Mass General Brigham
Health Plan

Skyrizi (risankizumab-rzaa)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
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	Skyrizi IV is only available on the Medical Benefit		

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

<u>Plaque psoriasis (PsO)</u>
Authorization may be granted for members who meet ALL the following criteria and documentation has been submitted:

1. The member has diagnosis of moderate to severe plaque psoriasis
2. Member has at least 3% 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. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
        i. Corticosteroids (e.g., betamethasone, clobetasol)
        ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        iii. Tazarotene
        iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        v. Anthralin
        vi. Coal tar
    b. 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 has diagnosis of active psoriatic arthritis
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Crohn's Disease (CD)

Authorization may be granted for members who meet ALL the following criteria and documentation has been submitted:

1. The member has diagnosis of active Crohn's disease
2. ONE of the following:
    a. Frequent diarrhea and abdominal pain
    b. At least 10% weight loss
    c. Complications such as obstruction, fever, abdominal mass
    d. Abnormal lab values (e.g., C-reactive protein [CRP])
    e. CD Activity Index (CDAI) great than 220
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
    a. 6-mercaptopurine
    b. Azathioprine
    c. Corticosteroids (e.g., prednisone)
    d. methotrexate

Continuation of Therapy

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

Limitations

1. Initial approvals and reauthorizations will be granted for 24 months
2. 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.

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 11/1/22
01/11/2023 – Reviewed for Jan P&T; updated 'exceptions' to allow new formulation of Skyrizi IV under the Medial Benefit only. Effective 2/1/2023
06/14/2023 – Reviewed and Updated for Jun P&T; added Skyrizi IV to exceptions as it is available under Medical Benefit Only.
11/15/2023 – Reviewed and Updated for Nov P&T; removed TB requirement. Psoriatic arthritis – removed conventional therapies and added member meets one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis – changed from 5% BSA to 3% BSA. Removed appendix. Consolidated conventional therapies for plaque psoriasis. Crohns disease – added Frequent diarrhea and abdominal pain, at least 10% weight loss, Complications such as obstruction, fever, abdominal mass, Abnormal lab values (e.g., C-reactive protein [CRP]), or CD Activity Index (CDAI) great than 20. Effective 1/1/24