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 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Ilumya (tildrakizumab)

Policy

Summary of Evidence:

Clinical trials evaluating the efficacy and safety of Ilumya have demonstrated its effectiveness in achieving significant improvements in psoriasis severity, as measured by the Psoriasis Area and Severity Index (PASI) and static Physician's Global Assessment (sPGA) scores, compared to placebo or active comparators. Notably, a high percentage of patients treated with Ilumya achieved PASI 75, PASI 90, and PASI 100 responses, indicating substantial reductions in psoriasis symptoms. Ilumya has shown a favorable safety profile, with adverse events typically being mild to moderate in severity and manageable with appropriate monitoring and intervention.

Initial Criteria:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Moderate to severe plaque psoriasis

- Patient must be 18 years of age or older: AND
- Patient has a diagnosis of moderate to severe plaque psoriasis: AND
- Patient has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB); AND
- Is prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- At least 10% of BSA is affected OR crucial body areas (i.e., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; AND
- Member meets either of the following:
    - Member has had an inadequate response to at least a 3-month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin (see Appendix A); OR
    - Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced; AND
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab and at least a 6-month trial of ustekinumab at maximum tolerated doses.
- Ilumya will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Ustekinumab, (e.g., Stelara, Wezlana), Tremfya

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

Continuation of Therapy Criteria:

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

Coverage durations:

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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY 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 INTEGRITY (Medicare-Medicaid Plan) 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.; April 2023. Accessed February 2024.
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.