

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Inflammatory Conditions – Ilumya Utilization Management Medical Policy

- Ilumya<sup>®</sup> (tildrakizumab-asmn subcutaneous injection – Sun)

**REVIEW DATE:** 06/12/2024

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### OVERVIEW

Ilumya, an interleukin (IL)-23 blocker, is indicated for the treatment of adults with moderate to severe **plaque psoriasis** who are candidates for systemic therapy or phototherapy. It is administered subcutaneously at Weeks 0 and 4 and then once every 12 weeks thereafter. Ilumya should be administered by a healthcare professional. Safety and efficacy have not been established in patients < 18 years of age.

### Guidelines

Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.<sup>2</sup> These guidelines list Ilumya as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara<sup>®</sup> [ustekinumab subcutaneous injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.<sup>3</sup>

### POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Ilumya. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ilumya, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ilumya to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ilumya is recommended in those who meet the following criteria:

#### FDA-Approved Indication

- 1. Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) Initial Therapy.** Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
    - i.** Patient is  $\geq 18$  years of age; AND
    - ii.** Patient meets ONE of the following (a or b):

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- a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR  
Note: Examples of one traditional systemic agent include methotrexate, cyclosporine, or acitretin tablets. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
  - b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND
  - iii. The medication is prescribed by or in consultation with a dermatologist.
- B) Patient is Currently Receiving Ilumya.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
- i. Patient has been established on therapy for at least 3 months; AND  
Note: A patient who has received < 3 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
  - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
  - iii. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

**Dosing.** Approve the following dosing (A and B):

- A) The dose is 100 mg given as a subcutaneous injection; AND
- B) Doses are administered at Weeks 0 and 4, then not more frequently than once every 12 weeks thereafter.

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ilumya is not recommended in the following situations:

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Data are lacking evaluating concomitant use of Ilumya with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack controlled trial data in support of additive efficacy.<sup>4</sup>  
Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Ilumya.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**

1. Ilumya [prescribing information]. Cranbury, 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.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/10/2023
Selected Revision	<b>Plaque Psoriasis:</b> For a patient currently taking Ilumya, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024
Annual Revision	<b>Plaque Psoriasis:</b> In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy.	06/12/2024

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications*
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira <sup>®</sup> , biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia<sup>®</sup></b> (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
<b>Etanercept SC Products</b> (Enbrel <sup>®</sup> , biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
<b>Infliximab IV Products</b> (Remicade <sup>®</sup> , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Zymfentra<sup>®</sup></b> (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
<b>Simponi<sup>®</sup>, Simponi<sup>®</sup> Aria<sup>™</sup></b> (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA
<b>Tocilizumab Products<sup>®</sup></b> (Actemra IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
<b>Kevzara<sup>®</sup></b> (sarilumab SC injection)	Inhibition of IL-6	RA
<b>Orencia<sup>®</sup></b> (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan <sup>®</sup> , biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret<sup>®</sup></b> (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Stelara<sup>®</sup></b> (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
<b>Siliq<sup>™</sup></b> (brodalumab SC injection)	Inhibition of IL-17	PsO
<b>Bimzelx<sup>®</sup></b> (bimekizumab-bkzx SC injection)	Inhibition of IL-17A and IL-17F	PsO
<b>Cosentyx<sup>®</sup></b> (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
<b>Taltz<sup>®</sup></b> (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Ilumya<sup>™</sup></b> (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
<b>Omvoh<sup>®</sup></b> (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
<b>Skyrizi<sup>®</sup></b> (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO IV formulation: CD
<b>Tremfya<sup>™</sup></b> (guselkumab SC injection)	Inhibition of IL-23	PsO
<b>Entyvio<sup>™</sup></b> (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	IV formulation: CD, UC SC formulation: UC
<b>Oral Therapies/Targeted Synthetic DMARDs</b>		
<b>Otezla<sup>®</sup></b> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinqo<sup>™</sup></b> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant<sup>®</sup></b> (baricitinib tablets)	Inhibition of JAK pathways	RA
<b>Rinvoq<sup>®</sup></b> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, CD, nr-axSpA, RA, PsA, UC
<b>Sotyktu<sup>™</sup></b> (deucravacitinib tablets)	Inhibition of TYK2	PsO
<b>Xeljanz<sup>®</sup></b> (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
<b>Xeljanz<sup>®</sup> XR</b> (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
<b>Zeposia<sup>®</sup></b> (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
<b>Velsipity<sup>®</sup></b> (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

\* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; <sup>^</sup> Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; TYK2 – Tyrosine kinase 2.