ILUMYA™ (TILDRAKIZUMAB-ASMN)

Policy Number: PHARMACY 314.2 T2 **Effective Date**: January 1, 2019

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Related Policies

- Drug Coverage Guidelines
- Specialty Medication Administration – Site of Care Review Guidelines

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, 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.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package[2]
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes[1,2,3,4]
Precertification with Medical Director Review Required	Yes[1,4]
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All
Special Considerations	[1]Precertification with review by a Medical Director or their designee is required. [2]Ilumya for subcutaneous injection is obtained under the pharmacy benefit when self-administered; refer to the policy titled Drug Coverage Guidelines for precertification guidelines.

Special Considerations *(continued)*	[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 policy titled Specialty Medication Administration - Site of Care Review Guidelines.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Ilumya, for subcutaneous injection, is obtained under the pharmacy benefit when self-administered, and is indicated in the treatment of plaque psoriasis.

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)]

  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.

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 psoriasis[1,2,3,6,8]; **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

      and
    - 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)

and

- **One** of the following:
  - 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:[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)]

  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.

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 **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)]

  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.

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.

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.

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.

HCPCS Code	Description
J3245	Injection, tildrakizumab, 1 mg

ICD-10 Diagnosis Code	Description
L40.0	Psoriasis vulgaris

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]

Professional Societies

American Academy of Dermatology (AAD)

The American Academy of Dermatology (AAD) defines moderate to severe psoriasis as affecting more than 5% of the body surface area (BSA) or affecting crucial body areas such as the hands, feet, face, or genitals. According to the AAD Practice Guidelines for the management of psoriasis, the potential importance of TNF-α in the pathophysiology of psoriasis is underscored by the observation that there are elevated levels of TNF-α in both the affected skin and serum of patients with psoriasis. These elevated levels have a significant correlation with psoriasis severity as measured by the PASI score. Furthermore, after successful treatment of psoriasis, TNF-α levels are reduced to normal levels. The guidelines support the use of infliximab for psoriasis based on evidence ranked as consistent, good quality, and patient-oriented (Strength of Recommendation: A).[3]

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. [*2018D0074A*]

1. Ilumya [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc.; March 2018.
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
7. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
8. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
9. 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 randomised controlled, phase 3 trials. Lancet. 2017 Jul 15;390(10091):276-288.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	• Updated list of related policies: ○ Added reference link to the policy titled *Review at Launch for New to Market Medications* ○ Removed reference link to the policy titled *Specialty Medication Administration – Site of Care Review Guidelines* • Revised conditions of coverage/precertification requirements to indicate: ○ Precertification with review by a Medical Director or their designee is required

Date	Action/Description
	○ Ilumya for subcutaneous injection is obtained under the pharmacy benefit when self-administered; refer to the policy titled *Drug Coverage Guidelines* for precertification guidelines ○ New Jersey small group plan members should refer to their Certificate of Coverage for precertification and quantity limit guidelines ○ Additional precertification requirements apply to requests for hospital outpatient facility infusion; refer to the policy titled *Specialty Medication Administration - Site of Care Review Guidelines* • Updated list of applicable HCPCS codes: ○ Added J3245 *(annual code edit)* ○ Removed C9399 and J3590 • Archived previous policy version PHARMACY 314.1 T2