



NCPE Plain English Summary

Drug name: Bempedoic acid (*pronounced: Bem pe doic acid*) for the treatment of adults with hypercholesterolaemia (high cholesterol)

Brand name: Nilemdo® and Nustendi®

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 bempedoic acid used for?

Bempedoic acid is used to treat adult patients who present with high cholesterol. It lowers cholesterol by inhibiting a key enzyme (ATP-citrate lyase) involved in the synthesis of cholesterol. By lowering cholesterol it is envisaged that bempedoic acid will protect against cardiovascular disease. It will be used as an addition to current therapy when cholesterol targets are not achieved.

Statins are considered first line therapy and ezetimibe is added if statins are not reducing cholesterol levels adequately. If patients are intolerant of statins then patients will be treated with ezetimibe alone. Bempedoic acid is considered if target cholesterol levels are not achieved with a statin + ezetimibe or with ezetimibe alone (where statins are not tolerated). It comes in two formulations including bempedoic acid alone (Nilemdo[®]) or as a fixed dose combination with ezetimibe (Nustendi[®]).

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding bempedoic acid 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 recommend that the HSE consider not providing bempedoic acid unless the HSE can agree a suitable price reduction with the pharmaceutical company. This is because we believe the medicine may work as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition.

Next steps

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

Where can I get more information?

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

- the NCPE Technical Summary Document
- Searching for bempedoic acid on our website (www.ncpe.ie);
- searching for bempedoic acid 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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