Effective Date **1/1/2023**
Next Review Date… **1/1/2024**
Coverage Policy Number **IP0476**

Risankizumab Intravenous

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Related Coverage Resources

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. 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

This policy supports medical necessity review for risankizumab (Skyrizi®) intravenous infusion.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Risankizumab intravenous infusion (Skyrizi) is considered medically necessary when the following are met:

1. **Crohn's Disease.** Individual meets **ALL** of the following criteria (A, B, C, D and E):
   A. Individual is 18 years of age or older
   B. The medication will be used as induction therapy
   C. Documentation of **ONE** of the following (i, ii, iii, or iv):

i. Inadequate response, contraindication, or intolerance to corticosteroids OR Skyrizi will be taken concurrently with a corticosteroid
ii. Inadequate response, contraindication, or intolerance to **ONE** conventional systemic therapy OR Skyrizi will be taken concurrently with a conventional systemic therapy

Examples of conventional systemic therapy: azathioprine, 6-mercaptopurine, methotrexate.

iii. Individual has Already tried a biologic for Crohn's disease

Refer to Appendix for biologics used in Crohn's disease.

iv. Individual meets **ONE** of the following conditions (a, b, c, d, e, f, g, h, i or j):
   a. severe disease needing hospitalization
   b. involvement of the upper GI tract
   c. smoker
   d. less than 40 years of age
   e. stricturing disease
   f. perianal disease or other enterocutaneous fistula
   g. extraintestinal manifestations (ankylosing spondylitis, pyoderma gangrenosum, erythema nodosum)
   h. previous Crohn's disease-related surgery (for example, ileocolonic resection to reduce the chance of Crohn's disease recurrence)
   i. bowel obstruction
   j. history of abscess or perforation (after healing)

D. The medication is prescribed by, or in consultation with, a gastroenterologist
E. Individual meets the preferred covered alternatives criteria as indicated in the table below [Individual and Family Plan]

Dosing for Crohn's Disease: Individual meets the following dosing regimen (A):
A. 600 mg intravenous infusion administered at Weeks 0, 4, and 8

Coverage varies across plans and may requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group - Standard/Performance, Value/Advantage, Legacy, Cigna Total Savings Covered Alternatives	
Condition	**Criteria**
Crohn's Disease – Adults	**Preferred** [requires prior authorization]

Individual and Family Plan Covered Alternatives	
Condition	**Criteria**
Crohn's Disease - Adults	**Preferred** [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

A single induction regimen consisting of three doses (600 mg each) administered as an intravenous infusion at weeks 0, 4, and 8.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Data are lacking evaluating concomitant use of Skyrizi with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see Appendix for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack controlled trial data in support of additive efficacy.

   This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat Crohn's disease) in combination with Skyrizi.

Coding

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

Background

OVERVIEW
Skyrizi intravenous (IV), an interleukin (IL)-23 blocker, is indicated for **Crohn's disease**, in patients with moderate to severe active disease. In Crohn's disease, a three-dose induction regimen (600 mg at Weeks 0, 4, and 8) is administered by IV infusion. Following induction therapy with the IV product, the recommended maintenance is Skyrizi subcutaneous injection, given as a 360 mg subcutaneous injection administered 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 indicated.

- **Crohn's Disease:** Skyrizi is not addressed in current guidelines. The American College of Gastroenterology has guidelines for Crohn's disease (2018).[2] Biologics are a treatment option in patients who have moderate to severe disease despite treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors). Guidelines from the American Gastroenterological Association (2021) include biologics among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.[3]

References

1. Skyrizi® [prescribing information]. North Chicago, IL: AbbVie; June 2022.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2018;113(4):481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.

Appendix

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Humira	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitor; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology				Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Janus Kinases Inhibitors						
Olumiant	√	--	--	--	--	--
Rinvoq	√	--	√	√	--	√

Xeljanz tablets	√	√#	√	√	--	√
Xeljanz oral solution	--	√#	--	--	--	--
Xeljanz XR	√	--	√	√	--	√
Phosphodiesterase Type 4 Inhibitor						
Otezla	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator						
Zeposia	--	--	--	--	--	√

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.