NCPE Assessment

Plain English Summary

July, 2024

Drug name: Fenfluramine (pronounced *[fen-flur-a-meen])* for the treatment of seizures associated with Dravet syndrome as add-on therapy to other anti-seizure medicines for patients two years of age and older

Brand name: Fintepla®

HTA ID: 23048

NCPE
National Centre for Pharmacoeconomics, Ireland

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 fenfluramine used for?

Fenfluramine is used to treat seizures associated with Dravet syndrome in patients who are aged two years or older. It is used as an add-on treatment to other anti-seizure medicines when they are not adequately controlling the patients seizures.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding fenfluramine if its cost

effectiveness can be improved relative to existing treatments. 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.

We have received a Patient Organisation Submission from Dravet Syndrome Ireland and Epilepsy Ireland about fenfluramine and shared it with the HSE. This submission will form part of the data that the HSE considers.

Why did we make this recommendation?

We recommend that the HSE consider providing this medicine if the HSE can agree a suitable price reduction with the pharmaceutical company. We believe that fenfluramine treatment may add benefit by reducing seizures in patients with Dravet syndrome, thereby improving patients quality of life. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is not value for money.

Next steps

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

Where can I get more information?

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

- the NCPE Technical Summary Document
- Fintepla European Public Assessment Report (EPAR) – Summary for the public or
- searching for fenfluramine on our website (www.ncpe.ie);
- searching for fenfluramine 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