Brinsupri®
(brensocatib) tablets, 10 mg·25 mg

Instructions to create a patient list to identify patients aged 12 years and older with a diagnosis of non-cystic fibrosis bronchiectasis in the Oracle Health® EHR system

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.

EHR=electronic health record.

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Please see additional Important Safety Information on last page and full Prescribing Information.

Overview and Limitations

This document is intended to provide health systems with instructions to create a patient list in the Oracle Health® electronic health record (EHR) system to identify patients aged 12 years and older with a diagnosis of non-cystic fibrosis bronchiectasis (NCFB). The instructions are for the Oracle Health EHR system and are not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.

The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for the implementation, testing, monitoring, and ongoing operation of any EHR tools.

Suggested Patient List Criteria

Consider using the clinical criteria below to help identify patients aged 12 years and older with a diagnosis of NCFB who may be candidates for BRINSUPRI®. The clinical data elements provided are only suggestions, and it is strongly recommended that clinical and operational leadership ensure that the final elements align with the expectations and goals of the organization. Eligibility for treatment and treatment selection are always decisions made by the healthcare provider.

- Age: 12 years and older
- Diagnoses:
  - 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
- Treatments for NCFB (antimicrobial medications, airway clearance, pulmonary rehabilitation, etc)

Note: Consider running the report on a regular basis. Once the initial report has been created, it can be saved for future use and subsequent reports can be rerun. Running reports over time helps identify new patients who meet the inclusion criteria.

Instructions

Consider using Oracle Health's Discern Analytics 2.0 (DA2) to create the patient list. Consult your organization if administrative user rights are required to access the reporting tool. Review documentation practices in the EHR before creating the patient report.

1. Launch Discern Analytics 2.0. It may be found as DA2.exe in the applications folder.
2. Click the Domains tab to access available domains.
3. Select File > New > Query, or select the desired domain by double-clicking it. The query wizard will display available categories.
4. In the Qualifications window, select the Age filter and click Modify Filter List. Set the age range to 12 years and older.
5. In the Qualifications window, select the Diagnosis Code filter and click Modify Filter List.
6. Enter and select the bronchiectasis diagnoses ICD-10-CM codes J47.0, J47.1, and J47.9. Click Include.
7. In the Qualifications window, select the Orders > Orders Synonym ID filter and click Modify Filter List.
8. Enter and select the desired treatments for NCFB (antimicrobial therapies, airway clearance, pulmonary rehabilitation, etc). Consider searching by pharmaceutical class, or enter and select individual medications or procedures. Click Include.
9. Set the logic to include the age, the diagnosis codes, 1 or more antimicrobial therapies, and procedures (if included).
10. Add the desired display columns by selecting them and clicking the right arrow or dragging them to the Selected Columns window. Consider current and past medications, encounter history, and other desired patient information to display in the report.
11. Save the query with a unique name (e.g., "Patients aged 12 years and older with a diagnosis of bronchiectasis on treatments for NCFB").
12. Click Query > Query Review or Run Query in Viewer in the Query tab to run and save the query.
13. The results will display. The results may be further manipulated if desired or exported to Excel.

Note: Prior authorization requirements vary by health plan. When reviewing the results of the patient report, consider adjusting the age result filter. Some plans may require that patients aged 18 years and older have 2 or more exacerbations but that adolescents aged 12 to 17 years have 1 or more exacerbations (with the exacerbations requiring antibiotic treatment in the past 12 months).

Notes

- The customer (e.g., physician, medical group, integrated delivery network) shall be solely responsible for the implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and setup (customization) for each EHR system may vary. Insmed Incorporated shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Insmed Incorporated
- While Insmed Incorporated tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and Insmed Incorporated shall have no liability thereto. The instructions are current as of January 2026
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Insmed Incorporated shall have no liability thereto
- The instructions have not been designed for, and are not tools and/or solutions for, meeting Advancing Care Information and/or any other quality/accreditation requirement
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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.

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