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Mr. Marc McSharry, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

24th July, 2019

PQ: 30373/19

To ask the Minister for Health the estimated budgetary impact for all medicines for rare cancers that are seeking reimbursement with the HSE; and if he will make a statement on the matter. - Marc MacSharry

Dear Deputy McSharry,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 30373/19), which you submitted to the Minister for Health for response.

Assessments are ongoing in relation to a range of such applications currently. One of the roles of the assessment process is to establish the potential budget impact of medicines and until the assessments are completed information in relation to budget impact is not available and/or is not validated for all such medicines. The following is the list of current medicines which fall within the scope of the PQ and a summary of where they are within the process:

Generic Name	Brand	Indication	Company	Position as at June 2019
Irinotecan Liposome Injection	Onivyde	Pancreatic Cancer	Shire	Health Technology Assessment commissioned
Daratumumab in combination with Bortezomib and Dexamethasone (DAR+BOR+DEX)	Darzalex	Multiple Myeloma (Combination Therapy)	Janssen	Drugs Group recommendation with HSE Senior Leadership
Eltrombopag Review	Revolade	Idiopathic Thrombocytopenia	Novartis	Health Technology Assessment commissioned
Avelumab	Bavencio	1st line Metastatic Merkel Cell Carcinoma	Merck Serono	Additional clinical information being reviewed

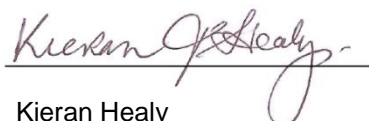
Generic Name	Brand	Indication	Company	Position as at June 2019
Brentuximab	Adcetris	License extension for CD30+ cutaneous T cell lymphoma (CTCL)	Takeda	Health Technology Assessment commissioned
Gemtuzumab Ozogamicin	Mylotarg	Acute Myeloid Leukaemia	Pfizer	Health Technology Assessment commissioned
Niraparib	Zejula	Ovarian Cancer	Tesarobio	Health Technology Assessment commissioned
Midostaurin	Rydapt	Acute Myeloid Leukaemia & Aggressive Systemic Mastocytosis	Novartis	Health Technology Assessment commissioned
Axicabtagene Ciloleucel	Yescarta	DLBCL / PMBCL	Kite Pharma (Gilead)	Health Technology Assessment commissioned
Liposomal Daunorubicin / Cytarabine	Vyxeos	AML	Jazz Pharmaceuticals	Health Technology Assessment commissioned
Tisanglecleucel	Kymriah	DLBCL / ALL	Novartis	Health Technology Assessment commissioned
Venetoclax	Venclyxto	Combination CLL	Abbvie	Health Technology Assessment commissioned
Lutetium-177	Lutathera	Gastroenteropancreatic Neuroendocrine Tumours	Advanced Accelerator Apps	Health Technology Assessment commissioned
Carfilzomib in combination with Dexamethasone	Kyprolis	Multiple Myeloma	Amgen	Drugs Group recommendation with HSE Senior Leadership

Daratumumab in combination with Bortezomib and Dexamethasone is the application in the above for which a full assessment has been completed, the NCPE reported (on its website: <http://www.ncpe.ie/wp-content/uploads/2017/11/Summary-Daratumumab-Combination-Final.pdf>) the following in relation to the potential budget impact of this combination therapy:

“The price to wholesaler is €456 for a 5ml vial containing 100mg of DAR (20mg/ml) and €1,824 for a 20ml vial containing 400mg of DAR (20mg/ml). The average annual cost per patient of DAR+BOR+DEX, including all relevant fees, mark-ups and rebates, is estimated as €111,365 and €104,969 for DAR alone. Based on company estimates of market share, the applicant estimates that there will be 38 patients receiving DAR+BOR+DEX in year 1, rising to 81 in year 5. The projected gross budget impact including drug acquisition costs only for DAR+BOR+DEX is estimated as €4,320,945 (year 1), €8,743,480 (year 2), €10,289,434 (year 3), €9,836,161 (year 4) and €8,986,771 (year 5). This results in a cumulative gross budget impact of €42.2M over 5-years. The applicant also presented a net drug budget impact representing the gross budget impact when DAR is introduced minus the gross budget impact of continuing the current treatment pathway for RRMM assuming DAR+BOR+DEX is not introduced. The cumulative net drug budget impact over 5-years is estimated as €16.4M. An additional net budget impact is presented including costs associated with administration, subsequent treatment, AEs, monitoring and a one-off cost for terminal care. The cumulative net budget impact over 5-years is estimated as €11.8M.”

The HSE following the HTA report engaged in commercial discussions with Janssen (the applicant company) and has achieved price reductions which will reduce the above budgets impact. This medicine is the subject of a Drugs Group recommendation which is under deliberation at the HSE Senior Leadership Team. Janssen, the applicant company as a condition of making any commercial offer required that the terms of any such offer be maintained as commercially confidential by the HSE.

Yours sincerely,

A handwritten signature in cursive script, reading "Kieran Healy", written over a horizontal line.

Kieran Healy
Primary Care Eligibility & Reimbursement Service