INSTRUCTIONS FOR USE

This Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. 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 Drug Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Drug 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 Drug Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This 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 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.

BENEFIT CONSIDERATIONS

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

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, and 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.

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 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 psoriasis1,2,3,6,8; 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)
      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.

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<td>J3245</td>
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<th>ICD-10 Diagnosis Code</th>
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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


POLICY HISTORY/REVISION INFORMATION

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<tr>
<td>01/01/2019</td>
<td>Updated list of applicable HCPCS codes to reflect annual code edits; replaced C9399 and J3590 with J3245. Policy 2018D0074A archived.</td>
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<td>07/01/2018</td>
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