CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Ilumya (tildrakizumab-asmn)
BILLING CODE	J3245
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
STATUS	Prior Authorization Required

Ilumya (tildrakizumab-asmn) 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. It is a humanized IgG1/k antibody that specifically binds to the p19 subunit of interleukin-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 that occur with psoriasis. It was initially approved by the FDA in 2018.

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

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member is at least 18 years of age; 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 tested negative for tuberculosis (TB) within the past 12 months; 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 preferred biologic drugs indicated for psoriasis. (See Appendix). Treatment failure requires at least 12 weeks of therapy with each drug.
8. **Dosage allowed/Quantity Limit:** 100 mg subcutaneously at Weeks 0, 4, and every twelve weeks thereafter (1 syringe every 12 weeks)

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

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease (e.g., 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.
02/22/2022	Ilumya policy transferred to new template. Removed "all initial criteria" from reauth. Reworded TB test. Removed specific drug names from 2nd set of preferred trials.

References:

1. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc., July 2020.
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: 01/01/2023
Revised date: 02/22/2022

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Humira • Stelara
Approved for Ulcerative Colitis	• Humira • Stelara • Rinvoq