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Denis Naughton, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

3rd March, 2020

PQ: 2994/20

To ask the Minister for Health when an assessment (details supplied) will be completed; the status of same; and if he will make a statement on the matter. - Denis Naughten

Burosumab NCPE assessment

Dear Deputy Naughton,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 2994/20), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible in as timely a fashion as possible using the resources available (provided) to it.

In doing so, the HSE robustly assesses applications to ensure available resources can be stretched as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients. Were the HSE not to do so, the Irish taxpayer would be faced with funding demands of hundreds of millions in excess of current demands i.e. the assessment and decision making processes continue to deliver significantly improved offerings to the Irish State enabling the State to provide patient access to medicines.

The HSE will consider a pricing application for each new medicine or indication (approved use) in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE considers the following criteria prior to making any decision on funding / reimbursement:

(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

There are formal processes negotiated between the representative body of the pharmaceutical industry ("IPHA") and the State which govern the pricing and reimbursement of new medicines to be funded and / or reimbursed. The application for burosumab (Crysvita®) for the treatment of X-linked hypophosphataemia (XLH) with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons is being progressed as per national processes.

In terms of the specific details of the application for pricing and reimbursement of burosumab (Crysvita®):

The HSE received an application from Kyowa Kirin for pricing and reimbursement of burosumab (Crysvita®) on 22nd November 2018.

- Following receipt and consideration of the rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) on 21st December 2018 advised that a full Health Technology Assessment (HTA) was required.

- The HSE commissioned a full HTA on 8th January 2019. The company HTA dossier was received by the NCPE on 3rd July 2019. The NCPE has published the details of its engagements on the HTA on its website and these are available at: http://www.ncpe.ie/drugs/burosumab-crysvita/

- The HSE received the HTA assessment report from the NCPE on the 13th March 2020. The NCPE HTA report recommended that burosumab (Crysvita®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments.

- This report and the pricing & reimbursement application is currently being considered by the HSE. If necessary the HSE Corporate Pharmaceutical Unit (CPU) will engage with the applicant company to discuss and explore solutions to issues raised in NCPE HTA report.

- The HSE Drugs Group is an internal expert committee of the HSE. Its principal function is to provide advice to the HSE Executive Management Team in relation to applications for the pricing and reimbursement of medicines arising out of the information included in the NCPE HTA report, the company response, patient interest group submission and any commercial discussions. The responsibility of the Drugs Group is to make a recommendation in relation to each individual application having considered the criteria set out in the Health (Pricing and Supply of Medical Goods) Act 2013 in relation to pricing and reimbursement of new medicines.

- The final decision making is reserved to the HSE Executive Management Team.

- The HSE does not reimburse medicines or agree reimbursement terms in advance of the completion of the required processes and considerations. Therefore a decision has yet to be made in relation to the application for burosumab (Crysvita®) for the treatment of X-linked hypophosphataemia (XLH) with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons.

In summary, the HSE is committed to providing access to as many medicines as possible in as timely a fashion as possible from the resources available (provided) to it. There are formal processes which govern the pricing and reimbursement of medicines and the application process for new medicines to be funded via hospitals and / or reimbursed via the Community Drug Schemes. HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds. The HSE robustly assesses applications for 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. The application for reimbursement of burosumab (Crysvita®) is still under consideration and the HSE cannot comment on likely or possible decisions while this process is ongoing.

Yours sincerely,

Kieran Healy
Primary Care Eligibility & Reimbursement Service