Ilumya (tildrakizumab-asmn)
Effective January 15, 2020

Plan	☐ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderate to severe plaque psoriasis (PsO)

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Ilumya, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when all the following criteria are met:

1. The member has a diagnosis of moderate to severe plaque psoriasis
2. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member meets ONE of the following criteria:
    a. Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:

i. 1 topical agent + 1 systemic agent (methotrexate, acitretin or cyclosporine)
ii. 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
iii. 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
iv. 2 systemic agents

b. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). (See Appendix C)
c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Continuation of Therapy

Authorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Ilumya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

Initial approvals and reauthorizations will be granted for 24 months

Appendices

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Cannot be used due to risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or planning pregnancy (male or female)

Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

References

1. Ilumya (tildrakizumab-asmn) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; August 2018.
2. Menter A, Tyring SK, Gordon K, et al. Adalimumab therapy for moderate to severe psoriasis: A randomized, controlled phase III trial. J Am Acad Dermatol 2008; 58:106
3. Menting SP, Coussens E, Pouw MF, et al. Developing a Therapeutic Range of Adalimumab Serum Concentrations in Management of Psoriasis: A Step Toward Personalized Treatment. JAMA Dermatol 2015; 151:616
4. Bagel J, Lynde C, Tyring S, et al. Moderate to severe plaque psoriasis with scalp involvement: a randomized, double-blind, placebo-controlled study of etanercept. J Am Acad Dermatol 2012; 67:86
5. Nast A, Spuls PI, van der Kraaij G, et al. European S3-Guideline on the systemic treatment of psoriasis vulgaris - Update Apremilast and Secukinumab - EDF in cooperation with EADV and IPC. J Eur Acad Dermatol Venereol 2017; 31:1951
6. Nast A, Spuls PI, van der Kraaij G, et al. European S3-Guideline on the systemic treatment of psoriasis vulgaris - Update Apremilast and Secukinumab - EDF in cooperation with EADV and IPC. J Eur Acad Dermatol Venereol 2017; 31:1951

Review History

06/19/19 – Reviewed

11/20/19 - Added Skyrizi as required preferred product
10/31/2020 – Reviewed; Updated criteria to have preferred agent as Remicade for Comm/Exch strategy for implementation on 1/1/21

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