CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## Georgia Medicaid

| DRUG NAME | Ilumya (tildrakizumab-asmn) |
|---|---|
| BENEFIT TYPE | Medical |
| STATUS | Prior Authorization Required |

Ilumya 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. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Ilumya inhibits the release of proinflammatory cytokines and chemokines.
Psoriasis is recognized as the most prevalent immune-mediated inflammatory disease with plaque psoriasis being the most common. Plaque psoriasis presents with large oval-circular plaques over the scalp, trunk, legs and arms. It is marked by periods of acute flares and relapses.

Ilumya (tildrakizumab-asmn) will be considered for coverage when the following criteria are met:

## 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 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
5. 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
6. Member has tried and failed **TWO** preferred biologic DMARDs for at least 3 months each; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** 100 mg subcutaneously at week 0, 4, and every 12 weeks thereafter. Quantity limit: 1 syringe per 12 weeks after loading doses.

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease such as documented member's BSA improvement, etc.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Ilumya (tildrakizumab-asmn) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

| 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. |
| **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. |
| **10/16/2024** | Transferred to new template; removed compliance with initial criteria from reauthorization criteria; simplified TB test requirement; replaced "trial of at least two of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least 12 weeks of therapy with each drug" with trial of two preferred biologic DMARDs |

References:


1. Ilumya [package insert]. Merck & Co., Inc.; 2024.
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. Papp K, Thaçi D, Reich K, et al. Tildrakizumab (MK-3222), an anti-interleukin-23p19 monoclonal antibody, improves psoriasis in a phase IIb randomized placebo-controlled trial [published correction appears in Br J Dermatol. 2016 Jun;174(6):1426. doi: 10.1111/bjd.14752]. *Br J Dermatol.* 2015;173(4):930-939. doi:10.1111/bjd.13932
8. 2021 Georgia Code Title 33 – Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/.


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