

Ilumya™ (tildrakizumab-asmn)

When requesting Ilumya™ (tildrakizumab-asmn), the individual requiring treatment must be diagnosed with an 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.

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

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

- Does not have any clinically active infection
- Ilumya (tildrakizumab-asmn) will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor, T-cell costimulation modulator)
- Is at least 18 years of age
- For an initial authorization request:
 - o An individual has been screened for latent tuberculosis (TB). For positive latent TB, an individual has started/completed or will be treated for TB prior to starting Ilumya (tildrakizumab-asmn) AND
 - o Had an inadequate response or intolerance to prior biologic therapy OR
 - o Has affected body surface area (BSA) greater than 5% OR has psoriasis in vulnerable areas such as the face, genitals, hands and feet, or scalp and adversely affects quality of life AND
 - o Has tried and failed phototherapy or traditional systemic therapy (e.g., methotrexate, cyclosporine, acitretin) unless has one of the following conditions:
 - Contraindicated to traditional systemic therapy
 - Intolerant to traditional systemic therapy
 - Phototherapy not accessible/available
- For a re-authorization request, an individual's condition has improved or stabilized with Ilumya (tildrakizumab-asmn) therapy

Approval duration (initial and renewal): 12 months

Dosing Recommendations

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

References

1. Ilumya prescribing information. Whitehouse Station NJ; Merck & CO., Inc., March 2018.
2. American Academy of Dermatology. 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;58:826-850.
3. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008;58:851-864.
4. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol* 2011;65:137-174.