Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 190.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ilumya (tildrakizumab-asmn)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Ilumya (tildrakizumab-asmn)

II. Purpose/Objective:
To provide a policy of coverage regarding Ilumya (tildrakizumab-asmn)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Ilumya (tildrakizumab-asmn) is a human IgG1/k monoclonal antibody which selectively binds to the p19 subunit of interleukin (IL)-23, thereby inhibiting its interaction with the IL-23 receptor, resulting in inhibition of the proinflammatory cytokines and chemokines associated the binding of naturally occurring IL-23.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Ilumya (tildrakizumab-asmn) will be considered medically necessary for the commercial, exchange and CHIP lines of business when ALL of the following criteria are met:

- Prescribed by a dermatologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Ilumya is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of two (2) preferred formulary biologics for the treatment of psoriasis.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of Ilumya therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on Ilumya therapy.

Ilumya (tildrakizumab-asmn) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescribed by a dermatologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Ilumya is not being used concurrently with a TNF blocker or other biologic agent

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of Ilumya therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on Ilumya therapy.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Ilumya [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Inc; December 2022.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 1/15/19

Revised: 12/23/22 (LOB carve out, formulary alternative), 12/19/23 (Medicaid business segment), 12/29/23 (references added), 12/2/24 (LOB table, taglines)

Reviewed: 1/10/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23, 12/31/24