Medical Policy:

Skyrizi® (risankizumab-rzaa) intravenous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.362	September 5, 2024	September 26, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Risankizumab-rzaa (Skyrizi®) is an interleukin-23 antagonist that selectively binds to the p19 subunit of human 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.

Skyrizi intravenous (IV) 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. Skyrizi intravenous (IV) is indicated for the treatment of moderately to severely active ulcerative colitis in adults. The recommended induction dosage of Skyrizi is 1,200 mg administered by intravenous infusion over a period of at least two hours at Week 0, Week 4, and Week 8. Following induction therapy with the IV product in both Crohn's Disease and Ulcerative Colitis, the recommended maintenance is Skyrizi subcutaneous injection.

Length of Authorization

Coverage will be provided for 11 weeks (3 induction doses) and cannot be renewed.

Dosing Limits [Medical Benefit]

Crohn's Disease

- Induction dose: 600 billable units (600 mg) at Week 0, 4, & 8

Ulcerative Colitis

- Induction dose: 1200 billable units (1200 mg) at Week 0, 4, & 8

Guideline

I. Initial Approval Criteria:

1. Patient is 18 years or older (unless otherwise specified); **AND**
2. Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
3. Patient is free of any clinically important active infections; **AND**
4. Therapy will not be administered concurrently with live vaccines; **AND**
5. Patient is not on concurrent treatment with another biologic therapy (e.g., IL-inhibitor, TNF-inhibitor, integrin receptor antagonist, T cell costimulation modulator, etc.) or targeted synthetic therapy (e.g., apremilast, tofacitinib, baricitinib, upadacitinib, abrocitinib, deucravacitinib, ritlecitinib, ruxolitinib, etrasimod, ozanimod, etc.); **AND**
6. Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
7. Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; **AND**

Crohn's Disease (CD)

1. Documented moderate to severely active disease; **AND**
    A. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of **ONE** corticosteroid or immunomodulator (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **OR**
    B. Patient is already established on a biologic or targeted synthetic therapy for the treatment of CD; **AND**
2. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, certolizumab, or infliximab)

Ulcerative Colitis (UC)

1. Documented moderate to severe active disease; **AND**
    A. Documented failure or ineffective response to a minimum 3-month trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6- mercaptopurine, methotrexate, etc.] at maximum tolerated doses, unless there is a contraindication or intolerance to use; **OR**
    B. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such as adalimumab, golimumab, or infliximab; **OR**
    C. Patient is already established on a biologic or targeted synthetic therapy for the treatment of UC

Applicable Procedure Codes

Code	Description
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg; 1 billable unit = 1 mg

Applicable NDCs

Code	Description
00074-5015-01	Skyrizi carton containing one 600 mg/10 mL single-dose vial

ICD-10 Diagnoses

Code	Description
K50.0-K50.019	Crohn's disease of small intestine
K50.1-K50.119	Crohn's disease of large intestine
K50.8-K50.819	Crohn's disease of both small and large intestine
K50.9-K50.919	Crohn's disease, unspecified
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011-K51.19	Ulcerative(chronic) pancolitis
K51.20	Ulcerative (chronic) proctitis without complications
K51.211-K51.219	Ulcerative (chronic) proctitis
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311-K51.319	Ulcerative (chronic) rectosigmoiditis
K51.50	Left sided colitis without complications
K51.511-K51.519	Left sided colitis
K51.80	Other ulcerative colitis without complications
K51.811-K819	Other ulcerative colitis
K51.90	Ulcerative colitis, unspecified, without complications
K51.911-K51.919	Ulcerative colitis, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	9/5/2024	Updated format for clarity
EmblemHealth & ConnectiCare	8/5/2024	Revision- Updated Definitions, Length of Authorization and Dosing Limits; Initial Approval Criteria: Updated the following statement: "Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, abrocitinib, deucravacitinib, etc.); AND " to read: "Patient is not on concurrent treatment with another biologic therapy (e.g., IL-inhibitor, TNF-inhibitor, integrin receptor antagonist, T cell costimulation modulator, etc.) or targeted synthetic therapy (e.g., apremilast, tofacitinib, baricitinib, upadacitinib, abrocitinib, deucravacitinib, ritlecitinib, ruxolitinib, etrasimod, ozanimod, etc.); AND" and added: "Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; AND" Crohn's Disease: added: "OR Patient is already established on a biologic or targeted synthetic therapy for the treatment of CD; AND" added Ulcerative Colitis indication and criteria. Updated ICD 10 codes.
EmblemHealth & ConnectiCare	1/5/2024	Annual Review: updated wording of dosage limits, added additional non-biologic agent examples (upadacitinib, abrocitinib, deucravacitinib), added "intravenous" to the title for clarification
EmblemHealth & ConnectiCare	4/28/2023	Annual Review: removed codes J3590 and C9399, added Code J2327
EmblemHealth & ConnectiCare	09/26/2022	New Policy

References

1. Skyrizi [package insert]. North Chicago, IL; AbbVie, Inc.; June 2022. Accessed August 2022
2. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. Lancet. 2022 May 28;399(10340):2015-2030. doi: 10.1016/S0140-6736(22)00467-6
3. National Institute for Health and Care Excellence. NICE 2019. Crohn’s Disease: Management. Published 03 May 2019. NICE Guideline [NG129]. https://www.nice.org.uk/guidance/ng129.