Clinical Policy: Brepocitinib (Lisraya)

Reference Number: CP.PHAR.793
Effective Date: 08.27.26
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Brepocitinib (Lisraya™) is a Janus kinase 1 (JAK1) and tyrosine kinase 2 (TYK2) inhibitor.

FDA Approved Indication(s)

Lisraya is indicated for the treatment of dermatomyositis (DM).

Limitation(s) of use: Lisraya is not recommended for use in combination with other JAK inhibitors, other TYK2 inhibitors, or biologic disease-modifying antirheumatic drugs (DMARDs).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Lisraya is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dermatomyositis (must meet all)**:**

1. Diagnosis of DM;
2. Prescribed by or in consultation with a dermatologist, rheumatologist, neurologist, or neuromuscular specialist;
3. Age ≥ 18 years;
4. Member has all of the following assessed within the last 30 days (a, b, and c):
   a. Absolute lymphocyte count ≥ 500 cells/mm^3;
   b. Absolute neutrophil count ≥ 1,000 cells/mm^3;
   c. Hemoglobin ≥ 8 g/dL;
5. Failure of a 4-month trial of a systemic corticosteroid (e.g., prednisone) in combination with one of the following immunosuppressive agents, both at up to maximally indicated doses unless clinically significant adverse effects are experienced or all are contraindicated: methotrexate, azathioprine, cyclophosphamide, mycophenolate mofetil, tacrolimus, cyclosporine (see *Appendix B*);*
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
6. Failure of a trial of rituximab* (*Ruxience® or Truxima® are preferred)*, unless contraindicated or clinically significant adverse effects are experienced;
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

7. Failure of a trial of immune globulins* (*Gammagard® or Gammunex®-C are preferred)*, unless contraindicated or clinically significant adverse effects are experienced;
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
8. At the time of request, the member does not have active hepatitis B or hepatitis C infection and does not have untreated tuberculosis;
9. Member does not have combination use with biological disease-modifying antirheumatic drugs, JAK inhibitors (e.g., Olumiant®, Rinvoq®, Cibinqo®, Opzelura™), or TYK2 inhibitors (e.g., Sotyktu®);
10. Dose does not exceed 30 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Dermatomyositis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy (*see Appendix D)*;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs, JAK inhibitors (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura), or TYK2 inhibitors (e.g., Sotyktu);
4. If request is for a dose increase, new dose does not exceed 30 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DMARDs: disease-modifying antirheumatic drugs
DM: dermatomyositis
eGFR: estimated glomerular filtration rate
FDA: Food and Drug Administration
JAK: Janus kinase 1 (JAK1)
TYK2: tyrosine kinase 2

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Imuran®)	2 mg/kg PO QD or 50 mg/day PO up to 2 to 3 mg/kg/day	3 mg/kg/day
cyclophosphamide (Cytoxan®)	1 to 3 mg/kg/day PO QD or 500 mg IV every 2 weeks for 6 doses	Not applicable
cyclosporine (Gengraf®, Neoral®, Sandimmune®)	5 to 10 mg/kg/day PO	Not applicable

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methotrexate (Rheumatrex®)	10 to 25 mg/week PO/IV	50 mg/week
mycophenolate mofetil (Cellcept®)	250 to 500 mg PO BID, increasing to a target dose of 1,500-3,000 mg/day	3 g/day
tacrolimus (Prograf®)	0.075mg/kg/day PO BID OR begin at 1 mg PO BID, increase to reach trough of 5-10 ng/ml	Not applicable
systemic corticosteroids (e.g., prednisone, prednisolone, methylprednisolone)	An equivalent dose of prednisone 1 mg/kg/day (with or without tapering)	2 mg/kg/day
Rituxan® and rituximab biosimilars	1,000 mg/m^2 IV weekly x 2 weeks	1,000 mg/m^2 per week for total 2 doses
immune globulins (e.g., Alyglo™, Asceniv™, Bivigam®, Gammagard®, Gammaplex®, Octagam®, Panzyga®, Privigen®, Qivigy®, Yimmugo®)	2 g/kg IV or SC divided in equal doses given over 2-5 consecutive days every 4 weeks	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of hypersensitivity reactions to brepocitinib or any of the excipients in Lisraya
- Boxed warning(s): serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis

Appendix D: General Information

- Per the 2020 American Academy of Dermatology treatment guidelines for DM, in cases where a combination of systemic corticosteroids and an oral immunosuppressant fail, rituximab is the appropriate next step in therapy. In individuals with vasculopathic or calcinotic lesions, adults with anti-MDA5 positivity, or children with NXP-2 positivity, rituximab plus systemic corticosteroids can be considered first-line treatment.
- IV immune globulins may be medically necessary after less than 4 months trial of prednisone or prednisone combination therapies if the patient has profound, rapidly progressive and/or potentially life-threatening muscular weakness (e.g., life-threatening aggressive disease with involvement of respiratory musculature, possibly requiring hospitalization, elective intubation and mechanical ventilatory support) and is refractory to or intolerant of previous therapy.
- Failure or clinically significant adverse effects to continual high dose steroids in combination with other immunosuppressive agents is defined as the patient being unresponsive or poorly responsive to therapy (persistently elevated serum creatine kinase

(CK) levels and/or lack of improvement on muscle strength improvement scales) or intolerant of therapy (i.e., steroid myopathy or severe osteoporosis).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DM	30 mg PO QD	30 mg/day

VI. Product Availability

Tablet: 30 mg

VII. References

1. Lisraya Prescribing Information. Cambridge, MA: Takeda Pharmaceuticals USA, Inc; August 2026. Available at: https://lisraya.com/ Accessed September 24, 2026.
2. ClinicalTrials.gov. A study to investigate the efficacy and safety of brepocitinib in adults with dermatomyositis (VALOR). Available at: https://clinicaltrials.gov/study/NCT05437263. Accessed July 2, 2026.
3. Vleugels RA, Paik JJ, Ventura B, et al. A phase 3 trial of brepocitinib in dermatomyositis. N Engl J Med 2026;394(19): 1883-1893.
4. Waldman R, DeWane ME, Lu J. Dermatomyositis: diagnosis and treatment. J Am Acad Dermatol. 2020;82:283-96.
5. Cassard L, Seraly N, Riegert M, Patel A, and Fernandez AP. Dermatomyositis: Practical guidance and unmet needs. ImmunoTargets and Therapy 2024;13:151-172.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J8499	Prescription drug, oral, non chemotherapeutic, nos

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	07.14.26	08.26
Drug is now FDA approved – criteria updated per FDA labeling: added "member does not have combination use with DMARDs, JAK inhibitors, or TYK2 inhibitors"; added required pre-treatment monitoring parameters, including active infections screening, lymphocyte count, neutrophil count, hemoglobin level; added HCPC code [J8499]; references reviewed and updated.	10.30.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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