

Medical Policy:

Stelara (ustekinumab) IV solution and SC injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.106	March 1, 2024	April 1, 2019

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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Definitions

Stelara® 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

<u>Crohn's Disease and Ulcerative Colitis Intravenous:</u> Coverage will be provided for 1 intravenous induction dose

<u>Psoriasis</u>, <u>Psoriatic Arthritis</u>, <u>Crohn's Disease and Ulcerative Colitis Subcutaneous</u>: Coverage will be provided for 3 months

Dosing Limits [Medical Benefit]

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

Indication	Max Units
	Intravenous Induction (J3358):
Crohn's Disease, Ulcerative Colitis	520 billable units x 1 dose
	Subcutaneous Maintenance (J3357):

Indication	Max Units	
	90 billable units (90 mg) 8 weeks after induction & every 4 weeks	
	thereafter	
	Subcutaneous Loading (J3357):	
Psoriatic Arthritis	 45 billable units (45mg) at weeks 0 & 4; maintenance dosing 12 weeks later 	
PSOFIACE AFTITICIS	Subcutaneous Maintenance (J3357):	
	 45 billable units (45 mg) every 12 weeks 	
Plaque Psoriasis &	Subcutaneous Loading (J3357):	
Psoriatic Arthritis with co-existent	90 billable units (90 mg) at weeks 0 & 4; maintenance dosing 12	
	weeks later	
moderate-severe	Subcutaneous Maintenance (J3357):	
Plaque Psoriasis	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)

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
 - 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, hydroxychloroguine, 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);

 AND
- 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
 - ii. doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **OR**
 - iii. Documented failure, contraindication, or ineffective response at maximum tolerated
 - iv. 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 cannot be renewed.

Dosing/Administration

Indication	Dose	
	Intravenous Induction Dose (one-time only):	
	• ≤ 55 kg: 260 mg	
Crohn's Disease,	• > 55 kg to 85 kg: 390 mg	
Ulcerative Colitis	• > 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:	

Indication	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
	• >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
	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
Psoriatic Arthritis	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
J3357	Ustekinumab, for subcutaneous injection, 1 mg

Applicable NDCs

Code	Description
57894-0054-xx	Stelara 130 mg (5 mg/mL) single-dose vial
57894-0061-03	Stelara 90mg/ml solution for subcutaneous injection

57894-0060-02	Stelara 45mg/0.5mL solution for subcutaneous injection
57894-0060-03	Stelara 45mg/0.5mL solution for subcutaneous injection

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

K51.212 L K51.213 L	Ulcerative (chronic) proctitis with rectal bleeding Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	
<u> </u>	
VE4 24 4	Ulcerative (chronic) proctitis with fistula
K51.214 L	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 U	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 L	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.5 L	Left sided colitis
K51.50 L	Left sided colitis without complications
K51.51 L	Left sided colitis with complications
K51.511 L	Left sided colitis with rectal bleeding
K51.512 L	Left sided colitis with intestinal obstruction
K51.513 L	Left sided colitis with fistula
K51.514 L	Left sided colitis with abscess
K51.518 L	Left sided colitis with other complication
K51.519 L	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 L	Ulcerative colitis, unspecified with complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912 L	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914 L	Ulcerative colitis, unspecified with abscess
K51.918 L	Ulcerative colitis, unspecified with other complication
K51.919 L	Ulcerative colitis, unspecified with unspecified complications

Revision History

Company(ies)	DATE	REVISION

EmblemHealth & ConnectiCare	03/01/2024	Update: Added Stelara SC to policy, Dosing Limits, dosing chart, length of authorization and criteria. Added J3357 and SC formulation NDCs.	
EmblemHealth & ConnectiCare	4/27/2023	Annual Review: No criteria changes	
EmblemHealth &	1/12/2023		
ConnectiCare		Transfer to New Template	
EmblemHealth &	4/17/2020	The following ICD 10 Codes were added for Ulcerative Colitis:	
ConnectiCare		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 complication	
		K51.5 Left sided colitis	
		K51.50 Left sided colitis without complications	
		K51.51 Left sided colitis with complications	
EmblemHealth &	12/10/2019	The following ICD 10 Codes were added for Ulcerative Colitis:	
ConnectiCare		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	
EmblemHealth &	4/1/2019	-Under Guidelines added the following indication per FDA label:		
ConnectiCare		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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