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David Cullinane, T.D.
Dáil Éireann,
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1st May 2024

PQ: 19441/24

To ask the Minister for Health the reason public funding of CAR-T immunotherapy for leukaemia patients is limited to under 26 years of age; if consideration has been given to extending the age for funding of treatment option to beyond the age of 26 years; and if he will make a statement on the matter.-David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 19441/24), which you submitted to the Minister for Health for response.

Tisagenlecleucel (Kymriah®)

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 processing pricing and reimbursement applications from the pharmaceutical industry. Pharmaceutical companies are required to submit formal applications to the HSE if they wish their medicines to be added to the list of reimbursable items covered under community drugs schemes and arrangements / funded via hospitals. In order to submit a formal application the medicine must hold a marketing authorisation.

The European Medicines Agency (EMA) is a centralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. The EMA plays an integral role in the authorisation of medicines in the EU via the centralised procedure.

The Health Products Regulatory Authority (HPRA) is the competent authority responsible for the regulation of human medicines in Ireland. A company can submit an application for a marketing authorisation directly to the HPRA if the product in question is not required to be approved through the centralised procedure.

Tisagenlecleucel (Kymriah®) for the treatment of paediatric and young adult patients up to 25 years of age with B cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post transplant or in second or later relapse has been approved for reimbursement under the Oncology Drug Management System from 1st July 2021.

To date neither the EMA nor the HPRA have granted marketing authorisation for Tisagenlecleucel (Kymriah®) for the treatment of leukaemia in patients over 25 years of age.

As outlined above, the national assessment and decision process cannot commence in the absence of a marketing authorisation.

Brexucabtagene autoleucel (Tecartus®)

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 Brexucabtagene autoleucel (Tecartus®):

The HSE received a complete application for pricing and reimbursement on the 24th July 2023 from Gilead (the applicant) for Brexucabtagene autoleucel (Tecartus®) for the treatment of adults 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia:

- 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 24th July 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 10th August 2023. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Brexucabtagene autoleucel (Tecartus®) compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 31st August 2023 as per agreed processes.

- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessment(s) of Brexucabtagene autoleucel (Tecartus®) are available at: https://www.ncpe.ie/brexucabtagene-autoleucel-tecartus-hta-id-23045/

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications.

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

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

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie