Pharmacy Policy Bulletin: J-1465 Brinsupri (brensocatib) – Commercial and Healthcare Reform	
Number: J-1465	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Miscellaneous Specialty Oral= Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1465-001	**Original Date:** 09/17/2025
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Brinsupri (brensocatib)
FDA-Approved Indication(s):	• Treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age and older.

Background:	• Brinsupri is a competitive, reversible inhibitor of dipeptidyl peptidase 1 (DDP1). DPP1 activates pro-inflammatory neutrophil serine proteases (NSPs). By inhibiting DPP1, Brinsupri reduces the activity NSPs, which are implicated in neutrophil-mediated inflammation. • NCFB is a chronic lung condition characterized by permanent bronchial dilation and inflammation. This impairs mucus and bacteria clearance, leading to persistent inflammation and infection. Bronchiectasis typically presents with chronic cough, daily sputum production, and recurrent exacerbations (periods of symptom worsening). Exacerbations are associated with a progressive decline in lung function and symptoms such as increased cough, mucus production, shortness of breath, and fatigue, which can decrease quality of life. Management of bronchiectasis includes treating related conditions, employing airway clearance techniques, and administering oral or IV antibiotics for exacerbations. For patients experiencing frequent exacerbations (3 or more per year), long-term inhaled antibiotics or oral macrolides may be considered. Approximately 500,000 people in the United States (US) have NCFB, with estimates of millions more affected globally. • NCFB has been traditionally treated by focusing on managing symptoms. There are no specific US guidelines for treatment of NCFB. The 2019 British Thoracic Society Guideline for bronchiectasis in adults recommends for stable outpatients, regular airway clearance therapy using exercise and one or more of the following techniques: saline nebulizers, high-frequency chest wall oscillation (HFCWO), and chest physical and percussion therapy. For stable outpatients with three or more exacerbations per year, long-term inhaled and oral antibiotics are recommended. Pulmonary rehabilitation is recommended for individuals who are

	significantly limited by shortness of breath. In some severe cases, surgical resection of part of the lung or even lung transplantation is sometimes considered. Diagnosis should be determined via computed tomography (CT) to confirm a diagnosis of bronchiectasis when clinically suspected. Clinical symptoms of NCFB include cough most days of the week, production of mucopurulent and tenacious sputum most days of the week, a history of exacerbations, dyspnea, wheezing, rhinosinusitis, hemoptysis, and recurrent pleurisy. • The 2021 European Respiratory Society guidelines for the management of children and adolescents with bronchiectasis recommend utilizing regular airway clearance therapy, systemic courses of antibiotics to treat acute respiratory exacerbations, long-term antibiotic use for adolescents with recurrent exacerbations (>1 hospitalized or ≥3 non-hospitalized exacerbations in the previous 12-months), and inhaled mannitol or hypertonic saline may be considered in select patients with high daily symptoms, frequent exacerbations, difficulty in expectoration and/or poor quality of life. • Prescribing Considerations: o It is unknown whether administration of live attenuated vaccines during Brinsupri treatment will affect the safety or effectiveness of the vaccines. Avoid use of live attenuated vaccines. o Gingival and periodontal adverse reactions can occur with Brinsupri use. Refer to the dental care services for regular dental checkups and advise patients to perform routine dental hygiene. o Monitor for new rash or skin conditions and refer to dermatology for evaluation.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Brinsupri may be approved when all of the following criteria are met **(A. through E.):**

- **A.** The member is 12 years of age and older.
- **B.** The member has a diagnosis of non-cystic fibrosis bronchiectasis (NCFB) (ICD10: J47) confirmed by computed tomography (CT).
- **C.** The member has experienced at least one (1) of the following symptoms consistent with bronchiectasis **(1., 2., or 3.):**
  - **1.** Cough on most days of the week
  - **2.** Chronic sputum production
  - **3.** A history of recurrent respiratory infections
- **D.** For members who are 18 years of age and older, the member has experienced at least two (2) exacerbations in the previous twelve (12) months that led to antibiotic treatment.
- **E.** For members who are 12 years of age to < 18 years of age, the member has had at least one (1) pulmonary exacerbation in the previous twelve (12) months that led to antibiotic treatment.

II. Reauthorization

When a benefit, reauthorization of Brinsupri may be approved when the following criterion is met **(A.):**

- **A.** The member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; August 2025.
2. Barker AF, Karamooz E. Non-Cystic Fibrosis Bronchiectasis in Adults: A Review. *JAMA*. 2025:15;334(3):253-264.
3. Hill AT, Sullivan AL, Chalmers JD, et al. British Thoracic Society Guideline for bronchiectasis in adults. *Thorax*. 2019;74(Suppl 1):1-69.
4. Spinou A, Almagro M, Harris B, et al. Diagnostic delay and access to care in bronchiectasis: data from the EMBARC/ELF patient survey. *Eur Respir J*. 2024;25;64(1):2301504.
5. Chang AB, Fortescue R, Grimwood K, et al. European Respiratory Society guidelines for the management of children and adolescents with bronchiectasis. *Eur Respir J*. 2021: 26;58(2):2002990.