Skyrizi (risankizumab-rzaa)
Effective 11/01/2022

Plan	☐ MassHealth ☒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 is an interleukin (IL)-23 antagonist FDA indicated for moderate to severe plaque psoriasis, moderate to severe active Crohn's disease, and active psoriatic arthritis in adults. The inhibition of the interaction with the IL-23 receptor results in the inhibition of the of the release of proinflammatory cytokines and chemokines.

Coverage Guidelines
Authorization may be granted 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 program
OR

Plaque psoriasis (PsO)
Authorization may be granted for members who meet ALL the following criteria and documentation has been submitted:
1. The member is at least 18 years of age
2. The member has diagnosis of moderate to severe plaque psoriasis
3. The member has at least 5% of body surface area (BSA) affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
4. The member meets ONE of the following:
    a. Inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
        - 1 topical agent + 1 systemic agent (methotrexate, cyclosporine or acitretin)
        - 1 topical agent + phototherapy
        - 1 systemic agent + phototherapy

- 2 systemic agents

b. The member has a clinical reason to avoid ALL conventional therapies. *(*See Appendix A*)*
c. The member has severe psoriasis that warrants a biologic DMARD as first-line therapy

Psoriatic arthritis (PsA)
Authorization may be granted for members who meet ALL the following criteria and documentation has been submitted:
1. The member is at least 18 years of age
2. The member has diagnosis of active psoriatic arthritis
3. Member meets ONE of the following:
    a. The member has had an intolerance or inadequate response (after at least 3 months of treatment) with methotrexate or leflunomide
    b. The member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Crohn's Disease (CD)
Authorization may be granted for members who meet ALL the following criteria and documentation has been submitted:
1. The member is at least 18 years of age
2. The member has diagnosis of active Crohn's disease
3. The member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).

Continuation of Therapy
Reauthorization approvals will be granted when documentation has been submitted supporting clinical improvement in member's condition.

Limitations
1. Initial approvals will be granted for 24 months
2. Reauthorizations will be granted for 24 months
3. **For all indications,** member must have a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *
    a. Note: * Members who have received Skyrizi or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from all requirements related to TB screening in this Policy.
4. 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 IV 600mg/10mL and 360mg/2.4mL	*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
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. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    b. Azathioprine, mercaptopurine
    c. Alternative: methotrexate IM
5. Perianal and fistulizing disease – maintenance of remission
    d. Azathioprine, mercaptopurine
    e. Alternative: methotrexate IM

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

11/20/2019 – Reviewed at P&T
07/22/2020 – Reviewed and Updated July P&T; Updated Program Type to PA and QL; added TB testing requirement under Limitations. Effective 10/01/2020.
03/16/2022 – Reviewed and Updated March P&T; Added new indication psoriatic arthritis; added severe psoriasis may warrant a biologic DMARD as first-line therapy. Effective 05/01/2022
09/21/2022 – Reviewed and Updated for Sept P&T; added new indication for Crohn's disease. Effective 11/01/2022

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