NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Brensocatib for treating non-cystic fibrosis bronchiectasis in people 12 years and over

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of brensocatib within its marketing authorisation for treating non-cystic fibrosis bronchiectasis in people 12 years and over.

Background

Bronchiectasis is a long-term debilitating condition where the airways of the lungs are widened, leading to a build-up of excess mucus that can make the lungs more vulnerable to infection.[1] The most common symptom of bronchiectasis is a persistent cough that brings up a large amount of mucus. Other symptoms may include breathlessness, feeling tired, chest pain or tightness and rounded fingertips.[2] People with bronchiectasis can also experience 'flare ups' known as exacerbations. Bronchiectasis is sometimes called non-cystic fibrosis bronchiectasis. This is because bronchiectasis and cystic fibrosis have similar symptoms. However, the treatment and outlook are different for both conditions.[2]

Bronchiectasis may be caused by childhood infection, immunodeficiency or another trigger that results in inflammation in the airways of the lungs. However, in around 50% of cases, no obvious cause can be found.[1] The prevalence of bronchiectasis is increasing worldwide and in the UK is estimated to be up to 566 per 100,000 people.[3] Bronchiectasis is more common in women than in men and around 60% of people diagnosed with bronchiectasis are over 70 years old.[2]

Treatments for bronchiectasis aim to manage the symptoms, reduce the number of exacerbations and prevent further damage. Treatment can be broadly classified as relief of airway obstruction (for example, physiotherapy and medicines to improve clearance of mucus such as mucolytics and hypertonic saline); widening the airways (for example, bronchodilators) and treatment of acute infections.[1,2] Surgery may also be considered for people who have bronchiectasis in a specific area of the lungs and whose symptoms are not controlled by other treatment. For preventing acute exacbations of bronchiestasis, NICE guideline NG117 recommends a trial of antibiotic prophylaxis (with oral or inhaled antibiotics) only in people with repeated acute exacerbations on the advice of a specialist.

The technology

Brensocatib (brand name unknown, Insmed inc.) does not currently have a marketing authorisation in the UK for treating bronchiectasis. It is being studied in a phase 3 clinical trial compared with placebo in people aged 12 to 85 years with a clinical history consistent with non-cystic fibrosis bronchiectasis that is confirmed by chest computerised tomography scan.

Intervention(s)	Brensocatib
Population(s)	People 12 years and over with non-cystic fibrosis bronchiectasis
Comparators	• Established clinical management without brensocatib (such as but not limited to inhaled mucolytics, nebulised hypertonic saline, bronchodilators, and oral and intravenous antibiotics) • Antibiotic prophylaxis
Outcomes	The outcome measures to be considered include: • lung function • pulmonary exacerbations • symptom control • frequency and severity of acute infections • need for hospitalisation and other treatments • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.

Related NICE recommendations	**Related NICE guidelines:** Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing (2018; reviewed April 2019) NICE guideline 117. Review date not stated.

Questions for consultation

Where do you consider brensocatib will fit into the existing care pathway for non-cystic fibrosis bronchiectasis?

Please select from the following, will brensocatib be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would brensocatib be a candidate for managed access?

Do you consider that the use of brensocatib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

How is 'moderate to severe' non-cystic fibrosis bronchiectasis defined in clinical practice? How does this compare to the population included in the key clinical trial informing this evaluation?

Which treatments are considered established clinical management in the NHS for non-cystic fibrosis bronchiectasis in people 12 years and over?

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which brensocatib will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. NHS (2021) Bronchiectasis. Accessed May 2025

2. Asthma & Lung UK (2024) Bronchiectasis. Accessed May 2025

3. Chalmers, JD et al. (2023) Bronchiectasis in Europe: data on disease characteristics from the European Bronchiectasis registry (EMBARC) Lancet Respiratory Medicine, Volume 11, Issue 7: 637-649