Skyrizi® (risankizumab-rzaa)
(Intravenous/Subcutaneous)

Effective Date: 01/01/2023
Review Date: 10/6/2022, 8/10/23, 12/07/2023, 01/04/2024, 02/14/2024, 8/28/2024, 1/22/2025, 08/27/2025, 08/17/2026

Medical Scope for Intravenous (IV) Formulations: Medicaid, Commercial, Medicare

Pharmacy Scope for Subcutaneous (SC) formulations: Medicaid

I. Length of Authorization

Moderately to severely active Crohn's Disease (CD):
Coverage will be provided once (one time induction doses) for 8 weeks for Skyrizi IV.
** For members that meet criteria, Skyrizi 360mg (subcutaneous dose) will be approved for week 12, and then every 8 weeks thereafter for 4 months for Medicaid and Commercial ONLY**

Moderately to severely active Ulcerative Colitis (UC):
Coverage will be provided once (one time induction doses) for 8 weeks for Skyrizi IV.
** For members that meet criteria, Skyrizi 180mg or 360mg (subcutaneous dose) will be approved for week 12, and then every 8 weeks thereafter for 4 months for Medicaid and Commercial ONLY**

Plaque psoriasis and Active psoriatic arthritis
Initial coverage will be provided for 6 months and may be renewed for 12 months for Skyrizi SC.

II. Dosing Limits

Pharmacy

Indication	Dose (subcutaneous)	Quantity Limit
Plaque Psoriasis & Psoriatic Arthritis (6 years of age or older)	Members weighing ≥40kg: 150mg at Week 0, Week 4, and every 12 weeks thereafter Members weighing < 40kg: 55 mg at Week 0, Week 4, and every 12 weeks thereafter.	150mg prefilled syringe/pen per 12 weeks (daily dose of 0.012), with post-limit for loading dose of 300mg per month (daily dose of 0.07) 55mg prefilled syringe per 12 weeks (daily dose of 0.005), with post-limit for loading dose of 110mg per month (daily dose of 0.03)

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Crohn's disease (maintenance dose)	360mg at week 12, and then every 8 weeks	360mg per 8 weeks or a daily dose of 0.05.
Ulcerative colitis (maintenance dose)	180mg or 360mg at week 12, and then every 8 weeks	360mg per 8 weeks or a daily dose of 0.05.

Medical

A. Quantity Limit (max daily dose) [NDC Unit]:

- Skyrizi carton containing one 600 mg/10 mL single-dose vial: 3 for Weeks 0, 4 & 8

B. Max Units (per dose and over time) [HCPCS Unit]:

- Crohn's Disease
  - Induction dose: 600 mg or units at Week 0, 4, & 8
- Ulcerative Colitis
  - Induction dose: 1200 mg or units at Week 0, 4, & 8

III. Summary of Evidence

Skyrizi is an interluekin-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, active psoriatic arthritis in adults and moderately to severe active Crohn's disease in adults. The clinical studies of Skyrizi assessed its efficacy and safety in treating plaque psoriasis, psoriatic arthritis, and Crohn's disease. In the treatment of plaque psoriasis, four multicenter, randomized, double-blind studies (PsO-1, PsO-2, PsO-3, and PsO-4) involving 2,109 adults with moderate to severe disease demonstrated that Skyrizi significantly improved skin symptoms. At Week 16, patients treated with Skyrizi showed a notable reduction in both co-primary endpoints: the proportion of subjects achieving a static Physician's Global Assessment (sPGA) score of 0 or 1 and a 90% reduction in the Psoriasis Area and Severity Index (PASI 90). The improvements were maintained at Week 52, with high proportions of patients continuing to achieve PASI 90 and PASI 100.

For psoriatic arthritis (PsA), the safety and efficacy of Skyrizi were evaluated in two studies (PsA-1 and PsA-2) with 1,407 adults. Both studies demonstrated that treatment with Skyrizi resulted in significant improvement in disease activity compared to placebo, with a marked improvement in physical function as measured by the Health Assessment Questionnaire Disability Index (HAQ-DI). By Week 24, Skyrizi-treated patients showed significant reductions in tender and swollen joint counts and improvements in dactylitis and enthesitis. Moreover, for patients with coexisting plaque psoriasis, there were significant improvements in skin lesions, with many patients achieving PASI 90 at Week 24.

For Crohn's disease, two induction studies (CD-1 and CD-2) assessed Skyrizi in adults with moderately to severely active disease. The studies involved 1,419 patients, many of whom had failed previous biologic therapies. Treatment with Skyrizi, administered intravenously at doses of 600 mg or 1,200 mg at Weeks 0, 4, and 8, showed significant clinical and endoscopic responses at Week 12. However, no additional benefit was observed with the higher 1,200 mg dosage, which led to the recommendation of the 600 mg regimen. This demonstrated the drug's potential in treating active Crohn's disease, especially in patients who had failed prior treatments. Across all

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studies, Skyrizi was generally well tolerated, with consistent efficacy observed across various patient subgroups, including those with previous treatment failures. These findings support the use of Skyrizi as an effective treatment option for managing plaque psoriasis, psoriatic arthritis, and Crohn's disease.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Skyrizi will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek etc.), Tremfya (guselkumab), Icotyde (icotrokinra), Ilumya (tildrakizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.); AND

Moderate to severe plaque psoriasis

- Member is at least 6 years of age or older; AND
- Skyrizi is prescribed by, or in consultation with, a specialist in dermatology; AND
- Documentation has been submitted of one or more of the following:
  - BSA affected is at least 10%; OR
  - Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
  - Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g., tacrolimus), vitamin D analogs (e.g., calcipotriene), retinoids (e.g., tazarotene); AND
- Documentation has been submitted that member meets any of the following criteria:
  - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine or acitretin); OR
  - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
  - Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
- Documentation has been submitted that the member meets either of the following criteria:
  - If member is 18 years of age or older, member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab AND at least a 6-month trial of ustekinumab at maximum tolerated doses; OR
  - If member is under 18 years of age, member has an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

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Active psoriatic arthritis (PsA)

- Member is 6 years of age or older; AND
- Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Documentation has been submitted indicating one of the following:
    - Member has mild to moderate disease and meets one of the following criteria:
        - Member has had an inadequate response, intolerance, or contraindication to methotrexate, or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.); OR
        - Member has enthesitis or predominantly axial disease; OR
    - Member has severe disease; AND
- Documentation has been submitted that the member meets either of the following criteria:
    - If member is 18 years of age or older, member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab AND to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.
    - If member is under 18 years of age, member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

Moderately to severely active Crohn's Disease (CD)

- Member is 18 years of age or older; AND
- Prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member has documented moderate to severe active disease; AND
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab at maximum tolerated doses

Moderately to severely active Ulcerative Colitis

- Member is 18 years of age or older; AND
- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member has documented moderate to severe disease ; AND
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

† FDA Approved Indication(s); **‡** Compendia recommended indication(s); **Φ** Orphan Drug

V. Renewal Criteria [1]

Skyrizi IV

- Coverage cannot be renewed. Induction doses cannot be renewed.

Skyrizi SC

- **Moderate to severe plaque psoriasis (PsO)**

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Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity (e.g., reduction in BSA from baseline), or improvement in signs and symptoms of the condition (e.g., itching, redness, flaking scaling, burning, cracking, pain); AND

- Documentation has been submitted that the member has previously had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at the maximum tolerated dose.

- **Active psoriatic arthritis (PsA)**
  - Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    - Number of swollen joints
    - Number of tender joints
    - Dactylitis
    - Enthesitis
    - Axial disease
    - Skin and/or nail involvement
    - Functional status
    - C-reactive protein (CRP)**;** AND
  - Documentation has been submitted that the member has previously had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at the maximum tolerated dose.

- **Moderately to severely active Crohn's disease (CD)**
  - Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and documentation is submitted indicating one of the following:
    - Member has achieved or maintained remission; OR
    - Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
      - Abdominal pain or tenderness
      - Diarrhea
      - Body weight
      - Abdominal mass
      - Hematocrit
      - Endoscopic appearance of the mucosa
      - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

- **Moderately to severely active ulcerative colitis (UC)**
  - Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and documentation is submitted indicating one of the following:

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- Member has achieved or maintained remission; OR
- Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    - Stool frequency
    - Rectal bleeding
    - Urgency of defecation
    - C-reactive protein (CRP)
    - Fecal calprotectin (FC)
    - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    - Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

VI. Dosage/Administration

Indication	IV Dose
Crohn's Disease	**Induction:** 600 mg administered intravenously at Week 0, Week 4, and Week 8. **Maintenance:** 360 mg administered subcutaneously at Week 12 and every 8 weeks thereafter *(refer to criteria for self-administration under the applicable benefit).*
Ulcerative Colitis	**Induction**: 1200 mg administered intravenously at Week 0, Week 4, and Week 8. **Maintenance**: 180 mg or 360 mg administered subcutaneously at Week 12 and every 8 weeks thereafter *(refer to criteria for self-administration under the applicable benefit).*
	SC Dose
Plaque Psoriasis & Psoriatic Arthritis (6 years of age or older)	Weight < 40kg: 55mg at Week 0, Week 4, and every 12 weeks thereafter Weight ≥ 40kg: 150mg at Week 0, Week 4, and every 12 weeks thereafter
Crohn's disease (maintenance dose)	**Maintenance:** 360mg at week 12, and then every 8 weeks
Ulcerative colitis (maintenance dose)	**Maintenance:** 180mg or 360mg at week 12, and then every 8 weeks

VII. Billing Code/Availability Information

HCPCS Code:

- J2327 – injection, risankizumab-rzaa, intravenous, 1mg

NDC(s):

- Skyrizi carton containing one 600 mg/10 mL single-dose vial: 00074-5015-xx
- Skyrizi 150mg/ml single dose pen: 0074-2100-xx
- Skyrizi 150mg/ml single dose prefilled syringe: 0074-1050-xx
- Skyrizi 55mg/ml single dose prefilled syringe: 0074-4059-xx

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Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication

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ICD-10 Codes	ICD-10 Description
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complication
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.811	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.00	Ulcerative (chronic) pancolitis
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complication
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula

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ICD-10 Codes	ICD-10 Description
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale: Skyrizi was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Skyrizi according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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