Mass General Brigham
Health Plan

Skyrizi (risankizumab-rzaa)
Effective 01/01/2025

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 in adults for: moderate-to-severe plaque psoriasis, moderately to severely active Crohn's disease, moderately to severely active ulcerative colitis, and moderate-to-severe plaque psoriasis, and active psoriatic arthritis. 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 within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
Authorization may be granted when all the following diagnosis-specific criteria have been met:

<u>Plaque psoriasis (PsO)</u>
1. 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)

1. 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

Moderately to severely active Crohn's disease (CD)

1. Diagnosis of moderately to severely 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) greater 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

Moderately to severely active ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids
3. Member has had a trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
    c. Azathioprine
    d. Corticosteroids (e.g., prednisone)

Continuation of Therapy

Requests for reauthorizations for all diagnoses will be granted when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals for Skyrizi IV will be granted for 8 weeks
2. Initial and reauthorization approvals for Skyrizi SC will be granted for 24 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 IV 600mg/10mL and 180 mg/1.2 mL 360mg/2.4mL	*Crohn's Disease:* IV Loading dose: 600mg at weeks 0, 4, and 8 Maintenance SC: 180 mg or 360mg at week 12, and every 8 weeks after.
Skyrizi IV 600 mg/10 mL and 180 mg/1.2 mL and 360 mg/2.4 mL	*Ulcerative Colitis:* IV loading dose: 1,200 mg at weeks 0, 4, and 8 Maintenance SC: 180 mg or 360 mg at week 12, and every 8 weeks thereafter

References

1. Skyrizi (risankizumab-rzaa) [prescribing information]. North Chicago, IL: AbbVie Inc; June 2024.
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. Crohn's 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
09/11/2024 – Reviewed and updated for September P&T. Added criteria for ulcerative colitis. Updated approval length for Skyrizi IV to 8 weeks. Effective 12/1/24.
10/09/2024 – Reviewed and updated for October P&T. Updated Crohn's disease criteria to require moderately to severely active disease. Updated reauthorization criteria to require documentation of clinical improvement to therapy. Effective 1/1/2025.