Reference number(s)
7627-A

Specialty Guideline Management
Lisraya

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lisraya	brepocitinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Lisraya is indicated for the treatment of dermatomyositis in adult patients.

All other indications are considered experimental and not medically necessary.

Limitations of Use

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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Initial Requests:

- Chart notes, medical records, or lab results documenting the following, if applicable:
  - Proximal muscle weakness.
  - Elevated serum creatinine kinase (CK) or aldolase level.
  - Myogenic changes on electromyogram (EMG).
  - Serology results showing myositis-specific or myositis-associated autoantibodies.
  - Pathological findings compatible with inflammatory myositis.
  - Muscle magnetic resonance imaging (MRI) demonstrating findings consistent with inflammatory myositis.
  - Cutaneous disease manifestation.
  - Other extramuscular disease manifestation.
- Chart notes, medical records, or claims history supporting either of the following:
  - Member's current oral corticosteroid, non-steroidal immunomodulatory/immunosuppressive therapy, and/or intravenous immunoglobulin (IVIG) therapy regimen.
  - Oral corticosteroid, non-steroidal immunomodulatory/immunosuppressive therapy, and/or IVIG therapies tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation Requests:

- Chart notes, medical records, or lab results documenting a clinically positive response to therapy which shall include improvement, stabilization, or slowing of disease progression (e.g., improvement, stabilization, or slowing of disease progression demonstrated by serum muscle enzyme measurements; Manual Muscle Testing-8 [MMT8]; Functional Index-2 [FI-2]; Functional Index-3 [FI-3]; Cutaneous Dermatomyositis Disease Area and Severity Index [CDASI] Activity Score; reduction in corticosteroid exposure; Medical Research Council [MRC] scale; muscle magnetic resonance imaging [MRI]).

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist, rheumatologist, pulmonologist, or neurologist.

Coverage Criteria

Dermatomyositis[1-6]

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Authorization of 12 months may be granted for treatment of dermatomyositis when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has at least 3 of the following:
    - One of the following features suggestive of muscle disease manifestation:
        - Proximal muscle weakness (e.g., symmetric proximal muscle weakness of the upper extremities and/or lower extremities, weakness of the neck flexors).
        - Elevated serum creatinine kinase (CK) or aldolase level.
        - Myogenic changes on electromyogram (EMG) (e.g., short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials).
        - Pathological findings compatible with inflammatory myositis (e.g., perivascular inflammation, perifascicular atrophy, rimmed vacuoles, active regeneration).
        - Muscle magnetic resonance imaging (MRI) demonstrating findings consistent with inflammatory myositis (e.g., muscle edema).
    - Positive for a myositis-specific or myositis-associated autoantibody (e.g., anti-Mi-2, anti-TIF1γ, anti-SAE, anti-NXP2, anti-MDA5, anti-Jo-1, anti-PL-7, anti- PL-12, anti-EJ, anti-OJ, anti-KS, anti-Zo, anti-Ha, anti-SSA, anti-RNP, anti-PM/Scl, anti-KU).
    - Cutaneous disease manifestation (e.g., Heliotrope rash, Gottron's papules, Gottron's sign, shawl sign, V-sign, holster sign, mechanic's hands, calcinosis).
    - Other extramuscular disease manifestation (e.g., Raynaud's phenomenon, bilateral and symmetric polyarthritis, interstitial lung disease, esophageal dysmotility).
- Member is experiencing active skin and/or muscle disease at baseline.
- Member meets either of the following:
    - Member is currently receiving an oral corticosteroid, non-steroidal immunomodulatory/immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil, mycophenolic acid, leflunomide, sulfasalazine, hydroxychloroquine), or intravenous immunoglobulin (IVIG) for the treatment of dermatomyositis.
    - Member has a documented inadequate response, intolerance, or contraindication to at least one oral corticosteroid, non-steroidal immunomodulatory/immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil, mycophenolic acid, leflunomide, sulfasalazine, hydroxychloroquine), or intravenous immunoglobulin (IVIG) therapy.
- The requested medication will not be used in combination with other JAK inhibitors, other TYK2 inhibitors, or biologic disease-modifying antirheumatic drugs (DMARDs).

Continuation of Therapy[1-3,6]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who meet all of the following criteria:

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- Member demonstrates a clinically positive response to therapy which shall include improvement, stabilization, or slowing of disease progression (e.g., improvement, stabilization, or slowing of disease progression demonstrated by serum muscle enzyme measurements; Manual Muscle Testing-8 [MMT8]; Functional Index-2 [FI-2]; Functional Index-3 [FI-3]; Cutaneous Dermatomyositis Disease Area and Severity Index [CDASI] Activity Score; reduction in corticosteroid exposure; Medical Research Council [MRC] scale; muscle magnetic resonance imaging [MRI]).
- The requested medication will not be used in combination with other JAK inhibitors, other TYK2 inhibitors, or biologic disease-modifying antirheumatic drugs (DMARDs).

References

1. Lisraya [package insert]. Durham, NC: pRIOVANT Therapeutics, Inc.; August 2026.
2. Vleugels RA, Paik JJ, Bauer Ventura I, et al. A Phase 3 Trial of Brepocitinib in Dermatomyositis. N Engl J Med. 2026;394(19):1883-1893. doi:10.1056/NEJMoa2503531.
3. Allenbach Y, Benveniste O. Inflammatory Myopathies. N Engl J Med. 2026;394(19):1925-1938. doi:10.1056/NEJMra2415426.
4. Bohan A, Peter JB. Polymyositis and dermatomyositis (first of two parts). N Engl J Med. 1975;292(7):344-347. doi:10.1056/NEJM197502132920706.
5. Bohan A, Peter JB. Polymyositis and dermatomyositis (second of two parts). N Engl J Med. 1975;292(8):403-407. doi:10.1056/NEJM197502202920807.
6. Keret S, Pongtarakulpanit N, Aggarwal R. Expert Perspective: Toward Treat-to-Target Management in Adult Idiopathic Inflammatory Myopathies. *Arthritis Rheumatol*. Published online September 14, 2026. doi:10.1002/art.70335

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