

NCPE Assessment

Plain English Summary

March, 2026

Drug name: Givinostat (pronounced [*giv-IN-oh-stat*]) for the treatment of Duchenne muscular dystrophy in ambulant patients aged six years and older with concomitant corticosteroid treatment.

Brand name: Duvyzat®

HTA ID: 25048

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 givinostat used for?

Duchenne muscular dystrophy (DMD) is a severe, progressive genetic muscle disorder, primarily affecting young boys. It is characterised by loss of dystrophin protein leading to muscle weakness and wasting. Early symptoms include an unsteady gait, frequent falls, difficulty in standing from a seated position and in climbing stairs. At ages ten to twelve years many patients require the use of a wheelchair. Assisted ventilation may be required by fifteen to twenty years of age. Givinostat is approved for the treatment of DMD in patients

aged six years and older who are able to walk and are already being treated with corticosteroids.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding givinostat 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.

We have received a Patient Organisation Submission from Muscular Dystrophy Ireland about givinostat and shared it with the HSE. This submission will form part of the data that the HSE considers.

Why did we make this recommendation?

The severity of a diagnosis of DMD is appreciated and the benefit of givinostat is documented in the pivotal clinical trial. Although givinostat is not considered a cure for DMD the combination of givinostat plus corticosteroid treatment may lead to improved health outcomes in patients with DMD. After reviewing the data presented by the pharmaceutical company, we recommend that the HSE consider not providing this medicine unless the HSE can agree a suitable price reduction.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data in relation to givinostat. The HSE makes the final decision on reimbursement.

Where can I get more information?

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

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

- searching for givinostat on the European Medicines Agency (EMA) website (www.ema.europa.eu).

Please refer to the [HSE website](#) for updated information on the reimbursement status of this medicine.