Ilumya (tildrakizumab-asmn)
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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
Ilumya (tildrakizumab-asmn) is an Interleukin-23 blocker indicated for:
- Treatment of moderate-to-severe plaque psoriasis

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan 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 if the member meets ALL following criteria and documentation has been submitted:

Plaque Psoriasis

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see appendix A)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing (see Appendix for more frequent or higher doses)

4. Prescriber provides clinical rationale for use of Ilumya instead of Stelara®

Off-Label Indications

Pityriasis rubra pilaris (PRP)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of pityriasis rubra pilaris (PRP)
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** topical corticosteroid or contraindication to **ALL** topical corticosteroids
3. Clinical rationale for use of the requested agent instead of Stelara® and Taltz®

New members currently stable on Ilumya® can be approved without documentation of failed trials with the conventional therapies.

Continuation of Therapy

Reauthorization requires physician documentation of a positive response to therapy.

Limitations

1. Initial approvals will be granted for: 3 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Ilumya 100mg/mL	1 injections per 84 days

Appendix A. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix B. More Frequent or Higher Doses

Requests for more frequent or higher doses of injectable biologics may be approved if ALL of the following is provided:

1. Severe disease
2. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** other injectable biologic which is FDA-approved for the requested indication
3. Partial response to FDA-approved dosing of current biologic therapy
4. Specialist consult for the requested indication

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
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
11/1/2021 – Reviewed and Updated for Nov P&T; Guideline updated to reflect multiple criteria changes and appendices changes based on clinical literature. Effective 01/01/2022
01/11/2023 – Reviewed and updated for Jan P&T. Matched MH. Appropriate diagnosis was replaced with a specific indication throughout. Off-label indications added for: PRP. Added language regarding stability of requested medication for new members. Updated Appendix sections by adding higher dose criteria. Effective 3/1/23.

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