

Skyrizi® (risankizumab-rzaa) (Intravenous)

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I. Length of Authorization

Crohn's Disease:

Coverage will be provided for 9 weeks (63 days) and cannot be renewed.

II. Dosing Limits

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

- Skyrizi carton containing one 600 mg/10 mL single-dose vial: 1 vial at Weeks 0, 4 & 8 (3 vials total)

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

- Crohn's Disease
 - Induction dose: 600 billable units (600 mg) at Week 0, 4, & 8

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to Stelara OR Wezlana (ustekinumab) prior to initiating therapy with Skyrizi (risankizumab); **AND**
- 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 concurrent treatment with another IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (e.g., apremilast, tofacitinib, baricitinib, upadacitinib, abrocitinib, deucravacitinib, etc.); **AND**
- Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; **AND**

Crohn's Disease (CD) † 1,25-29

- Documented moderate to severe active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate, etc.); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier (e.g., adalimumab, certolizumab, or infliximab)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
Crohn's Disease	<p>Induction: Administer 600 mg intravenously at Week 0, Week 4, and Week 8.</p> <p>Maintenance: Administer 180mg or 360 mg subcutaneously at Week 12 and every 8 weeks thereafter (<i>see Skyrizi SQ [Document Number: IC-0459] for medical necessity criteria</i>)</p>

VI. Billing Code/Availability Information

HCPCS Code:

- J2327 – Injection, risankizumab-rzaa, intravenous, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Skyrizi carton containing one 600 mg/10 mL single-dose vial: 00074-5015-xx

VII. References

1. Skyrizi [package insert]. North Chicago, IL; AbbVie, Inc.; May 2023. Accessed July 2023.
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. (2022). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Dec 01, 2022; Accessed on: July 20, 2023. 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. Hoönigsmann H. (2023). UVB therapy (broadband and narrowband). In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Jan 18, 2023; Accessed on July 20, 2023. 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>.
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>.

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
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

ICD-10 Codes	ICD-10 Description
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

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 VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC