Stelara® (ustekinumab)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Plaque Psoriasis and Psoriatic arthritis with co-existent plaque psoriasis

Loading:

Stelara 90 mg: 1 prefilled syringe at weeks 0 & 4; then begin maintenance dose 12 weeks later

Maintenance:

Stelara 90 mg: 1 prefilled syringe every 84 days

Psoriatic arthritis

Loading:

Stelara 45 mg: 1 prefilled syringe at weeks 0 & 4; then begin maintenance dose 12 weeks later

Maintenance:

Stelara 45 mg: 1 prefilled syringe every 84 days

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

Plaque Psoriasis and Psoriatic arthritis with co-existent plaque psoriasis

Loading:

Male: 90 billable units at weeks 0 & 4; then begin maintenance dose 12 weeks later

Female 90 billable units at weeks 0 & 4; then begin maintenance dose 12 weeks later

Maintenance:

Male: 90 billable units every 84 days

Female: 90 billable units every 84 days

Psoriatic arthritis

Loading:

Male: 45 billable units at weeks 0 & 4; then begin maintenance dose 12 weeks later

Female 45 billable units at weeks 0 & 4; then begin maintenance dose 12 weeks later

Maintenance:

Male: 45 billable units every 84 days

Female: 45 billable units every 84 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Adult patient (18 years or older); **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**
- Stelara will not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent treatment with any other biological response modifier or biologic DMARD; **AND**

Plaque Psoriasis†

- Patient has Moderate to severe plaque psoriasis for at least 6 months with at least 1 of the following:
  - Involvement of at least 10% of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 12 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 to 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 1 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) †

- 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

†FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug; **AND**
- Ongoing monitoring for TB; **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.

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.

V. Dosage/Administration

Indication	Dose
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	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 Maintenance Dose: • <100 kg: 45 mg every 12 weeks • >100 kg: 90 mg every 12 weeks
Psoriatic Arthritis	Loading Dose:

Indication	Dose
	• 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later Maintenance Dose: • 45 mg every 12 weeks

VI. Billing Code/Availability Information

Jcode:

- J3357 – Stelara (Janssen Biotech) 45 mg, 90 mg Injection: 1 billable unit = 1mg

NDC:

- Stelara 45 mg vial – 57894-0060-02 (Janssen Biotech)
- Stelara 45 mg prefilled syringe – 57894-0060-03 (Janssen Biotech)
- Stelara 90 mg vial– 57894-0061-02 (Janssen Biotech)
- Stelara 90 mg prefilled syringe – 57894-0061-03 (Janssen Biotech)

VII. References

1. Stelara [package insert]. Horsham, PA; Janssen Biotech, Inc; March 2014. Accessed February 2016.
2. Leonardi CL, Kimball AB, Papp KA, et al, "Efficacy and Safety of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients With Psoriasis: 76-Week Results from a Randomised, Double-Blind, Placebo-Controlled Trial (PHOENIX 1)," *Lancet*, 2008, 371(9625): 1665-74.
3. Papp KA, Langley RG, Lebwohl M, et al, "Efficacy and Safety of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients With Psoriasis: 52-Week Results from a Randomised, Double-Blind, Placebo-Controlled Trial (PHOENIX 2)," *Lancet*, 2008, 371(9625): 1675-84.
4. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
5. Papp KA, Griffiths CE, Gordon K, et al. Long-term safety of ustekinumab in patients with moderate-to-severe psoriasis: final results from 5 years of follow-up. Br J Dermatol. 2013 Apr;168(4):844-54.
6. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008 May;58(5):826-50. doi: 10.1016/j.jaad.2008.02.039.
7. Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, Van Voorhees AS, Elmets CA, Leonardi CL, Beutner KR, Bhushan R, Menter A. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and

guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008 May;58(5):851-64.

8. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis. 2015 Dec 7. pii: annrheumdis-2015-208337. doi: 10.1136/annrheumdis-2015-208337.

Appendix 1 – Covered Diagnosis Codes

ICD-9 Codes	Diagnosis
696.0	Psoriatic arthropathy
696.1	Other psoriasis

ICD-10	ICD-10 Description
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy

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):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E	CA,HI, NV, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC