Medical Policy

Ilumya® (tildrakizumab-asmn)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-098
CURRENT VERSION EFFECTIVE DATE	1/1/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Ilumya® (tildrakizumab-asmn) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Ilumya will be provided for 6 months and may be renewed.

- Max Units (per dose and over time):
  - Loading: 100 units at Weeks 0 & 4
  - Maintenance: 100 units every 12 weeks

Initial

A. Patient is 18 years of age or older; **AND**

B. Provider has assessed baseline disease severity utilizing an objective measure/tool; **AND**
C. Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
D. Patient has been evaluated and screened for the presence of latent TB (tuberculosis) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
E. Patient does not have an active infection, including clinically important localized infections; **AND**
F. Patient will not receive live vaccines during therapy; **AND**
G. Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib), upadacitinib, etc.); **AND**

Plaque Psoriasis

A. Patient has a documented diagnosis of moderate to severe plaque psoriasis for at least 6 months with at least ONE of the following:
    a. Involvement of at least 3% of body surface area (BSA); **OR**
    b. Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
    c. Incapacitation or serious emotional consequences due to plaque location (i.e. hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
B. 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, retinoic acid derivatives, and/or vitamin D analogues); **AND**
C. 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**
D. 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)

*Examples of contraindications to phototherapy (PUVA or UVB) include the following:

- 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)

Renewal

A. Patient continues to meet the Initial criteria; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infections, severe hypersensitivity reactions, etc.; **AND**

Plaque Psoriasis

A. 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 a four-point reduction in the DLQI from when treatment started].

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. ILUMYA (tildrakizumab-asmn) injection, for subcutaneous use Initial U.S. Approval: 2018
   a. ILUMYA (tildrakizumab-asmn) Injection is a sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution. ILUMYA is supplied as one single-dose prefilled syringe per carton that delivers 1 mL of a 100 mg/mL solution.

CODING

Applicable NDC Codes	
47335-0177-95	Ilumya 100 mg prefilled syringe

Applicable Procedure Code	
J3245	Injection, tildrakizumab, 1 mg: 1 billable unit = 1 mg

Applicable ICD-10 Codes	
L40.0	Psoriasis vulgaris

EVIDENCE BASED REFERENCES

1. Product Information: ILUMYA(TM) subcutaneous injection, tildrakizumab-asmn subcutaneous injection. Merck & Co. Inc (per manufacturer), Whitehouse Station, NJ, 2018.

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POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	3/21/2022