



PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Myopathy – Lisraya Prior Authorization Policy

- Lisraya® (brepocitinib tablets – Priovant)

REVIEW DATE: 08/28/2026; selected revision 09/23/2026

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Lisraya, a Janus kinase (JAK) and tyrosine kinase-2 (TYK2) inhibitor, is indicated for the treatment of dermatomyositis in adults.¹

Limitation of use: Lisraya is not recommended for use in combination with other JAKis, TYK2is, or biologics.¹

Disease Overview

Dermatomyositis is a rare immune mediated muscle disease characterized by skin rash and muscle weakness.² It is classified as one of the idiopathic inflammatory myopathies (IIM) and presents with characteristic skin findings and symmetric proximal muscle weakness.^{2,3} Patients may present with a range of cutaneous findings, including rashes, photosensitivity, pigment changes, and pruritus. Pathognomonic cutaneous features include Gottron's papules, Gottron's sign, and heliotrope rash. Cutaneous manifestations may precede or may coincide with the

onset of muscle weakness. The associated myopathy usually has a subacute onset, characterized by progressively worsening muscle weakness affecting the upper and lower extremities; with more severe muscle disease, patients can develop dysphagia, respiratory insufficiency, and aspiration pneumonia. Dermatomyositis is also associated with systemic manifestations which contribute to morbidity and mortality, including interstitial lung disease, cardiovascular disease, gastrointestinal involvement, and malignancy. The European League Against Rheumatism and the American College of Rheumatology (EULAR/ACR) published classification criteria (2017) to help identify IIM and its major subgroups, including dermatomyositis.⁴ The criteria use a scoring system that combines characteristic skin findings, muscle weakness, laboratory findings, and, when available, muscle biopsy results to estimate the probability of IIM. Patients with characteristic dermatomyositis skin manifestations and sufficient clinical, laboratory, and/or biopsy findings can be classified as having probable or definite IIM and assigned to the dermatomyositis subtype.

Clinical Efficacy

Lisraya was evaluated in a double-blind, placebo-controlled, multicenter, Phase III pivotal trial called VALOR.^{1,5} In the study, adults with active skin and muscle disease were randomized to Lisraya 30 mg, Lisraya 15 mg, or placebo. All patients had received prior treatment with glucocorticoids, conventional immunosuppressants, intravenous immune globulin, or a rituximab product. Additionally, majority (81%) of patients were receiving at least two concomitant background conventional systemic therapies (glucocorticoid and a disease modifying anti-rheumatic drug [DMARD]). The primary endpoint was the mean total improvement score (TIS) at Week 52. TIS is a validated composite endpoint that measures overall improvement in dermatomyositis by combining changes across six core disease domains, including muscle strength, physical function, physician and patient assessments, muscle enzymes, and extra-muscular disease activity. TIS ranges from 0 to 100, with scores of ≥ 20 , ≥ 40 , and ≥ 60 representing minimal, moderate, and major clinical improvement, respectively. As TIS does not assess cutaneous improvement, one of the key secondary endpoints was the change from baseline in the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI-A) score. The CDASI-A is a validated measure that assesses skin disease activity in dermatomyositis. At Week 52, Lisraya 30 mg demonstrated a significantly greater mean TIS than placebo (46.5 vs. 37.5, respectively). A significant improvement in CDASI-A was also observed with Lisraya 30 mg compared with placebo as early as Week 4 and maintained through Week 52. Overall, patients who received Lisraya 30 mg had significant improvements across all nine secondary end points, including multiple measures of muscle and skin disease activity, glucocorticoid-sparing efforts, and patient-reported assessments of functional muscle strength. A significant difference in the primary and secondary endpoints between Lisraya 15 mg and placebo was not observed.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lisraya. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lisraya as well as the monitoring required for adverse events and long-term efficacy, approval requires Lisraya to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Lisraya® (brepocitinib tablets – Priovant) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. Dermatomyositis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is ≥ 18 years of age; AND

ii. According to the prescriber, the diagnosis is supported by ONE of the following (a or b):

a) Typical dermatomyositis skin manifestations; OR

Note: Skin manifestations include heliotrope rash, Gottron papules, and Gottron sign.

b) Objective signs of myositis; AND

Note: Objective signs of myositis include proximal muscle weakness, elevated muscle enzymes, abnormal electromyographic (EMG) findings, or abnormal muscle biopsy results.

iii. Patient has tried a systemic corticosteroid, unless contraindicated; AND

iv. Patient has tried at least one conventional systemic agent, unless contraindicated; AND

Note: Examples of conventional systemic agents include azathioprine, chloroquine, cyclosporine, hydroxychloroquine, leflunomide, methotrexate, mycophenolate mofetil, sulfasalazine, and tacrolimus. A patient who has already tried intravenous immune globulin or a rituximab intravenous product is not required to “step back” and try a conventional systemic agent.

v. The medication is prescribed by or in consultation with a dermatologist, neurologist, or rheumatologist; OR

B) Patient is Currently Receiving Lisraya. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Lisraya is reviewed under criterion A (Initial Therapy).

- ii. According to the prescriber, the patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Lisraya).

Note: Examples of a response to therapy includes improved muscle strength, improved functional ability, reduction in muscle enzyme levels, improvement in skin disease activity, and reduction in corticosteroid requirements.

CONDITIONS NOT COVERED

Lisraya® (brepocitinib tablets – Priovent) is(are) considered not medically necessary for ANY other use(s) 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.** This medication should not be administered in combination with another biologic (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.
- 2. Concurrent Use with a Janus Kinase (JAK) or Tyrosine Kinase-2 (TYK2) Inhibitor.** This medication should not be administered in combination with other JAK inhibitors or TYK2 inhibitors (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.

REFERENCES

1. Lisraya™ tablets [prescribing information]. Durham, NC: Priovent; August 2026.
2. Qudsiya Z, Waseem M. Dermatomyositis. [Updated 2023 Aug 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK558917/>. Accessed on August 20, 2026.
3. DeWane ME, Waldman R, Lu J. Dermatomyositis: Clinical features and pathogenesis. *J Am Acad Dermatol*. 2020 Feb;82(2):267-281.
4. The International Myositis Classification Criteria Project Consortium, the Euromyositis Register, and the Juvenile Dermatomyositis Cohort Biomarker Study and Repository (UK and Ireland) (2017). 2017 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Adult and Juvenile Idiopathic Inflammatory Myopathies and Their Major Subgroups. *Arthritis Rheumatol*, 69: 2271-2282.
5. Vleugels RA, Paik JJ, Bauer Ventura I, et al. A Phase 3 Trial of Brepocitinib in Dermatomyositis. *N Engl J Med*. 2026 May 14;394(19):1883-1893.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/28/2026

Selected Revision	Dermatomyositis: For diagnostic confirmation, the requirement for both skin manifestations and objective signs of myositis was revised to require either skin manifestations or objective signs of myositis.	09/23/2026
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APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, HS, PJIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, PJIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, PJIA, 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
Omvo® (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: PJIA, PsA, RA
		IV formulation: PJIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed antibody	RA

Oral Therapies/ Targeted Synthetic Oral Small Molecule Drugs		
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO, PsA
Cibinco™ (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
Tofacitinib tablets/oral solution (Xeljanz®, generics)	Inhibition of JAK pathways	Tablets: AS, PsA, RA, UC
		Oral solution: PJIA, PsA
Tofacitinib XR extended-release tablets (Xeljanz XR, generics)	Inhibition of JAK pathways	AS, PsA, RA, 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; PJIA – Polyarticular juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ERA – Enthesitis-related arthritis; TYK2 – Tyrosine kinase 2; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata.

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