Medical Policy:

Ilumya™ (tildrakizumab-asmn) Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.114	April 2, 2025	

Definitions

Ilumya (tildrakizumab-asmn) is a humanized IgG1/k monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine thatis involved in inflammatory and immune responses. Ilumya inhibits the release of pro-inflammatory cytokines and chemokines.

Ilumya (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Length of Authorization

Coverage will be provided for 6 months and may be renewed

Dosing Limits [Medical Benefit]

Max dose (per dose and over time):

- Loading: 100 mg at week 0 and 4
- Maintenance: 100 mg every 12 weeks

Guideline

I. Initial

Ilumya (tildrakizumab-asmn) is considered medically necessary for the following diagnosis when subsequent criteria are met

1. **Plaque Psoriasis:**
   - A. Patient is 18 years of age or older; **AND**
   - B. Patient has been evaluated and screened for the presence of latent TB infectionprior to initiating treatment; **AND**
   - C. Patient does not have a clinically important active infection; **AND**
   - D. Patient will not receive live vaccines during therapy; **AND**
   - E. 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**
   - F. Patient has had moderate to severe plaque psoriasis for at least 6 months and at least one of the following:
     - i. Involvement of at least 3% of body surface area (BSA); **OR**
     - ii. Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
     - iii. Incapacitation due to plaque location (i.e. head and neck, palms, soles or genitalia) or with intractable pruritis; **AND**
   - G. Patient has not responded 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, retinoic acidderivatives, and/or Vitamin D analogues); **AND**
   - H. Patient has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 non-biologic systemic agent (i.e. immunosuppressives, retinoic acidderivatives, and/or methotrexate); **AND**
   - I. Patient has not responded adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (i.e. Psoralens with UVA light (PUVA) OR UVB withcoal tar or dithranol)

II. Renewal

Coverage for Ilumya (tildrakizumab-asmn) may be renewed for the following diagnosis when the subsequent criteria are met:

Plaque Psoriasis:

- A. Patient continues to meet the initial approval criteria above; **AND**
- B. Absence of unacceptable toxicity from the drug; **AND**
- C. Patient will receive ongoing monitoring for presence of TB or other active infections: **AND**
- D. 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.].

Applicable Procedure Codes

Code	Description
J3245	Injection, tildrakizumab-asmn, 1 mg

Applicable NDCs

Code	Description
47335-0177-xx	Ilumya 100mg/mL Syringe

ICD-10 Diagnoses

Code	Description
L40.0	Psoriasis vulgaris

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/02/2025	Annual Review: Initial Criteria: Plaque Psoriasis: Reworded: "Patient will not concurrently receive treatment with another TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent; AND " to: "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" added: "or with intractable pruritis " to the following statement: "Incapacitation due to plaque location (i.e. head and neck, palms, soles orgenitalia) or with intractable pruritis; AND" Renewal Criteria: reworded the following: "Patient has responded to treatment as indicated by at least one of the following: Improvement in signs and symptoms compared to baseline such as redness, thicknessscaliness; OR Reduction in the amount of surface area involved; OR Improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75)." To: " 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.]."
EmblemHealth & ConnectiCare	11/1/2024	Revision: Plaque Psoriasis: Initial Criteria- removed: "Patient has a documented failure, or intolerance to, TWO of the following: Humira/ Adalimumab, Otezla, Skyrizi, Stelara SC, Tremfya, Enbrel , Taltz"
EmblemHealth & ConnectiCare	2/28/2024	Annual Review: added length of authorization, no criteria changes
EmblemHealth & ConnectiCare	9/25/2023	Annual Review: Plaque Psoriasis: Initial Criteria: Added "for at least 6 months" to the Statement: "Patient has had moderate to severe plaque psoriasis for at least 6 months and at least one of the following:" Changed from 10% to 3% in the following statement: "Involvement of at least 3% of body surface area (BSA); OR" Updated from 3 months to 4-weeks in the following statement: "Patient has not responded 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, retinoic acidderivatives, and/or Vitamin D analogues); AND" Added "non-biologic" in the following statement: "Patient has

		not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 non-biologic systemic agent (i.e. immunosuppressives, retinoic acidderivatives, and/or methotrexate); AND" Added: "adalimumab" to the following section: "Patient has a documented failure, or intolerance to, TWO of the following: Humira/ Adalimumab"
EmblemHealth & ConnectiCare	7/6/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	1/1/2021	1. Added Taltz and Enbrel as preferred option for Psoriasis 2. Removed Cosentyx as a preferred product for Psoriasis 3. Removed following requirement "for at least 6 months"
EmblemHealth & ConnectiCare	10/31/2019	1. Removed criteria - "Patient's baseline disease severity has been assessed by aphysician utilizing an objective measure; AND" 2. Added examples for "Incapacitation due to plaque location"- (i.e. head andneck, palms, soles or genitalia) 3. Added examples of medications patient has to try and fail a. For topical agents added: (i.e. Anthralin, Coal Tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) b. For systemic agents added: (i.e. immunosuppressives, retinoic acidderivatives, and/or methotrexate) c. For phototherapy added: (i.e. Psoralens with UVA light (PUVA) ORUVB with coal tar or dithranol) 4. Continuation criteria- removed portion that includes a different scoring toolthan initiation criteria 5. Added J3245 injection, tildrakizumab-asmn, 1mg
EmblemHealth & ConnectiCare	7/19/2019	Added Skyrizi and Tremfya to preferred options

References

1. Ilumya [package insert]. Whitehouse Station, NJ; MSD-Sun Pharmaceuticals; March 2018. Accessed October2019.
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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. Ja
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].
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.2018.10.017