



NCPE Plain English Summary

Drug name: Inhaled liposomal amikacin (*pronounced: am-ik-ay-sin*) for the treatment of non-tuberculosis mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis (CF).

Brand name: Arikayce®

What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What is inhaled liposomal amikacin?

Inhaled liposomal amikacin is an aminoglycoside, a type of antibiotic which is used as part of a combination antibiotic drug treatment plan. In this submission, we are considering the use of inhaled liposomal amikacin in adults with refractory (difficult to treat) Mycobacterium avium complex (MAC) lung disease. The place in therapy of this medicine is for patients who have not responded to at least six months of oral antibiotic regimens (referred to as guideline-based therapy (GBT)). The inhaled liposomal amikacin is given in addition to GBT.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding inhaled liposomal amikacin if cost effectiveness (value for money) can be improved. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional [criteria](#) outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that inhaled liposomal amikacin in combination with GBT works better than the current treatments (GBT) available for this disease. However, it is considerably more expensive than current treatments and a price reduction is needed.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about inhaled liposomal amikacin. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about inhaled liposomal amikacin from the following online options:

- the NCPE Technical Summary Document
- Arikayce[®] European Public Assessment Report (EPAR) – [Summary for the Public](#)
or
- searching for inhaled liposomal amikacin on our website (www.ncpe.ie);
- searching for inhaled liposomal amikacin on the European Medicines Agency (EMA) website (www.ema.europa.eu).

Please refer to the NCPE website for updated information on the reimbursement status of this medicine.

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