

Drug Policy

Policy:	201810	Annual Review Date: 08/15/2024 Last Revised Date: 08/15/2024
Code(s):	HCPCS J3590, C9399	
SUBJECT:	Ilumya® (tildrakizumab-asmn)	

OVERVIEW

Ilumya is a humanized immunoglobulin (Ig)G monoclonal antibody that binds to interleukin (IL)-23, a pro-inflammatory cytokine. It binds to the p19 subunit of IL-23 and inhibits the intracellular and downstream signaling of IL-23 which is required for the terminal differentiation and survival of T helper (Th)17 cells. Ilumya is indicated for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is administered subcutaneously (SC) at Weeks 0 and 4 and then once every 12 weeks (Q12W) thereafter. Ilumya is intended for use under the guidance and supervision of a physician.

POLICY STATEMENT

This policy involves the use of Ilumya. Prior authorization is recommended for medical benefit coverage of Ilumya. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. **Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ilumya as well as the monitoring required for AEs and long-term efficacy, initial approval requires Ilumya be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Ilumya is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

RECOMMENDED AUTHORIZATION CRITERIA

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

Food and Drug Administration (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 if the patient meets ALL 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 if the patient meets ALL the following criteria (i, ii, and iii):

- i. Patient has been established on therapy for at least 90 days; AND

Note: A patient who has received < 90 days 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 in Plaque Psoriasis. Dosing must meet the following: The dose is 100 mg subcutaneously (SC) at Weeks 0 and 4 and then once every 12 weeks (Q12W) thereafter and should be administered by a healthcare professional.

Initial Approval/Extended Approval.

A) Initial Approval: 3 months (90 days)

B) Extended Approval: 1 year (365 days)

Duration of Therapy in Plaque Psoriasis. Indefinite

Labs/Diagnostics. Evaluate patients for TB infection prior to starting Ilumya. Do not administer to patients with an active TB infection.

Waste Management for All Indications.

Ilumya is available in a preservative-free, single-use, 100 mg/1 mL prefilled syringe with a 29-gauge one-half inch needle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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Ilumya has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: this is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1. Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Ilumya should not be administered in combination with another biologics or with a targeted synthetic DMARD for an inflammatory condition. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of additive efficacy. Note: This does NOT exclude the use of MTX (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.

*MMO Site of Care Medical Necessity Criteria:

- Medications in this policy will be administered in a place of service that identifies the location to be a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:
 1. Age less than 18 years; or
 2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
 3. History of a severe adverse event from previous administration of the prescribed medication; or
 4. Requested medication is being administered as follows:
 - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
 - administered with dialysis; or
 5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
 6. Ilumya: 2 doses allowed in a hospital based outpatient facility doses. All other doses need to be at NHFBL
 7. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves

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the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Code J3245

References

1. Ilumya™ injection [prescribing information]. Whitehouse Station, NJ: Sun Pharmaceuticals/Merck; August 2018.
2. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol.* 2012;148(1):95-102.
3. Menter A, Gottlieb A, Feldman SR, et al. 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.
4. 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.
5. 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.
6. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis.* 2013;72 Suppl 2:ii2-34.
7. Tildrakizumab-asmn. In: DRUGDEX (online database). Truven Health Analytics: Greenwood Village, CO. Last updated 22 March 2018. Accessed on 15 April 2018.

Edits and Denials:

Prior approval: Prior approval is required for Ilumya (**HCPCS Code J3245**). Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J3245** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3245	Injection tildrakizumab, 1mg (effective date 1/1/19)

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APPENDIX

	Mechanism of Action	Examples of Inflammatory 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
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, 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
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
Kevzara® (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
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)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsA, PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, 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; [^] 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.