

## Clinical Policy: Tildrakizumab-asmn (Ilumya)

Reference Number: NH.PHAR.386

Effective Date: 12.21

Last Review Date: 04.25

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Tildrakizumab-asmn (Ilumya™) is an interleukin-23 (IL-23) blocker.

### FDA Approved Indication(s)

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

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Ilumya is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Plaque Psoriasis (must meet all):

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
  - a.  $\geq 3\%$  of total body surface area;
  - b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age  $\geq 18$  years;
4. Member meets one of the following (a or b):
  - a. Failure of a trial of  $\geq 3$  consecutive months of methotrexate (MTX) at up to maximally indicated doses;
  - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a trial of  $\geq 3$  consecutive months of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
  - c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a  $\geq 3$  consecutive month trial of Enbrel® unless contraindicated or clinically significant adverse effects are experienced;

*\*Prior authorization may be required for Enbrel*

6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed 100 mg at weeks 0 and 4, followed by maintenance dose of 100 mg every 12 weeks.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Plaque Psoriasis (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 100 mg every 12 weeks.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B.** Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

#### IV. Appendices/General Information

##### Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

IL-23: interleukin-23

JAKi: Janus kinase inhibitors

MTX: methotrexate

PsO: plaque psoriasis

##### Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

| Drug Name   | Dosing Regimen   | Dose Limit/<br>Maximum Dose |
|---|--|-----------------------------|
| acitretin<br>(Soriatane <sup>®</sup> )                              | <b>PsO</b><br>25 or 50 mg PO daily   | 50 mg/day                   |
| cyclosporine<br>(Sandimmune <sup>®</sup> ,<br>Neoral <sup>®</sup> ) | <b>PsO</b><br>2.5 – 4 mg/kg/day PO divided BID   | 4 mg/kg/day                 |
| methotrexate<br>(Rheumatrex <sup>®</sup> )                          | <b>PsO</b><br>10 – 25 mg/week PO or 2.5 mg PO Q12 hr<br>for 3 doses/week   | 30 mg/week                  |
| Taltz <sup>®</sup><br>(ixekizumab)                                  | <b>PsO</b><br><u>Initial dose:</u><br>160 mg (two 80 mg injections) SC at week<br>0, then 80 mg SC at weeks 2, 4, 6, 8, 10,<br>and 12<br><u>Maintenance dose:</u><br>80 mg SC every 4 weeks  | 80 mg every 4 weeks         |
| Enbrel <sup>®</sup><br>(etanercept)                                 | <b>PsO</b><br>Adults:<br><u>Initial dose:</u><br>50 mg SC twice weekly for 3 months<br><u>Maintenance dose:</u><br>50 mg SC once weekly<br><br><i>Pediatrics:</i><br>Weight < 63 kg: 0.8 mg/kg SC once<br>weekly Weight ≥ 63 kg: 50 mg SC once<br>weekly | 50 mg/week                  |
| Otezla <sup>®</sup><br>(apremilast)                                 | <b>PsO</b><br><u>Initial dose:</u><br>Day 1: 10 mg PO QAM<br>Day 2: 10 mg PO QAM and 10 mg PO<br>QPM   | 60 mg/day                   |



| Drug Name | Dosing Regimen   | Dose Limit/<br>Maximum Dose |
|-----------|--|-----------------------------|
|           | Day 3: 10 mg PO QAM and 20 mg PO QPM<br>Day 4: 20 mg PO QAM and 20 mg PO QPM<br>Day 5: 20 mg PO QAM and 30 mg PO QPM<br><u>Maintenance dose:</u><br>Day 6 and thereafter: 30 mg PO BID |                             |

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): Serious hypersensitivity reaction to tildrakizumab or to any of the excipients
- Boxed warning(s): none reported

*Appendix D: General Information*

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.

**V. Dosage and Administration**

| Indication | Dosing Regimen   | Maximum Dose          |
|------------|--|-----------------------|
| PsO        | <u>Initial dose:</u><br>100 mg SC at weeks 0 and 4<br><u>Maintenance dose:</u><br>100 mg SC every 12 weeks<br><br>Ilumya should only be administered by a healthcare professional. | 100 mg every 12 weeks |

**VI. Product Availability**

Single-dose prefilled syringe: 100 mg/1 mL

## VII. References

1. Ilumya Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; March 2018. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/761067s0001bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761067s0001bl.pdf). Accessed February 18, 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80:1029-72. doi:10.1016/j.aad.201811.057.

| Reviews, Revisions, and Approvals  | Date  | P&T Approval Date |
|--|-------|-------------------|
| Policy created   | 10.21 | 10.21             |
| 2Q 2022 annual review: for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references updated. | 3.22  | 4.22              |
| Annual review, no changes  | 01.23 | 01.23             |
| Annual review, no changes  | 12.23 | 12.23             |
| 2Q 2024 annual review: added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated.  | 04.24 | 04.24             |
| Annual review, no significant changes  | 04.25 | 04.25             |

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.