



NCPE Plain English Summary

Drug name: Daunorubicin and cytarabine (*pronounced: daw-noh-roo-bih-sin and sy-tayr-uh-been*) **liposomal formulation** for the treatment of adults with newly diagnosed therapy-related acute myeloid leukaemia (AML) or AML with myelodysplasia-related changes.

Brand name: Vyxeos Liposomal®

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 daunorubicin and cytarabine (liposomal formulation) used for?

Daunorubicin and cytarabine (liposomal formulation) is a cancer medicine used to treat adults with newly diagnosed acute myeloid leukaemia, a cancer of white blood cells. It is

used with the leukaemia was caused by previous treatments (e.g. for other cancers) or is associated with certain changes in the bone marrow known as myelodysplasia.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding daunorubicin and cytarabine liposomal formulation 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 daunorubicin and cytarabine liposomal formulation may work as well or better than other ways to manage this condition. However, the price of daunorubicin and cytarabine liposomal formulation is too high compared with other ways to manage this condition, and 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 daunorubicin and cytarabine liposomal formulation. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about daunorubicin and cytarabine liposome from the following online options:

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

Date published: April 2020