Ilumya® (Tildrakizumab-Asmn)

Policy Number: CS2025D0074O
Effective Date: January 1, 2025

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Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Immunomodulators for Inflammatory Conditions (for Indiana Only)
Kansas	Refer to the state's Medicaid clinical policy
Louisiana	Refer to the state's Medicaid clinical policy
North Carolina	None
Ohio	Immunomodulatory Agents for Systemic Inflammatory Diseases (for Ohio Only)
Pennsylvania	Refer to the state's Medicaid clinical policy
Washington	Refer to the state's Medicaid clinical policy

Coverage Rationale

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

Initial Therapy

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:

- 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;[1,2,3,6,8] **and**
  - **One** of the following:
    - **Both** of the following:
      - History of failure, contraindication, or intolerance to **one** of the following topical therapies:[4]
        - 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[6,7]

or

▪ Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

and

- History of failure, contraindication, or intolerance to **three** targeted immunomodulators FDA-approved for the treatment of plaque psoriasis (document drug, date, and duration of trial); **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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), 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

Continuation Therapy

Ilumya (tildrakizumab) will be reauthorized for provider administration based on all of the following criteria:

- 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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), 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

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 federal, state, or contractual requirements 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.

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.[1,9]

Professional Societies

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.

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Coverage Rationale** • Revised coverage criteria for: ***Initial Therapy*** ○ Replaced criterion requiring "the patient has a history of failure, contraindication, or intolerance to three *biologic DMARDs* FDA-approved for the treatment of plaque psoriasis" with the patient has a history of failure, contraindication, or intolerance to three *targeted immunomodulators* FDA-approved for the treatment of plaque psoriasis" ○ Revised list of targeted immunomodulators the patient must have previously received for treatment: ▪ Added: – Olumiant (baricitinib) – Rinvoq (upadacitinib) – Simponi (golimumab) – Xeljanz (tofacitinib) ▪ Removed: – Ilumya (tildrakizumab) ○ Revised list of targeted immunomodulators the patient must not be receiving in combination with Ilumya; added: ▪ Enbrel (etanercept) ▪ Olumiant (baricitinib) ▪ Rinvoq (upadacitinib) ▪ Siliq (brodalumab) ▪ Stelara (ustekinumab) ▪ Tremfya (guselkumab) ***Continuation of Therapy*** ○ Revised list of targeted immunomodulators the patient must not be receiving in combination with Ilumya; added: ▪ Enbrel (etanercept) ▪ Olumiant (baricitinib) ▪ Rinvoq (upadacitinib) ▪ Siliq (brodalumab) ▪ Stelara (ustekinumab) ▪ Tremfya (guselkumab) **Supporting Information** • Archived previous policy version CS2024D0074N

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves

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