Tildrakizumab-asmn (Ilumya®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration* [*Prior authorization required – see section (1)] HCPCS: J3245 per 1 mg

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

- Plaque psoriasis

AHFS therapeutic class: Antipsoriatic agent, systemic

Mechanism of action: Interleukin-23 antagonist

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO, Shared Advantage and HMO (non-direct contract)** 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.

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

1. **Patient is receiving their first injection 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.*

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

2. **Patient has experienced a previous severe adverse event to Ilumya based on documentation submitted.**
3. **Patient continues to experience moderate to severe adverse events to 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for tildrakizumab-asmn (Ilumya®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Plaque Psoriasis

1. Disease is moderate to severe, **AND**
2. Age ≥ 18 years of age, **AND**
3. Prescribed by or in consultation with a dermatologist or rheumatologist, **AND**
4. One of the following:
    a. Baseline PASI score is 10 or more prior to starting biological therapy, OR
    b. Baseline BSA (body surface area) affected is 3% or more prior to starting biological therapy, OR
    c. Sensitive area is involved (i.e., groin, face, etc.), OR
    d. Disease is otherwise debilitating

AND

5. Inadequate response, intolerable side effect, or contraindication to one of the following:
    a. Methotrexate, cyclosporine (Neoral), acitretin (Soriatane), OR
    b. PUVA or UVB treatment

AND

6. Not used with Otezla or another targeted biologic, **AND**
7. Inadequate response, intolerable side effect, with two BSC-preferred agents, Enbrel, Humira, preferred infliximab (Inflectra or Avsola), Otezla, Skyrizi, Stelara, Taltz, and Tremfya, or contraindication to all preferred agents

Covered Doses
Up to 100 mg SC at Weeks 0, 4, and every twelve weeks thereafter.

Coverage Period
Initial: 24 weeks
Reauthorization: Yearly if meets the following:

8. Not being used in combination with other targeted biologics, AND
9. One of the following:
    a. Improvement in PASI score from baseline, OR
    b. Improvement in BSA from baseline, OR
    c. Decrease in sensitive area disease severity, OR
    d. Decrease in debilitating disease severity

ICD-10:
L40.0-L40.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for tildrakizumab-asmn (Ilumya™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
100 mg/mL solution in a single-dose prefilled syringe

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Ilumya® (tildrakizumab-asmn) [Prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 7/2020.
- 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.
- 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.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee