Original Effective Date: 12/11/2025
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Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C29946-A

Brinsupri (brensocatib)

PRODUCTS AFFECTED

Brinsupri (brensocatib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Non-cystic fibrosis bronchiectasis (NCFB)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NON-CYSTIC FIBROSIS BRONCHIECTASIS:
1. Documented diagnosis of non-cystic fibrosis bronchiectasis (NCFB)
   AND
2. Documentation of at least 2 pulmonary exacerbations (requiring a prescription, urgent care, or hospitalization) within the past 12 months, OR for members 12 to 17 years of age, documentation of at least 1 pulmonary exacerbation
   AND
3. Documentation of baseline forced expiratory volume in one second (FEV_1), frequency and severity of exacerbations, or symptoms
   AND
4. Documentation of trial and inadequate response to inhaled or oral antibiotics

CONTINUATION OF THERAPY:
A. NON-CYSTIC FIBROSIS BRONCHIECTASIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by improvement in lung function (forced expiratory volume in one second, FEV_1) from baseline, decreased frequency or severity of exacerbations, improvement in symptoms, decreased hospitalizations or medical interventions

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified pulmonologist or physician experienced in the management of lung disease [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
10mg or 25mg once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Dipeptidyl Peptidase 1 (DPP1) Inhibitors

FDA-APPROVED USES:
Indicated for the treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Non-cystic fibrosis bronchiectasis (NCFB) is a chronic lung condition caused by permanent bronchial dilation and inflammation. It is characterized by daily cough, sputum, and recurrent exacerbations. Bronchiectasis is also accompanied by recurrent respiratory tract infections (RTIs) and pulmonary exacerbations. Diagnosis of NCFB is made using high-resolution chest computed topography (CT) scans. Acute exacerbations require culture-directed antibiotics. Patients with more severe disease may require long-term macrolides (e.g., azithromycin) or inhaled antibiotics (e.g., gentamicin).

Prior to FDA approval of Brinsupri, (brensocatib), there were no medications indicated for the treatment of NCFB. The standard of care focused on reducing mortality, pulmonary exacerbations, and infections, as well as slow disease progression, relieve symptoms, and improve quality of life. This was achieved using combinations of short- and long-term systemic or inhaled antibiotics, systemic and inhaled corticosteroids, bronchodilators, mucolytics, and nonpharmacological strategies, such as pulmonary rehabilitation and airway clearance devices/techniques. Brinsupri (brensocatib) is the first drug of its class, and the first FDA-approved drug for NCFB.

It is believed that neutrophil-mediated inflammation plays a central role in the pathophysiology of bronchiectasis, where structural airway damage, impaired mucous clearance, chronic lung infection, and neutrophilic inflammation continuously reinforce each other, worsening pulmonary conditions. Brinsupri (brensocatib) is a dipeptidyl peptidase 1 (DPP1) inhibitor that is thought to decrease the damaging effects of neutrophil-driven inflammation in the lungs.

The approval of Brinsupri (brensocatib) was supported by results from the Phase 3 ASPEN (NCT04594369) and Phase 2 WILLOW (NCT03218917) studies. ASPEN included patients ≥12 years of age with NCFB and a history of pulmonary exacerbations in the past 12 months.

Over the 52-week treatment period in ASPEN, there was a 21% and 19% reduction in pulmonary exacerbations with Brinsupri 10 mg and 25 mg daily, respectively. In WILLOW, which included adult patients only, both doses prolonged time to first pulmonary exacerbations over the 24-week treatment period compared to placebo. Brinsupri was well tolerated; the most common adverse

events (≥2%) included upper respiratory tract infection, headache, rash, dry skin, hyperkeratosis, and hypertension.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Brinsupri (brensocatib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Brinsupri (brensocatib) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:
Dermatologic Adverse Reactions: Treatment with Brinsupri (brensocatib) is associated with an increase in dermatologic adverse reactions, including rash, dry skin, and hyperkeratosis. Monitor for new rash or skin conditions and refer to dermatology for evaluation.
Gingival and Periodontal Adverse Reactions: Treatment with Brinsupri (brensocatib) is associated with an increase in gingival and periodontal adverse reactions. Refer patients to dental care services for regular dental checkups and advise patients to perform routine dental hygiene.
Live Attenuated Vaccines: 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.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Brinsupri TABS 10MG
Brinsupri TABS 25MG

REFERENCES

1. Brinsupri (brensocatib) tablets, for oral use [prescribing information]. Bridgewater, NJ: Insmed Incorporated; August 2025.
2. Barker, A. F., & Karamooz, E. (2025). Non-Cystic Fibrosis Bronchiectasis in Adults: A Review. JAMA, 334(3), 253–264.

3. Shoaib, S., Feliciano, J., Dasenbrook, E. C., Maynard, J., Lakshmi Batchu, Mohanty, M., … Feld, A. J. (2025). Real-world disease burden, mortality, and healthcare resource utilization associated with bronchiectasis. Chronic Respiratory Disease, 22. https://doi.org/10.1177/14799731241310897
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5. Chalmers, J. D., Haworth, C. S., Metersky, M. L., Loebinger, M. R., Blasi, F., Sibila, O., O'Donnell, A. E., Sullivan, E. J., Mange, K. C., Fernandez, C., Zou, J., Daley, C. L., & WILLOW Investigators (2020). Phase 2 Trial of the DPP-1 Inhibitor Brensocatib in Bronchiectasis. The New England journal of medicine, 383(22), 2127–2137.
6. Keir HR, Chalmers JD. Pathophysiology of bronchiectasis. Semin Respir Crit Care Med. 2021;42(4):499-512.
7. O'Donnell AE. Bronchiectasis—a clinical review. N Engl J Med. 2022;387(6):533-545.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2025