Skyrizi (risankizumab-rzaa)
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	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
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
Skyrizi (Risankizumab-rzaa) is an interleukin (IL)-23 antagonist that works by inhibiting the interaction with the IL-23 receptor which results in the inhibition of the of the release of proinflammatory cytokines and chemokines. It is indicated for the treatment of moderate-to-severe plaque psoriasis, active psoriatic arthritis in adults, and moderate-to-severe active Crohn's disease in adults.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Skyrizi excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Moderate to severe 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 †
4. Prescriber provides clinical rationale for use of Skyrizi instead of Stelara®

Psoriatic arthritis
Prescriber providers documentation of **ALL** of the following:

1. Diagnosis of psoriatic arthritis
2. Member meets **BOTH** of the following:
   a. Paid claims or physician documented of inadequate response, adverse reaction, or contraindication to Stelara®
   b. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agent that is FDA-approved for psoriatic arthritis
3. Appropriate dosing (see appendix and availability and dosage section) †

Moderate to severe Crohn's disease
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe Crohn's disease
2. Appropriate dosing (see appendix and availability and dosage section) †
3. **BOTH** of the following:
   a. Paid claims or physician documentation of inadequate response, adverse reaction, or contraindication to Stelara®
   b. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that are FDA-approved for Crohn's disease

† Requests for more frequent or higher doses – See Appendix

Off-Label Indications
Pityriasis rubra pilaris (PRP)
Prescriber provides documentation of **ALL** of the following:

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

New members currently stable on Skyrizi® 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 authorizations will be granted for:
   a. Plaque Psoriasis and off-label indications: 3 months
   b. All other indications: 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Skyrizi 75mg and 150mg	*Psoriatic Arthritis/Plaque Psoriasis:* One loading dose: 150mg at weeks 0 and 4 Maintenance dose: 150mg every 12 weeks
Skyrizi 600mg/10mL vial and 360mg/2.4mL cartridge	*Crohn's Disease:* IV Loading dose: 600mg at weeks 0, 4, and 8 Maintenance SQ: 360mg at week 12, and every 8 weeks after.

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: Requests for More Frequent or Higher Doses

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

1. Documentation of severe disease
2. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
    b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

References

1. Skyrizi (risankizumab-rzaa) [prescribing information]. North Chicago, IL: AbbVie Inc; January 2022.
2. Flytström I, Stenberg B, Svensson A, Bergbrant IM. Methotrexate vs. ciclosporin in psoriasis: effectiveness, quality of life and safety. A randomized controlled trial. Br J Dermatol 2008; 158:116.
3. Lebwohl M, Drake L, Menter A, et al. Consensus conference: acitretin in combination with UVB or PUVA in the treatment of psoriasis. J Am Acad Dermatol 2001; 45:544
4. Chen X, Yang M, Cheng Y, et al. Narrow-band ultraviolet B phototherapy versus broad-band ultraviolet B or psoralen-ultraviolet A photochemotherapy for psoriasis. Cochrane Database Syst Rev 2013; :CD009481
5. Krueger JG, Ferris LK, Menter A, et al. Anti-IL-23A mAb BI 655066 for treatment of moderate-to-severe psoriasis: Safety, efficacy, pharmacokinetics, and biomarker results of a single-rising-dose, randomized, double-blind, placebo-controlled trial. J Allergy Clin Immunol 2015; 136:116

Review History

03/18/2020 – Reviewed at P&T (effective 6/1/20)

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
06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Added criteria for newly FDA-approved indication: Psoriatic Arthritis. Continuation of therapy language was updated. Added approval duration for initial auths for PsO – 3 months. Updated Overview and Reference sections. Added Appendix B for More Frequent/Higher Doses. Effective 08/01/2022
11/16/2022 – Reviewed and updated for Nov P&T. Guideline was updated following FDA-approval in moderate to severe Crohn's disease. Clarified QLs. Effective 11/01/2022
01/11//2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Off-label indications added for: PRP. Clarified initial approval durations: plaque psoriasis/off-label for 3 months, all other indications for 6 months. Effective 3/1/23.

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