Skyrizi® (risankizumab-rzaa)
(Intravenous)

Document Number: MODA-0671

Last Review Date: 08/01/2024
Date of Origin: 07/05/2022
Dates Reviewed: 07/2022, 10/2022, 08/2023, 07/2024, 08/2024

I. Length of Authorization

Coverage will be provided for 11 weeks (3 doses) 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: 2 vials at Weeks 0, 4 & 8 (6 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
- Ulcerative Colitis
  - Induction dose: 1200 billable units (1200 mg) at Week 0, 4, & 8

III. Initial Approval Criteria [1]

For Commercial Members Only
• Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to Entyvio IV (vedolizumab IV) AND Stelara (ustekinumab) or Wezlana (ustekinumab-auub) AND Cimzia (certolizumab pegol) prior to initiating therapy with Skyrizi (risankizumab); **AND**
For Medicaid Members Only
• Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to Stelara (ustekinumab) or Wezlana (ustekinumab-auub) prior to initiating therapy with Skyrizi (risankizumab); **AND**

Coverage is provided in the following conditions:

- 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 biologic therapy (e.g., IL-inhibitor, TNF-inhibitor, integrin receptor antagonist, T cell costimulation modulator, etc.) or targeted synthetic therapy (e.g., apremilast, tofacitinib, baricitinib, upadacitinib, abrocitinib, deucravacitinib, ritlecitinib, ruxolitinib, etrasimod, ozanimod, etc.); **AND**
- Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; **AND**

Crohn's Disease (CD) † [1,2-6]

- 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, methotrexate, etc.); **OR**
  - Patient is already established on a biologic or targeted synthetic therapy for the treatment of CD; **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)

Ulcerative Colitis † [1,7-14]

- Documented moderate to severe active disease; **AND**
  - Documented failure or ineffective response to a minimum 3-month trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.] at maximum tolerated doses, unless there is a contraindication or intolerance to use; **OR**
  - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such as adalimumab, golimumab, or infliximab; **OR**
  - Patient is already established on a biologic or targeted synthetic therapy for the treatment of UC

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

IV. Renewal Criteria [1]

Coverage cannot be renewed.

V. Dosage/Administration [1]

Indication	Dose
Crohn's Disease	**Induction:** Administer 600 mg intravenously at Week 0, Week 4, and Week 8. **Maintenance:** Administer 180 mg or 360 mg subcutaneously at Week 12 and every 8 weeks thereafter *(***NOTE:** for maintenance therapy, refer to criteria for the subcutaneous formulation for self-administration under applicable benefit)*
Ulcerative Colitis	**Induction:** Administer 1200 mg intravenously at Week 0, Week 4, and Week 8. **Maintenance:** Administer 180 mg or 360 mg subcutaneously at Week 12 and every 8 weeks thereafter *(***NOTE:** for maintenance therapy, refer to the criteria for the subcutaneous formulation for self-administration under applicable benefit)*

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References

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6. 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.
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12. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on therapeutics in ulcerative colitis: medical treatment. J Crohns Colitis. 2022 Jan 28. 16 (1):2-17. Doi: 10.1093/ecco-jcc/jjab178.
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14. Louis E, Panaccione R, Parkes G, et al. OP06 Risankizumab Maintenance Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Efficacy and Safety in the Randomised Phase 3 COMMAND Study, Journal of Crohn's and Colitis, Volume 18, Issue Supplement_1, January 2024, Pages i10–i12, https://doi.org/10.1093/ecco-jcc/jjad212.0006

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

ICD-10 Codes	ICD-10 Description
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
K51.00	Ulcerative (chronic) pancolitis without complications
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 complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula

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
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	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
K51.90	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 complications
R19.7	Diarrhea, unspecified

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-

database/search.aspx. Additional indications, including any preceding information, may be applied 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		
Jurisdicti	**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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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