

NCPE Assessment

Plain English Summary

March 2025

Drug name: Ivosidenib (pronounced *i-VOH-sih-deh-nib*) for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation who were previously treated with at least one prior line of systemic therapy.

Brand name: Tibsovo®

HTA ID: 23016

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 ivosidenib used for?

Ivosidenib is a cancer medicine that is used to treat adults with the following cancers, but only where the cancer has a change (mutation) in the gene called IDH1 R132:

- Cholangiocarcinoma (a type of biliary tract cancer) that is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body). For this indication, the medicine is used on its own, in patients who have received at least

one prior treatment.

- Acute myeloid leukaemia (a type of blood cancer) that is newly diagnosed, in patients who cannot be treated with standard chemotherapy. For this indication, the medicine is used in combination with azacitidine (another cancer medicine).

In this review we are considering ivosidenib for the treatment of advanced or metastatic cholangiocarcinoma.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding ivosidenib, 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 it is not clear that ivosidenib works better than other ways to manage this condition. The price of ivosidenib is too high compared with other ways to manage this condition and we consider this medicine is very poor value for money.

Next steps

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

Where can I get more information?

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

- the NCPE Technical Summary Document
- Tibsovo® European Public Assessment Report (EPAR) – [Medicine overview](#)
- searching for ivosidenib on our website (www.ncpe.ie)
- searching for ivosidenib 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