Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Sean Sherlock, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

8th August 2024

PQ: 31553/24

To ask the Minister for Health the process for making a medicine available to a patient under section 23 of the Health (Pricing and Supply of Medicinal Goods) Act 2013 when the medicine identified by a clinician is not on the reimbursement list; and if he will make a statement on the matter. -Sean Sherlock

Dear Deputy Sherlock,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 31553/24), which you submitted to the Minister for Health for response.

There is a National Application, Assessment & Decision Process for new medicines which is underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE must comply with the relevant legislation when considering investment decisions around new medicines. The Corporate Pharmaceutical Unit (CPU) is the unit within the HSE that is responsible for accepting and considering pricing and reimbursement applications from the pharmaceutical industry.

Pharmaceutical companies are required to submit formal applications if they wish their medicines to be added to the list of reimbursable items / funded via hospitals. This process first involves a company making an application and submitting a clinical and economic dossier to support its pricing and reimbursement application. That dossier is reviewed by experts at the National Centre for Pharmacoeconomics (NCPE). The NCPE then provides a report to the HSE in relation to the company dossier. The NCPE process also enables the provision of a Patient Interest Group Submission. The NCPE uses a decision framework to systematically assess whether a drug is cost-effective as a health intervention. The NCPE makes recommendations on reimbursement to assist HSE decisions.

The HSE must then consider the report and the pricing & reimbursement application from the company. Frequently the HSE Corporate Pharmaceutical Unit will engage with companies to discuss and explore solutions to issues raised in NCPE reports.

The HSE has a national committee, the HSE Drugs Group, which is set up to provide advice to the HSE Executive Management Team (EMT) arising out of the information included in the NCPE 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 down by the Oireachtas in relation to pricing and reimbursement of new medicines.

The HSE must consider 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

Final Decision making is reserved to the HSE Executive Management Team (EMT).

Exceptional arrangements are considered under Section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013 - Supply of items not on Reimbursement List. The HSE must be satisfied that:

(a)The patient requires that item for clinical reasons, and
(b) There is no listed item which is a suitable alternative for that item in so far as that patient is concerned.

Medicines not on the Reimbursement List such as exempt medicinal products (unlicensed medicines) are considered under Section 23 of the Act on an individual patient basis. This is a prescriber progressed exceptional arrangement for unmet clinical need. It does not include licensed medicinal products undergoing formal pricing and reimbursement as outlined above in line with the 2013 Act.

Applications for reimbursement support for items not on the Reimbursement List are reviewed on an individual patient basis. An individual reimbursement application is required to be completed and submitted by the prescribing consultant in all cases. It is important in any individual reimbursement application that there is sufficient detail to enable a positive decision.

Yours sincerely,

Suzanne Doyle