ILUMYA™ (TILDRAKIZUMAB-ASMN)

Policy Number: PHARMACY 314.5 T2  
Effective Date: September 1, 2019

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CONDITIONS OF COVERAGE

Applicable Lines of Business/Products:  
This policy applies to Oxford Commercial plan membership.

Benefit Type

General Benefits Package / Pharmacy

Referral Required
(Does not apply to non-gatekeeper products)

Authorization Required
(Precertification always required for inpatient admission)

Precertification with Medical Director Review Required

Applicable Site(s) of Service
(If site of service is not listed, Medical Director review is required)

Special Considerations

1 Precertification with review by a Medical Director or their designee is required.
2 Ilumya for self-administered subcutaneous injection is obtained under the pharmacy benefit; refer to the Clinical Policy titled Drug Coverage Guidelines for precertification guidelines.
3 New Jersey small group plan members should refer to their Certificate of Coverage for precertification and quantity limit guidelines.
4 Additional precertification requirements apply to requests for hospital outpatient facility infusion of Ilumya; refer to the Clinical Policy titled Provider Administered Drugs - Site of Care.

COVERAGE RATIONALE

Ilumya 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 for provider administration for the treatment of moderate to severe plaque psoriasis when ALL of the following criteria are met:

- 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), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
  - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
  - 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.

**Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when ALL of 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 5 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis1,2,3,6,8; and
  - 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
    - History of contraindication, intolerance, or failure of a 3 month trial of methotrexate; 6,7 and
  - History of failure, contraindication, or intolerance to two of the following preferred biologic products:
    - Humira (adalimumab)
    - Stelara (ustekinumab)
    - Tremfya (guselkumab)
    - Cimzia (certolizumab)
    - 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.

**Continuation Therapy**

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

- 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:1
  - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
  - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
  - 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.
• 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 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 may apply.

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<th>HCPCS Code</th>
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<td>J3245</td>
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<th>ICD-10 Diagnosis Code</th>
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<tr>
<td>L40.0</td>
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**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 indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.1,9,10,11

**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)**

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**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare Pharmacy, Clinical Pharmacy Program that was researched, developed and approved by the UnitedHealth Group National Pharmacy & Therapeutics Committee. [2019D0074D]


POLICY HISTORY/REVISION INFORMATION

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<tr>
<td>09/01/2019</td>
<td><strong>Conditions of Coverage</strong></td>
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<td>• Updated language to clarify that Ilumya for <em>self-administered</em> subcutaneous</td>
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<td>injection is obtained under the pharmacy benefit</td>
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<td><strong>Template Update</strong></td>
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<td>• Reorganized policy template; relocated <em>Background</em> and <em>FDA</em> sections</td>
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<td><strong>Supporting Information</strong></td>
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<td>• Updated <em>Clinical Evidence</em> and <em>References</em> sections to reflect the most current</td>
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<td>• Archived previous policy version PHARMACY 314.4 T2</td>
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INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.