

## Medical Policy

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

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

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### 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):
  - o Loading: 100 units at Weeks 0 & 4
  - o Maintenance: 100 units every 12 weeks

#### **Initial**

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

## Medical Policy

- 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**

## Medical Policy

### 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  $\leq 1\%$ ), 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.

## Medical Policy

### POLICY HISTORY

<b>Original Effective Date</b>	1/1/2022
<b>Revised Date</b>	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)
<b>P&amp;T Committee Endorsement</b>	3/21/2022