MEDICAL MUTUAL®

Drug Policy

Policy:	**201810**	**Initial Effective Date: 05/19/2018**
Code(s):	**HCPCS J3245**	**Annual Review Date: 11/15/2018**
SUBJECT:	**Ilumya ® (tildrakizumab-asmn)**	**Last Revised Date: 12/26/2018**

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. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate.

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.The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations.

RECOMMENDED AUTHORIZATION CRITERIA

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

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Food and Drug Administration (FDA)-Approved Indication

1. **Moderate to Severe Plaque Psoriasis.**
   a. **Initial Therapy.** Approve for 3 months if patient meets (i, ii, iii, iv, and v):
      i. Patients is a candidate for systemic therapy or phototherapy; AND
      ii. Patient is 18 years of age or older; AND
      iii. Ilumya is prescribed by or in consultation with a dermatologist; AND
      iv. The patient meets one of the following (1 or 2):
         1. Patient has tried at least one of the following agents for at least 3 months for plaque psoriasis: an oral therapy for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets); oral methoxsalen plus ultraviolet A light (PUVA); or a biologic agent (e.g., Enbrel, Humira, Remicade, Stelara, Cosentyx, Remicade, Siliq, Taltz, Tremfya, Inflectra, Renflexis); OR
         2. Patient has a contraindication to one oral agent for psoriasis, such as MTX, or the other biologic agents, as determined by the prescribing physician
      v. Site of care medical necessity is met.

2. **Continuation of Therapy**
      i. Patient is Currently Receiving Ilumya. Approve for 1 year if the patient has responded, as determined by the prescriber and site of care medical necessity is met. The patient may not have a full response, but there should have been a recent or past response to Ilumya.

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.

Approval Duration
Initial Approval = 90 Days (3 months)
Re-authorization = 365 Days (1 year)

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.

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

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.

*** Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.**

[†]This criterion does not apply to Medicare or Medicare Advantage members.

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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 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 Codes 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.

HCPCS Code(s):	
J3245	Injection, tildrakizumab, 1 mg