Effective Date: 1/2020
Reviewed: 12/2019, 8/2020, 12/2020, 5/2021, 4/2022, 7/2022, 12/2022, 8/2023, 12/2023, 01/2024, 02/2014, 1/2025, 4/2026, 8/2026 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare

Ilumya (tildrakizumab)

POLICY

Summary of Evidence:
Ilumya (tildrakizumab-asmn) is a humanized monoclonal antibody that selectively targets the p19 subunit of interleukin-23 (IL-23), a key cytokine involved in the inflammatory pathway of psoriasis. It is FDA approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Clinical efficacy was based on the pivotal Phase 3 reSURFACE 1 and reSURFACE 2 trials, which enrolled more than 1,800 patients with moderate-to-severe plaque psoriasis. In reSURFACE 1, approximately 64% of patients receiving ILUMYA 100 mg achieved a Psoriasis Area and Severity Index (PASI 75) response at Week 12 compared with approximately 6% of patients receiving placebo. Similarly, in reSURFACE 2, approximately 61% of patients treated with ILUMYA 100 mg achieved PASI 75 at Week 12 compared with approximately 6% of placebo-treated patients. Both studies also demonstrated significantly higher Physician Global Assessment (PGA) response rates compared with placebo, with efficacy maintained during long-term follow-up. The most common adverse reactions reported in clinical trials (occurring in at least 1% of patients) were upper respiratory tract infections, injection site reactions, and diarrhea.

CRITERIA FOR INITIAL APPROVAL:

For all indications:

- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
- Member will not receive live vaccines during therapy; AND
- Ilumya will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi,

Steqeyma, and Yesintek, etc.), Icotyde (icotrokinra), Tremfya (guselkumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.).

A. Moderate to severe plaque psoriasis

- Member is 18 years of age or older: AND
- Prescribed by, or in consultation with, a specialist in dermatology; AND
- Documentation has been submitted indicating member has moderate to severe plaque psoriasis and one or more of the following:
    - BSA affected is at least 10%; OR
    - Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    - Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
- Documentation has been submitted that member meets any of the following criteria:
    - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine or acitretin); OR
    - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    - Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
- Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab AND to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

CONTINUATION OF THERAPY:

A. Moderate to severe plaque psoriasis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity (e.g., reduction in BSA from baseline), or improvement in signs and symptoms of the condition (e.g., itching, redness, flaking scaling, burning, cracking, pain); AND

Coverage durations:

- Initial coverage: 12 months
- Continuation of therapy coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Ilumya was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Ilumya according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	**Dose**	**Maximum Dosing (1 billable unit = 1 mg)**
Plaque Psoriasis	100 mg subcutaneously at Week 0 and 4 then 100 mg every 12 weeks thereafter. Ilumya should be administered by a health care provider only	Loading: 100 units (100 mg) at Week 0 & 4 Maintenance: 100 units (100 mg) every 12 weeks

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.

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)

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J3245	Injection, tildrakizumab, 1 mg

References:

1. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2025. Accessed May 2026.
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.