tildrakizumab-asmn (Ilumya)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first dose of Ilumya or is being re-initiated on Ilumya after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Ilumya based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Ilumya based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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. 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 two BSC-preferred agents (e.g., adalimumab-aacf, Cosentyx SC, Enbrel, infliximab (Avsola or Inflectra), Otezla, Sotyktu, Skyrizi SC, Yesintek SC, and Tremfya SC) or contraindication to all preferred agents

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:

- Plaque psoriasis: Clarified preferred drugs

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