

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Ilumya Utilization Management Medical Policy

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

REVIEW DATE: 06/12/2024; selected revision 09/11/2024

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.¹ 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.² 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® [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.³

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):

- 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.

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 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.
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 | Plaque Psoriasis: 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 | Plaque Psoriasis: 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 |
| Selected Revision | Conditions Not Recommended for Approval: Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug). | 09/11/2024 |

APPENDIX

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

* 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.