HSE Drugs Group –September 2020 Minutes

Meeting 2020.07: Tuesday 8th September, 14.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the July 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 one new medicine and three license extensions (new use) from 1st October 2020.

4. Updates / reports from TRCs

None

5. Declaration of Interests / Nil Interest

No potential conflicts arose.

[redacted]

6. Medicines for Consideration

i. 20019 Olaparib 1L maintenance in BRCAm positive advanced ovarian cancer

The Drugs Group unanimously recommended in favour of reimbursement of Olaparib (Lynparza®) tablets under High Tech arrangements for the treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

In the pivotal PIII study SOLO-1 (n=391) Olaparib was associated with a significant and clinically meaningful improvement in progression free survival (PFS) compared with placebo. OS data remained immature but the group noted that PFS benefit was observed out to 4 years, with less patients experiencing recurrence of their disease compared with placebo (53% vs. 11%).

[redacted]

ii. 20020 Letermovir for prophylaxis of CMV infection

The Drugs Group accepted there was an unmet need for efficacious prophylactic treatments for haematopoietic stem-cell transplantation (HSCT) recipients at risk of cytomegalovirus (CMV) reactivation, some of which may be addressed if Letermovir were to be approved for reimbursement based on the evidence from the pivotal multicentre double-blind pivotal PIII study (PN001).

The majority of the Drugs Group supported reimbursement of Letermovir. Several members of the group considered there to be significant uncertainty remaining, in relation to both cost and cost-

effectiveness, which wasn't fully addressed in the commercial proposal submitted by MSD. In respect of this CPU were to establish with the applicant whether the offer could be enhanced with the view to addressing concerns raised during the course of the Drugs Group deliberations.

iii. 20021 Pembrolizumab for adjuvant melanoma

The Drugs Group was unable to support reimbursement on the basis of the application submitted to date (including the commercial offerings). This was the unanimous view of the Drugs Group.

The HSE Drugs Group sought 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]

7. Medicines under representations process

i. **19015 Rivaroxaban for coronary artery disease (CAD)/ peripheral artery disease (PAD)**

In previous deliberations for this medicine the Drugs Group did not support reimbursement of Rivaroxaban under the Community Drugs Schemes, when co-administered with acetylsalicylic acid (ASA), for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events. In particular the group had concerns related to the pivotal PIII COMPASS trial lacking data that all patients included in the study were optimised on secondary prevention therapies and on that basis would derive further benefit from a relative expensive combination dual antithrombotic therapy.

CPU presented a summary which covered details of the application received from Bayer, European treatment guidelines, the HTA process, commercial negotiations undertaken as well as further evidence submitted as part of the representations in response to the HSE proposed decision not to support reimbursement.

The group ultimately agreed unanimously that it could not recommend funding on the basis of the clinical evidence presented to date. While the anticipated budget impact is uncertain the Drugs Group was of the opinion that it was likely to remain substantial. The group also considered the applicants proposal to restrict treatment initiation at a hospital consultant level is unlikely to address the concerns related to the budget impact and may not be clinically appropriate in all instances for this cohort of patients.

7. AOB / Members Time

i. The Drugs Group were notified that the CAR-T applications that were anticipated to be included on the September agenda of the Drugs Group would be for discussion in October as the commercial proposals remained under review.

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)	Apologies received
Position Vacant	Public Interest Member / Ethicist	Position Vacant
Mr Michael Power	Public Interest Member	In attendance*
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	Apologies received
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	In attendance
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	Apologies received
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance*

*In attendance from 2pm but not available for part of meeting/all discussions

In attendance (non-voting):
Ms Kate Mulvenna
Ms Lesley Tilson (NCPE)

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