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Deputy Louise O'Reilly,
Dáil Eireann,
Leinster House,
Kildare Street,
Dublin 2

PQ 3598/20 –To ask the Minister for Health the number of cancer medicines that have been fully approved by the HSE leadership team but are awaiting funding for reimbursement; and the names of such medicines and the cancers they treat.

Dear Deputy O'Reilly,

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

The following drug applications have received positive recommendations from the Drugs Group and have been progressed to the HSE Executive Management Team for consideration for reimbursement, but note that none have been fully approved by the HSE - nor can they be fully approved until funding has been identified in order to commence reimbursement.

Name	Indication
Carfilzomib (Kyprolis®)	Carfilzomib in combination with Dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
Daratumumab (Darzalex®)	Daratumumab in combination with Bortezomib and Dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
Osimertinib (Tagrisso®)	Osimertinib for the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation positive non-small cell lung cancer
Gemtuzumab ozogamicin (Mylotarg®)	Gemtuzumab ozogamicin in combination with Daunorubicin (DNR) and Cytarabine (AraC) for the treatment of patients ≥15 years with previously untreated, <i>de novo</i> CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL)
Pertuzumab (Perjeta®)	Pertuzumab for the treatment of adult patients in combination with Trastuzumab and chemotherapy in the neoadjuvant treatment of HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence

Pembrolizumab (Keytruda®)	Pembrolizumab in combination with Carboplatin and either Paclitaxel or nab-Paclitaxel, for the first line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in adults
Pembrolizumab (Keytruda®)	Pembrolizumab in combination with Pemetrexed and platinum chemotherapy, for the first line treatment of metastatic non-squamous non-small cell lung cancer (NSCLC) in adults whose tumours have no EGFR or ALK positive mutations
Pembrolizumab (Keytruda®)	Pembrolizumab as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy
Pembrolizumab (Keytruda®)	Pembrolizumab as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10
Venetoclax (Venclyxto®)	Venetoclax in combination with Rituximab, is indicated for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy
Nivolumab (Opdivo®)	Nivolumab as monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection

The above applications are currently receiving active consideration by the HSE but in the context that no specific funding has been provided in 2020 for the reimbursement of new drugs. The challenges around affordability of new medicines generally are significant and many of these drugs are expensive medicines. The HSE estimates that it would require in excess of €30m in 2020 to provide access to the new medicines which are currently being assessed. This is on top of the €2.5bn the HSE is already spending this year on medicines and in the context that the cost of medicines is increasing at about three times the rate of inflation, due in large part to the very high prices now being charged by manufacturers for many medicines. It should also be noted that the HSE as a public body is required to manage and operate within the resources provided to it.

I can assure you that the HSE is continuing to review all options internally to try to address the needs of all of the patients in this position, and that we are in regular contact with the Department of Health in relation to the affordability issues and the possible sources of funding for new drugs in 2020.

I trust this information is of assistance to you and I will be in contact as soon as further information is available.

Yours sincerely,


John Hennessy
National Director
Acute Strategy & Planning