Ilumya® (tildrakizumab-asmn)
(Subcutaneous)

Document Number: IC-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) [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]

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**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria [1]

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during 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 IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, etc.); **AND**

Plaque Psoriasis (PsO) † [1,7,12,14,16-19]

- 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 (e.g.., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
- 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, tapinarof, roflumilast, 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 non-biologic 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 did not respond adequately to a 3 month trial of at least one preferred tumor necrosis factor inhibitor (e.g. infliximab, adalimumab products, or etanercept). Prior authorization may be required for these agents; AND
- Patient did not respond adequately to a 3 month trial of at least two other preferred agents (including apremilast, ixekizumab, guselkumab, or risankizumab). Prior authorization may be required for these agents.

***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)* – Young age < 12 years old *(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, (e.g., angioedema, urticaria, etc.), etc.; **AND**

Plaque Psoriasis (PsO) [6,12,19]

- 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 ≥ 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

1. Ilumya [package insert]. Cranbury, NJ; Sun Pharmaceuticals Inc.; Dec 2022. Accessed June 2023.
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.
7. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Feb 13. Pii: S0190-9622(18)33001-9. https://doi.org/10.1016/j.jaad.2018.11.057.
8. Richard EG. (2022). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Dec 01, 2022. Accessed on: June 12, 2023. Available from https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20(PUVA)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
9. HoönigsmannH. (2023). UVB therapy (broadband and narrowband). In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Jan 18, 2023; Accessed on June 12, 2023. Available from https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1#H10844627.
10. Reich K, Warren RB, Iversen L, et al. Long-term efficacy and safety of tildrakizumab for moderate-to-severe psoriasis: pooled analyses of two randomized phase III clinical trials (reSURFACE 1 and reSURFACE 2) through 148 weeks. *Br J Dermatol*. 2020;182(3):605-617. Doi:10.1111/bjd.18232. Epub 2019 Jul 18.
11. American Academy of Dermatology Work Group. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
12. Smith CH, Yiu ZZN, Bale T, et al. British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update. Br J Dermatol. 2020 Oct;183(4):628-637. Doi: 10.1111/bjd.19039.
13. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol 2020; 82:1445.
14. National Institute for Health and Care Excellence (NICE). Tildrakizumab for treating moderate to severe plaque psoriasis. Technology appraisal guidance Published: 17 April 2019. www.nice.org.uk/guidance/ta575.
15. Kerbusch T, Li H, Wada R, et al. Exposure-response Characterization of tildrakizumab in chronic plaque psoriasis: Pooled analysis of 3 randomised controlled trials. Br J Clin Pharmacol. 2020 Sep;86(9):1795-1806. Doi: 10.1111/bcp.14280. Epub 2020 Mar 25.
16. National Institute for Health and Care Excellence. NICE 2013. Psoriasis. Published 06 August 2013. Quality standard [QS40]. https://www.nice.org.uk/guidance/qs40. Accessed June 2023.
17. National Institute for Health and Care Excellence. NICE 2017. Psoriasis: assessment and management. Published 24 October 2012. Clinical guideline [CG153]. https://www.nice.org.uk/guidance/CG153. Accessed June 2023.
18. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National

Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. 2019 Sep;81(3):775-804. Doi: 10.1016/j.jaad.2019.04.042

19. **Inflammatory Bowel Disease: Serologic Markers, Fecal Calprotectin, and Diagnostic Testing** Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021 Feb; 84(2):432-470. Doi: 10.1016/j.jaad.2020.07.087

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