

Ilumya® (tildrakizumab-asmn) (Subcutaneous)

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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) [NDC Unit]:

- Loading:
Ilumya 100 mg single-dose prefilled syringe: 1 syringe at Weeks 0 & 4
- Maintenance:
Ilumya 100 mg single-dose prefilled syringe: 1 syringe every 12 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

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

III. Initial Approval Criteria ¹

Note: For Medicaid members, please refer to the [Medicaid specific criteria](#).

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

Universal Criteria ¹

- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**

Plaque Psoriasis † ^{1,7,12,14,16-18}

- Therapy must be initiated or recommended by a dermatologist; **AND**
- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:

- Involvement of at least 3% of body surface area (BSA); **OR**
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
 - Patient did not respond adequately (or is not a candidate) to a trial of topical agents (i.e., corticosteroids); **AND**
 - Patient did not respond adequately (or is not a candidate*) to a trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)
- Patient must have failed or experienced intolerable side effects to:
 - Any THREE (3) of the following: certolizumab (Cimzia), adalimumab (Humira), adalimumab-atto (Amjevita), ustekinumab (Stelara), risankizumab (Skyrizi), or guselkumab (Tremfya); **AND**
 - ixekizumab (Taltz)

***Examples of contraindications to phototherapy (PUVA or UVB) include the following: ^{8,9}**

- Xeroderma pigmentosum
- Pregnancy or lactation (*PUVA only*)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (*PUVA only*), or treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infections, severe hypersensitivity reactions, etc.; **AND**

Plaque Psoriasis ^{6,12}

- 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 \geq 4-point reduction in the Dermatology Life Quality Index [DLQI] from when treatment started].

V. Dosage/Administration ¹

Indication	Dose
Plaque Psoriasis	Administer 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

HCPCS Code:

- J3245 – Injection, tildrakizumab, 1 mg: 1 billable unit = 1 mg

NDC:

- Ilumya 100 mg single-dose prefilled syringe: 47335-0177-xx

VII. References

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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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/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/LCA): 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 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