

Ilumya (tildrakizumab-asmn)
Effective 01/02/2024

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions			

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:

Plaque Psoriasis

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. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Ilumya instead of Stelara® and Taltz®

Off-Label Indications

Pityriasis rubra pilaris (PRP)

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. **If reviewing under Pharmacy Benefit:** 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 for moderate to severe plaque psoriasis will infer positive response to therapy. Reauthorization for any off-label indication requires documentation of positive response to therapy from the prescriber.

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 injection per 84 days
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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, Tying 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, Tying 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.

06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through MB. Effective 6/30/23

11/15/23 – Reviewed and updated for P&T. Taltz was added as a step through for plaque psoriasis. Clarified reauthorization requirements. Effective 1/2/24.

