Brinsupri™ (brensocatib) tablets, 10 mg • 25 mg | inLighten™ Patient Support

This resource and the template letters of medical necessity/exception and appeal at the links within this document provide general guidance for information that health plans/payers may require be submitted as part of prior authorization (PA) requests or appeals of coverage denials. They are not intended to provide legal advice. PA and coverage requirements vary among health plans/payers, and healthcare providers should contact the appropriate health plan or payer for specific information on current coverage policies applicable to BRINSUPRI™ (brensocatib). Healthcare providers are solely responsible for determining the medical necessity for any treatment. This resource and the template letters are not intended to be a substitute for, or an influence on, the healthcare provider's independent clinical decision. Use of these templates or the information presented in this resource does not guarantee coverage for or access to BRINSUPRI.

Completing a PA request for BRINSUPRI

When requesting a PA for BRINSUPRI 10 mg or 25 mg, you may need to provide a **letter of medical necessity or exception** or complete a **medical exception form**, which may require:

- Patient information
- An appropriate diagnosis
- A report on current therapy
- Rationale for use of BRINSUPRI
- Supporting clinical information

PA criteria will vary by health plan and may include*:

- Diagnosis of bronchiectasis based on clinical history and confirmed by chest computed tomography scan

  Example diagnosis codes†:
  - ICD-10-CM J47.0: Bronchiectasis with acute lower respiratory infection
  - ICD-10-CM J47.1: Bronchiectasis with (acute) exacerbation
  - ICD-10-CM J47.9: Bronchiectasis, uncomplicated

- Diagnosis by or in consultation with a specialist
- Patients aged 18 years and older with ≥2 exacerbations **OR** adolescents aged 12 to 17 years with ≥1 exacerbation
- Exacerbations that required antibiotic treatment in the past 12 months

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

*The criteria listed are not exhaustive. PA requirements are plan-specific and vary across health plans and payers.

†ICD-10-CM codes and descriptions are sourced from the Centers for Disease Control and Prevention and National Center for Health Statistics and are used in accordance with public domain guidelines. Information related to diagnostic codes is provided for reference only. Providers should fully evaluate patients and make an independent medical diagnosis and select diagnosis codes that are most appropriate for the specific patient's condition. This information does not guarantee that a patient is appropriate for, or will have insurance coverage for, BRINSUPRI.

Brinsupri™ (brensocatib) tablets, 10 mg • 25 mg | inLighten™ Patient Support

Completing a PA request for BRINSUPRI (cont'd)

Submit forms electronically or by fax, based on plan requirements. Possible outcomes may include approval, request for more information, or denial.

As the healthcare provider, you should modify these letters based on your sole medical judgment and discretion, including details related to your patient's medical history, diagnosis, and treatment plan. Insurance providers may have specific criteria, forms, or procedures that should be used for the PA process.

Click below to download a sample letter of medical necessity/exception for BRINSUPRI.


Sample Letter of Medical Necessity/Exception

Letter of Medical Necessity/Exception

Considerations for submission

- ☐ Submit accurate and complete PA information to reduce delays and unnecessary denials
- ☐ Be sure to meet submission deadlines and keep a record of forwarded documents
- ☐ Follow up with the patient's insurer if you do not receive a decision within a week

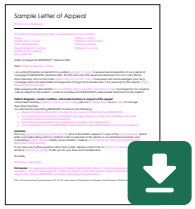
If you have questions related to access for BRINSUPRI, a Field Access Manager may be able to provide support.

Brinsupri™ (brensocatib) tablets, 10 mg • 25 mg | inLighten™ Patient Support

Navigating the appeal process

If a PA request for BRINSUPRI is denied, both you and your patient will receive a letter from the payer specifying the reason for denial and instructions for submitting an appeal. A payer may request additional information or documentation to ensure accurate coverage determination.

Click below to download a sample letter of appeal for BRINSUPRI.



Letter of Appeal

How to appeal a denied claim

- Review the denial letter and/or explanation of benefits. You will want to demonstrate that you understand the reason for the denial
  - Some denials are the result of simple errors (eg, coding) or missing information on forms—correct these as directed by the payer
- Verify the available methods for submitting an appeal, which may include submission in writing or a live peer-to-peer review of the patient's case
- Gather all relevant clinical documentation
- Complete and submit any forms the payer requests as part of your appeal
- Explain why the patient is an appropriate candidate for the medication, despite not meeting the plan's specific criteria, and why an exception is appropriate
- If the appeal is denied, review instructions on the appeal denial letter on how to escalate the appeal

Some plans may require submission electronically, or via phone, fax, or mail. Depending on the plan, there may be an option for a second-level appeal. The denial letter should indicate available options.

INDICATION

BRINSUPRI is indicated for the treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Dermatologic Adverse Reactions

Treatment with BRINSUPRI is associated with an increase in dermatologic adverse reactions, including rash, dry skin, and hyperkeratosis. Monitor patients for development of new rashes or skin conditions and refer patients to a dermatologist for evaluation of new dermatologic findings.

Gingival and Periodontal Adverse Reactions

Treatment with BRINSUPRI is associated with an increase in gingival and periodontal adverse reactions. Refer patients to dental care services for regular dental checkups while taking BRINSUPRI. 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 these vaccines. The use of live attenuated vaccines should be avoided in patients receiving BRINSUPRI.

ADVERSE REACTIONS

The most common adverse reactions ≥2% in the ASPEN trial included upper respiratory tract infection, headache, rash, dry skin, hyperkeratosis, and hypertension. The safety profile for adult patients with NCFB in WILLOW was generally similar to ASPEN, except for a higher incidence of gingival and periodontal adverse reactions.

Less Common Adverse Reactions

Liver Function Test Elevations

In ASPEN, there was an increase from baseline in average ALT, AST, and alkaline phosphatase levels at all time points from Week 4 through Week 56 in both BRINSUPRI 10 mg and 25 mg arms compared to placebo. The incidence of ALT >3X upper limit of normal (ULN) was 0%, 1.2%, and 0.9%; the incidence of AST >3X ULN was 0.2%, 0.3%, and 0.5%; and the incidence of alkaline phosphatase >1.5X ULN was 2.5%, 4.1%, and 4.0% in patients treated with placebo and BRINSUPRI 10 mg and 25 mg, respectively.

Skin Cancers

In ASPEN, the incidence of skin cancers among patients treated with BRINSUPRI 10 mg and 25 mg was 0.5% and 1.9%, respectively, compared to 1.1% in placebo-treated patients.

Alopecia

In ASPEN, the incidence of alopecia among patients treated with BRINSUPRI 10 mg and 25 mg was 1.5% and 1.6% respectively, compared to 0.4% in placebo-treated patients.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no clinical data on the use of BRINSUPRI in pregnant women.

Lactation: There is no information regarding the presence of BRINSUPRI and/or its metabolite(s) in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BRINSUPRI and any potential adverse effects on the breastfed child from BRINSUPRI or from the underlying maternal condition.

Pediatric use: The safety and effectiveness of BRINSUPRI for the treatment of NCFB have been established in pediatric patients aged 12 years and older. Common adverse reactions in pediatric patients aged 12 years and older enrolled in ASPEN were consistent with those in adults. The safety and effectiveness of BRINSUPRI have not been established in pediatric patients younger than 12 years of age.

Please see full Prescribing Information.

insmed®

PP-BRIN-US-00069 08/2025

Brinsupri™
(brensocatib) tablets, 10 mg • 25 mg

inLighten™ Patient Support