Ilumya™ (tildrakizumab-asmn)
(Subcutaneous)

Document Number: IH-0358

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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]:

Loading:
Ilumya 100 mg prefilled syringe: 1 at Week 0 & 4
Maintenance:
Ilumya 100 mg prefilled syringe: 1 every 12 weeks

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

- Loading:
  100 units (100 mg) at Week 0 & 4
- Maintenance:
  100 units (100 mg) every 12 weeks

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 does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib, etc.); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **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 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 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); **AND**

- Patient must have tried and failed to respond to treatment with at least two of the following: Cimzia, Remicade, Stelara, Tremfya or a contraindication exists.
- The use of samples and free goods do not qualify as an established clinical response.

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infections, severe hypersensitivity reactions, 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 ≤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].

V. Dosage/Administration

Indication	Dose
Plaque Psoriasis	100 mg subcutaneously at Week 0 and 4 then 100 mg every 12 weeks thereafter. Ilumya should be administered by a health care provider only.

VI. Billing Code/Availability Information

Jcode:

- J3245 – Injection, tildrakizumab, 1 mg: 1 billable unit = 1 mg (effective 1/1/19)
- J3590 – Unclassified biologic

NDC:

- Ilumya 100 mg prefilled syringe: 00006-4241-xx

VII. References

1. Ilumya [package insert]. Whitehouse Station, NJ; MSD-Sun Pharmaceuticals; March 2018. Accessed June 2018.
2. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
3. 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.
4. National Institute for Health and Care Excellence. NICE 2008. Infliximab for the treatment of adults with psoriasis. Published 23 January 2008. Technology Appraisal Guidance [TA134]. https://www.nice.org.uk/guidance/ta134/resources/infliximab-for-the-treatment-of-adults-with-psoriasis-pdf-82598193811141.
5. Smith CH, Jabbar-Lopez ZK, Yiu ZK, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017 Sep;177(3):628-636. doi: 10.1111/bjd.15665.
6. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. J Am Acad Dermatol. 2017 Feb; 76(2):290-298. doi: 10.1016/j.jaad.2016.10.017.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
L40.0	Psoriasis vulgaris

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): N/A

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 Government Benefit Administrators, 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