

Ilumya® (tildrakizumab-asmn)

When requesting Ilumya® (tildrakizumab-asmn), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Ilumya is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Coverage Guidelines

Plaque Psoriasis

The individual must meet **all** of the following criteria for initial authorization:

- Is 18 years of age or older;
- Ilumya is prescribed by or in consultation with a dermatologist;
- Meets one of the following:
 - o Had a 3-month trial of or intolerance to at least one biologic or traditional systemic agent for psoriasis (e.g., adalimumab, certolizumab, etanercept, infliximab, methotrexate, cyclosporine, acitretin, psoralen plus ultraviolet A light, etc.); OR
 - o Has a contraindication to methotrexate therapy.

The individual must meet **all** of the following criteria reauthorization:

- Has been established on Ilumya therapy for at least 3 months (*Note: A patient who has received < 3 months of therapy, or who is restarting therapy with Ilumya, is reviewed under initial authorization criteria*);
- Has experienced a beneficial clinical response, defined as improvement from baseline in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis;
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, itching, and/or burning).

Approval duration (initial and renewal): 12 months

Dosing Recommendation

The recommended dose is 100 mg administered via subcutaneous injection at weeks 0, 4, and every 12 weeks thereafter.

References

1. Ilumya [prescribing information]. Whitehouse Station, NJ: Sun; April 2024.
2. 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.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol*. 2015;29(12):2277-2294.
4. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. *Lancet*. 2017;390(10091):276-288.