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Monday, 22<sup>nd</sup> July 2019

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

**PQ 29464/19 – To ask the Minister for Health the decisions taken by the senior leadership team of the HSE at its monthly sittings relating to drugs reimbursement and the recommendations issued by the drugs group of the HSE to the team on same in tabular form; and if he will make a statement on the matter.**

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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.

Please find attached a list of drugs which were submitted by the Drugs Group to the Leadership Team for decision for the period 2017 to 2019 (year to date), including the decision of both groups.

I trust the attached information is of assistance to you but please contact me if you have any further queries.

Yours sincerely,

  
**John Hennessy  
National Director  
Acute Strategy & Planning**

No.	Generic Name	Brand	Indication	Company	Drugs Group Recommendation	Leadership Decision
1	Isavuconazole	Cresemba (oral)	Invasive Aspergillosis and Mucormycosis	Basilea	Recommended (Mar-17)	Approved for funding / reimbursement
2	Isavuconazole	Cresemba (IV)	Invasive Aspergillosis and Mucormycosis	Basilea	Recommended (Mar-17)	Approved for funding / reimbursement
3	Mepolizumab	Nucala	Severe refractory eosinophilic asthma in adult	GSK	Recommended (Jun-17)	Approved for funding / reimbursement
4	Trametinib	Mekinist	Melanoma (in combination with Dabrafenib)	Novartis	Recommended (May-17)	Approved for funding / reimbursement
5	Cobimetinib	Cotellic	Melanoma (in combination with Vemurafenib)	Roche	Recommended (May-17)	Approved for funding / reimbursement
6	Pembrolizumab	Keytruda	1st Line Non-small cell lung carcinoma (PD-L1 TPS ≥50%)	MSD	Recommended (Dec-17)	Approved for funding / reimbursement
7	Daratumumab	Darzalex	Multiple Myeloma	Janssen	Recommended (Dec-17)	Approved for funding / reimbursement
8	Nivolumab	Opdivo	Head & Neck Squamous Cell Carcinoma progressing after platinum based chemotherapy	BMS	Recommended (Feb-18)	Approved for funding / reimbursement
9	Elosulfase Alfa	Vimizim	Mucopolysaccharidosis type IV A (Morquio A syndrome, MPS IVA) in patients of all ages.	Biomarin	Not Recommended for general reimbursement (Jan-18)	Approved for funding / reimbursement under managed access arrangement.
10	Palbociclib	Ibrance	Metastatic Breast Cancer	Pfizer	Recommended (Mar-18)	Approved for funding / reimbursement
11	Carfilzomib (Car)	Kyprolis	In combination with Lenalidomide (Len) and Dexamethasone (Dex) for the treatment of adult patients with multiple myeloma who have received at least one prior therapy	Amgen	Recommended (May-18)	Approved for funding / reimbursement
12	Nivolumab	Opdivo	2nd Line Non-Small Cell lung Carcinoma	BMS	Recommended (June-18)	Approved for funding / reimbursement
13	Pembrolizumab	Keytruda	RESTRICTED: adult patients who are transplant-ineligible and have failed brentuximab vedotin (BV)	MSD	Recommended (June 18)	Approved for funding / reimbursement

No.	Generic Name	Brand	Indication	Company	Drugs Group Recommendation	Leadership Decision
14	Venetoclax	Venclyxto	Relapsed Refractory Chronic lymphocytic leukaemia (CLL)	Abbvie	Recommended (Sep 18)	Approved for funding / reimbursement
15	Ixazomib	Ninlarno	In combination with Lenalidomide (Len) and Dexamethasone (Dex) for the treatment of adult patients with multiple myeloma who have received at least one prior therapy	Takeda	Recommended (Sep 18)	Approved for funding / reimbursement
16	Sapropterin	Kuvan	Hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU)	Biomarin	Recommended (Sep 18)	Approved for funding / reimbursement
17	Obeticholic Acid	Ocaliva	Primary Biliary Cholangitis	Intercept	Not Recommended (Sep-18)	Negative Recommendation accepted, process ongoing
18	Benralizumab	Fasenri	Severe refractory eosinophilic asthma in adult	Astra Zeneca	Recommended	Approved for funding / reimbursement
19	Reslizumab	Cinquaero	Severe refractory eosinophilic asthma in adult	Teva	Recommended	Approved for funding / reimbursement
20	Selexipag	Uptravi	Pulmonary Arterial Hypertension	Actelion	Recommended (Oct-18)	Approved for funding / reimbursement
21	Blinatumomab	Blinicyto	Relapsed Refractory Acute Lymphocytic Leukaemia	Amgen	Recommended (Oct-18)	Approved for funding / reimbursement
22	Inotuzumab	Besponsa	Relapsed Refractory Acute Lymphocytic Leukaemia	Pfizer	Recommended (Oct-18)	Approved for funding / reimbursement
23	Naltrexone Bupropion	Mysimba	Weight Loss	Orexigon	Not Recommended (Oct-18)	Negative Recommendation accepted, process ongoing
24	Evolocumab	Repatha	Hypercholestoraemia	Amgen	Recommended (Oct-18)	Approved for funding / reimbursement
25	Tolvaptan	Jinarc	Autosomal Dominant Polycystic Kidney Disease	Otsuka	Recommended (Oct-18)	Approved for funding / reimbursement
26	Idebenone	Raxone	Leber's Hereditary Optic Neuropathy	Santhera	Recommended (Oct-18)	Approved for funding / reimbursement
27	Ataluren	Translarna	Duchenne Muscular Dystrophy	PTC	Recommended (Nov-18)	Approved for funding / reimbursement

No.	Generic Name	Brand	Indication	Company	Drugs Group Recommendation	Leadership Decision
28	Obinotuzumab	Gazyvaro	1st Line Follicular Lymphoma	Roche	Recommended (Oct-18)	Approved for funding / reimbursement
29	Avelumab	Bavencio	Metastatic Merkel Cell Carcinoma	Merck Serono	Recommended (Dec-18)	Approved for funding / reimbursement
30	Dinutuximab	Qarziba	Neuroblastoma	EUSA Pharma	Recommended (Jan-19)	Approved for funding / reimbursement
31	Alectinib	Alecensa	1st line ALK+ Non small cell lung cancer	Roche	Recommended (Feb-19)	Approved for funding / reimbursement
32	Mercaptamine	Procysbi	Cystinosis	Chiesi	Recommended (subject to price Dec-18)	Approved for funding / reimbursement
33	Sebelipase alfa	Kanuma	LAL Deficiency	Alexion	Recommended (Feb-19)	Approved for funding / reimbursement
34	Cariprazine	Reaglia	Schizophrenia	Recordati	Recommended (Mar-19)	Approved for funding / reimbursement
35	Blinatumomab	Blinicyto	Paediatric ALL	Amgen	Recommended (Mar-19)	Approved for funding / reimbursement
36	Ocrelizumab	Ocrevus	Multiple Sclerosis (RMS)	Roche	Recommended subject to control system (Apr-19)	Approved for funding / reimbursement
37	Nusinersen	Spinraza	Spinal Muscular Atrophy	Biogen	Not Recommended for general reimbursement (Apr-19)	Approved for funding / reimbursement under managed access arrangement.
38	Osimertinib	Tagrisso	2nd Line Non Small Cell Lung Cancer	Astra Zeneca	Recommended (May-19)	Ongoing
39	Carfilzomib	Kyprolis	Multiple Myeloma	Amgen	Recommended (May-19)	Ongoing
40	Ocrelizumab	Ocrevus	Multiple Sclerosis (PPMS)	Roche	Recommended (Jun-19)	Ongoing
41	Daratumumab	Darzalex	Multiple Myeloma	Janssen	Recommended (May-19)	Ongoing