Ilumya® (tildrakizumab-asmn)
(Subcutaneous)

Document Number: OHSU HEALTHSERVICES-0358

Last Review Date: 03/04/2025
Date of Origin: 04/03/2018
Dates Reviewed: 04/2018, 08/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 08/2024, 03/2025

I. Length of Authorization

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

II. Dosing Limits

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 or targeted synthetic therapy; **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); **AND**
    - **¥** *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.*

For Commercial Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC (secukinumab), ustekinumab SC^, Tremfya SC (guselkumab), or Otezla (apremilast); **OR** • Patient is continuing treatment
Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz ***^Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)***
For Medicaid Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC (secukinumab), or ustekinumab SC^; **OR** • Patient is continuing treatment
Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz

^Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)

***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/mL 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)

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		
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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