria) **AND**
3. 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)

1. 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 ≤ 1%), and/or an improvement on a disease activity scoring tool [e.g., Psoriasis Area and Severity Index (PASI) score ≤ 3, physician's global assessment (PGA) score ≤ 1, etc.].

Adult Psoriatic Arthritis (PsA)

1. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI), 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].

Juvenile Psoriatic Arthritis (JPsA)

1. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI), and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

Crohn's Disease

1. 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 regain, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, improvement in biomarker levels [i.e., fecal calprotectin or serum C-reactive protein (CRP)], and/or an improvement on a disease activity scoring tool (e.g., Harvey-Bradshaw Index score, etc.)

Ulcerative Colitis

1. Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, 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.

Dosing/Administration

Indication	Dose
Crohn's Disease, Ulcerative Colitis	Intravenous Induction Dose (one-time only): • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg Subcutaneous Maintenance Dose: 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter
Plaque Psoriasis	Adult Subcutaneous Loading Dose: • ≤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 Adult Subcutaneous Maintenance Dose: • ≤100 kg: 45 mg every 12 weeks

Indication	Dose
	• >100 kg: 90 mg every 12 weeks Pediatric Subcutaneous Loading Dose: • <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 Pediatric Subcutaneous Maintenance Dose: • <60 kg: 0.75 mg/kg every 12 weeks • 60 – 100 kg: 45 mg every 12 weeks • >100 kg: 90 mg every 12 weeks
Psoriatic Arthritis	Adult Subcutaneous Loading Dose: • 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Adult Subcutaneous Maintenance Dose: • 45 mg every 12 weeks • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg every 12 weeks Pediatric Subcutaneous Loading Dose: • <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • ≥60 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Pediatric Subcutaneous Maintenance Dose: • <60 kg: 0.75 mg/kg every 12 weeks • ≥60 kg: 45 mg every 12 weeks • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg every 12 weeks

Applicable Procedure Codes

Code	Description
J3358	Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg (Stelara IV only)
J3357	Ustekinumab, for subcutaneous injection, 1 mg (Stelara SQ only)
J3590	Unclassified biologics (Imuldosa, Steqeyma/Ustekinumab-stba, and Yesintek ONLY) (Discontinue use on 07/01/2025)
Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg; 1 billable unit = 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg; 1 billable unit = 1 mg
Q9996	Ustekinumab-ttwe (pyzchiva) , for subcutaneous injection, 1 mg
Q9997	Ustekinumab-ttwe (pyzchiva) , for intravenous injection 1 mg
Q9998♦	Ustekinumab-aekn (selarsdi), for subcutaneous injection 1mg
Q9999♦	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg
Q5098♦	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg; 1 billable unit = 1 mg (Effective 07/01/2025)
Q5100♦	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg; 1 billable unit = 1 mg (Effective 07/01/2025)
Q5099♦	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg; 1 billable unit = 1 mg (Includes unbranded biologic§) (Effective 07/01/2025)

♦ ***Note**: CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.*

Applicable NDCs – Subcutaneous

Code	Description
57894-0060-xx	Stelara 45 mg/0.5 mL single-dose prefilled syringe
57894-0061-xx	Stelara 90 mg/mL single-dose prefilled syringe
57894-0060-xx	Stelara 45 mg/0.5 mL single-dose vial
84612-0076-xx	Wezlana 45 mg/0.5 mL single-dose prefilled syringe
84612-0876-xx	Wezlana 45 mg/0.5 mL single-dose prefilled syringe
84612-0089-xx	Wezlana 90 mg/mL single-dose prefilled syringe
84612-0889-xx	Wezlana 90 mg/mL single-dose prefilled syringe
84612-0055-xx	Wezlana 45 mg/0.5 mL single-dose vial
84612-0855-xx	Wezlana 45 mg/0.5 mL single-dose vial
83257-0023-xx	Yesintek 45 mg/0.5 mL single-dose prefilled syringe
83257-0025-xx	Yesintek 90 mg/mL single-dose prefilled syringe
83257-0024-xx	Yesintek 45 mg/0.5 mL single-dose vial
72606-0027-xx	Steqeyma 45 mg/0.5 mL single-dose prefilled syringe
72606-0028-xx	Steqeyma 90 mg/mL single-dose prefilled syringe
61314-0651-xx	Pyzchiva 45 mg/0.5 mL single-dose prefilled syringe
61314-0652-xx	Pyzchiva 90 mg/mL single-dose prefilled syringe
61314-0651-xx	Pyzchiva 45 mg/0.5 mL single-dose vial
65219-0824-xx	Otulfi 45 mg/0.5 mL single-dose prefilled syringe:
65219-0826-xx	Otulfi 90 mg/mL single-dose prefilled syringe:
65219-0822-xx	Otulfi 45 mg/0.5 mL single-dose vial
69448-0017-xx	Imuldosa 45 mg/0.5 mL single-dose prefilled syringe
69448-0018-xx	Imuldosa 90 mg/mL single-dose prefilled syringe:
51759-0505-xx	Selarsdi 45 mg/0.5 mL single-dose prefilled syringe:
51759-0607-xx	Selarsdi 90 mg/mL single-dose prefilled syringe:
51759-0505-xx	Selarsdi 45 mg/0.5 mL single-dose vial:
57894-0440-xx	Ustekinumab 45 mg/0.5 mL single-dose prefilled syringe
57894-0441-xx	Ustekinumab 90 mg/mL single-dose prefilled syringe (§Unbranded biologic of Stelara)
57894-0440-xx	Ustekinumab 45 mg/0.5 mL single-dose vial (§Unbranded biologic of Stelara)
51759-0709-xx	Ustekinumab-aekn 45 mg/0.5 mL single-dose prefilled syringe (§Unbranded biologic of Stelara)
51759-0710-xx	Ustekinumab-aekn 90 mg/mL single-dose prefilled syringe (§Unbranded biologic of Selarsdi)
82009-0160-xx	Ustekinumab-ttwe 45 mg/0.5 mL single-dose prefilled syringe (§Unbranded biologic of Pyzchiva)
82009-0162-xx	Ustekinumab-ttwe 90 mg/mL single-dose prefilled syringe (§Unbranded biologic of Pyzchiva)
65219-0862-xx	Ustekinumab-aauz 45 mg/0.5 mL single-dose prefilled syringe (§Unbranded biologic of Otulfi)
65219-0866-xx	Ustekinumab-aauz 90 mg/mL single-dose prefilled syringe (§Unbranded biologic of Otulfi)
65219-0864-xx	Ustekinumab-aauz 45 mg/0.5 mL single-dose vial (§Unbranded biologic of Otulfi)
72606-0055-xx	Ustekinumab-stba 45 mg/0.5 mL single-dose prefilled syringe (§Unbranded biologic of Steqeyma)
72606-0056-xx	Ustekinumab-stba 90 mg/mL single-dose prefilled syringe (§Unbranded biologic of Steqeyma)

Applicable NDCs – Intravenous

Code	Description
57894-0054-xx	Stelara 130 mg/26 mL (5 mg/mL) single-dose vial
84612-0066-xx	Wezlana 130 mg/26 mL (5 mg/mL) single-dose vial
83257-0026-xx	Yesintek 130 mg/26 mL (5 mg/mL) single-dose vial
72606-0029-xx	Steqeyma 130 mg/26 mL (5 mg/mL) single dose vial
61314-0654-xx	Pyzchiva 130 mg/26 mL (5 mg/mL) single-dose vial
65219-0828-xx	Otulfi 130 mg/26 mL (5 mg/mL) single-dose vial:
69448-0019-xx	Imuldosa 130 mg/26 mL (5 mg/mL) single-dose vial
51759-0708-xx	Selarsdi 130 mg/26 mL (5 mg/mL) single-dose vial
57894-0444-xx	Ustekinumab 130 mg/26 mL (5 mg/mL) single-dose vial (§Unbranded biologic of Stelara)
51759-0711-xx	Ustekinumab-aekn 130 mg/26 mL (5 mg/mL) single-dose vial (§Unbranded biologic of Selarsdi)
82009-0163-xx	Ustekinumab-ttwe 130 mg/26 mL (5 mg/mL) single-dose vial (§Unbranded biologic of Pyzchiva)
65219-0868-xx	Ustekinumab-aauz 130 mg/26 mL (5 mg/mL) single-dose vial (§Unbranded biologic of Otulfi)
72606-0057-xx	Ustekinumab-stba 130 mg/26 mL (5 mg/mL) single-dose vial (§Unbranded biologic of Steqeyma)

§An unbranded biologic is the same as the brand biologic and uses the same cell-line as the brand-name reference biologic.

ICD-10 Diagnoses

Code	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	Ulcerative Colitis
K51.00	Ulcerative (chronic) pancolitis without complications
K51.01	Ulcerative (chronic) pancolitis with 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
K51.2	Ulcerative (chronic) proctitis
K51.20	Ulcerative (chronic) proctitis without complications
K51.21	Ulcerative (chronic) proctitis with 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
K51.3	Ulcerative (chronic) rectosigmoiditis
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.31	Ulcerative (chronic) rectosigmoiditis with 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
K31.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.5	Left sided colitis
K51.50	Left sided colitis without complications
K51.51	Left sided colitis with 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
K51.8	Other ulcerative colitis
K51.80	Other ulcerative colitis without complications
K51.81	Other ulcerative colitis with 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
K51.9	Ulcerative colitis, unspecified
K51.90	Ulcerative colitis, unspecified without complications
K51.91	Ulcerative colitis, unspecified with 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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	5/29/2025	Update: Wezlana intravenous was added to the policy; the same criteria apply for Wezlana and for Stelara intravenous. Selarsdi, Steqeyma, and Yesintek intravenous were added to the policy; the same criteria apply for all ustekinumab intravenous products. Ustekinumab-ttwe intravenous was added to the policy; the same criteria apply as the other ustekinumab intravenous products. Ustekinumab intravenous (unbranded Stelara) was added to the policy; the same criteria apply as the other ustekinumab intravenous products. Update and separated applicable NDC for subcutaneous and IV products available,
EmblemHealth & ConnectiCare	4/8/2025	Update: changed policy name from Stelara to Ustekinumab. Addition of Otulfi to policy, dosing limits/charts/length of authorization and criteria. Added Otulfi NDCs and Jcode Updated length of authorizations Addition of criteria for Crohn's Disease: i. Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary; OR ii. Patient is already established on biologic or targeted synthetic therapy for the treatment of CD. Addition of Renewal criteria
EmblemHealth & ConnectiCare	11/12/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	4/1/2024	Update: Initial Criteria: Crohn's Disease subcutaneous: updated from "AND" to "OR" in between the following statements: "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, certolizumab, or infliximab)"
EmblemHealth & ConnectiCare	3/12/2024	Corrected formatting

<table>
<tr><td>EmblemHealth & ConnectiCare</td><td>03/01/2024</td><td>Update: Added Stelara SC to policy, Dosing Limits, dosing chart, length of authorization and criteria. Added J3357 and SC formulation NDCs.</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>4/27/2023</td><td>Annual Review: No criteria changes</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>1/12/2023</td><td>Transfer to New Template</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>4/17/2020</td><td>The following ICD 10 Codes were added for Ulcerative Colitis:<table>
<tr><td>K51</td><td>Ulcerative Colitis</td></tr>
<tr><td>K51.00</td><td>Ulcerative (chronic) pancolitis without complications</td></tr>
<tr><td>K51.01</td><td>Ulcerative (chronic) pancolitis with complications</td></tr>
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<tr><td>K51.21</td><td>Ulcerative (chronic) proctitis with complications</td></tr>
<tr><td>K51.211</td><td>Ulcerative (chronic) proctitis with rectal bleeding</td></tr>
<tr><td>K51.212</td><td>Ulcerative (chronic) proctitis with intestinal obstruction</td></tr>
<tr><td>K51.213</td><td>Ulcerative (chronic) proctitis with fistula</td></tr>
<tr><td>K51.214</td><td>Ulcerative (chronic) proctitis with abscess</td></tr>
<tr><td>K51.218</td><td>Ulcerative (chronic) proctitis with other complication</td></tr>
<tr><td>K51.219</td><td>Ulcerative (chronic) proctitis with unspecified complications</td></tr>
<tr><td>K51.3</td><td>Ulcerative (chronic) rectosigmoiditis</td></tr>
<tr><td>K51.30</td><td>Ulcerative (chronic) rectosigmoiditis without complications</td></tr>
<tr><td>K51.31</td><td>Ulcerative (chronic) rectosigmoiditis with complications</td></tr>
<tr><td>K51.311</td><td>Ulcerative (chronic) rectosigmoiditis with rectal bleeding</td></tr>
<tr><td>K51.312</td><td>Ulcerative (chronic) rectosigmoiditis with intestinal obstruction</td></tr>
<tr><td>K51.313</td><td>Ulcerative (chronic) rectosigmoiditis with fistula</td></tr>
<tr><td>K51.314</td><td>Ulcerative (chronic) rectosigmoiditis with abscess</td></tr>
<tr><td>K51.318</td><td>Ulcerative (chronic) rectosigmoiditis with other complication</td></tr>
<tr><td>K31.319</td><td>Ulcerative (chronic) rectosigmoiditis with unspecified complications</td></tr>
<tr><td>K51.5</td><td>Left sided colitis</td></tr>
<tr><td>K51.50</td><td>Left sided colitis without complications</td></tr>
<tr><td>K51.51</td><td>Left sided colitis with complications</td></tr>
</table></td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>12/10/2019</td><td>The following ICD 10 Codes were added for Ulcerative Colitis:<table>
<tr><td>K51</td><td>Ulcerative Colitis</td></tr>
<tr><td>K51.00</td><td>Ulcerative (chronic) pancolitis without complications</td></tr>
<tr><td>K51.01</td><td>Ulcerative (chronic) pancolitis with complications</td></tr>
<tr><td>K51.011</td><td>Ulcerative (chronic) pancolitis with rectal bleeding</td></tr>
</table></td></tr>
</table>

		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
		K51.2	Ulcerative (chronic) proctitis
		K51.20	Ulcerative (chronic) proctitis without complications
		K51.21	Ulcerative (chronic) proctitis with 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
		K51.3	Ulcerative (chronic) rectosigmoiditis
		K51.30	Ulcerative (chronic) rectosigmoiditis without complications
		K51.31	Ulcerative (chronic) rectosigmoiditis with 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
		K31.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
		K51.5	Left sided colitis
		K51.50	Left sided colitis without complications
		K51.51	Left sided colitis with 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
		K51.8	Other ulcerative colitis
		K51.80	Other ulcerative colitis without complications
		K51.81	Other ulcerative colitis with 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
		K51.9	Ulcerative colitis, unspecified
		K51.90	Ulcerative colitis, unspecified without complications
		K51.91	Ulcerative colitis, unspecified with 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
EmblemHealth & ConnectiCare	4/1/2019	-Under Guidelines added the following indication per FDA label: • Moderately to severely active ulcerative colitis † - Under Limitations/Exclusions: added Stelara (ustekinumab) is not considered medically necessary for indications other those listed above due to insufficient evidence of therapeutic value.	

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