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Risankizumab-rzaa

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: Risankizumab-rzaa (Skyrizi®) may be self-administered. For self-administered medications, please refer to the applicable pharmacy benefit plan.

NOTE 2: When meeting criteria below, adults will receive the first three doses of Skyrizi through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider at week 0, week 4 and week 8. Individuals may then receive Skyrizi as an injection under the skin (subcutaneous injection) thereafter.

Risankizumab-rzaa (Skyrizi®) **may be considered medically necessary** for the following indications:

- Adults (18 years of age or older) with moderate to severely active Crohn's disease;
- Adults (18 years of age or older) with moderate to severely active ulcerative colitis.

Intravenous formulations of risankizumab-rzaa (Skyrizi®) **are considered experimental, investigational and/or unproven** for all other non-Food and Drug Administration approved indications.

Policy Guidelines

None.

Description

Crohn's Disease
Crohn's disease is a chronic, systemic disease that manifests as inflammation within the gastrointestinal (or digestive) tract, causing persistent diarrhea and abdominal pain. It is a progressive disease, meaning it gets worse over time, and in many cases leads to surgery. Because the signs and symptoms of Crohn's disease are unpredictable, it causes a significant burden on people living with the disease.

Ulcerative Colitis
Ulcerative colitis is an inflammatory bowel disease that causes inflammation and ulcers or sores in the digestive tract. It usually develops over time and can cause diarrhea (often with blood or pus), rectal bleeding, abdominal pain and cramping, and weight loss. Treatment usually involves either medications or surgery.

Risankizumab-rzaa
Risankizumab-rzaa, an interleukin-23 (IL-23) antagonist, is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that inhibits the release of pro-inflammatory cytokines and chemokines. IL-23, a cytokine involved in inflammatory processes, is thought to be linked to a number of chronic immune-mediated diseases, including Crohn's disease or ulcerative colitis. (1)

Regulatory
Risankizumab-rzaa (Skyrizi®) was approved by the U.S. Food and Drug Administration (FDA) in 2022 for adults with moderately to severely active Crohn's disease. In 2024, the FDA approved risankizumab-rzaa for adults with moderately to severely active ulcerative colitis. (2)

Rationale

This medical policy is based on the U.S. Food and Drug Administration (FDA) labeled indications for risankizumab-rzaa (Skyrizi®).

Crohn's Disease (1)

Induction Trials (Studies CD-1 and CD-2)

In two 12-week induction studies (CD-1; NCT03105128 and CD-2; NCT03104413), subjects with moderately to severely active Crohn's disease (CD) were randomized to receive Skyrizi 600 mg, Skyrizi 1,200 mg, or placebo as an intravenous infusion at Week 0, Week 4, and Week 8. Moderately to severely active CD was defined as a Crohn's Disease Activity Index (CDAI) of 220 to 450 and Simple Endoscopic Score for Crohn's disease (SES-CD) ≥6 (or ≥4 for isolated ileal disease). Subjects with inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunosuppressants, and/or biologic therapy were enrolled.

At baseline, the median CDAI was 307 (range: 76 – 634) and 307 (range: 72 – 651), and the median SES-CD was 12 (range: 4 – 45) and 13 (range 4 – 40), in CD-1 and CD-2, respectively. In CD-1, 58% (491/850) of subjects had failed or were intolerant to treatment with one or more biologic therapies (prior biologic failure). All subjects in CD-2 had prior biologic failure. At baseline, 30% and 34% of patients were receiving corticosteroids, 24% and 23% of patients were receiving immunomodulators (azathioprine, 6-mercaptopurine, methotrexate), and 31% and 19% of patients were receiving aminosalicylates in CD-1 and CD-2, respectively. In CD-1 and CD-2 combined, the median age was 36 years (ranging from 16 to 80 years), 81% (1145/1419) of subjects were White, and 53% (753/1419) were male.

In CD-1 and CD-2, the co-primary endpoints were clinical remission and endoscopic response at Week 12. Secondary endpoints included clinical response and endoscopic remission (see Table 1 and Table 2). The Skyrizi 1,200 mg dosage did not demonstrate additional treatment benefit over the 600 mg dosage and is not a recommended regimen.

Table 1. Proportion of Subjects Meeting Efficacy Endpoints at Week 12 – Study CD-1

Endpoint	**Placebo**	**Skyrizi 600 mg Intravenous Infusion[a]**	**Treatment Difference[b] (95% CI)**
Clinical Remission[c,d]			
Total Population	N=175 25%	N=336 45%	21%[e] (12%, 29%)
Prior biologic failure[f]	N=97 26%	N=195 42%	
Without prior biologic failure	N=78 23%	N=141 49%	
Endoscopic Response[c,g]			
Total Population	N=175 12%	N=336 40%	28%[e] (21%, 35%)
Prior biologic failure[f]	N=97	N=195	

	11%	33%	
Without prior biologic failure	N=78 13%	N=141 50%	
Clinical Response[h]			
Total Population	N=175 37%	N=336 60%	23%[e] (14%, 32%)
Prior biologic failure[f]	N=97 34%	N=195 58%	
Without prior biologic failure	N=78 40%	N=141 62%	
Endoscopic Remission[i]			
Total Population	N=175 9%	N=336 24%	15%[e] (9%, 21%)
Prior biologic failure[f]	N=97 5%	N=195 18%	
Without prior biologic failure	N=78 14%	N=141 32%	

[a] Skyrizi 600 mg as an intravenous infusion at Week 0, Week 4, and Week 8.
[b] Adjusted treatment difference (95% CI [confidence interval]) based on Cochran-Mantel-Haenszel method adjusted for randomization stratification factors.
[c] Co-primary endpoints.
[d] Crohn's Disease Activity Index (CDAI) <150.
[e] p <0.001.
[f] Prior biologic failure includes inadequate response, loss of response, or intolerance to one or more biologic treatments for CD.
[g] A decrease in Simple Endoscopic Score for Crohn's disease (SES-CD) > 50% from baseline, or a decrease of at least 2 points for subjects with a baseline score of 4 and isolated ileal disease, based on central reading.
[h] A reduction of CDAI ≥ 100 points from baseline.
[i] SES-CD ≤ 4 and at least a 2-point reduction from baseline, with no individual subscore greater than 1, based on central reading.

Table 2. Proportion of Subjects Meeting Efficacy Endpoints at Week 12 – Study CD-2[a]

Endpoint	**Placebo N=187**	**Skyrizi 600 mg Intravenous Infusion[b] N=191**	**Treatment Difference[c] (95% CI)**
Clinical Remission[d,e]	20%	42%	22%[f] (13%, 31%)
Endoscopic Response[d,g]	11%	29%	18%[f] (10%, 25%)
Clinical Response[h]	30%	60%	29%[f] (20%, 39%)
Endoscopic Remission[i]	4%	19%	15%[f] (9%, 21%)

[a] All subjects enrolled in CD-2 had prior biologic failure. Prior biologic failure includes inadequate response, loss of response, or intolerance to one or more biologic treatments for CD (Crohn's Disease).
[b] Skyrizi 600 mg as an intravenous infusion at Week 0, Week 4, and Week 8.
[c] Adjusted treatment difference (95% CI [confidence interval]) based on Cochran-Mantel-Haenszel method adjusted for randomization stratification factors.
[d] Co-primary endpoints.
[e] Crohn's Disease Activity Index (CDAI) score <150.
[f] $p < 0.001$.
[g] A decrease in Simple Endoscopic Score for Crohn's disease (SES-CD) > 50% from baseline, or a decrease of at least 2 points for subjects with a baseline score of 4 and isolated ileal disease, based on central reading.
[h] A reduction of CDAI ≥ 100 points from baseline.
[i] SES-CD ≤ 4 and at least a 2-point reduction versus from baseline, with and no individual subscore greater than 1, based on central reading.

Onset of clinical response and clinical remission based on CDAI occurred as early as Week 4 in a greater proportion of subjects treated with the Skyrizi 600 mg induction regimen compared to placebo.

Reductions in stool frequency and abdominal pain were observed in a greater proportion of subjects treated with the Skyrizi 600 mg induction regimen compared to placebo at Week 12.

Study CD-3

The maintenance study CD-3 evaluated 382 subjects who achieved clinical response defined as a reduction in CDAI of at least 100 points from baseline after 12 weeks of induction treatment with intravenous Skyrizi in studies CD-1 and CD-2. Subjects were randomized to receive a maintenance regimen of Skyrizi 180 mg or Skyrizi 360 mg or placebo at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks. The co-primary endpoints in CD-3 were clinical remission and endoscopic response at Week 52 (see Table 3).

Table 3. Proportion of Subjects Meeting Efficacy Endpoints at Week 52 – Study CD-3

Endpoint	**Placebo[a]**	**Skyrizi 180 mg Subcutaneous Injection[b]**	**Skyrizi 360 mg Subcutaneous Injection[c]**	**Treatment Difference vs. Placebo[d] (95% CI)**	
				Skyrizi 180 mg	Skyrizi 360 mg
Clinical Remission[e,f]					
Total Population	N=130 46%	N=135 61%	N=117 57%	17%[g] (6%, 28%)	14%[g] (3%, 26%)
Prior biologic failure[h]	N=99 40%	N=95 56%	N=83 51%		
Without prior biologic failure	N=31 65%	N=40 75%	N=34 71%		
Endoscopic Response[e,i]					
Total Population	N=130	N=135	N=117	30%[g]	31%[g]

	22%	50%	48%	(20%, 39%)	(21%, 41%)
Prior biologic failure[h]	N=99 21%	N=95 44%	N=83 44%		
Without prior biologic failure	N=31 23%	N=40 65%	N=34 59%		

[a] The placebo group consisted of patients who were in response to Skyrizi and were randomized to receive placebo at the start of maintenance therapy.
[b] Skyrizi 180 mg at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks.
[c] Skyrizi 360 mg at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks.
[d] Adjusted treatment difference and 95% CI (confidence interval) computed using Cochran-Mantel-Haenszel method adjusted for randomization stratification factors.
[e] Co-primary endpoints.
[f] Crohn's Disease Activity Index (CDAI) <150.
[g] $p < 0.05$
[h] Prior biologic failure includes inadequate response, loss of response, or intolerance to one or more biologic treatments for CD (Crohn's disease).
[i] A decrease in Simple Endoscopic Score for Crohn's disease (SES-CD) > 50% from baseline, or a decrease of at least 2 points for subjects with a baseline score of 4 and isolated ileal disease, based on central reading.

Endoscopic remission was observed at Week 52 in 33% (44/135) of subjects treated with the Skyrizi 180 mg maintenance regimen and 41% (48/117) of subjects treated with the Skyrizi 360 mg maintenance regimen, compared to 13% (17/130) of subjects treated with placebo. This endpoint was not statistically significant under the prespecified multiple testing procedure.

Ulcerative Colitis (1)

Induction Trial (Study UC-1)

In the 12-week induction study (UC-1; NCT03398148), 966 subjects with moderately to severely active ulcerative colitis were randomized and received Skyrizi 1,200 mg or placebo as an intravenous infusion at Week 0, Week 4, and Week 8. Disease activity was assessed by the modified Mayo score (mMS), a 3-component Mayo score (0-9) which consists of the following subscores (0 to 3 for each subscore): stool frequency (SFS), rectal bleeding (RBS), and findings on centrally read endoscopy score (ES). An ES of 2 was defined by marked erythema, lack of vascular pattern, any friability, and/or erosions; an ES of 3 was defined by spontaneous bleeding and ulceration. Enrolled subjects had a mMS between 5 and 9, with an ES of 2 or 3. Subjects with inadequate response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators, biologics, Janus Kinase inhibitors (JAKi), and/or sphingosine-1-phospate receptor modulators (S1PRM) were enrolled.

At baseline in UC-1, the median mMS was 7; 37% had severely active disease (mMS >7); 69% had an ES of 3. In UC-1, 52% (499/966) of subjects had failed (inadequate response or intolerance) treatment with one or more biologics, JAKi or S1PRM. Of these 499 subjects, 484 (97%) failed biologics and 90 (18%) failed JAK inhibitors. Enrolled subjects were permitted to use a stable dose of oral corticosteroids (up to 20 mg/day prednisone or equivalent), immunomodulators, and aminosalicylates. At baseline, 36% of subjects were receiving

corticosteroids, 16% of subjects were receiving immunomodulators (including azathioprine, 6mercaptopurine, methotrexate), and 73% of subjects were receiving aminosalicylates in UC-1.

In UC-1, the primary endpoint was clinical remission defined using the mMS at Week 12 (see Table 4). Key secondary endpoints included clinical response, endoscopic improvement, and histologic endoscopic mucosal improvement (see Table 4).

Table 4. Proportion of Subjects Meeting Efficacy Endpoints at Week 12 - Study UC-1

Endpoint	**Placebo**	**Skyrizi 1200 mg Intravenous Infusion[a]**	**Treatment Difference (95% CI)[b]**
Clinical Remission[c]			
Total population	N=320 8%	N=646 24%	16%[h] (12%, 20%)
Prior biologic, JAKi or S1PRM failure[d]	N=168 6%	N=331 14%	
Without prior biologic, JAKi or S1PRM failure	N=152 9%	N=315 33%	
Clinical Response[e]			
Total population	N=320 36%	N=646 65%	29%[h] (23%, 35%)
Prior biologic, JAKi or S1PRM failure[d]	N=168 32%	N=331 56%	
Without prior biologic, JAKi, or S1PRM failure	N=152 41%	N=315 75%	
Endoscopic Improvement[f]			
Total population	N=320 12%	N=646 36%	25%[h] (20%, 30%)
Prior biologic, JAKi or S1PRM failure[d]	N=168 10%	N=331 26%	
Without prior biologic, JAKi, or S1PRM failure	N=152 14%	N=315 47%	
Histologic Endoscopic Mucosal Improvement (HEMI)[g]			
Total population	N=320 7%	N=646 24%	17%[h] (3%, 21%)
Prior biologic, JAKi or S1PRM failure[d]	N=168 7%	N=331 16%	
Without prior biologic, JAKi, or S1PRM failure	N=152 8%	N=315 33%	

CI: confidence interval; JAKi: Janus Kinase inhibitors; S1PRM: sphingosine-1-phospate receptor modulators.
[a] Skyrizi 1,200 mg as an intravenous infusion at Week 0, Week 4, and Week 8.
[b] Adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method adjusted for stratification factors.
[c] Per modified Mayo score (mMS): stool frequency (SFS) ≤ 1 and not greater than baseline, rectal bleeding (RBS) = 0, and endoscopic score (ES) ≤ 1 without friability.
[d] Prior failure includes inadequate response or intolerance to treatment with one or more of the following: biologic therapies, Janus Kinase inhibitors (JAKi), and/or sphingosine-1-phospate receptor modulators (S1PRM).
[e] Per mMS: decrease ≥ 2 points and ≥ 30% from baseline, and a decrease in RBS ≥ 1 from baseline or an absolute RBS ≤ 1.
[f] ES ≤ 1 without the evidence of friability.
[g] ES ≤ 1 without the evidence of friability and Geboes score ≤ 3.1 (indicating neutrophil infiltration in <5% of crypts, no crypt destruction and no erosions, ulcerations, or granulation tissue).
[h] $p < 0.001$.

UC-1 was not designed to evaluate the relationship of histologic endoscopic mucosal improvement at week 12 to disease progression and long-term outcomes.

Rectal Bleeding and Stool Frequency Subscores
Decreases in rectal bleeding and stool frequency subscores in subjects treated with Skyrizi compared to placebo were observed as early as 4 weeks.

Endoscopic Assessment
Endoscopic remission was defined as ES of 0. At Week 12, a greater proportion of subjects treated with Skyrizi compared to placebo achieved endoscopic remission (11% vs 3%).

Bowel Urgency
A greater proportion of subjects treated with the Skyrizi 1,200 mg induction regimen compared to placebo had no bowel urgency (44% vs 27%) at Week 12.

Fatigue
In UC-1, subjects treated with Skyrizi experienced a clinically meaningful improvement in fatigue, assessed by change from baseline in FACIT-F score, at Week 12, compared to placebo-treated subjects. The effect of Skyrizi to improve fatigue after 12 weeks of induction has not been established.

Other UC Symptoms
The proportion of subjects who had no nocturnal bowel movements was greater in subjects treated with Skyrizi compared to placebo at Week 12 (67% vs 43%).

<u>Maintenance Study UC-2</u>
The maintenance study (UC-2; NCT03398135) evaluated 547 subjects who received one of three Skyrizi induction regimens, including the 1,200 mg regimen, for 12 weeks in Studies UC-1

or UC-3 and demonstrated clinical response per mMS after 12 weeks. Subjects were randomized to receive a maintenance regimen of subcutaneous (SC) Skyrizi 180 mg or Skyrizi 360 mg or placebo at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks.

In UC-2, 75% (411/547) of subjects had failed (inadequate response or intolerance) treatment with one or more biologics, JAKi, or S1PRM. Of these 411 subjects, 407 (99%) failed biologics and 78 (19%) failed JAK inhibitors.

The primary endpoint in UC-2 was clinical remission using mMS at Week 52 (see Table 5). Key secondary endpoints included corticosteroid-free clinical remission, endoscopic improvement, and histologic endoscopic mucosal improvement (see Table 5).

Table 5. Proportion of Subjects Meeting Efficacy Endpoints at Week 52 – Study UC-2

Endpoint	**Placebo[a]**	**Skyrizi 180 mg SC Injection[b]**	**Skyrizi 360 mg SC Injection[c]**
Clinical Remission[d]			
Total population	N=182 26%	N=179 45%	N=186 41%
Treatment difference vs placebo[e] (95% CI)		20%[j] [11%, 29%]	16%[j] [7%, 25%]
Prior biologic, JAKi or S1PRM failure[f]	N=138 24%	N=134 41%	N=139 32%
Without prior biologic, JAKi or S1PRM failure	N=44 32%	N=45 58%	N=47 67%
Corticosteroid-free Clinical Remission[g]			
Total population	N=182 26%	N=179 45%	N=186 40%
Treatment difference vs placebo[e] (95% CI)		20%[j] [11%, 29%]	16%[j] [7%, 25%]
Prior biologic, JAKi or S1PRM failure[f]	N=138 24%	N=134 40%	N=139 32%
Without prior biologic, JAKi, or S1PRM failure	N=44 32%	N=45 58%	N=47 64%
Endoscopic Improvement[h]			
Total population	N=182 31%	N=179 51%	N=186 48%
Treatment difference vs placebo[e] (95% CI)		20%[j] [11%, 30%]	18%[j] [8%, 27%]

Prior biologic, JAKi or S1PRM failure[f]	N=138 30%	N=134 48%	N=139 39%
Without prior biologic, JAKi, or S1PRM failure	N=44 34%	N=45 60%	N=47 76%
Histologic Endoscopic Mucosal Improvement (HEMI)[i]			
Total population	N=182 24%	N=179 43%	N=186 42%
Treatment difference vs placebo[e] (95% CI)		20%[j] [11%, 29%]	20%[j] [11%, 29%]
Prior biologic, JAKi or S1PRM failure[f]	N=138 22%	N=134 39%	N=139 33%
Without prior biologic, JAKi, or S1PRM failure	N=44 30%	N=45 55%	N=47 69%

CI: confidence interval; JAKi: Janus Kinase inhibitors; S1PRM: sphingosine-1-phospate receptor modulators; SC: subcutaneous.

[a] The placebo group consisted of subjects who were in response to 12 weeks of Skyrizi induction and were randomized to receive placebo at the start of maintenance therapy.

[b] Skyrizi 180 mg at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks.

[c] SKYRIZI 360 mg at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks.

[d] Per mMS: SFS ≤ 1 and not greater than baseline, RBS = 0, and ES ≤ 1 without friability.

[e] Adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method adjusted for stratification factors.

[f] Prior failure includes inadequate response or intolerance to treatment with one or more of the following: biologic therapies, Janus Kinase inhibitors (JAKi), and/or sphingosine-1-phospate receptor modulators (S1PRM).

[g] Clinical remission per mMS at Week 52 and corticosteroid-free for ≥90 days

[h] ES ≤ 1 without the evidence of friability.

[i] ES ≤ 1without the evidence of friability and Geboes score ≤ 3.1 (indicating neutrophil infiltration in <5% of crypts, no crypt destruction and no erosions, ulcerations, or granulation tissue).

[j] $p < 0.001$.

Endoscopic Assessment

Endoscopic remission was defined as ES of 0. In UC-2, a greater proportion of subjects treated with Skyrizi 180 mg and Skyrizi 360 mg compared to placebo achieved endoscopic remission at Week 52 (23% and 24% vs 15%).

Summary of Evidence

Based on the clinical studies provided to the U.S. Food and Drug Administration (FDA), intravenous administration of risankizumab-rzaa (Skyrizi®) may be considered medically necessary for adults aged 18 years and older for moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	J2327

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

U.S Food and Drug Administration Label:

1. FDA – Skyrizi® Highlights of Prescribing Information. Drugs @ FDA. U.S. Food and Drug Administration. Revised June 2024. Available at: <https://www.fda.gov> (accessed June 25, 2025).

Other:

2. Skyrizi FDA Approval History. Drugs.com. Last updated June 19, 2024. Available at: <https://www.drugs.com> (accessed June 25, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
08/15/2025	Document updated with literature review. The following change was made to Coverage: 1) Removed "Individual will not receive risankizumab-rzaa (Skyrizi®) concurrently with other biologics used to treat Crohn's disease

	(e.g., infliximab, vedolizumab, ustekinumab)" and 2) Revised the EIU statement to include "non-FDA approved." References updated; one removed.
10/15/2024	Document updated with literature review. Coverage revised to state Risankizumab-rzaa (Skyrizi®) may be considered medically necessary for adults with moderately to severely active ulcerative colitis. References revised; none added.
03/15/2024	Document updated with literature review. Coverage unchanged. No new references added; some updated.
09/15/2023	Reviewed. No changes.
03/01/2023	New medical document. Risankizumab-rzaa (Skyrizi®) may be considered medically necessary for adult patients with moderately to severely active Crohn's disease who will not be receiving it concurrently with other biologics used to treat Crohn's disease (e.g., infliximab, vedolizumab, ustekinumab). NOTE 1: Risankizumab-rzaa (Skyrizi®) may be self-administered. For self-administered medications, please refer to the applicable pharmacy benefit plan. NOTE 2: When meeting criteria noted above, adults with Crohn's disease will receive the first three doses of Skyrizi through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provide at week 0, week 4 and week 8. Patients may then receive Skyrizi as an injection under the skin (subcutaneous injection) at week 12 and every 8 weeks thereafter.