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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	April 20, 2018
Subject:	Ilumya	**Page:**	1 of 8

Last Review Date: March 8, 2024

Ilumya

Description

Ilumya (tildrakizumab-asmn)

Background
Ilumya (tildrakizumab-asmn) is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis. Ilumya is a biologic medication that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor. Since IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses, by inhibiting the release of this cytokine, Ilumya ultimately inhibits the release of proinflammatory cytokines and chemokines which cause plaque psoriasis (1).

Regulatory Status
FDA-approved indication: Ilumya is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy (1).

Treatment with Ilumya should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated. Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Ilumya. Initiate treatment of latent TB prior to administering Ilumya (1).

Prior to initiating therapy with Ilumya, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with Ilumya. No data are available on the response to live or inactive vaccines (1).

The safety and effectiveness of Ilumya have not been evaluated in pediatric patients (1).

Related policies
Skyrizi, Stelara, Tremfya

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ilumya may be considered **medically necessary** if the conditions indicated below are met.

Ilumya may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Moderate to severe plaque psoriasis (PsO)

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
    i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
b. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 12 weeks
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (Appendix 3)
d. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
e. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
f. **NOT** given concurrently with live vaccines

g. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Plaque psoriasis (PsO)

AND ALL of the following:

a. Condition has improved or stabilized with therapy
b. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 12 weeks
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (Appendix 3)
d. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
e. **NOT** given concurrently with live vaccines
f. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 syringes

(injection at Week 0, 4, then every 12 weeks)

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 8 syringes

Duration 18 months

Rationale

Summary

Ilumya (tildrakizumab) is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis. Ilumya is a biologic medication that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor. Treatment with Ilumya should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Ilumya while maintaining optimal therapeutic outcomes.

References

1. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2022.

Policy History

Date	Action
April 2018	Addition to PA
June 2018	Annual review
September 2018	Annual editorial review
	Change in initiation requirements: if the patient is intolerant or contraindicated to either therapy then the other treatment option needs to be tried
November 2018	Annual review
September 2019	Annual review and reference update
December 2019	Annual review. Addition of requirement to trial preferred product
September 2020	Annual review

December 2020	Annual editorial review. Added Appendix 4 with a list of preferred medications based on diagnosis and plan. Added requirements to dose within the FDA labeled maintenance dosing
March 2021	Annual editorial review. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 3 updated.
June 2022	Annual review and reference update
September 2022	Annual review
December 2022	Annual review
June 2023	Annual review
March 2024	Annual editorial review and reference update. Revised FDA dosing language

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1
Clinical Reasons to Avoid Pharmacological Treatment

Contraindications
Alcoholism, alcoholic liver disease, other chronic liver disease
Breastfeeding
Drug interaction
Cannot be used due to risk of treatment- related toxicity
Pregnancy or planning pregnancy (male or female)
Significant comorbidity prohibits the use of systemic agents (liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix 2
Conventional Systemic Therapy for Plaque Psoriasis

Generic	Brand
Methotrexate	Rheumatrex/Trexall
Cyclosporine	Sandimmune
Acitretin	Soriatane
Dexamethasone	Decadron
Predisone	Deltasone
Prednisolone	Orapred
Leflunomide	Arava
Tacrolimus	Astagraf/Envarsus/Hecoria/Prograf
Azathioprine	Azasan/Imuran
Sulfasalazine	Azulfidine/Sulfazine
Mycophenolate mofetil	Cellcept
Hydroxyurea	Droxia/hydrea
Fumaric acid esters	fumaderm

Appendix 3

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 4 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Plaque Psoriasis (PsO)	*must try **TWO** preferred products: Enbrel Humira** Otezla Skyrizi	*must try ONE preferred product: Enbrel Humira**

	Stelara (SC) Taltz Tremfya	

**Including all preferred biosimilars (see reference product criteria)