blue california
Promise Health Plan

tildrakizumab-asmn (Ilumya)

Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Interleukin-23 antagonist
HCPCS:
J3245:Injection, tildrakizumab, 1 mg
How Supplied:
100 mg/mL (single-dose prefilled syringe)

Condition(s) listed in policy *(see coverage criteria for details)*

- Plaque Psoriasis, moderate to severe

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Plaque Psoriasis, moderate to severe
Meets medical necessity if all the following are met:

Initial:

1. Age is consistent with the FDA-approved indication (Patient is 18 years of age and older)
2. Prescribed by or in consultation with a dermatologist or rheumatologist
3. Meets ONE of the following:
   a. Baseline PASI score is 10 or more prior to starting biological therapy

b. Baseline BSA (body surface area) affected is 3% or more prior to starting biological therapy
c. Sensitive area is involved (i.e., groin, face, etc.)
d. Disease is otherwise debilitating

4. Inadequate response, intolerable side effect, or contraindication to one of the following: methotrexate, cyclosporine (Neoral), acitretin (Soriatane), or light therapy
5. Not used with Otezla or another targeted immunomodulator
6. Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Reauthorization:

1. Not being used in combination with other targeted biologics
2. Meets ONE of the following:
   a. Improvement in PASI score from baseline
   b. Improvement in BSA from baseline
   c. Decrease in sensitive area disease severity
   d. Decrease in debilitating disease severity

Covered Doses:
Up to 100 mg given subcutaneously at weeks 0, 4, and every twelve weeks thereafter

Coverage Period:
Initial: 24 weeks
Reauthorization: Yearly

ICD-10:
L40.0-L40.4

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Ilumya (tildrakizumab-asmn) Prescribing Information. Sun Pharmaceutical Industries, Inc., Cranbury, NJ. 4/2024.
4. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB,et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008 May;58(5):826-50.
5. 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: 1029-72.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee