Humana.

CareSource™

# PHARMACY POLICY STATEMENT
## Kentucky Medicaid

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|---|---|
| DRUG NAME | Ilumya (tildrakizumab-asmn) |
| BILLING CODE | J3590 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>Alternative preferred products include Humira and Enbrel<br>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 (PP)

For **initial** authorization:

1. Member must be 18 years of age or older with a diagnosis of moderate-to-severe chronic plaque psoriasis (PP); AND
2. Member must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a dermatologist or rheumatologist; AND
4. Member has PP for 6 months or longer; AND
5. Member is not going to receive systemic therapy or phototherapy while on Ilumya; AND
6. Member's PP involving 10% or more of the body surface area (BSA) or 5% or more of BSA if psoriasis involves sensitive areas (hands, feet, face, or genitals); AND
7. Member's Psoriasis Area and Severity Index (PASI) score ≥12; AND
8. Member's static Physician's Global Assessment (sPGA) score ≥3 in the overall assessment (plaque thickness/induration, erythema, and scaling); AND
9. Member has tried and failed to respond to treatment with at least one of the following:
   a) a) At least 30 days of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
   b) b) At least 30 days 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
10. Member has tried and failed to respond to treatment of traditional oral/systemic therapies (i.e. cyclosporine, methotrexate, acitretin) for at least 30 days; AND
11. Member has tried and failed to respond to treatment with **both** Enbrel and Humira.
12. **Dosage allowed:** 100 mg at Weeks 0, 4, and every twelve weeks thereafter.

***If member meets all the requirements listed above, the medication will be approved for 4 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; AND
4. Documented member's PASI score improvement; AND
5. Documented member's sPGA score improvement.

***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. Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- 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
- Vogt-Koyanagi

| DATE | ACTION/DESCRIPTION |
|---|---|
| **09/13/2018** | New policy for Ilumya created. |

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.
5. Ed. Lebwohl MG, et al. Treatment of Skin Disease: Comprehensive Therapeutic Strategies. 5th ed. Philadelphia, PA: Saunders; 2018.
6. Bolognia JL, et al. Dermatology. 4th ed. Philadelphia, PA: Saunders; 2018.
7. Feldman SR. Treatment of psoriasis. In: UpToDate. Waltham, MA: UpToDate; 2018.

Effective date: 10/01/2018
Revised date: 09/13/2018