Ilumya® (tildrakizumab-asmn)
(Subcutaneous)

Document Number: IC-0358

Last Review Date: 08/01/2024
Date of Origin: 04/03/2018
Dates Reviewed: 04/2018, 08/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 08/2024

I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

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 biologic therapy (e.g., IL-inhibitor, TNF-inhibitor, integrin receptor antagonist, T cell costimulation modulator, etc.) or targeted synthetic

therapy (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, ritlecitinib, ruxolitinib, etrasimod, ozanimod, 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 meets ALL of the following **¥**:
  - 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)

¥ *For patients already established on biologic therapy, targeted synthetic therapy, or those with > 10% BSA involvement, trial and failure of topical agents, non-biologic systemic agents, and phototherapy is not required.*

***Examples of contraindications to phototherapy (PUVA or UVB) include the following:** [8,9]
– Xeroderma pigmentosum – Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) *(UVB only)* – Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) *(UVB only)* – 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)* – Anatomical location has been deemed ineligible for phototherapy (i.e., face, genital, scalp, or nail)
Note: *Patients who do not have access to phototherapy will be reviewed on a case-by-case basis*

† 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) [6,12,19,20]

- 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. Psoriasis Area and Severity Index (PASI) score ≤ 3, physician's global assessment (PGA) score ≤ 1, etc.].

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 Pharmaceutical Industries, Inc.; April 2024. Accessed July 2024.
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: July 2, 2024. 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. Elments, CA. (2024). UVB therapy (broadband and narrowband). In Callen J, Corona R (Eds.), *UptoDate*. Last updated: March 27, 2024; Accessed on July 2, 2024. 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 July 2024.

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 July 2024.
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. Elmets CA, Korman NL, Prater EF, et al. 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
20. Foley P, Gebaur K, Sullivan J, et al. Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Adult patients. Australas J Dermatol. 2023 Nov;64(4):467-487. doi:10.1111/ajd.14138

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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		
Jurisdicti	**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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdicti	**Applicable State/US Territory**	**Contractor**
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