Effective Date: 2/2020
Reviewed: 12/2019, 8/2020, 12/2020, 5/2021, 4/2022, 7/2022, 12/2022, 8/2023 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

ILUMYA (tildrakizumab-asmn)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INTIAL AND CONTINUATION OF THERAPY

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
   2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

IV. CRITERIA FOR INITIAL APPROVAL

Moderate to severe plaque psoriasis
Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis for members who are 18 years of age or older when all of the following criteria are met:

1. Ilumya is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.

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2. At least 10% of BSA is affected OR crucial body areas (i.e., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member meets either of the following:
   a. Member has had an inadequate response to at least a 3 month trial methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
   b. Member has had an inadequate response to at least a 3 month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
4. Member has had an inadequate response, intolerance, or contraindication to at least a 3 month trial of adalimumab at maximum tolerated doses.
5. Ilumya will not be used concomitantly with any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).
6. Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received Ilumya or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.]*

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are using Ilumya for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

VI. QUANTITY LIMIT

Ilumya has a quantity limit of 100mg (1ml) per 12 weeks, with post-limit for loading dose of 200 mg (2 ml) per month.

Indication	Dose (subcutaneous)
Plaque Psoriasis	100 mg at Weeks 0, 4, and every twelve weeks thereafter

VII. Appendix:

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin:

- Alcoholism, alcoholic liver disease or other chronic liver disease
- Breastfeeding
- Cannot be used due to risk of treatment-related toxicity
- Drug interaction
- Pregnancy or planning pregnancy (male or female)

- Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

VIII. REFERENCES

1. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2021.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009;61:451-485.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.