ILUMYA™ (TILDRAKIZUMAB-ASMN)

Policy Number: 2019D0074C **Effective Date**: March 1, 2019

Instructions for Use

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Related Commercial Policy

- Provider Administered Drugs – Site of Care Review Guidelines
- Self-Administered Medications

COVERAGE RATIONALE

See Benefit Considerations

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 the following criteria are met:

I. Diagnosis of moderate to severe plaque psoriasis; **and**
II. 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**
III. Patient is not receiving Ilumya in combination with **any** of the following:
   A. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
   B. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   C. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
   and
IV. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
V. 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 the following criteria are met:

I. **Submission of medical records** (e.g., chart notes, laboratory values) documenting **all** of the following:
   A. Diagnosis of chronic moderate to severe plaque psoriasis; **and**
   B. Greater than or equal to 5 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis[1,2,3,6,8]; **and**
   C. **Both** of the following:
      1. History of failure, contraindication, or intolerance to **one** of the following topical therapies [4]:
         a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
         b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
         c. Tazarotene
         d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
         e. Anthralin
         f. Coal tar
         and
      2. History of contraindication, intolerance, or failure of a 3 month trial of methotrexate [6,7]; **and**
   D. History of failure, contraindication, or intolerance to **two** of the following preferred biologic products:

1. Humira (adalimumab)
2. Stelara (ustekinumab)
3. Tremfya (guselkumab)
4. Cimzia (certolizumab)

and

E. **One** of the following:
   1. History of a 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity
      or
   2. **Both** of the following:
      a. History of intolerance or adverse event to Cosentyx
      b. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Ilumya

   and

F. 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**
G. Patient is not receiving Ilumya in combination with **any** of the following:[1]
   1. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
   2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

   and

H. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
I. 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:

I. Documentation of positive clinical response to Ilumya therapy; **and**
II. 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**
III. Patient is not receiving Ilumya in combination with **any** of the following:
   A. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
   B. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
   C. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

   and

IV. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
V. 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 and Coverage Determination Guidelines may apply.

HCPCS Code	Description
J3245	Injection, tildrakizumab, 1 mg

ICD-10 Diagnosis Code	Description
L40.0	Psoriasis vulgaris

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. See the Policy and Procedure addressing the treatment of serious rare diseases.

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

Plaque Psoriasis

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]

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for ILUMYA™ (tildrakizumab-asmn) injections. Local Coverage Determinations (LCDs) 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 (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals. (Accessed May 1, 2018)

REFERENCES

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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
04/01/2019	• Updated list of related policies: ○ Added reference link to the policy titled *Provider Administered Drugs – Site of Care Review Guidelines* ○ Removed reference link to the policy titled *Review at Launch for New to Market Medications*
03/01/2019	Off cycle review. Relocated *Instructions for Use* and *Benefit Considerations* sections. Revised coverage rationale to add Cimzia to list of preferred products for the treatment of plaque psoriasis. Policy 2019D0074B archived.
01/01/2019	Updated list of applicable HCPCS codes to reflect annual code edits; replaced C9399 and J3590 with J3245. Policy 2018D0074A archived.
07/01/2018	New policy 2018D0074A.

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, 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 MCG™ Care Guidelines, 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.