HSE Drugs Group – November 2020 Minutes

Meeting 2020.09: Tuesday 10th November 2020, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

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

2. Confidentiality forms

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

3. 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 EMT approved two new medicines and one license extension (new use) from November 2020.

The Budget had referred to €50m for funding of new medicines in 2021 which was reflected in the Department of Health's Letter of Determination to the HSE. The National Service Plan was under development.

Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations in relation to Tisagenlecleucel DLBCL was available for the HSE Drugs Group and considered in the discussions for this medicine.

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

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

There was insufficient time for the Drugs Group to conclude deliberations on this application.

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

The Drugs Group had previously requested that the CPU reengage with the applicant company on a managed entry agreement for the pALL indication with the view to address the uncertainty in both the clinical and cost-effectiveness evidence presented. The follow-up engagements had concluded and a revised commercial offer was now available for consideration.

The Drugs Group agreed to deliberate on the DLBCL indication first, [redacted]

Extensive discussions ensued on the DLBCL indication. The high level of unmet need was recognised in the context of limited treatment options in relapsed / refractory DLBCL. The Drugs Group

accepted that CAR-T could potentially offer durable responses for a proportion of the patients who would be considered eligible for this treatment option. Some members of the group felt that patients, if eligible for CAR-T, should be treated within Irish specialist centres given the nature and the associated complexities of this treatment. The Drugs Group also noted the very high upfront drug acquisition costs, the [redacted] and the uncertainty in the clinical and cost-effectiveness evidence presented.

At the end of all deliberations the Drugs Group was unable to support reimbursement (in the majority) on the basis of the application submitted to date (including the commercial offerings).

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)

[redacted]

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 December 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 December 2020 meeting

vi. 20027 Upadacitinib for rheumatoid arthritis

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

vii. 20004 Niraparib for ovarian cancer

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

6. AOB / Members Time

Meeting dates for 2021 were shared with the Group.

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)	In attendance
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	Apologies received

*In attendance until 3pm 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