

Medical Policy:

Ilumya™ (tildrakizumab-asmn) Subcutaneous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 that is 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 infection prior 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 acid derivatives, 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 acid derivatives, 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. Psoralen with UVA light (PUVA) OR UVB with coal 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 $\leq 1\%$) 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 or genitalia) 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, thickness, scaliness; 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 acid derivatives, 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 acid derivatives, 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Removed criteria - "Patient's baseline disease severity has been assessed by a physician utilizing an objective measure; AND" 2. Added examples for "Incapacitation due to plaque location" - (i.e. head and neck, palms, soles or genitalia) 3. Added examples of medications patient has to try and fail <ol style="list-style-type: none"> 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 acid derivatives, and/or methotrexate) c. For phototherapy added: (i.e. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol) 4. Continuation criteria- removed portion that includes a different scoring tool than initiation criteria 5. Added J3245 injection, tildrakizumab-asman, 1mg
EmblemHealth & ConnectiCare	7/19/2019	Added Skyrizi and Tremfya to preferred options

References

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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