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Deputy Michael Healy-Rae
Dáil Éireann
Leinster House
Kildare Street
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11th December 2023

PQ52008/23- Deputy Healy-Rae- To ask the Minister for Health if the provision of an osteoporosis medication (details supplied) for the Irish market will be examined and expedited; and if he will make a statement on the matter.

Dear Deputy Healy-Rae,

Thank you for your representation.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from available resources.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement, in line with the Health (Pricing and Supply of Medical Goods) Act 2013:

(1) The health needs of the public,
(2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(3) The availability and suitability of items for supply or reimbursement,
(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,

(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and,
(9) The resources available to the HSE.

In terms of the specific details of the application for pricing and reimbursement of Romosozumab (Evenity®):

- The HSE received an application for pricing and reimbursement of Romosozumab (Evenity®) on the 20th April 2021 from UCB Pharma (the applicant) indicated for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 21st April 2021.

- The NCPE Rapid Review assessment report was completed by the NCPE on the 27th May 2021. A full HTA was recommended to assess the clinical effectiveness and cost effectiveness of Romosozumab (Evenity®) compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 28th June 2021 as per agreed processes.

- The NCPE Health Technology Assessment report (https://ncpe.ie/wp-content/uploads/2021/05/Technical-summary-romosozumab-Evenity-21016.pdf) was received by the HSE on the 7th of March 2023. The NCPE recommended that Romosozumab (Evenity®), for the treatment of women who are postmenopausal with severe osteoporosis who have experienced a major osteoporotic fracture (hip, vertebrae, distal radius, proximal humerus) within the previous 24 months and who are at imminent risk of another fragility fracture, be considered for reimbursement if cost-effectiveness can be improved relative to existing treatments. This is a subpopulation of the product licence (indication).

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. The HSE Drugs Group consider all of the evidence and make a recommendation to the HSE Executive Management Team. The application for Romosozumab (Evenity®) was considered by the Drugs Group at the August 2023 meeting. The Drugs Group recommended in favour of reimbursement of Romosozumab (Evenity®) subject to an improved commercial offering. This recommendation (if realised) is also subject to there being an individual patient approval system put in place by the HSE, to enable reimbursement for patients who meet the pre-defined criteria as per a HSE devised managed access protocol.

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

The application for Romosozumab (Evenity®) remains under consideration and therefore at this point the HSE cannot make any comment on possible outcomes from the ongoing process.

I hope this provides you with some assistance.

Yours sincerely

Sharon Hayden
General Manager
Office of the Chief Clinical Officer