Tildrakizumab-asmn (llumya®)

<u>Place of Service</u> 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.

(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 or recommended or by 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 immunomodulator, AND
- 7. Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Covered Doses

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

Coverage Period Initial: 24 weeks

PHP Medi-Cal

tildrakizumab-asmn (llumya®)

Reauthorization: Yearly if meets the following:

- 1. Not being used in combination with other targeted biologics, AND
- 2. 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) <u>DO NOT</u> 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)

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code §</u> 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

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

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- 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 revision: 4Q2023 Date of next review: 2Q2024 Changes from previous policy version:

• No clinical change to policy following revision.

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