CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Ilumya (tildrakizumab-asmn)
BILLING CODE	J3245 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Taltz, Enbrel, and Humira QUANTITY LIMIT— 100 mg (1 syringe) every 12 weeks after loading doses
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ilumya (tildrakizumab-asmn) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed treatment with at least **two** of the following: Humira, Enbrel, or Taltz. Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred IL-17 inhibitor (e.g., Cosentyx) or TNF inhibitor (e.g., Cimzia) that is indicated for PsO, then the trial can be accepted.
8. **Dosage allowed:** 100 mg subcutaneously at Weeks 0, 4, and every twelve weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ilumya (tildrakizumab-asmn) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
09/13/2018	New policy for Ilumya created.
02/26/2019	Humira trial removed from criteria; Cimzia, Cosentyx, Otezla and Siliq added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements. Static Physician's Global Assessment (sPGA) score removed. Ulcerative Colitis added to not covered diagnosis. BSA less than 10% allowed if there is sensitive area involvement.
01/19/2020	Updated alternative preferred products and trial agents to match Ohio Department of Medicaid Unified Preferred Drug List.
11/01/2020	Updated list of preferred agents and drug trials for PsO to match Ohio Department of Medicaid Unified Preferred Drug List. Added that if member previously tried a non-preferred option in the same drug class as preferred options, the trial is accepted.
11/18/2020	Updated J code. Removed rheumatologist from prescriber requirement. Removed PsO 6 months or longer. Removed not going to receive systemic/phototherapy while on Ilumya. Changed BSA to 3% or sensitive areas. Removed PASI score. Removed repeat TB for reauth. Updated references.

References:

1. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc., March, 2018.
2. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. *J Am Acad Dermatol*. 2020;S0190-9622(20)32288-X.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
5. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. *J Am Acad Dermatol*. 2019;81(3):775-804.
6. Menter A, Cordoro KM, Davis DM, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol* 2020;82:161-201.
7. ClinicalTrials.gov. Identifier NCT01225731. A Study to Determine the Optimal Dose of Tildrakizumab (SCH 900222/MK-3222) for the Treatment of Moderate-to-severe Chronic Plaque Psoriasis (P05495) (MK-3222-003). Available at: https://clinicaltrials.gov/ct2/show/NCT01225731?term=tildrakizumab&rank=1. Accessed on March 26, 2018.

Effective date: 04/01/2021
Revised date: 11/18/2020