CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Ilumya (tildrakizumab-asmn)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Cosentyx, Enbrel, and Humira QUANTITY LIMIT— 100 mg every 12 weeks after 4th week
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 with a diagnosis of moderate-to-severe chronic PsO; AND
2. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a dermatologist or rheumatologist; AND
4. Member has PsO for 6 months or longer; AND
5. Member is not receiving Ilumya in combination with other systemic therapies (e.g., Enbrel, Humira, Cimzia, Simponi, Xeljanz, Otezla, etc.) or phototherapy; AND
6. Member's PsO involving 10% or more of the body surface area (BSA), or BSA less than 10% if there is sensitive area involvement (hands, feet, face, or genitals); AND
7. Member's Psoriasis Area and Severity Index (PASI) score ≥ 12; AND
8. Member has tried and failed to respond to treatment with at least one of the following:
   a) a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments (tanning beds emit mostly UVA light and therefore would not meet this criteria));
   c) c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
9. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
10. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Humira, Otezla and Siliq. Treatment failure requires at least for 12 weeks of therapy with each drug.
11. **Dosage allowed:** 100 mg subcutaneously at Weeks 0, 4, and every twelve weeks thereafter, and should only be administered by a healthcare provider.

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

For **reauthorization**:

1. Member must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score 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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing spondylitis
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Juvenile idiopathic arthritis
- Lupus perino
- Osteoarthritis
- Psoriatic Arthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Ulcerative Colitis
- Vogt-Koyanagi

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.

References:

1. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc., March, 2018.
2. Menter A, Korman NJ, Elmets CA, et al. 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. Journal of the American Academy of Dermatology, Volume 65, Issue 1, 137 – 174.
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
4. 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.
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6. Bolognia JL, et al. Dermatology. 4th ed. Philadelphia, PA: Saunders; 2018.
7. Feldman SR. Treatment of psoriasis. In: UpToDate. Waltham, MA: UpToDate; 2018.

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