Ilumya® (Tildrakizumab-Asmn)

Policy Number: IEXD0074.11
Effective Date: June 1, 2026

➲ Instructions for Use

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Related Policy

- Self-Administered Medications

Applicable States

This Medical Benefit Drug Policy applies to Individual Exchange benefit plans in all states except for Nevada. For Nevada, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy.

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 and 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; **and**
  - **One** of the following:
    - **Both** of the following:
      - History of failure, contraindication, or intolerance to **one** of the following topical therapies:
        - 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 three-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced

    or
    - Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab),

Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab]

and

- History of failure, contraindication, or intolerance to **three** biologic products such as:
  - One of the preferred adalimumab products*
  - One of the preferred ustekinumab products*
  - Cimzia (certolizumab)
  - Skyrizi (risankizumab)

  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 another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **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 another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **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 products, refer to the drug coverage tools on 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.

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 regards 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.

References

1. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2025.
2. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomized controlled, phase 3 trials. Lancet. 2017 Jul 15;390(10091):276-288.
3. Reich K, Warren RB, Iversen L, et al. Long-term efficacy and safety of tildrakizumab for moderate-to-severe psoriasis: pooled analyses of two randomised phase III clinical trials (reSURFACE 1 and reSURFACE 2) through 148 weeks. Br J Dermatol. 2019 Jun 19.
4. 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.
5. 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 Apr;80(4):1029-1072.

Policy History/Revision Information

Date	Summary of Changes

06/01/2026	**Applicable States**
	Massachusetts *and* ***New York***
	• Removed language indicating this Medical Benefit Drug Policy does not apply to the states of **Massachusetts** and **New York**
	Nevada
	• Added instruction to refer to the UnitedHealthcare Commercial policy version for the state of **Nevada**
	Coverage Rationale
	• Replaced references to "targeted immunomodulator" with "*systemic* targeted immunomodulator"
	• Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Ilumya for treatment of the same indication:
	  ○ Added:
	  ▪ Bimzelx (bimekizumab-bkzx)
	  ▪ Sotyktu (deucravacitinib)
	  ○ Removed:
	  ▪ Olumiant (baricitinib)
	  ▪ Orencia (abatacept)
	  ▪ Rinvoq (upadacitinib)
	  ▪ Simponi (golimumab)
	  ▪ Xeljanz (tofacitinib)
	• Updated list of examples of systemic targeted immunomodulators U.S. FDA-approved for the treatment of plaque psoriasis with which the patient has been previously treated for initial therapy:
	  ○ Added:
	  ▪ Bimzelx (bimekizumab-bkzx)
	  ▪ Sotyktu (deucravacitinib)
	  ○ Removed:
	  ▪ Olumiant (baricitinib)
	  ▪ Orencia (abatacept)
	  ▪ Rinvoq (upadacitinib)
	  ▪ Simponi (golimumab)
	  ▪ Xeljanz (tofacitinib)
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy version IEXD0074.10

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare 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 benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® 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.