

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

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

Pharmacy Scope for Subcutaneous (SC) formulations: Medicaid

I. Length of Authorization

Crohn's Disease:

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**

Ulcerative Colitis:

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

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	150mg at Week 0, Week 4, and every 12 weeks thereafter	150mg (1 box) per 12 weeks, with post-limit for loading dose of 300mg per month
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. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

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

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient 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**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concomitant treatment with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Wezlana, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.); **AND**

Moderate to severe plaque psoriasis

- Skyrizi is prescribed by, or in consultation with, a specialist in dermatology or rheumatology
- At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
- Documentation that member meets either of the following criteria:
 - Member has had an inadequate response to at least a 3-month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
 - Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
- Documentation that member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented (Note: If the member's BSA is greater than or equal to 20%, they are not required to trial Zoryve before Skyrizi)

- Documentation that the 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

Active psoriatic arthritis (PsA)

- Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
- Documented moderate to severe active disease and member meets either of the following criteria:
 - If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
 - If member has peripheral arthritis, member has experienced an inadequate response to at least a 3-month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced
- Documentation that the 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

Crohn's Disease

- Prescribed by, or in consultation with, a specialist in gastroenterology
- Documented moderate to severe active disease
- Patient has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses
- Patient has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

Ulcerative Colitis

- Must be prescribed by, or in consultation with, a specialist in gastroenterology
- Documented moderate to severe disease
- Patient has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses
- Patient has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

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

IV. Renewal Criteria ¹

Skyrizi IV

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

Skyrizi SC

- **Moderate to severe plaque psoriasis (PsO)**
 - 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 or improvement in signs and symptoms of the condition when any of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)
- **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
 - Skin and/or nail involvement
- **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 who achieve or maintain remission.
 - 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 who achieve or maintain 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 who achieve or maintain remission.
 - 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 who achieve or maintain 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)

V. Dosage/Administration

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

VI. 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

VII. References

1. Skyrizi [package insert]. North Chicago, IL; AbbVie, Inc.; June 2024. Accessed August 2024.
2. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
3. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008 May;58(5):826-50.
4. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008 May;58(5):851-64.
5. National Institute for Health and Care Excellence. NICE 2008. Infliximab for the treatment of adults with psoriasis. Published 23 January 2008. Technology Appraisal Guidance [TA134].
<https://www.nice.org.uk/guidance/ta134/resources/infliximab-for-the-treatment-of-adults-with-psoriasis-pdf-82598193811141>.

6. Smith CH, Jabbar-Lopez ZK, Yiu ZK, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. *Br J Dermatol*. 2017 Sep;177(3):628-636. Doi: 10.1111/bjd.15665.
7. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. *J Am Acad Dermatol*. 2017 Feb; 76(2):290-298. Doi: 10.1016/j.jaad.2016.10.017.
8. Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet*. 2018 Aug 25;392(10148):650-661. Doi: 10.1016/S0140-6736(18)31713-6. Epub 2018 Aug 7.
9. Langley R, Blauvelt A, Gooderham M, et al. Efficacy and safety of continuous Q12W risankizumab versus treatment withdrawal: results from the phase 3 IMMhance trial [poster no. 10093]. In: AAD Annual Meeting. 2019.
10. Reich K, Gooderham M, Thaçi D, et al. Efficacy and safety of continuous risankizumab or switching from adalimumab to risankizumab treatment in patients with moderate-to-severe plaque psoriasis: results from the phase 3 IMMvent trial [poster no. 10218]. In: AAD Annual Meeting. 2019.
11. Richard EG. (2021). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmetts CA, Corona R (Eds.), *UptoDate*. Last updated: June 28, 2021; Accessed on: June 20, 2022. Available from [https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20\(PUVA\)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1](https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20(PUVA)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1).
12. Honigsman H. (2020). UVB therapy (broadband and narrowband). In Elmetts CA, Corona R (Eds.), *UptoDate*. Last updated: August 19, 2022; Accessed on June 20, 2022. Available from [https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20\(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1](https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1).
13. American Academy of Dermatology Work Group. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Jul;65(1):137-74.
14. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol* 2019; 80:1029. <https://doi.org/10.1016/j.jaad.2018.11.057>.
15. Smith CH, Yiu ZZN, Bale T, et al; British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update. *Br J Dermatol*. 2020 Oct;183(4):628-637. doi: 10.1111/bjd.19039.
16. National Institute for Health and Care Excellence. NICE 2017. Psoriasis: assessment and management. Published 24 October 2012. Clinical guideline [CG153]. <https://www.nice.org.uk/guidance/CG153>. Accessed June 2022.
17. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol* 2020; 82:1445.
18. National Institute for Health and Care Excellence (NICE). Risankizumab for treating moderate to severe plaque psoriasis. Technology appraisal guidance. Published: 21 August 2019. www.nice.org.uk/guidance/ta596.

19. American Academy of Dermatology Work Group. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
20. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020 Jun;79(6):700-712. doi: 10.1136/annrheumdis-2020-217159.
21. National Institute for Health and Care Excellence. NICE 2017. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs. Published 24 May 2017. Technology Appraisal Guidance [TA445].
22. Kristensen LE, Keiserman M, Papp K, et al. Efficacy and safety of risankizumab for active psoriatic arthritis: 24-week results from the randomised, double-blind, phase 3 KEEPsAKE 1 trial. Ann Rheum Dis. 2022 Feb;81(2):225-231. doi: 10.1136/annrheumdis-2021-221019.
23. Östör A, Van den Bosch F, Papp K, et al. Efficacy and safety of risankizumab for active psoriatic arthritis: 24-week results from the randomised, double-blind, phase 3 KEEPsAKE 2 trial. Ann Rheum Dis. 2021 Nov 23;annrheumdis-2021-221048. doi: 10.1136/annrheumdis-2021-221048.
24. National Institute for Health and Care Excellence. NICE 2013. Psoriasis. Published 06 August 2013. Quality standard [QS40]. <https://www.nice.org.uk/guidance/qs40>. Accessed June 2022.
25. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. Lancet. 2022 May 28;399(10340):2015-2030. doi: 10.1016/S0140-6736(22)00467-6.
26. Lichtenstein GR, Loftus EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018; 113:481–517; doi: 10.1038/ajg.2018.27.
27. Torres J, Bonovas S, Doherty G, et al. European Crohn's and Colitis Organisation [ECCO] Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. Journal of Crohn's and Colitis, 2020, 4–22 doi:10.1093/ecco-jcc/jjz180.
28. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the use of Thiopurines, Methotrexate, and Anti-TNF- α Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease. Gastroenterology 2013;145:1459-1463.
29. National Institute for Health and Care Excellence. NICE 2019. Crohn's Disease: Management. Published 03 May 2019. NICE Guideline [NG129]. <https://www.nice.org.uk/guidance/ng129>.

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

ICD-10 Codes	ICD-10 Description
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
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

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