HSE Drugs Group –October 2020 Minutes

Meeting 2020.08: Tuesday 13th October 2020, 14.00
Via videoconference

1. Dr Cliona McGovern was introduced and welcomed as a new member of the Drugs Group (as Public Interest Member / Ethicist).

2. Draft Minutes for Consideration

The minutes of the September 2020 meeting were considered and approved.

3. Confidentiality forms

It had previously been agreed that all members (including public servants) would sign confidentiality forms (once off action).

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

CPU provided the members with an update in relation to items at the EMT which were previously considered by the group. The group were made aware that the current EMT agenda included medicines for approval based on efficiencies created through the 2020 pricing realignment (as part of the extension to the 2016 IPHA agreement).

Regarding the pricing and reimbursement application for Letermovir (Prevymis®) reengagements with the applicant company on pricing, post the September 2020 Drugs Group, had concluded. In order to provide assurances on appropriate use the Drugs Group supported a position whereby the HSE / PCERS would limit the number of dispensing episodes that would be permitted via the High Tech hub to three months. Approval for patients requiring longer durations of treatment would be on a case by case basis in line with the current market authorisation of Letermovir. A positive recommendation was to be progressed to the HSE EMT.

5. Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations in relation to Pembrolizumab, Lutetium (^{177}Lu) Oxodotreotide and Tisagenlecleucel pALL were available for the HSE Drugs Group and considered in the discussions for these medicines.

6. Declaration of Interests / Nil Interest

No potential conflicts arose.

7. Miscellaneous

The Chair invited Professor Michael Barry, in attendance at the Drugs Group in an advisory capacity as head of the National Centre for Pharmacoeconomics (NCPE), to provide members with an overview on CAR-T. Some of the key concepts Professor Barry raised with potentially curative gene therapies, such as CAR-T, was that within the model the high, upfront and once-off drug acquisition costs are certain and the clinical benefits that accrue over the time horizon of model were uncertain when based on extrapolations and immature clinical data. The HSE may be able to address such uncertainty through instalment payments over a longer duration of time that are linked to specific clinical outcomes being obtained. Professor Barry addressed a number of queries raised by Drugs Group members and was thanked by the Chair thereafter for his time and the effort undertaken to provide the Drugs Group with this information.

8. Medicines previously reviewed by Drugs Group (updated information now available)

ii. 20015 Lutetium (^{177} Lu) Oxodotreotide for gasteroenteropancreatic neuroendocrine tumours

The application for Lutetium (^{177}Lu) Oxodotreotide was previously considered at the July 2020 meeting of the Drugs Group. The unanimous view was that additional information was required before the Drugs Group could make a recommendation. This additional information now available allowed the Drugs Group to conclude its deliberations and unanimously recommend in favour of reimbursement.

The Drugs Group additional information included the current treatment costs within the Treatment Abroad Service (TAS). Peptide Receptor Radionuclide Therapy (PRRT) was made available through the TAS when classified as a device. [redacted] Enhanced commercial terms to that available in July 2020 had also been negotiated. The Drugs Group noted [redacted] While there were several uncertainties and limitations associated with the clinical evidence underpinning assumptions used in the economic model the group considered, on the whole, there to be sufficient supportive evidence to recommend reimbursement of Lutathera®.

iii. 20021 Pembrolizumab for adjuvant melanoma

The application for Pembrolizumb for adjuvant melanoma was previously reviewed by the Drugs Group at its September 2020 meeting. At that time the Drugs Group requested additional information via the National Cancer Control Programme (NCCP), specifically for clinicians to set out whether there are any compelling clinical grounds for the Drugs Group to consider in its deliberations around [redacted]

The Drugs Group did not support reimbursement on the basis of the application submitted (including the commercial offerings). This was the majority view of the Drugs Group.

The Drugs Group noted that the cost-effectiveness evidence and clinical data from the pivotal PIII study Keynote-054 would persuade towards a positive recommendation if considered in isolation. However Nivolumab, another PD-1 immunotherapy, indicated for the adjuvant treatment of melanoma, was considered to be a relevant comparator and was omitted from the Pembrolizumab Health Technology Assessment (HTA). While the Drugs Group recognised that there is no direct head-to-head comparative evidence for Pembrolizumab versus Nivolumab in adjuvant melanoma the consensus view of the clinical experts in Ireland suggest that these medicines can be considered to be equally efficacious, both in terms of clinical outcomes and safety, for this cohort of patients. [redacted] The Drugs Group did not recommend in favour of reimbursement for Pembrolizumab, [redacted]

9. Medicines for Consideration

i. 20022 Tisagenlecleucel for the treatment of relapsed and/or refractory B-cell acute lymphoblastic leukaemia (ALL)

The Drugs Group fully appreciated that relapsed and/or refractory paediatric ALL (pALL) is a rare condition with a high unmet need and recognised that a potential curative therapy would have a high impact when the likely available option other than CAR-T in this difficult to treat cohort would be palliation.

The Group noted that there was uncertainty in the clinical benefits obtained from Tisagenlecleucel in pALL arising from no comparative data with all clinical studies available being open label and single-arm design and overall survival (OS) data that was immature. The Drugs Group noted that this uncertainty led to high and uncertain incremental cost effectiveness ratios (ICERs) in the HTA.

At the end of extensive deliberations the Drugs Group ultimately considered that it did not have sufficient information to proceed in making its recommendation for the pALL indication. The Drugs Group requested that the CPU reengage with the applicant company on a managed entry agreement for the medicine with the view to address the uncertainty in both the clinical and cost-effectiveness evidence presented.

ii. 20023 Tisagenlecleucel for the treatment of relapsed and/or refractory diffuse large B cell lymphoma (DLBCL)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the November 2020 meeting.

iii. 20024 Axicabtagene Ciloleucel for the treatment of relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the November 2020 meeting.

iv. 20025 Lanadelumab for the routine prevention of recurrent attacks of hereditary angioedema (HAE)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the November 2020 meeting.

v. 20026 Liposomal Daunorubicin and Cytarabine for the treatment of acute myeloid leukaemia (AML)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the November 2020 meeting.

10. AOB / Members Time

The Chair requested individual member feedback on their views on what an appropriate duration for the Drugs Group meetings would be. The members agreed to feed this back to the Chair for further consideration.

Appendix 1: Members Present on Microsoft Teams

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Mr Shaun Flanagan	Primary Care Reimbursement Service (Assistant National Director)	In attendance
Ms Aoife Kirwan	Public Interest Member	In attendance
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Ms Patricia Heckmann for Professor Risteárd Ó Laoide	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)	In attendance*
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
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	In attendance
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
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance

*In attendance until 4pm so not available for part of meeting/all discussions
**In attendance from 2.30pm-4pm so not available for part of meeting/all discussions

In attendance (non-voting):
Ms Kate Mulvenna
Professor Michael Barry (NCPE)

Secretariat:
Ms Fiona Mulligan, Senior Pharmacist, CPU PCRS
Ms Maria Daly, Chief II Pharmacist, CPU PCRS
Ms Ellen McGrath, Chief II Pharmacist, CPU PCRS