Medical Policy Bulletin

Title:
Risankizumab-rzaa (Skyrizi®) for Intravenous Use
Policy #:
MA08.153c

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

Ulcerative Colitis
Risankizumab-rzaa (Skyrizi) for intravenous use is considered medically necessary and, therefore, covered for moderately to severely active Ulcerative Colitis when all of the following criteria, including dosing and frequency, are met:

- The individual is 18 years of age or older
- There is documentation of Inadequate response, contraindication, or intolerance to conventional (non-advanced) and/or advanced therapies of at least one of the following:
    - Corticosteroids (e.g., budesonide, prednisone, hydrocortisone, methylprednisolone)
    - Biologic therapy (e.g., infliximab [Remicade]), adalimumab [Humira], golimumab [Simponi Aria], vedolizumab [Entyvio])
    - Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
    - JAK Inhibitors (e.g., tofacitinib [Xeljanz], Upadacitinib [Rinvoq])
    - S1P receptor modulators (e.g., ozanimod [Zeposia])
- Prescribed by or in consultation with a gastroenterologist
- No concurrent use with any other biologic therapy (i.e., tumor necrosis factor antagonists)
- Dosing and frequency: Induction dosage is 1,200 mg administered by intravenous infusion at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter.

Crohn's Disease
Risankizumab-rzaa (Skyrizi) for intravenous use is considered medically necessary and, therefore, covered for moderately to severely active Crohn's disease when all of the following criteria, including dosing and frequency, are met:

- The individual is 18 years of age or older

- There is documentation of failure, contraindication, or intolerance to a trial of at least one of the following:
    - Corticosteroids (e.g., budesonide [Entocort EC], prednisone, hydrocortisone, methylprednisolone)
    - Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
    - Biologic therapy (e.g., certolizumab [Cimzia], adalimumab [Humira], infliximab [Remicade]), ustekinumab (Stelara), vedolizumab [Entyvio])
- Prescribed by or in consultation with a gastroenterologist
- No concurrent use with any other biologic therapy (i.e., tumor necrosis factor antagonists)
- Dosing and frequency: 600 mg administered by intravenous infusion at Weeks 0, 4, and 8. (Maintenance doses are administered by subcutaneous injection.)

EXPERIMENTAL/INVESTIGATIONAL

All other uses for risankizumab-rzaa (Skyrizi) for intravenous use are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

DOSING AND FREQUENCY REQUIREMENTS

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of risankizumab-rzaa (Skyrizi). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) to request coverage for an amount of risankizumab-rzaa (Skyrizi) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct postpayment review and audit procedures for any claims submitted for risankizumab-rzaa (Skyrizi).

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

When coverage of risankizumab-rzaa (Skyrizi) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

Guidelines

There is no Medicare coverage determination addressing risankizumab-rzaa (Skyrizi) for intravenous use; therefore, the Company policy is applicable.

BENEFIT APPLICATION

Subject to the applicable Evidence of Coverage, risankizumab-rzaa (Skyrizi) for intravenous use is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria and Dosing and Frequency Requirements listed in this medical policy are met.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances risankizumab-rzaa (Skyrizi) for intravenous use is covered under a member's medical benefit (Part B benefit). It does not address instances when risankizumab-rzaa (Skyrizi) for intravenous use is covered under a member's pharmacy benefit (Part D benefit).

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Risankizumab-rzaa (Skyrizi) for intravenous use was approved by the US Food and Drug Administration (FDA) on June 16, 2022, for the treatment of moderately to severely active Crohn's disease in adults.

Supplemental approvals for risankizumab-rzaa (Skyrizi) have since been issued by the FDA.

PEDIATRIC USE
The safety and effectiveness in pediatric individuals have not been established.

Description

ULCERATIVE COLITIS AND CROHN'S DISEASE

Inflammatory bowel disease (IBD) is a chronic inflammatory disorder of the gastrointestinal tract of unknown etiology. IBD has two major categories: ulcerative colitis (UC) and Crohn's disease (CD). The most common symptoms in UC and CD are diarrhea, rectal bleeding, urgency to have bowel movements, abdominal cramps, pain, fever, and weight loss. Although UC and CD have similar clinical presentations, they differ in the body areas affected. UC primarily causes inflammation of the mucosal lining and is generally limited to the colon and rectum, whereas CD affects the entire digestive system and can produce ulcers that extend deep into the intestinal wall. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline, and during induction at least up to 12 weeks of treatment. Monitor thereafter according to routine patient management.

The treatment of UC and CD is focused on stopping the inflammation and preventing flare-ups. The type of treatment depends on the type and severity of symptoms. Mild symptoms may respond to an antidiarrheal medicine such as loperamide (e.g., Imodium). Treatment for individuals who may be having mild-to-moderate symptoms include aminosalicylates and antibiotics, whereas individuals with severe symptoms may be treated with corticosteroids, immunomodulators, or biologics.

RISANKIZUMAB-RZAA (SKYRIZI)

Risankizumab-rzaa (Skyrizi) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin-23 (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 proinflammatory cytokines and chemokines. Risankizumab-rzaa (Skyrizi) was first approved in the United States in April 2019 as a subcutaneous injection to treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; supplemental approvals for this formulation have since been issued by the US Food and Drug Administration (FDA). Risankizumab-rzaa (Skyrizi) for intravenous (IV) use was approved by the FDA on June 16, 2022, for the treatment of moderately to severely active Crohn's disease in adults.

The recommended induction dosage is 600 mg administered by intravenous infusion over a period of at least 1 hour at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 180mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dosage needed to maintain therapeutic response.

ULCERATIVE COLITIS PEER-REVIEWED LITERATURE

Summary

The approval for risankizumab-rzaa (Skyrizi) for IV use is based on 12-week, phase 3, double-blind, randomized, placebo-controlled induction study. INSPIRE (n=650) evaluated the efficacy and safety of risankizumab-rzaa (Skyrizi) 1200 mg IV at weeks 0,4, and 8 compared with a placebo as induction therapy for with moderately to severely active

ulcerative colitis (defined as adapted Mayo score of 5-9 and endoc subscore of 2-3 (central review) with biopsy confirmed diagnosis ≥3 months prior to baseline) who had an intolerance or inadequate response to conventional (non-advanced) and/or advanced therapies (e.g., infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, filgotinib, upadacinib, ozanimod). At Week 12, the treatment difference of clinical remission between risankizumab-rzaa (Skyrizi) 1200 mg IV at Weeks 0, 4, 8, and placebo was 14%, which is statistically significant (P<0.001). The treatment difference of endoscopic response was >24% increase from baseline between risankizumab-rzaa (Skyrizi) and placebo at Week 12 (risankizumab-rzaa (Skyrizi) 36.5%, placebo 12.1%, P<0.001).

Adverse event rates were consistent with the known safety profile of risankizumab-rzaa (Skyrizi) across inflammatory bowel syndrome and other indications. No new safety risks were observed. Adverse event rates were similar among groups, and the most frequently reported adverse events in all treatment groups were worsening ulcerative colitis, COVID-19, and anemia.

A total of 584 participants who achieved clinical response after 12 weeks of induction treatment enrolled in the maintenance study (COMMAND), based on 52-week, phase 3, multicenter, randomized, double-blind, placebo-controlled, maintenance studies evaluating the efficacy and safety of risankizumab-rzaa (Skyrizi) 180mg and 360mg SC compared to the withdrawal from risankizumab-rzaa (Skyrizi) IV induction only treatment as the control group), as maintenance therapy for participants with moderately to severely active Ulcerative Colitis who responded to induction treatment. Participants were randomly assigned to receive a maintenance regimen of risankizumab-rzaa (Skyrizi) 180 mg or 360 mg subcutaneously or placebo at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks. At Week 52, the treatment difference of clinical remission between risankizumab-rzaa (Skyrizi) and placebo was 20% at the 180 mg dose and 16% at the 360mg dose (p<0.001)**.** The treatment difference of endoscopic response between risankizumab-rzaa (Skyrizi) and placebo at Week 12 was 20.1% at the 180mg dose and 17.4 % at the 360mg dose (p<0.001).

CROHN'S DISEASE PEER-REVIEWED LITERATURE

Summary

The approval for risankizumab-rzaa (Skyrizi) for IV use is based on two 12-week, phase 3, multicenter, double-masked, randomized, placebo-controlled induction studies: ADVANCE (n=931) and MOTIVATE (n=618). Participants who had moderately to severely active Crohn's disease (defined as 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]) and had inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators, and/or biologic therapy. All participants in the MOTIVATE study and approximately half of the participants in the ADVANCE study had previously tried at least one biologic; approximately half of the participants in both studies had prior therapy with an anti-TNF agent. At Week 12, the treatment difference of clinical remission (defined as CDAI <150) between risankizumab-rzaa (Skyrizi) 600 mg IV at Weeks 0, 4, 8, and placebo was 21% (ADVANCE) and 22% (MOTIVATE) (*P*<0.001). The treatment difference of endoscopic response (defined as a >50% decrease in SES-CD from baseline [or for isolated ileal disease and a baseline SES-CD of 4, at least a 2-point reduction from baseline]) between risankizumab-rzaa (Skyrizi) and placebo at Week 12 was 28% (ADVANCE) and 18% (MOTIVATE) (*P*<0.001).

A total of 542 participants who achieved clinical response (defined as a reduction in CDAI of at least 100 points from baseline) after 12 weeks of induction treatment enrolled in the the maintenance study (FORTIFY), a phase 3 multicenter, randomized, double-blind, placebo-controlled, maintenance withdrawal study. Participants were randomly assigned to receive a maintenance regimen of risankizumab-rzaa (Skyrizi) 360 mg subcutaneously or placebo at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks. At Week 52, the treatment difference of clinical remission between risankizumab-rzaa (Skyrizi) and placebo was 14%. The treatment difference of endoscopic response between risankizumab-rzaa (Skyrizi) and placebo at Week 12 was 31% (*P*<0.05). Adverse event rates were similar among groups, and the most frequently reported adverse events in all treatment groups were worsening Crohn's disease, arthralgia, and headache.

OFF-LABEL INDICATION

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)

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
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

HCPCS Level II Code Number(s)

J2327 Injection, risankizumab-rzaa, intravenous, 1 mg

Revenue Code Number(s)

N/A

Coding And Billing Requirements

BILLING REQUIREMENTS

If there is no specific HCPCS code available for the drug administered, then the drug must be reported with the most appropriate unlisted code along with the corresponding National Drug Code (NDC).

Policy History

Revisions From MA08.0153c:

12/15/2025	This policy has been reissued in accordance with the Company's annual review process.
12/16/2024	This version of the policy will become effective 12/16/2024.

	This policy has been updated to communicate the Company's coverage criteria for risankizumab-rzaa (Skyrizi) for intravenous use for the treatment of ulcerative colitis. The following ICD-10 code has been **added** to this policy: K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.419, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.913, K51.914, K51.918, K51.919

Revisions From MA08.153b:

09/16/2024	This version of the policy will become effective 09/16/2024. The following ICD-10 CM code has been **added** to this policy: K50.00 Crohn's disease of small intestine without complications

Revisions From MA08.153a:

05/07/2024	This policy has been reissued in accordance with the Company's annual review process.
09/05/2023	This policy has been reissued in accordance with the Company's annual review process.
01/01/2023	This version of the policy will become effective 01/01/2023. The following HCPCS code has been **added** to this policy: J2327 Injection, risankizumab-rzaa, intravenous, 1 mg The following HCPCS codes have been **removed** from this policy: C9399 Unclassified drugs or biologicals J3590 Unclassified biologics

Revisions From MA08.153:

10/24/2022	This version of the policy will become effective 10/24/2022. The following new policy has been developed to communicate the Company's coverage criteria for risankizumab-rzaa (Skyrizi) for intravenous use.

Version Effective Date:
12/16/2024
Version Issued Date:
12/16/2024
Version Reissued Date:
N/A