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BY EMAIL ONLY

Deputy Jennifer Whitmore
Dáil Éireann
Leinster House
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7th November 2024

PQ44901/24-Deputy Jennifer Whitmore- To ask the Minister for Health the reasons the administration of interferon-alpha (details supplied) has been suspended; the alternative that is offered to patients previously on the drug; and if he will make a statement on the matter.

Dear Deputy Whitmore,

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 the resources available (provided) to it.

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 Ropeginterferon alfa-2b (Besremi®):

- The HSE received an application for pricing and reimbursement of Ropeginterferon alfa-2b (Besremi®) on the 20th January 2023 from AOP Orphan (the applicant) indicated as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly.

- 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 20th January 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 15th March 2023. The NCPE advised the HSE that a full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Ropeginterferon alfa-2b compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 29th March 2023 as per agreed processes.

- The NCPE Health Technology Assessment Report was received by the HSE on the 15th August 2024. The NCPE recommended that Ropeginterferon alfa-2b (Besremi®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments. (https://www.ncpe.ie/ropeginterferon-alfa-2b-besremi/)

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. CPU have offered to meet the applicant to discuss this application and address any issues arising from the HTA report.

- The HSE 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 pharmacoeconomic report will be reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group will consider all of the evidence and make a recommendation to the HSE Senior Leadership Team.

- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership 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 uses 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.

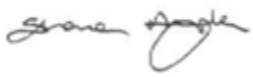
The application remains under consideration. The HSE cannot make any comment on possible outcomes from the ongoing process.

The HSE is aware of the ongoing shortage of Pegasys® (Peginterferon-alfa-2a) solution for injection in pre-filled syringe 135mcg and 180mcg which is under High Tech Arrangements. The supplier has stated that the recent shortage is due to an unexpected increase in demand. The HPRA works with a variety of stakeholders including the HSE to respond to potential shortages and reduce the impact of shortages on patients. Where community pharmacies are unable to access the licensed product due to supply issues, the HSE Primary Care Reimbursement Service (PCRS) have supported reimbursement of Exempt Medicinal Products (EMPs) under Community Drug Schemes.

Furthermore, the HSE PCRS have progressed reimbursement of Pegasys® 90mcg under High Tech Arrangements. Community pharmacy contractors can contact PCRS with queries regarding reimbursement support of Pegasys® under Community Drug Schemes.

I hope this provides you with some assistance.

Yours sincerely



Sharon Hayden
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