Clinical Policy: Brensocatib (Brinsupri)

Reference Number: PA.CP.PMN.303
Effective Date: 11/2025
Last Review Date: 10/2025

Description
Brensocatib (Brinsupri™) is a dipeptidyl peptidase 1 (DPP1) inhibitor.

FDA Approved Indication(s)
Brinsupri is indicated for the treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older.

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 PA Health & Wellness® that Brinsupri is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Cystic Fibrosis Bronchiectasis (must meet all)**:**

1. Diagnosis of non-cystic fibrosis bronchiectasis confirmed by chest computed tomography (CT) scan;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 12 years;
4. Provider attestation that member is currently receiving optimal supportive therapy (examples include but are not limited to: airway clearance techniques, pulmonary rehabilitation, mucoactives [e.g., nebulized hypertonic saline, mannitol, antibiotics [e.g., oral – azithromycin, erythromycin; inhaled – tobramycin, aztreonam]);
5. Documentation of one of the following despite at least 3 months of optimal supportive therapy (a or b):
   a. Adults (age ≥ 18 years): Member has had at least 2 pulmonary exacerbations (*see Appendix D*) requiring systemic antibiotics in the last 12 months;
   b. Pediatrics (age 12 to 17 years): Member has had at least 1 pulmonary exacerbation (*see Appendix D*) requiring systemic antibiotics in the last 12 months;
6. If a current smoker, has documentation of being advised by the prescriber to stop smoking;
7. Dose does not exceed 25 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Non-Cystic Fibrosis Bronchiectasis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 25 mg (1 tablet) per day.

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CT: computed tomography
DPP1: dipeptidyl peptidase 1
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- In the pivotal ASPEN study (NCT04594369), pulmonary exacerbations were defined as worsening of 3 or more of the following major symptoms over 48 hours, resulting in a healthcare provider's decision to prescribe systemic antibiotics: increased cough, increased sputum volume or change in sputum consistency, increased sputum purulence, increased breathlessness, decreased exercise tolerance, fatigue and/or malaise, and hemoptysis.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Non-cystic fibrosis bronchiectasis	10 mg or 25 mg PO QD	25 mg/day

VI. Product Availability

Tablets: 10 mg, 25 mg

VII. References

1. Brinsupri Prescribing Information. Bridgewater, NJ: Insmed Incorporated; August 2025. Available at: www.brinsupri.com. Accessed August 20, 2025.
2. Chalmers JD, Burgel P, Daley CL, et al. Phase 3 trial of the DPP-1 inhibitor brensocatib in bronchiectasis. N Engl J Med. 2025; 392(16): 1569-1581.
3. Chalmers JD, Haworth CS, Metersky ML, et al. Phase 2 trial of the DPP-1 inhibitor brensocatib in bronchiectasis. N Engl J Med. 2020; 383(22): 2127-2137.
4. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. Eur Respir J. 2017; 50(3): 1700629. doi: 10.1183/13993003.00629-2017.
5. Hill AT, Sullivan AL, Chalmers JD, et al. British Thoracic Society guideline for bronchiectasis in adults. Thorax. 2019; 74(Suppl 1): 1-69.
6. Wasfy JH, Kim K, Touchette DR, et al. Brensocatib for non-cystic fibrosis bronchiectasis: Effectiveness and value; Evidence report. Institute for Clinical and Economic Review. Published September 8, 2025. Available at: https://icer.org/assessment/ncfb-2025/. Accessed September 16, 2025.

Reviews, Revisions, and Approvals	Date
Policy created	10/2025