Policy Title:	Ilumya (tildrakizumab-asmn) subcutaneous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	9/18/2019 , 12/20/2019, 1/22/2020, 8/3/2020, 6/24/2021, 4/14/2022		
Revision Date:	9/18/2019, 12/20/2019, 1/22/2020, 8/3/2020		

Purpose: To support safe, effective and appropriate use of Ilumya (tildrakizumab-asmn).

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

Policy Statement:

Ilumya (tildrakizumab-asmn) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Ilumya (tildrakizumab-asmn) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

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; OR
  - Member has had an inadequate response to at least a 3 month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced; AND
- Ilumya will not be used concomitantly with any other biologic DMARD or targeted synthetic DMARD; AND
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- Authorization may be granted for all members (including new members) who achieve or maintain positive clinical response within FDA dosing guidelines after at least 4 months of therapy with Ilumya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

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

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 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.