PRIOR AUTHORIZATION POLICY

POLICY: Pulmonary – Brinsupri Prior Authorization Policy
- Brinsupri™ (brensocatib tablets – Insmed)

REVIEW DATE: 08/13/2025; selected revision 09/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Brinsupri, a dipeptidyl peptidase 1 (DPP1) inhibitor, is indicated for the treatment of **non-cystic fibrosis bronchiectasis** in adult and pediatric patients 12 years of age and older.[1]

Disease Overview

Non-cystic fibrosis bronchiectasis is a chronic lung disease characterized by the cough and sputum production, as well as the presence of abnormal thickening and dilation of the bronchial wall visible on lung imaging.[2] Bronchiectasis affects patients to varying degrees; some patients will develop repeated respiratory infections requiring long-term antibiotic therapies, disabling productive cough, shortness of breath, and occasional hemoptysis. An estimated 500,000 Americans have been diagnosed with bronchiectasis; however, it is expected to be underdiagnosed or misdiagnosed. One review reported that bronchiectasis was the third most common airway disease after chronic obstructive pulmonary disease and

asthma. Recurrent pulmonary exacerbations are common in non-cystic fibrosis bronchiectasis; they are defined as worsening of three or more of the following major symptoms over 48 hours that results in the prescription of an antibiotic agent: increased cough, increased sputum volume or change in sputum consistency, increased sputum purulence, increased breathlessness, decreased exercise tolerance, fatigue and/or malaise, and hemoptysis.[6]

There are no approved treatments or therapies for bronchiectasis; treatments have previously revolved around antibiotics to treat infections and airway clearance to remove excessive mucus.[6] Targeting DPP1 (also known as cathepsin C [CatC]) is a novel anti-inflammatory treatment strategy.

Guidelines

There are no US guidelines for the treatment of bronchiectasis. However, there are several other international guidelines, including by the European Respiratory Society (ERS) and the British Thoracic Society (BTS).[4-5] Brinsupri is not yet included. The American Thoracic Society has not developed standalone guidelines but has endorsed both ERS and BTS recommendations.[3] The management of bronchiectasis generally depends on the number of exacerbations patients have in one year. All existing guidelines and recommendation statements recommend against the routine use of corticosteroids in non-cystic fibrosis bronchiectasis. Other core components of treatment include airway clearance, use of exercise programs and pulmonary rehabilitation, mucolytics, and consideration of long-term antibiotics (e.g., macrolides and inhaled antibiotics) for patients with frequent exacerbations or bacterial isolation.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Brinsupri. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Brinsupri as well as the monitoring required for adverse events and long-term efficacy, approval requires Brinsupri to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Bronchiectasis, Non-Cystic Fibrosis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):

i. Patient is ≥ 12 years of age; AND
ii. Patient has a history of bronchiectasis as diagnosed by chest computed tomography; AND
iii. Patient meets ONE of the following (a or b):
a) Patient is ≥ 12 years of age and < 18 years of age: Patient has had at least one pulmonary exacerbation in the last 12 months that resulted in the prescription of an antibiotic agent; OR
b) Patient is ≥ 18 years of age: Patient has had at least two pulmonary exacerbations in the last 12 months that resulted in the prescription of an antibiotic agent; AND
iv. According to the prescriber, respiratory symptoms are not driven primarily by chronic obstructive pulmonary disease or asthma; AND
v. Patient does not have cystic fibrosis; AND
vi. According to the prescriber, patient is a current non-smoker; AND
vii. The medication is prescribed by or in consultation with a pulmonologist or infectious disease physician; OR

B) Patient is Currently Receiving Brinsupri. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
i. Patient is ≥ 12 years of age; AND
ii. Patient does not have cystic fibrosis; AND
iii. According to the prescriber, patient is a current non-smoker; AND
iv. According to the prescriber, patient has experienced a beneficial clinical response; AND
Note: Examples of beneficial clinical response may include a reduction in the number of exacerbations, preservation of lung function, reduced cough, reduced sputum production, or less shortness of breath.
v. The medication is prescribed by or in consultation with a pulmonologist or infectious disease physician.

CONDITIONS NOT COVERED

- **Brinsupri™ (brensocatib tablets – Insmed)**

is(are) considered not medically necessary for ANY other use(s). Criteria will be updated as new published data are available.

REFERENCES

1. Brinsupri™ tablets [prescribing information]. Bridgewater, NJ: Insmed Incorporated; August 2025.
2. Wang L, Wang J, Zhao G, et al. Prevalence of bronchiectasis in adults: a meta-analysis. *BMC Public Health*. 2024;24(2675): 1-11.
3. McShane PJ, Naureckas ET, Tino G, et al. Non-cystic fibrosis bronchiectasis. *ATS Journals.* 2013;188(6): 1-10.
4. Polverino E, Geominne PC, and McDonnell MJ. European respiratory society guidelines for the management of adult bronchiectasis. *ERJ*. 2017;50(3): 1-23.
5. Hill AT, Sullivan Al, Chalmers JD, et al. British thoracic society guideline for bronchiectasis in adults. *International Journal of Respiratory Medicine*. 2019;74(1): 1-80.
6. Johnson E, Gilmour A, Chalmers JD. Dipeptidyl peptidase-1 inhibitors in bronchiectasis. *Eur Respir Rev*. 2025;34(176): 1-17.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/13/2025
Selected Revision	**Bronchiectasis, Non-Cystic Fibrosis**. For initial therapy, the diagnostic requirement was changed to state that a patient has a history of bronchiectasis as diagnosed by chest computed tomography and the statement in the last five years was removed. The corresponding note defining bronchiectasis was removed. The diagnostic requirement was removed for patients currently receiving Brinsupri. For initial therapy, the requirement that a patient ≥ 12 years of age and < 18 years of age had at least one pulmonary exacerbation was updated to also include that this exacerbation resulted in the prescription of an antibiotic agent. For initial therapy, the requirement that a patient ≥ 18 years of age had at least two pulmonary exacerbations was updated to include that this exacerbation resulted in the prescription of an antibiotic agent. The Note defining pulmonary exacerbations was removed. For initial therapy, the requirement regarding other comorbid respiratory conditions was updated to state that "respiratory symptoms are not driven primarily by chronic obstructive pulmonary disease or asthma." The Note of examples of other comorbid respiratory conditions was removed. For both initial therapy and a patient currently receiving Brinsupri, the specialist requirement was updated to include an infectious disease physician. For a patient currently receiving Brinsupri, the Note of examples defining a beneficial clinical response was updated to include reduced cough, reduced sputum production, or less shortness of breath.	09/03/2025