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PQ 49594/25 To ask the Minister for Health the current policy regarding access to CAR-T cell therapy for patients over the age of 26 with refractory acute lymphoblastic leukaemia; the rationale for the existing eligibility criteria; whether funding or pathways are available for patients to access this treatment abroad where clinically appropriate; and if she will make a statement on the matter

Dear Deputy O Shea,

CAR-T cell therapy is available for specific indications and patient populations in Ireland.

Before a medicine can be marketed for sale in the EU it must receive a marketing authorisation (licence) from the European Medicines Agency (EMA). The EMA is responsible for the approval and regulation of medicines across all European Union member states and the European Economic Area (EEA). This involves the scientific evaluation, supervision and safety monitoring of to ensure that all medicines available on the EU market are safe, effective and of high quality.

A medicine may be licensed by the EMA with an age restriction due to regulatory review processes and the available clinical trial data. This decision will reflect specific data used to support the marketing authorisation which may have identified that there was not sufficient robust evidence presented to support its use in certain age groups. With regard to refractory acute lymphoblastic leukaemia (ALL) there can be differences in the management and outcomes of patients under 26 years of age with relapsed/refractory B-cell ALL that influence regulatory decisions. Factors like disease progression and response to other treatments may be different in this age group.

The HSE has a standard assessment process in place for the consideration of the reimbursement of new drugs and new indications for existing drugs. This process is intended to arrive at decisions on the funding of drugs that are clinically appropriate, fair, consistent and sustainable. The assessment process is underpinned by the Framework Agreement on the Supply and Pricing of Generic, Biosimilar and Hybrid Medicines (2021) and the Health (Pricing and Supply of Medical Goods) Act 2013. All cancer drugs including immunotherapy agents which have been approved for reimbursement since 2012 have gone through this process. Before a medicine is licensed for use and can be marketed for sale in the European Union, it must receive a market authorisation (license) from the European Medicines Agency (EMA), which as per the above may include an age restriction. Once a drug/ drug indication is licensed the company may apply to the HSE for reimbursement approval using the standard assessment process. The authority to

approve the expenditure of funds on new medicines or new uses of existing medicines across the HSE is reserved to the HSE National Senior Leadership Team.

The table below outlines the EMA licensed CAR-T therapies currently approved for reimbursement by the HSE to date:

Drug	Indication	Date Approved for reimbursement by the HSE
Tisagenlecleucel (Kymriah®)	For the treatment of paediatric and young adult patients up to and including 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse.	July 2021
	For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.	July 2021
	For the treatment of adult patients with relapsed/refractory follicular lymphoma after 2 or more lines of therapy.	July 2025
Axicabtagene ciloleucel (Yescarta®)	For the treatment of adult patients with relapsed or refractory DLBCL and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy.	April 2022
Ciltacabtagene autoleucel (Carvykti®)	For the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy	October 2025

Brexucabtagene autoleucel (Tecartus®) is licensed by the EMA for the following indication:

- treatment of adult patients 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL)

The company, Gilead Sciences Ireland, have made an application to the HSE for reimbursement for the use of brexucabtagene autoleucel for the above indication. This is being considered in line with the standard assessment process.

There are other CAR-T therapy indications under consideration by the HSE and people with other types of cancer might receive it as part of a clinical trial.

Yours sincerely,

Patricia Heckmann
Assistant National Director
National Cancer Control Programme