



Drug Coverage Policy

Effective Date03/15/2026
Coverage Policy Number.....IP0669
Policy Title....Skyrizi Intravenous Prior
Authorization Policy

Inflammatory Conditions – Skyrizi Intravenous Prior Authorization Policy

- Skyrizi® (risankizumab-rzaa intravenous infusion – Abbvie)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Skyrizi intravenous (IV), an interleukin (IL)-23 blocker, is indicated for:¹

- **Crohn's disease**, in adults with moderate to severe active disease.
- **Ulcerative colitis**, in adults with moderate to severe active disease.

Dosing

Crohn's disease

In Crohn's disease (CD), a three-dose induction regimen (600 mg at Weeks 0, 4, and 8) is administered by IV infusion.¹ Following induction therapy with the IV product, the recommended maintenance dose is 180 mg or 360 mg administered by subcutaneous (SC) injection at Week 12 (4 weeks following the last induction dose), then once every 8 weeks thereafter.

Ulcerative colitis

In ulcerative colitis (UC), a three-dose induction regimen (1,200 mg at Weeks 0, 4, and 8) is administered by IV infusion.¹ Following induction therapy with the IV product, the recommended maintenance dose is 180 mg or 360 mg administered by SC injection at Week 12 (4 weeks following the last induction dose), then once every 8 weeks thereafter.

Guidelines

The following guidelines address indications for which Skyrizi IV is utilized.

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] and the American Gastroenterological Association (AGA) [2025] have guidelines for the management of CD in adults.^{2,3} Both guidelines recommend upfront use of advanced therapies, rather than step-up therapy after failure of corticosteroids and/or immunomodulators. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab IV infusion, SC injection), IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib extended-release tablets).
- **Ulcerative colitis:** The AGA (2024) and the ACG (2025) have clinical practice guidelines on the management of moderate to severe UC.^{4,5} In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNF inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.⁵ Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.^{4,5}

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for benefit coverage of Skyrizi IV. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). Because of the specialized skills required for evaluation and diagnosis of patients treated with Skyrizi IV as well as the monitoring required for adverse events and long-term efficacy, approval requires Skyrizi IV to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 3 months, which is an adequate duration for the patient to receive three doses.

Skyrizi intravenous is considered medically necessary when ONE of the following is met (1 or 2):

FDA-Approved Indications

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- 1. Crohn’s Disease.** Approve three doses for induction if the patient meets ALL of the following (A, B, and C):
- A)** Patient is ≥ 18 years of age; AND
 - B)** The medication will be used as induction therapy; AND
 - C)** The medication is prescribed by or in consultation with a gastroenterologist.

Dosing: Approve 600 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

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- 2. Ulcerative Colitis.** Approve three doses for induction if the patients meets ALL of the following (A, B, and C):
- A)** Patient is ≥ 18 years of age; AND
 - B)** The medication will be used as induction therapy; AND
 - C)** The medication is prescribed by or in consultation with a gastroenterologist.

Dosing: Approve 1,200 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

Conditions Not Covered

Skyrizi intravenous for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| HCPCS Codes | Description |
|-------------|---|
| J2327 | Injection, risankizumab-rzaa, intravenous, 1 mg |

References

1. Skyrizi® [prescribing information]. North Chicago, IL: AbbVie; May 2025.
2. Lichtenstein, G, Loftus E, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2025 June;120(6):1225-1264.
3. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025 Dec;169(7):1397-1448.
4. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
5. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol*. 2025 June;120(6):1187-1224.

Revision Details

| Type of Revision | Summary of Changes | Date |
|-------------------|--|------------|
| New | New policy | 11/01/2024 |
| Annual Revision | No criteria changes. | 08/01/2025 |
| Selected Revision | Ulcerative Colitis: For initial therapy, removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. | 09/01/2025 |
| Selected Revision | Crohn's Disease: For initial therapy, the following options of approval were removed: The patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated; patient has tried one conventional systemic therapy for Crohn's disease along with the associated Note; patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Appendix: Otezla XR (apremilast extended-release tablets) was added. | 03/15/2026 |

The policy effective date is in force until updated or retired.

APPENDIX

| | Mechanism of Action | Examples of Indications* |
|--|---------------------|--------------------------------|
| Biologics | | |
| Adalimumab SC Products (Humira®, biosimilars) | Inhibition of TNF | AS, CD, JIA, PsO, PsA, RA, UC |
| Cimzia® (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, nr-axSpA, PsO, PsA, RA |
| Etanercept SC Products (Enbrel®, biosimilars) | Inhibition of TNF | AS, JIA, PsO, PsA, RA |

| | | |
|---|----------------------------------|---|
| Infliximab IV Products (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC |
| Zymfentra® (infliximab-dyyb SC injection) | Inhibition of TNF | CD, UC |
| Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC |
| | | IV formulation: AS, PJIA, PsA, RA |
| Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA |
| | | IV formulation: PJIA, RA, SJIA |
| Kevzara® (sarilumab SC injection) | Inhibition of IL-6 | RA |
| Orencia® (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: JIA, PSA, RA |
| | | IV formulation: JIA, PsA, RA |
| Rituximab IV Products (Rituxan®, biosimilars) | CD20-directed cytolytic antibody | RA |
| Kineret® (anakinra SC injection) | Inhibition of IL-1 | JIA^, RA |
| Omvoh® (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | CD, UC |
| Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| Siliq® (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| Cosentyx® (secukinumab SC injection; secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA |
| | | IV formulation: AS, nr-axSpA, PsA |
| Taltz® (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA |
| Bimzelx® (bimekizumab-bkzx SC injection) | Inhibition of IL-17A/17F | PsO, AS, nr-axSpA, PsA |
| Ilumya® (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO, UC |
| | | IV formulation: CD, UC |
| Tremfya® (guselkumab SC injection, guselkumab IV infusion) | Inhibition of IL-23 | SC formulation: CD, PsA, PsO, UC |
| | | IV formulation: CD, UC |
| Entyvio® (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | CD, UC |
| Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs | | |
| Otezla® (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| Otezla XR™ (apremilast extended-release tablets) | Inhibition of PDE4 | PsO, PsA |
| Cibinqo™ (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| Olumiant® (baricitinib tablets) | Inhibition of JAK pathways | RA, AA |
| Litfulo® (ritlecitinib capsules) | Inhibition of JAK pathways | AA |
| Leqselvi® (deuruxolitinib tablets) | Inhibition of JAK pathways | AA |
| Rinvoq® (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, nr-axSpA, RA, PsA, CD, UC |
| Rinvoq® LQ (upadacitinib oral solution) | Inhibition of JAK pathways | PsA, PJIA |

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|---|--|-------------------|
| Sotyktu ® (deucravacitinib tablets) | Inhibition of TYK2 | PsO |
| Xeljanz ® (tofacitinib tablets/oral solution) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| Xeljanz ® XR (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC |
| Zeposia ® (ozanimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |
| Velsipity ® (etrasimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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