Medical Benefit Drug Policy

Skyrizi (risankizumab-rzaa) injection, for intravenous use

Policy Number: MC/PC 040
Effective Date: August 1, 2025

Instructions for Use

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Related Policies

- N/A

Coverage Rationale

This policy is applicable to Skyrizi (risankizumab-rzaa) injection, for intravenous use only.

Treatment of Moderately to Severely Active Crohn's Disease

For initial coverage of Skyrizi (risankizumab-rzaa) injection for the treatment of moderately to severely active Crohn's disease in adults, the following will be required:

- Diagnosis of moderately to severely active Crohn's disease (CD) **and**
- One of the following:
  - 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])
  - CD Activity Index (CDAI) greater than 220 **and**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies:
  - 6-mercaptopurine
  - Azathioprine
  - Methotrexate
  - Corticosteroid (e.g., prednisone) **and**
- Will be administered as an intravenous induction dose **and**
- Prescribed by or in consultation with a gastroenterologist

Treatment of Moderately to Severely Active Ulcerative Colitis

For initial coverage of Skyrizi (risankizumab-rzaa) injection for the treatment of moderately-to-severely active ulcerative colitis disease in adults, the following will be required:

- Diagnosis of moderately to severely active ulcerative colitis **and**
- One of the following:
    - Greater than 6 stools per day
    - Frequent blood in the stools
    - Frequent urgency
    - Presence of ulcers
    - Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)
    - Dependent on, or refractory to, corticosteroids **and**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies:
    - 6-mercaptopurine
    - Azathioprine
    - Corticosteroid (e.g., prednisone)
    - Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine) **and**
- Will be administered as an intravenous induction dose **and**
- Prescribed by or in consultation with a gastroenterologist

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg

ICD-10 Code	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

ICD-10 Code	Description
K50.812	Crohn's disease of both small and large intestine with inte
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
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) recto sigmoiditis without complications
K51.311	Ulcerative (chronic) recto sigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) recto sigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) recto sigmoiditis with fistula
K51.314	Ulcerative (chronic) recto sigmoiditis with abscess
K51.318	Ulcerative (chronic) recto sigmoiditis with other complication
K51.319	Ulcerative (chronic) recto sigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications

ICD-10 Code	Description
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
K52.1	Toxic gastroenteritis and colitis

Background

Inflammatory bowel disease (IBD) is a spectrum of chronic idiopathic inflammatory intestinal conditions that cause gastrointestinal symptoms including diarrhea, abdominal pain, bleeding, fatigue, and weight loss. The exact cause of IBD is unknown; however, proposed etiologies involve a combination of infectious, genetic, and lifestyle factors (Peppercorn and Cheifetz 2024, Peppercorn and Kane 2023). Complications of IBD include hemorrhage, rectal fissures, fistulas, peri-rectal and intra-abdominal abscesses, and colon cancer as well as extra-intestinal complications such as hepatobiliary complications, anemia, arthritis and arthralgias, uveitis, skin lesions, and mood and anxiety disorders (Peppercorn and Kane 2023, Peppercorn and Kane 2024).

Crohn's Disease (CD) can involve any part of the gastrointestinal tract and is characterized by transmural inflammation and "skip areas." Transmural inflammation may lead to fibrosis, strictures, sinus tracts, and fistulae (Peppercorn and Kane 2023). The immune system is known to play a critical role in the underlying pathogenesis of IBD and it is suggested that abnormal responses of both innate and adaptive immunity mechanisms induce aberrant intestinal tract inflammation in IBD patients (Geremia et al 2014). Precise incidence and prevalence estimates of CD is limited by a lack of gold standard criteria for diagnosis, inconsistent case ascertainment, and disease misclassification but the existing data suggest that the incidence of CD varies from 3.1 to 20.2 per 100,000 person-years.

Ulcerative Colitis (UC) is characterized by recurrent episodes of inflammation of the mucosal layer of the colon. The inflammation, limited to the mucosa, commonly involves the rectum and may extend in a proximal and continuous fashion to affect other parts of the colon. The hallmark clinical symptom is an inflamed rectum accompanied by urgency,

bleeding, and tenesmus (Peppercorn and Kane 2024). As many as 3 million per :ers for Disease Control and Prevention [CDC] 2022, Molodecky et al 2012, Shivash

Risankizumab-rzaa is a humanized IgG1 monoclonal antibody that selectively binds to the p19 subunit of human IL-23 cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines.

Clinical Evidence

Two Phase 3 trials, ADVANCE and MOTIVATE, have demonstrated the efficacy and safety of Skyrizi (risankizumab) as induction therapy vs placebo for patients with moderately to severely active CD with intolerance or an inadequate response to biologics or conventional therapy (D'Haens et al 2022). The coprimary endpoints were clinical remission (CDAI or patient-reported outcome criteria) and endoscopic response at week 12. Results revealed that all coprimary endpoints at week 12 were met in both trials with both doses of risankizumab as compared to placebo (600 or 1200 mg IV at weeks 0, 4, and 8; $p \leq 0.0001$). These positive results were confirmed in the FORTIFY trial where SQ risankizumab was administered as maintenance therapy for 542 patients who had a clinical response to the drug in the ACTIVATE or MOTIVATE induction studies (Ferrante et al 2022).

The approval of Skyrizi for UC was based on a 12-week induction study (INSPIRE) in 966 patients with moderately to severely active UC. The primary endpoint was clinical remission defined using the modified Mayo score (mMS) at week 12. Clinical remission was achieved in 24% of patients with Skyrizi vs. 8% of patients with placebo (difference 16, 95% CI: 12, 20; $p < 0.001$) (Louis et al 2023) . A maintenance study (COMMAND) was also conducted in 547 patients who received induction regimens in a previous study and demonstrated clinical response per mMS after 12 weeks. Patients were randomized to receive a maintenance regimen of Skyrizi or placebo at week 12 and every 8 weeks thereafter for up to an additional 52 weeks. The primary endpoint was clinical remission using mMS at week 52. Clinical remission was achieved in 45% of patients with Skyrizi 180 mg (difference vs. placebo of 20, 95% CI: 11, 29; $p < 0.001$), 41% with Skyrizi 360 mg (difference vs. placebo of 16, 95% CI: 7, 25; $p < 0.001$), and 26% with placebo (Louis et al 2024).

Clinical Guidelines
A 2018 ACG guideline on the management of CD in adults recommends controlled ileal release budesonide at a dose of 9 mg once daily for induction of symptomatic remission for patients with mild to moderate ileocecal CD. The guideline also recommends against the use of oral mesalamine to treat patients with active CD, since it has not consistently been shown effective for inducing remission and achieving mucosal healing when compared to placebo. Sulfasalazine is recommended for symptoms of mild to moderate colonic CD. For patients with more severe disease, the ACG states that the TNF inhibitors adalimumab, certolizumab, and infliximab are effective in the treatment of moderate to severely active CD in patients who are resistant to corticosteroids or are refractory to thiopurines or methotrexate. Vedolizumab with or without an immunomodulator can be used for induction and maintenance of remission in patients with moderate to severe CD. Patients are candidates for ustekinumab therapy, including for the maintenance of remission, if they have moderate to severe CD and have failed corticosteroids, thiopurines, methotrexate, or TNF inhibitors. The guideline acknowledges the effectiveness of biosimilar infliximab and biosimilar adalimumab for the management of moderate to severe CD (Lichtenstein et al 2018). A 2021 AGA guideline on the medical management of moderate to severe CD strongly recommends the use of biologic monotherapy over thiopurine monotherapy for the induction of remission in adult outpatients and recommends TNF inhibitors or ustekinumab over no treatment for induction and maintenance of remission. In patients who are naïve to biologic drugs, infliximab, adalimumab, or ustekinumab are recommended over certolizumab pegol for the induction of remission and vedolizumab is suggested over certolizumab pegol. In patients who never responded to TNF inhibitors, the use of ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. In patients who previously responded to infliximab, the use of adalimumab or ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. (Feuerstein et al 2021).

The 2020 ECCO guideline on medical treatment in CD recommends the use of [redacted] b, and certolizumab pegol) to induce remission in patients with moderate-to-sev[redacted] conventional therapy (Torres et al 2020).

A 2019 guideline from the American College of Gastroenterology (ACG) recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, TNF inhibitor therapy (adalimumab, golimumab, or infliximab), vedolizumab, and tofacitinib for induction of remission in moderately to severely active disease. Vedolizumab and tofacitinib are recommended for induction of remission in patients who have failed previous TNF inhibitor therapy. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended, and in patients with previously moderately to severely active disease, continuation of TNF inhibitor therapy, vedolizumab, or tofacitinib is recommended after induction of remission with these agents (Rubin et al 2019).

For adult outpatients with moderate to severe UC, a 2020 AGA guideline strongly recommends using infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment (Feuerstein et al 2020). However, for patients with less severe disease who place a higher value on the safety of 5-ASA therapy and a lower value on the efficacy of biologic agents, it is reasonable to choose gradual step therapy with 5-ASA.The European Crohn's and Colitis Organisation (ECCO) recommends thiopurines for maintenance of remission in patients with steroid-dependent UC who are intolerant of 5-ASA. Remission can be induced with TNF inhibitors, vedolizumab, tofacitinib, or ustekinumab in patients with moderate to severe disease that has not responded to conventional therapy. Remission can be maintained with the same biologic agent that was used for induction therapy (Raine et al 2022).

The place of Skyrizi (risankizumab-rzaa) injection within the clinical guidelines is yet to be established.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

SKYRIZI is an interleukin-23 antagonist indicated for the treatment of:
- moderately to severely active Crohn's disease in adults.
- moderately to severely active ulcerative colitis in adults.
- moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- active psoriatic arthritis in adults.

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Policy History/Revision Information

Date	Summary of Changes
12/13/2023	Approved by OptumRx P&T Committee
5/16/2024	Annual Review. No changes made.
8/15/2024	Addition of moderately to severely active ulcerative colitis as an indication.
7/16/2025	Annual Review. References updated. No changes made.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administ cal Benefit Drug Policies are intended to be used in connection with the independ a qualified health care provider and do not constitute the practice of medicine o medical advice.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
mm/dd/yyyy – mm/dd/yyyy	######	Title of Policy Hyperlinked to KL or Other Internal Location

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).