



## Drug Coverage Policy

Effective Date .....07/01/2025  
Coverage Policy Number.....IP0659  
Policy Title...Ilumya Prior Authorization  
Policy

# Inflammatory Conditions – Ilumya Prior Authorization Policy

- Ilumya® (tildrakizumab-asmn subcutaneous injection – Sun)

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### INSTRUCTIONS FOR USE

*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

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## OVERVIEW

Ilumya, an interleukin (IL)-23 blocker, is indicated for the treatment of moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy.<sup>1</sup> 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 (2025) recommend biologics (including Ilumya) as second-line therapy for most patients requiring systemic treatment when there is inadequate response, contraindication, or intolerance to conventional systemic agents (e.g., methotrexate, cyclosporine, acitretin).<sup>3</sup>

## Coverage Policy

### POLICY STATEMENT

Prior Authorization is required for 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.

**NOTE:** This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Employer Plans: Standard/Performance, Value/Advantage, Total Savings Prescription Drug Lists (PSM001), Individual and Family Plans (PSM002), or Legacy Prescription Drug Lists (PSM017)* for additional preferred product criteria requirements and exceptions.

**Ilumya is considered medically necessary when the following are met:**

### FDA-Approved Indication

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- 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):
        - 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Conditions Not Covered

**Ilumya for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

**1. Concurrent Use with other Biologics or with Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

## Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HCP Codes	Description
J3245	Injection, tildrakizumab, 1 mg

## 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, Spuls PI, Dressler C, et al. EuroGuiDerm guideline for the systemic treatment of psoriasis vulgaris. Updated February 2025. Available at: <https://www.guidelines.edf.one/guidelines/psoriasis-guideline>. Accessed on: 05/21/2025.
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.

## Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024
Annual Revision	No criteria changes.	07/01/2025

The policy effective date is in force until updated or retired.

## APPENDIX

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

<b>Velsipity®</b> (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
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\* Not an all-inclusive list of indications. 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; ^ 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; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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