HSE Drugs Group – December 2019 Minutes

Meeting 2019.09: Monday 16th December, 14.00
HSE PCERS, Exit 5 M50, Finglas

1. Draft Minutes for Consideration

The minutes of the November 2019 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

[redacted]

4. Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations to the HSE Drugs Group were considered for the applicable medicines on the agenda.

5. Declaration of Interests / Nil Interest

No potential conflicts arose.

6. Medicines for Consideration

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

The Drugs Group unanimously 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. The NCPE's concerns regarding the applicant's model and the uncertainty of the budget impact estimates were noted by the Group. The Group considered the clinical evidence from the pivotal, phase III COMPASS trial at length. The Group noted the trial lacked more granular data detailing baseline characteristics such as LDL-cholesterol and patients on high-intensity lipid lowering therapies or HbA1c and % patients with elevated HbA1c. Such data would have given insight into the optimisation of treatment for risk factors before use of Rivaroxaban. They regarded optimisation of less expensive treatments such as antihypertensives and lipid-lowering therapies to be an important and rational consideration prior to initiating this therapy.

ii. 19020 Levodopa + Carbidopa Intestinal Gel (Duodopa®) for Parkinson's disease

The Drugs Group considered the application for expanded reimbursement of Duodopa®. To facilitate their deliberations, the Drugs Group requested input from the National Clinical Programme for Neurology to provide greater insight into the treatment options available for advanced Parkinson's Disease in Ireland. The Drugs Group deferred making a recommendation in advance of consideration of such information.

iii. 19016 Pembrolizumab + chemotherapy for 1st line non-squamous NSCLC

The HSE Drugs Group considered Pembrolizumab, in combination with Pemetrexed and platinum chemotherapy, for the first line treatment of metastatic non-squamous non-small cell lung cancer (NSCLC) in adults whose tumours have no EGFR or ALK positive mutations. The Group noted the improvement in overall survival and progression free survival over chemotherapy alone offered by this treatment option. The Group acknowledged the uncertainty regarding [redacted] but in their deliberations developed an agreed group position to address this. The Drugs Group were unanimously minded to support a positive recommendation if these terms were met in addition to the proposed commercial offer.

iv. 19017 Pembrolizumab + chemotherapy for 1st line squamous NSCLC

The Drugs Group considered Pembrolizumab in combination with Carboplatin and either Paclitaxel or nab-Paclitaxel for the first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in adults. The Group noted the improvement in overall survival and progression free survival over chemotherapy alone offered by this treatment option. The Group recommended that combination use of Pembrolizumab in this indication be restricted to Paclitaxel only in order to reduce the associated costs of treatment with nab-Paclitaxel. The Group acknowledged the uncertainty regarding [redacted] but in their deliberations developed an agreed group position to address this. The Group were unanimously minded to support a positive recommendation if these terms were met in addition to the proposed commercial offer (with restriction to Pembrolizumab in combination with Carboplatin and Paclitaxel only).

v. 19018 Pembrolizumab for 2nd line Urothelial Carcinoma

The Drugs Group considered Pembrolizumab monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy. The Group recognised an unmet need for treatments in the second line setting, with median overall survival in patients failing first-line platinum-based chemotherapy between 5-7 months. The Group noted the improvement in overall survival versus chemotherapy offered by this treatment option. The Group acknowledged the uncertainty regarding [redacted] but in their deliberations developed an agreed group position to address this. The Drugs Group were unanimously minded to support a positive recommendation if these terms were met in addition to the proposed commercial offer.

vi. 18025 Pembrolizumab + chemotherapy for 1st line Urothelial Carcinoma

The Drugs Group considered Pembrolizumab monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma (UC) in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥10. The Group noted approximately 5% patients with metastatic UC are alive at 5 years, with no defined standard treatment for cisplatin-ineligible patients. The Group reviewed the clinical evidence from the open-label, single-arm KEYNOTE-052 trial, noting the licence had since been restricted to those patients whose tumours express PD-L1 with a CPS ≥10 and in whom objective response rate (ORR) and overall survival (OS) had been superior for in the trial. The Group considered the safety profile compared favourably to chemotherapy and that Pembrolizumab offered an alternate option in this small patient cohort. The Group acknowledged the uncertainty regarding [redacted] but in their deliberations developed an agreed group position to address this. The Drugs Group were

unanimously minded to support a positive recommendation if these terms were met in addition to the proposed commercial offer.

7. AOB / Members Time

i. Obeticholic Acid for Primary Biliary Cholangitis/ Cirrhosis (PBC)

The Group considered the NCPE report on the updated clinical effectiveness of Obeticholic Acid following their engagement with Intercept in light of more mature data for this medicine. The Group acknowledged that a full HTA would be required to appraise the impact of this evidence on cost-effectiveness using the applicant's new economic model. The Group recommended a full HTA be conducted to re-determine cost-effectiveness for this new model or alternatively Intercept could meet the previously determined threshold set out by the Drugs Group for a positive recommendation.

Appendix 1: Members Present

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Ms Kate Mulvenna	Primary Care Reimbursement Service, Head of Pharmacy Function, For Primary Care Reimbursement Service (Assistant National Director)	In attendance
Ms Aoife Kirwan	Public Interest Member	Apologies received
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Ms Patricia Heckmann For Ms Fiona Bonas	Chief Pharmacist, National Cancer Control Programme For Interim National Director of the National Cancer Control Programme	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)	By Teleconference
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	Apologies received
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance
Position Vacant	Public Interest Member / Ethicist	Position Vacant
Mr Michael Power	Public Interest Member	Apologies received
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	By Teleconference
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	Apologies received

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

Secretariat:
Mr Shaun Flanagan (SF), Primary Care Reimbursement Service (Assistant National Director)-pending completion of outstanding matters
Ms Maria Daly (MD), Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan (FM), Senior Pharmacist, CPU PCRS