Drugs Group Minutes: Meeting of 11th September 2018, 14.00

Venue: Boardroom, Dr Steevens Hospital

1. **Minutes of Previous Meetings**

a. Minutes of June 2018 were approved

2. **Declaration of Interests / Nil Interests**: None. Professor Barry did not vote on the Sapropterin application due to his role in the production of the Guideline considered.

3. **Matters arising/ Update on Medicines considered at previous meetings:**

i. Carfilzomib for Multiple Myeloma: Approved by SLT, now reimbursed

ii. Nivolumab 2nd line Non-Small Cell Lung Cancer: Approved by SLT, now reimbursed

iii. Pembrolizumab for 2nd line Non-Small Cell Lung Cancer: A change in dose from weight based to a flat dose approved by the EMA resulted in a significant increase in cost for this indication over that assessed / recommended. The Drugs Group agreed that CPU should revert to MSD to discuss same and in parallel the NCCP might consider whether any issues arose in relation to preferential use of one immunotherapy over another given the revised flat dosing now approved for both agents currently available for reimbursement under the ODMS.

iv. Pembrolizumab for Classical Hodgkin Lymphoma: Approved by SLT 11/09/18 and would be progressed to reimbursement.

4. **Medicines for Consideration**

i. 18013 Osimertinib for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC): After a vote, the HSE Drugs Group did NOT support reimbursement of Osimertinib (Tagrisso®) for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation positive NSCLC. The Group considered the magnitude of unmet need and the overall survival evidence in the context of the costs that would have to be funded. Notwithstanding a confidential commercial offer the application could not be considered to be a cost-effective use of resources. Using the applicant preferred base case the final approximated ICER remains

substantially above conventional willingness to pay thresholds. Additionally concern remained that the applicants' submitted model may be an underestimate of the true ICER.

ii. 17016 Obeticholic acid for Primary Biliary Cholangitis/Cirrhosis (PBC): Following a revision in the commercial offering the Drugs Group reviewed Obeticholic acid. This was the 3rd review it had undertaken. The Drugs Group noted that it had discussed the medicine in detail at previous meetings and had previously set out a position in relation to same. Following a full review of the application, the Drugs Group unanimously recommended that the medicine not be reimbursed on the basis of the final offer received.

iii. 17007 Venetoclax for CLL: The Drugs Group unanimously decided that it could support a positive recommendation conditional on the ongoing availability of the proposed [redacted]. The Group directed that CPU ensure processes are in place to prevent the [redacted] being used as a lever in future assessments of this medicine.

iv. 17014 Sapropterin for PKU (resubmission): The Drugs Group unanimously (with 1 abstention) decided that it could support a positive recommendation conditional on the continued availability of the commercial offering AND the implementation of the prescribing guidelines and necessary controls arising from same.

v. 18003 Ixazomib for relapsed/refractory multiple myeloma: On the basis of the substantively revised commercial proposal, the Group decided unanimously that it could support reimbursement.

vi. 18002 Nusinersen for SMA – direction on commercial proposal. The Drugs Group considered Biogen's revised commercial proposal. The Drugs Group decided that the offer did not address its concerns of May 2018. The Drugs Group reiterated its belief that it would be in a positon to recommend Nusinersen for Type I SMA if cost effectiveness could be improved to satisfy / approach a cost effectiveness threshold of €45,000 per QALY based on the wider societal perspective model submitted by the company i.e. based on the most optimistic estimates of cost effectiveness. The Drugs Group reiterated that on the basis of the evidence submitted to date the Drugs Group was unable to recommend reimbursement of Nusinersen for Type II and Type III SMA. A negative recommendation for Type II and Type III SMA would be progressed to HSE Leadership.

Insufficient time was available to consider the following medicines at this meeting.

vii. 18014 Blinatumomab for Relapsed refractory Acute Lymphoblastic Leukaemia

viii. 18015 Selexipag in Pulmonary Arterial Hypertension

ix. 18016 Naltrexone / Bupropion for Weight Loss

x. 18017 Obinutuzumab for Follicular Lymphoma

xi. 18018 Evolocumab for Hypercholesterolaemia

xii. 18019 Cabozantinib for Renal Cell Carcinoma

5. **Update on Medicines in Process**

CPU flagged the significant volume of agenda items and the number of items likely to hit agenda in next few weeks. It was agreed that members would check diary availability for additional meeting(s) in October.

6. **AOB:** No AOB arose

7. **Members Time:** Members flagged the significant volume of documents to be considered. The members also flagged that due regard will have to be made to the presentation of data for new members (and particularly lay members).

The members noted that on occasion when a medicine is returning to Drugs Group a truncated synopsis may be appropriate (albeit it would be important to ensure that the members were provided with all information required to enable them to make independent decisions).

Appendix 1: Members Present

Dr Áine Carroll	Chair, National Director of Clinical Strategy and Programmes (Medical Consultant)	In attendance
Ms Anne Marie Hoey	Primary Care Reimbursement Service (Assistant National Director)	In attendance
Prof Michael Barry	Medicines Management Programme / National Centre for Pharmacoeconomics (Clinical Director - Consultant Pharmacologist)	In attendance
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Ms Patricia Heckmann For Dr Jerome Coffey	Chief Pharmacist, National Cancer Control Programme for National Director of the National Cancer Control Programme (Medical Consultant)	In attendance
Dr Philip Crowley	National Director for Quality Improvement (Medical Doctor)	Apologies Received
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	In attendance
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance
n/a	Social Care Division	Position vacant
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	Apologies Received

In attendance (non-voting):

Secretariat: Mr Shaun Flanagan (CPU PCRS), Ms Jennifer McCartan (CPU PCRS), Ms Ellen McGrath (CPU PCRS), Ms Kate Mulvenna (Head of Pharmacy Function, PCRS)

HSE Drugs Group – October Minutes

Meeting 2018.08: Tuesday 9th October 2018, 14.00
Board Room, Unit 4A, The Dargan Building, Heuston South Quarter, Military Road, Kilmainham, D8

1. Draft Minutes for Consideration

The minutes of the meeting of the 11th September 2018 were reviewed and approved.

2. Declaration of Interests / Nil Interest

No conflicts of interest arose.

3. Matters arising / Update on Medicines considered at previous meetings

CPU provided the members with an update in relation to items previously considered.

4. Medicines for Consideration

18014 Blinatumomab (Blincyto®) for relapsed/refractory Acute Lymphoblastic Leukaemia

After a long discussion the Drugs Group was unable to arrive at a recommendation. The Drugs Group decided to defer a recommendation on Blinatumomab to its next meeting when additional information might be available to assist it in its deliberations.

18015 Selexipag (Uptravi®) in Pulmonary Arterial Hypertension

The HSE Drugs Group (with 1 abstention) agreed that it could make a positive recommendation in relation to Selexipag if a commercial offering [redacted]. At such an offering the HSE Drugs Group would accept that Selexipag could satisfy a cost effectiveness threshold of €45,000 when modelled against inhaled iloprost (6 doses) and assuming that the estimated proportions of FCII (11%) / FCIII (89%) held. Given the absence of a proven benefit over Iloprost and the significant budget impact even if cost effective the Drugs Group felt that it could not make a positive recommendation at any point below this level of discount and that there had to be a very clear demonstration of cost effectiveness as the funding of such a recommendation was likely to present a challenge.

18016 Naltrexone / Bupropion (Mysimba®) for Weight Loss

The Drugs Group (with 1 abstention) did not support reimbursement of Naltrexone / Bupropion fixed dose combination. The Drugs Group had concerns due to uncertainties around long term efficacy and safety data, around the robustness of the economic model submitted and around the potential budget impact. The Drugs Group noted NCPE advice that *"The naltrexone/bupropion combination costs approximately €1,176 per patient per year and although the ICER fell below the €45,000/QALY threshold the ICER estimate is uncertain. This uncertainty could not be fully explored due to structural and methodological issues with the submitted model. Furthermore the budget impact estimate is inaccurate and likely represents an underestimate of the true figure."*

18017 Obinutuzumab (Gazyvaro®) for 1st line treatment of Follicular Lymphoma

The Drugs Group agreed (unanimously) that it would support reimbursement of Obinutuzumab for 1st line treatment of Follicular Lymphoma if an offer emerged that satisfied an ICER of €45,000 per QALY based on the NCPE model.

18018 Evolocumab (Repatha®) for Hypercholesterolaemia

The HSE Drugs Group did not have sufficient time to consider Evolocumab in detail. The Group deferred deliberations in relation to this medicine due to the significant budget impact involved.

18019 Cabozantinib (Cabometyx®) for Renal Cell Carcinoma

The Drugs Group (unanimously) supported reimbursement of Cabozantanib (oral medicine – high tech) for the treatment of adult patients with advanced renal cell carcinoma (RCC) previously treated with vascular endothelial growth factor (VEGF) targeted therapy. The recommendation covered both clear cell and non-clear cell RCC.

5. Update on Medicines in Process

CPU provided a short synopsis on the number of medicines in process and the likely number of medicines on the Drugs Group agenda to year end. It was agreed that the Drugs Group would reconvene on the 23rd October.

Meeting 2018.09: Tuesday 23rd October 2018, 14.00
Venue: PCRS, Exit 5, M50, Finglas, Dublin 11

1. Declaration of Interests / Nil Interest
   No conflicts of interest arose.

2. Medicines for Consideration
   18018 Evolocumab (Repatha®) for Hypercholesterolaemia

The Drugs Group (with 1 abstention) supported high tech reimbursement of Evolocumab for the following **subgroups** of the licensed population:

- Atherosclerotic cardiovascular disease (ASCVD i.e. Secondary Prevention): Heterozygous
  Familial Hypercholesterolemia (HeFH) and non-HeFH patients with an LDL-C persistently ≥4mmol/L
- No ASCVD (i.e. Primary Prevention): HeFH patients with LDL-C persistently ≥5mmol/L.

The Drugs Group recommendation was conditional on:

- an individual patient approval system being in place which only enabled reimbursement for patients who met the above conditions and for whom an application is made for reimbursement in advance;
- a rigidly enforced reimbursement approval process which included robust and rigorous definitions of (amongst other criteria):
  - maximum tolerated statin and ezetimibe therapy,
  - intolerance to those agents and
  - contra-indications to those agents;
- the commercial discount offered remaining in place and
- the cost per patient not exceeding the reduced cost of 140mg every two weeks (i.e. 420mg monthly dose not supported for this cohort).

Amgen had applied for reimbursement of and submitted an economic model for the restricted population outlined above. The Drugs Group did not specifically discuss the homozygous cohort indication.

18022 Inotuzumab ozogamicin (Besponsa ®) for Acute Lymphoblastic Leukaemia .
The Drugs Group (unanimously) supported reimbursement of Inotuzumab under the Oncology Drugs Management Scheme (ODMS) for the treatment of relapsed or refractory CD22-positive B cell precursor (BCP) acute lymphoblastic leukaemia (ALL). The group believed this medicine would compete with Blinatumomab for market share.

18014 Blinatumomab (Blincyto®) for Acute Lymphoblastic Leukaemia (ALL)
The Drugs Group (unanimously) supported reimbursement of Blinatumomab under the Oncology Drugs Management Scheme (ODMS) for a defined patient subgroup of the full licensed indication i.e. adult patients with relapsed or refractory B cell precursor (BCP) Philadelphia chromosome negative acute lymphoblastic leukaemia (ALL) who received no prior salvage treatment for relapsed/refractory (R/R) disease and considered eligible for transplant (i.e. as a bridge-to-transplant). The group believed this medicine will compete with Inotozumab ozogamicin for market share.

18020 Idebenone (Raxone®) for Leber's Hereditary Optic Neuropathy
The Drugs Group (unanimously) supported high tech reimbursement of Idebenone for the treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). The recommendation was conditional on a managed access process covering the initiation, review, data collection and continuation of treatment and with prescription initiation authority limited to named specialist(s) in the Royal Victoria Eye and Ear Hospital and the continued availability of the commercial in confidence offer.

18021 Tolvaptan (Jinarc®) for Autosomal Dominant Polcystic Kidney Disease
The Drugs group (unanimously) supported high tech reimbursement of Tolvaptan (oral medicine) for a defined patient subgroup of the full licensed indication i.e. to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease in adults with chronic kidney disease (CKD) stage 2 to 3 at initiation of treatment with evidence of rapidly progressing disease. The recommendation was conditional on an individual patient approval system which would only enable reimbursement for patients who met the above conditions and for whom an application is made in advance. The Group had concerns that without same Tolvaptan might be used for other (non-assessed) indications.

AOB

a. The Drugs Group was updated in relation to new medicines deliberations on the budget / National Service Plan 2019

b. A proposed initiation meeting for new and existing members on 27th November 2018 was flagged.

Appendix 1: Members Present

Member	Title	9th Oct 2018	23rd Oct 2018
Prof. Áine Carroll	Chair, Medical Consultant	In attendance	In attendance
Ms Anne Marie Hoey	Primary Care Reimbursement Service (Assistant National Director)	In attendance	In attendance
Prof. Michael Barry	Medicines Management Programme / National Centre for Pharmacoeconomics (Clinical Director - Consultant Pharmacologist)	Dr Lesley Tilson attended as alternate	In attendance
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance	Apologies Received
Dr Jerome Coffey	National Director of the National Cancer Control Programme (Medical Consultant)	In attendance	In attendance
Dr Philip Crowley	National Director for Quality Improvement (Medical Doctor)	Apologies Received	Apologies Received
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance	By Telephone
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	In attendance	In attendance
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received	In attendance
n/a	Social Care Division	Position vacant	Position vacant
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance	Apologies Received
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	In attendance (2pm – 330pm)	In attendance

In attendance (non-voting):

Secretariat:
Mr Shaun Flanagan (CPU PCRS), both meetings
Ms Jennifer McCartan (CPU PCRS), both meetings
Ms Ellen McGrath (CPU PCRS), both meetings
Ms Kate Mulvenna (Head of Pharmacy Function, PCRS), both meetings
Dr Róisín Adams, (Chief Pharmacist, Acute Hospital Division), by telephone 23rd Oct 2018