Ilumya (tildrakizumab-asmn)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Plaque psoriasis is a chronic autoimmune skin condition that affects approximately 2-3% of the global population. It is characterized by red, raised, scaly plaques on the skin, which can cause itching, pain, and significant psychological distress. Moderate to severe plaque psoriasis is typically defined as affecting more than 10% of the body surface area or having a significant impact on a patient's quality of life.

Drug treatment options for moderate to severe plaque psoriasis fall into several categories, including topical treatments, phototherapy, and systemic therapies.

- Topical treatments include treatment options such as vitamin D analogues, calcineurin inhibitors, keratolytics, and corticosteroids. These medications are applied directly to the skin and can help reduce inflammation and improve symptoms. However, they are generally only effective for mild to moderate psoriasis and may not be sufficient for patients with more severe disease, when a large portion of the body is affected, or those who may have difficulty applying the topical product to their own body.
- Phototherapy involves exposing the skin to ultraviolet (UV) light, which can help slow down the production of skin cells and reduce inflammation. This treatment can be effective for patients with moderate to severe plaque psoriasis, but it may require multiple sessions, can increase the risk of skin cancer, and may not be used on some sensitive affected areas (e.g., genitals, face).
- Systemic therapies include biologic agents, non-biologic agents, and oral medications. Biologic agents, such as tumor necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, infliximab) and interleukin (IL) inhibitors (e.g., bimekizumab, guselkumab, ixekizumab, risankizumab,secukinumab, tildrakizumab, ustekinumab), are targeted therapies that work by blocking specific molecules in the immune system that are involved in the development of psoriasis. Non-biologic agents, such as apremilast and tofacitinib, also work by targeting specific molecules in the immune system. Oral medications, such as methotrexate and acitretin, are systemic therapies that can help reduce inflammation and slow down the production of skin cells.

Ilumya (tildrakizumab-asmn) is FDA-approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Ilumya (tildrakizumab-asmn) 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, inhibiting the effects of IL-23, to decrease the immune/inflammatory response that leads to the symptoms seen with plaque psoriasis.

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. The head and neck, upper extremities, trunk, and lower extremities (including buttocks) typically correspond to approximately 10%, 20%, 30% and 40% of the BSA, respectively.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or

- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"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.

"[s]" indicates state mandates may apply.

"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 of psoriasis severity. It combines a measure of the severity of lesions (erythema, or redness; induration, or hardening or thickening of tissue; and scaling) and the area affected into a single score, ranging from 0 (no disease) to 72 (maximal disease).

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Moderate-to-severe plaque psoriasis

The Plan considers initial therapy for Ilumya (tildrakizumab-asmn) medically necessary when ALL of the following criteria are met:

1. The medication is being prescribed by or in consultation with a dermatologist; *AND*
2. The member is 18 years of age or older; *AND*

3. The member has a diagnosis of moderate to severe plaque psoriasis as defined by ONE (1) of the following:
    a. Psoriasis Area and Severity Index (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/groin, intertriginous area, hands, feet) or limit functional ability; *AND*
4. The member is unable to use, or has adequately tried and failed ONE (1) of the following[s]:
    a. Phototherapy (e.g., UVB, PUVA) OR topical treatments (e.g., anthralin, calcipotriene, coal tars, corticosteroids, and/or tazarotene); *or*
    b. At least 3 months of a conventional systemic therapy (e.g., methotrexate, cyclosporine, or acitretin) at maximally indicated doses; *AND*
5. The member meets ALL of the following:
    a. No evidence of active serious infection; *and*
    b. No evidence of active TB infection; *and*
    c. No evidence of concurrent use of a biologic or targeted synthetic disease-modifying antirheumatic drugs (DMARD) in combination with Ilumya; *AND*
6. The member has a documented negative tuberculosis skin test within the last 12 months.

If the above prior authorization criteria are met, Ilumya will be approved for up to 12-months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Moderate-to-severe plaque psoriasis

The Plan considers initial therapy for Ilumya (tildrakizumab-asmn) medically necessary when BOTH of the following criteria are met:

1. The member still meets the applicable initial criteria; *AND*
2. There is chart documentation showing ONE (1) of the following:
    a. At least 75% improvement in PASI score compared to baseline*; or*
    b. A reduction in body surface area (BSA) affected since starting treatment*; or*
    c. Chart documentation showing improvement or maintenance of signs and symptoms of disease activity (e.g., itching, redness, flaking, scaling, burning, cracking, pain).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months[s]

Experimental or Investigational or Unproven / Not Medically Necessary[5]

Ilumya (tildrakizumab-asmn) for any other indication is *not* considered medically necessary by the Plan, or it is considered experimental or investigational and 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 for the concomitant management of moderate-to-severe plaque psoriasis as there is limited evidence to support this:
    - Biologic Disease-modifying antirheumatic drugs (DMARDs)*; or*
    - Janus kinase inhibitors*; or*
    - Phosphodiesterase 4 (PDE4) inhibitors.
- In those needing or expected to receive a live vaccine. The use of live vaccines is not recommended with Ilumya (tildrakizumab-asmn).
- In those with latent or active TB. Individuals should be evaluated for TB prior to initiation of therapy with Ilumya (tildrakizumab-asmn). In those with active or latent TB, treatment of TB should be initiated.
- In those with a current active infection, including infections of the skin. Those with active infections or a history of recurrent infections were not included in the pivotal trial.
- To treat any other condition besides chronic plaque psoriasis (e.g., acute graft-versus-host disease, vitiligo, bullous pemphigoid, alopecia, psoriatic arthritis, ankylosing spondylitis, and/or non-radiographic axial spondyloarthritis). There are no high quality studies to support the safety and efficacy of Ilumya (tildrakizumab-asmn) for the management of graft-versus host disease, vitiligo, bullous pemphigoid, non-radiographic axial spondyloarthritis. Only one open-label study of individuals with alopecia found that only 2 of the 9 participants responded to Ilumya (tildrakizumab-asmn), further studies of higher quality and sample size are needed to support the safety and efficacy of Ilumya (tildrakizumab-asmn) for the management of alopecia. Only one randomized phase IIb clinical trial found Ilumya (tildrakizumab-asmn) effective for the management of psoriatic arthritis, further studies are needed to support this indication. A randomized, double-blind, phase IIa study found Ilumya (tildrakizumab-asmn) ineffective against placebo for the management of ankylosing spondylitis; no other clinical studies have been published to further support this indication.

Applicable Billing Codes

Table 1	
CPT/HCPCS Codes for moderate-to-severe plaque psoriasis considered medically necessary if criteria are met:	
Code	*Description*
J3245	Injection, tildrakizumab, 1 mg

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Table 2	
ICD-10 diagnosis codes considered medically necessary for moderate-to-severe plaque psoriasis with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
L40.0	Psoriasis vulgaris

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