CARECONTINUUM™

# UTILIZATION REVIEW MANAGEMENT POLICY

**POLICY:** Inflammatory Conditions – Skyrizi Intravenous Utilization Management Medical Policy
- Skyrizi® (risankizumab-rzaa intravenous infusion – Abbvie)

**REVIEW DATE:** 06/03/2026

## 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]


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## POLICY STATEMENT

Prior Authorization is recommended for medical 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.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Skyrizi IV is recommended in those who meet one of the following:

### FDA-Approved Indications

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.

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 RECOMMENDED FOR APPROVAL

Coverage of Skyrizi IV is not recommended in the following situations:

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.


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**2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Skyrizi® intravenous infusion, subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; March 2026.
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.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Ulcerative colitis:** This newly approved condition was added to the policy. | 06/26/2024 |
| Selected Revision | **Conditions Not Recommended for Approval:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug). | 09/11/2024 |
| Annual Revision | No criteria changes. | 06/25/2025 |
| 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. | 07/23/2025 |
| 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).<br>**Appendix:** Otezla XR (apremilast extended-release tablets) was added. | 02/11/2026 |
| Annual Revision | **Appendix:** Icotyde (icotrokinra tablets) was added. | 06/03/2026 |


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## APPENDIX

| | Mechanism of Action | Examples of Indications* |
|---|---|---|
| **Biologics** | | |
| **Adalimumab SC Products** (Humira®, biosimilars) | Inhibition of TNF | AS, CD, HS, JIA, PsO, PsA, RA, UC |
| **Cimzia®** (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, JIA, 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, IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC |
| | | IV formulation: AS, PJIA, PsA, RA |
| **Kineret®** (anakinra SC injection) | Inhibition of IL-1 | RA |
| **Tocilizumab Products** (Actemra® IV, biosimilars; Actemra SC, biosimilars) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA |
| | | IV formulation: PJIA, RA, SJIA |
| **Kevzara®** (sarilumab SC injection) | Inhibition of IL-6 | PJIA, RA |
| **Siliq®** (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| **Cosentyx®** (secukinumab SC injection; IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, HS, 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 | AS, HS, nr-axSpA, PsO, PsA |
| **Ustekinumab Products** (Stelara® IV, biosimilars; Stelara SC, biosimilars) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| **Ilumya®** (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| **Omvoh®** (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | CD, UC |
| **Skyrizi®** (risankizumab-rzaa SC injection, IV infusion) | Inhibition of IL-23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| **Tremfya®** (guselkumab SC injection, IV infusion) | Inhibition of IL-23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| **Entyvio®** (vedolizumab IV infusion, SC injection) | Integrin receptor antagonist | CD, UC |
| **Orencia®** (abatacept IV infusion, SC injection) | T-cell costimulation modulator | SC formulation: JIA, PsA, RA |
| | | IV formulation: JIA, PsA, RA |
| **Rituximab IV Products** (Rituxan®, biosimilars) | CD20-directed antibody | RA |
| **Oral Therapies/ Targeted Synthetic Oral Small Molecule Drugs** | | |
| **Icotyde®** (icotrokinra tablets) | Inhibition of IL-23 receptor | PsO |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Otezla® XR** (apremilast extended-release tablets) | Inhibition of PDE4 | PsO, PsA |
| **Sotyktu®** (deucravacitinib tablets) | Inhibition of TYK2 | PsO, PsA |
| **Cibinqo™** (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways | AA, RA |
| **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, CD, nr-axSpA, PJIA, PsA, RA, UC |
| **Rinvoq® LQ** (upadacitinib oral solution) | Inhibition of JAK pathways | PsA, PJIA |
| **Xeljanz®** (tofacitinib tablets/oral solution) | Inhibition of JAK pathways | Tablets: AS, PsA, RA, UC |
| | | Oral solution: PJIA, PsA |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of JAK pathways | AS, PsA, RA, 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; HS – Hidradenitis Suppurativa; 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; ERA – Enthesitis-related arthritis; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.


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