Effective Date **6/1/2024**
Coverage Policy Number **IP0236**

Tildrakizumab

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for tildrakizumab (**Ilumya®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Tildrakizumab (Ilumya) is considered medically necessary when the following are met:

1. **Plaque Psoriasis.** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Body Surface Area (BSA) of greater than 5% OR BSA less than 5% and there is involvement of the scalp, face, the palms and soles (i.e., palmoplantar disease), or genitals
   C. Documentation of **ONE** of the following:
      i. Failure to **ONE** of the following, unless contraindicated or intolerant to **ALL** of the following:

a. Topical therapy (for example, topical corticosteroids, topical vitamin D analogs, Tazorac)
b. Systemic therapy (for example, methotrexate, cyclosporine, Soriatane)
c. Phototherapy

ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Plaque Psoriasis

D. Medication is prescribed by, or in consultation with, a dermatologist
E. Non-Preferred Product Criteria is met, refer to the below table(s) [Employer Group Plans, Individual and Family Plans]

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Plans - Standard/Performance, Value/Advantage/ Legacy, Cigna Total Savings Covered Alternatives	
Condition	**Non-Preferred Product Criteria**
Plaque Psoriasis - Adult	Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product**: **Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** (by AbbVie) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Enbrel** [requires prior authorization] D. **Otezla** [requires prior authorization] E. **Skyrizi SC** [requires prior authorization] F. **Sotyktu** [requires prior authorization] G. **Stelara SC** [requires prior authorization] H. **Taltz** [requires prior authorization] I. **Tremfya** [requires prior authorization]

Individual and Family Plan Preferred Covered Alternatives	
Condition	**Non-Preferred Product Criteria**
Plaque Psoriasis - Adult	Documentation of failure, contraindication, or intolerance to **THREE** of the following: A. **Adalimumab Product**: **Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi,** or **Humira** (by AbbVie) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx** [requires prior authorization] D. **Enbrel** [requires prior authorization] E. **Otezla** [requires prior authorization] F. **Skyrizi SC** [requires prior authorization] G. **Stelara SC** [requires prior authorization] H. **Tremfya** [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of tildrakizumab (Ilumya) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs). Data are lacking evaluating concomitant use of Ilumya with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see Appendix for examples). Combination therapy with another biologic or a targeted synthetic DMARD has a potential for a higher rate of adverse effect(s) and lacks controlled trial data in support of additive efficacy.[4]

This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Ilumya.

Coding

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3245	Injection, tildrakizumab, 1 mg

Background

OVERVIEW
Ilumya, an interleukin (IL)-23 blocker, is indicated for the treatment of adults with moderate to severe **plaque psoriasis** who are candidates for systemic therapy or phototherapy. It is administered subcutaneously at Weeks 0 and 4 and then once every 12 weeks thereafter. Ilumya should be administered by a healthcare professional. Safety and efficacy have not been established in patients < 18 years of age.

Dosing and Availability
The recommended dose is 100 mg at Weeks 0, 4, and every twelve weeks thereafter. Ilumya is administered by subcutaneous injection.

Injection: 100 mg/mL solution in a single-dose prefilled syringe.

Guidelines
Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.[2] These guidelines list Ilumya as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara® [ustekinumab subcutaneous injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.[3]

References

1. Ilumya [prescribing information]. Whitehouse Station, NJ: Sun; October 2019.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol*. 2015;29(12):2277-2294.
4. Reich K, Papp KA, Blauvelt A, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. *Lancet*. 2017;390(10091):276-288.

Appendix

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√#	√	--	√	--	√
Xeljanz oral solution	--	√#	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Ankylosing Spondylitis**	**nr-axSpA**	**Psoriatic Arthritis**	**Plaque Psoriasis**	**Ulcerative Colitis**
Zeposia	--	--	--	--	--	--	√
Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.