Stelara® (ustekinumab)
(Intravenous/Subcutaneous)

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I. Length of Authorization

Crohn's Disease:
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) [Pharmacy Benefit]:

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

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

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

Indication	Max Units
	• 90 billable units 8 weeks after induction & every 8 weeks thereafter

III. Initial Approval Criteria

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

- Self-administered injectable medications are not covered when supplied in a provider's office, clinic or facility.

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**

Plaque Psoriasis †

- Patient is 12 years or older; **AND**
- Patient has moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Involvement of at least 10% of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
  - Incapacitation due to plaque location (i.e. head and neck, palms, soles or genitalia); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3 month 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 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); **AND**

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following: Enbrel, Humira and Cosentyx; **OR**
- Patient is continuing treatment

Psoriatic Arthritis (PsA) †

- Documented moderate to severe active disease; **AND**

- For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; **OR**
- For patients with peripheral arthritis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine; **AND**

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following: Enbrel, Humira and Cosentyx; **OR**
- Patient is continuing treatment

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); **AND**

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Humira; **OR**
- Patient is continuing treatment

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious infections, malignancy, severe hypersensitivity reactions, reversible posterior leukoencephalopathy syndrome (RPLS), non-infectious pneumonia, etc; **AND**
- Patient is receiving ongoing monitoring for presence of TB or other active infections; **AND**

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 (PsA)

- 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.]

V. Dosage/Administration

Indication	Dose
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe 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 • >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	Subcutaneous Loading Dose: • 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Subcutaneous Maintenance Dose: • 45 mg every 12 weeks
Crohn's Disease	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

VI. Billing Code/Availability Information

Jcode:

- 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:

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

VII. References

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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

ICD-10	ICD-10 Description
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
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

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

ICD-10	ICD-10 Description
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

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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-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):

J3358

Jurisdiction(s): E	**NCD/LCD Document (s):** A52953
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52953&bc=gAAAAAAAAAAA	

Jurisdiction(s): F	**NCD/LCD Document (s):** A52991
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52991&bc=gAAAAAAAAAAA	

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