NCPE Assessment

Plain English Summary

December 2024

Drug name: Selumetinib (pronounced SEL-yoo-MEH-tih-nib) for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above.

Brand name: Koselugo®

HTA ID: 22032

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 selumetinib used for?

Selumetinib is a medicine used to treat plexiform neurofibromas, benign (non-cancerous) tumours along the nerves, when they cause symptoms and cannot be removed by surgery in children from 3 years of age with neurofibromatosis type 1 (NF1).

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding selumetinib. 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 the Neurofibromatosis Association of Ireland about selumetinib and shared it with the HSE. This submission will form part of the data that the HSE considers.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that it is not clear that selumetinib works better than other ways to manage symptomatic and inoperable PNs, particularly in the long-term. The price of selumetinib is too high compared with other ways to manage this condition and we consider this medicine to be poor value for money.

Next steps

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

Where can I get more information?

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

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