Clinical Guideline

Guideline Number: CG053, Ver. 2

Ilumya (tildrakizumab-asmn)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

Clinical guidelines are applicable to certain plans. Clinical guidelines are applicable to members enrolled in Medicare Advantage plans only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of a prior authorization request. Services are subject to the terms, conditions, limitations of a member's policy and applicable state and federal law. Please reference the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Ilumya (tildrakizumab-asmn) is a specialty drug approved by the FDA on March 21, 2018. It is used as a monotherapy treatment option for adults diagnosed with moderate to severe plaque psoriasis who are candidates of systemic therapy or phototherapy. Ilumya must be administered as a subcutaneous injection by a healthcare professional. The recommended dosage is 100 mg at Weeks 0, 4, and every 12 weeks thereafter. The medication works as an IgG1 kappa monoclonal antibody to decrease the immune/inflammatory response that leads to the symptoms seen with plaque psoriasis.

Potential adverse reactions of Ilumya include hypersensitivity reactions and infections (e.g., pulmonary infections, injection site reactions, tuberculosis reactivation, and diarrhea).

Note: Oscar may require that preferred medications be used first. Please review Oscar Clinical Guideline CG052: Preferred Physician-Administered Specialty Drugs for a full list of our preferred and non-preferred drugs.

Definitions

"Body surface area (BSA)" is a measure of the total area involved by plaques in relation to the total body surface area. There are a number of different methods, however most clinical trials on plaque psoriasis use the "handprint method", where the patient's actual palm/hand size is estimated as 1% of BSA.

"Immune modulator" refers to the class of medications that function by inhibiting or activating various pathways of the immune system in an effort to reduce inflammatory/immune reactions.

"Monoclonal Antibody" is a type of drug that consists of a single clone of antibodies aimed against a specific target. Ilumya, for example, is a monoclonal antibody against IL-23.

"Plaque psoriasis" is a chronic skin disorder characterized by the formation of cutaneous plaques, which appear as scaly, raised lesions on the surface of the skin. These plaques can occur anywhere on the body and typically fluctuate in their location and severity.

"Systemic Therapy" refers to the broad category of agents infused for the treatment of plaque psoriasis.

"Phototherapy" is the use of ultraviolet light to treat the symptoms of plaque psoriasis. It can be performed as phototherapy alone with UVB or as photochemotherapy using UVA in combination with a photosensitizing drug (PUVA).

"PASI score" is the Psoriasis Area and Severity Index (PASI), which is the gold-standard for measurement psoriasis severity. It combines a measure of the severity of lesions and the area affected into a single score, ranging from 0 (no disease) to 72 (maximal disease).

Covered Services and Clinical Indications

Ilumya (tildrakizumab-asmn)

Oscar covers initial therapy for Ilumya when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; ***and***
2. The medication is being prescribed by a dermatologist; ***and***
3. The member has a documented negative tuberculosis skin test within the last 12 months; ***and***
4. The member must not be using a biologic or targeted synthetic DMARD in combination with Ilumya; ***and***
5. The member must have no evidence of infection; ***and***
6. The member has a diagnosis of moderate to severe plaque psoriasis as defined by **ONE** of the following:
    a. PASI score ≥12 or greater; *or*

b. Body Surface Area (BSA) is ≥10%; *or*
c. Body Surface Area (BSA) is ≥3% and plaques involve a sensitive region (e.g. face, head/neck/scalp, genitalia, palms, soles) or limit functional ability; ***and***

7. The member has had an adequate trial of phototherapy (e.g., UVB, PUVA) OR topical treatments (e.g., anthralin, calcipotriene, coal tars, corticosteroids, and/or tazarotene); ***and***
8. The member has had an adequate trial of at least 3 months of a conventional systemic therapy (e.g., methotrexate, cyclosporine, or acitretin) with an inadequate response or significant side effects /toxicity or has a contraindication to these therapies.
9. The member has undergone a minimum of a 3-month trial and failed, or has an intolerance or contraindication, to at least TWO of the following:
    a. Systemic therapy, including but not limited to methotrexate, cyclosporine and acitretin; *or*
    b. Phototherapy with PUVA (oral or bath psoralen followed by ultraviolet A (UVA) radiation) or UVB with tar (ultraviolet or narrowband); *or*
    c. Topical agents, including but not limited to anthralin, calcipotriene, coal tars, corticosteroids, and/or tazarotene

If the above prior authorization criteria are met, Ilumya will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Reauthorization for 12 months will be granted when the above criteria continue to be met and when **ONE** of the following criteria are met:

I. At least 75% improvement in PASI score compared to baseline; ***or***
II. A reduction in body surface area (BSA) affected since starting treatment; ***or***
III. Chart documentation showing improvement or maintenance of disease activity.

Experimental or Investigational / Not Medically Necessary

Ilumya (tildrakizumab-asmn) for any other indication is *not covered* by Oscar, as it is considered experimental or investigational. Non-covered indications include, but are not limited to, the following:

- Use in pediatric populations (<18 years old), as the safety and efficacy of Ilumya has not been evaluated in this patient population
- In combination with any of the following medications, as there is limited evidence to support this:
    - Biologic DMARDs including etanercept (Enbrel), adalimumab (Humira), certolizumab (Cimzia), golimumab (Simponi, Simponi ARIA), secukinumab (Cosentyx)

    - Janus kinase inhibitor including tofacitinib
    - Phosphodiesterase 4 (PDE4) inhibitor including apremilast
- In patients needing or expected to receive a live vaccine
- In patients with latent or active TB
- In patients with a current active infection, including infections of the skin
- To treat any other condition besides chronic plaque psoriasis

Applicable Billing Codes (HCPCS/CPT Codes)

Ilumya (tildrakizumab-asmn)	
CPT/HCPCS Codes covered if criteria are met:	
Code	*Description*
J3245	Injection, tildrakizumab, 1 mg
ICD-10 codes covered if criteria are met:	
Code	*Description*
L40.0 - L40.9	Moderate to severe chronic plaque psoriasis

References

1. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. J Am Acad Dermatol 2017; 76:290.
2. Feldman, SR. Treatment of psoriasis in adults. UpToDate. Last updated: Feb 11, 2019.
3. Food and Drug Administration. Tildrakizumab package insert. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761067s000lbl.pdf.
4. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities. Elmets, CA et al. Journal of the American Academy of Dermatology. DOI: https://doi.org/10.1016/j.jaad.2018.11.058. Published online: April 2019.
5. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Menter, Alan et al. Journal of the American Academy of Dermatology. DOI: https://doi.org/10.1016/j.jaad.2018.11.057. Published online: April 2019.
6. Menter A, Gelfand JM, Wu JJ, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Published: February 28, 2020. DOI:https://doi.org/10.1016/j.jaad.2020.02.044.
7. Merck & Co., Inc.Ilumya (tildrakizumab-asmn) injection, for subcutaneous use.Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; revised March 2018.
8. Papp K, Thaci D, Reich K, et al. Tildrakizumab (MK-3222), an anti-interleukin-23p19 monoclonal antibody, improves psoriasis in a phase IIb randomized placebo-controlled trial. Br J Dermatol. 2015;173(4):930-939.

9. 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 Jul 15;390(10091):276-288.
10. Sun Pharmaceutical Industries, Inc. Ilumya US Prescribing Information. Cranbury, NJ: Sun Pharma Global FZE; revised August 2018. Retrieved from www.ilumyapro.com.

Clinical Guideline Revision / History Information

Original Date: 3/6/2019
Reviewed/Revised: 8/6/2020