



NCPE Plain English Summary

Drug name: Lanadelumab for the routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older. **Brand name:** Takhzyro®

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 Lanadelumab used for?

Hereditary angioedema (HAE) is a disease characterized by recurrent episodes (also called attacks) of severe swelling of the skin and mucous membranes. The age at which attacks begin varies, but most people have their first one in childhood or adolescence.

Attacks most often affect 3 parts of the body: the skin, gastrointestinal tract and the upper airway such as the larynx or tongue. They always go away on their own but last from 2 to 4 days. Common triggers of attacks include emotional stress, physical stress, and dental procedures. With this condition the blood does not have enough of a protein called 'C1 inhibitor', or C1 inhibitor does not work properly. This leads to too much 'plasma kallikrein', which in turn produces higher levels of 'bradykinin' in the bloodstream. Too much bradykinin leads to symptoms of HAE like swelling and pain. Management of HAE involves treatment of sudden (acute) attacks and preventing attacks (prophylaxis). Lanadelumab works by blocking the 'plasma kallikrein', thus helping to reduce the amount of 'bradykinin' in the bloodstream and preventing swelling and related symptoms of angioedema. Lanadelumab is used to prevent recurrent attacks.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding lanadelumab unless its 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 lanadelumab may work as well or better than other ways to manage this condition. However, the price of lanadelumab is too high compared to how the condition is currently managed, and therefore we believe that the medicine is very poor value for money.

Next steps

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

Where can I get more information?

You can get more information about lanadelumab from the following online options:

- the NCPE Technical Summary Document
 - Takhzyro[®] European Public Assessment Report (EPAR) – [Summary for the public](#)
- or
- searching for lanadelumab on our website (www.ncpe.ie);

- searching for lanadelumab 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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