

# Ilumya® (Tildrakizumab-Asmn)

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[➔ Instructions for Use](#)

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## Coverage Rationale

[➔ See Benefit Considerations](#)

Ilumya to be used as a self-administered, subcutaneous injection for the treatment of plaque psoriasis should be obtained under the pharmacy benefit.

**Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:**

- For **initial therapy**:
  - Diagnosis of moderate to severe plaque psoriasis; **and**
  - Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and**
  - Patient is not receiving Ilumya in combination with any of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
  - and**
  - Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Initial authorization will be for no longer than 12 months.
- For **continuation of therapy**:
  - Documentation of positive clinical response to Ilumya therapy; **and**
  - Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and**
  - Patient is not receiving Ilumya in combination with any of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
  - and**

- Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
- Reauthorization will be for no longer than 12 months.

**Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:**

- For **initial therapy**, submission of medical records (e.g., chart notes, laboratory values) documenting all of the following:
  - Diagnosis of chronic moderate to severe plaque psoriasis; **and**
  - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis<sup>1,2,3,6,8</sup>; **and**
  - One of the following:
    - Both of the following:
      - History of failure, contraindication, or intolerance to **one** of the following topical therapies:<sup>4</sup>
        - Corticosteroids (e.g., betamethasone, clobetasol, desonide)
        - Vitamin D analogs (e.g., calcitriol, calcipotriene)
        - Tazarotene
        - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        - Anthralin
        - Coal tar
    - and**
    - History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced<sup>6,7</sup>
  - **or**
  - Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab), Enbrel (etanercept)]
- and**
- History of failure, contraindication, or intolerance to two of the following preferred biologic products: (for Medicare reviews, refer to the [CMS](#) section\*)
  - One of the preferred adalimumab products\* \*
  - Stelara (ustekinumab)
  - Tremfya (guselkumab)
  - Cimzia (certolizumab)
  - Skyrizi (risankizumab)
  - Enbrel (etanercept)
- and**
- **One** of the following: (for Medicare reviews, refer to the [CMS](#) section\*)
  - History of a 6-month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity; **or**
  - Both of the following:
    - History of intolerance or adverse event to Cosentyx
    - Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Ilumya
- and**
- Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and**
- Patient is not receiving Ilumya in combination with any of the following:<sup>1</sup>
  - Biologic DMARD [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept), Enbrel (etanercept)]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
  - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- and**
- Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
- Prescribed by or in consultation with a dermatologist; **and**
- Initial authorization will be for no longer than 12 months.

- For **continuation of therapy**:
  - Documentation of positive clinical response to Ilumya therapy; **and**
  - Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; **and**
  - Patient is not receiving Ilumya in combination with any of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
  - and**
  - Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Reauthorization will be for no longer than 12 months.

\* \*For a list of preferred adalimumab products, refer to the drug coverage tools on [UHCprovider.com](https://www.uhcprovider.com).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS Code | Description                    |
|------------|--------------------------------|
| J3245      | Injection, tildrakizumab, 1 mg |

| Diagnosis Code | Description        |
|----------------|--------------------|
| L40.0          | Psoriasis vulgaris |

## Background

Ilumya (tildrakizumab) 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. Tildrakizumab inhibits the release of pro-inflammatory cytokines and chemokines.

## Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

## Clinical Evidence

### Plaque Psoriasis

Ilumya (tildrakizumab) is an interleukin-23 antagonist indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.<sup>1,9,10,11</sup>

## Professional Societies

### Plaque Psoriasis

#### American Academy of Dermatology (AAD)

In 2019, the AAD and the National Psoriasis Foundation published updated treatment guidelines for the management and treatment of psoriasis with biologic therapies. In regard to tildrakizumab and/or IL-23 inhibitors, the guidelines state:

- Tildrakizumab is recommended as a monotherapy treatment option in adult patients with moderate-to-severe plaque psoriasis.
- The recommended dose is 100 mg given by in office physician-administered subcutaneous injection at week 0 and week 4 and every 12 weeks thereafter.
- There is no evidence to support combination of tildrakizumab with topical or systemic therapies, but there is no reason to consider such combination unsafe.
- Definitive response (positive or negative) to treatment with IL-23 antagonists is best ascertained after 12 weeks of continuous therapy. Consider dose escalation in partially responding patients. Consider the addition of other modalities (such as topical corticosteroids or vitamin D analogues, methotrexate, or ultraviolet B light) in partially responding patients. Although there are no published data supporting combination therapy for the IL-23 inhibitors, there is no reason to consider such combination therapy unsafe.
- The effect of guselkumab on solid tumor or lymphoreticular malignancy, when used as monotherapy for moderate-to-severe psoriasis, is unknown. Large long-term follow-up studies are necessary to more fully define the risk of cancer associated with IL-23 inhibitors.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Ilumya (tildrakizumab) is an interleukin-23 antagonist indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

## Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for Ilumya® (tildrakizumab-asmn). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

In general, Medicare may cover outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals](#). (Accessed February 13, 2023)

\*Preferred therapy criteria for Medicare Advantage members, refer to [Medicare Part B Step Therapy Programs](#).

## References

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11. Elewski B, Menter A, Crowley J, et al. Sustained and Continuously Improved Efficacy of Tildrakizumab in Patients with Moderate-to-Severe Plaque Psoriasis. J Dermatolog Treat. 2019 Jul 3:1-19.
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## Policy History/Revision Information

| Date       | Summary of Changes  |
|------------|---|
| 07/01/2023 | <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"><li>Revised list of preferred biologic products to which the patient must have a history of failure, contraindication, or intolerance; replaced “<i>Humira or Amjevita (adalimumab)</i>” with “<i>one of the preferred adalimumab products; for a list of preferred adalimumab products, refer to the drug coverage tools [on <a href="https://www.uhcprovider.com">UHCprovider.com</a>]</i>”</li></ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"><li>Archived previous policy version 2023D0074I</li></ul> |

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual<sup>®</sup> criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies 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.