**HSE Drugs Group – March 2020 Minutes**

**Meeting 2020.03: Tuesday 10th March, 14.00**
**Indigo Room, Dr Steevens Hospital, D8**

1. Draft Minutes for Consideration

The minutes of the February 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 previously considered.

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. 20003 Nivolumab + Ipilimumab for advanced renal cell carcinoma

The Drugs Group considered Nivolumab in combination with Ipilimumab for the first-line treatment of adult patients with intermediate/poor-risk advanced renal cell carcinoma. The Group reviewed the clinical, cost-effectiveness and budget impact data. Nivolumab + Ipilimumab demonstrated significantly improved overall survival compared to Sunitinib in the pivotal CheckMate 214 trial. The Group noted the recommendation of the NCPE to reconsider the clinical and cost-effectiveness data of this combination therapy upon publication of the EMA mandated post-authorisation efficacy study comparing Nivolumab + Ipilimumab to Nivolumab monotherapy for this indication. The Drugs Group unanimously supported reimbursement of Nivolumab + Ipilimumab for this indication.

ii. 20004 Niraparib for ovarian cancer

The Drugs Group considered Niraparib (Zejula®) as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. The Group considered the clinical evidence, noting the immaturity of the overall survival data. The Group reviewed the cost effectiveness data for the germline *BRCA* mutation and non-germline *BRCA* mutation populations, taking into account the proposed commercial offer for Niraparib. The Drugs Group unanimously did not support reimbursement and agreed that an enhanced commercial offering was required to improve cost-effectiveness relative to other comparators.

iii. 20005 Dupilumab for atopic dermatitis (adult)

The Drugs Group considered Dupilumab for the treatment of moderate-to-severe atopic dermatitis in refractory adult patients for whom immunosuppressant treatment has failed, is not tolerated, or is contraindicated. The Group reviewed the clinical data in depth. The Group noted that no active comparator was used in any of the trials and there was a paucity of long-term efficacy evidence available. The Group noted the limitations of the cost-effectiveness data and the significant budget impact despite the proposed commercial offer. The Group did not support reimbursement.

iv. 20006 Dupilumab for atopic dermatitis (adolescent)

The Drugs Group considered Dupilumab for the treatment of moderate-to-severe atopic dermatitis in refractory adolescent patients for whom immunosuppressant treatment has failed, is not tolerated, or is contraindicated. The Group noted the short duration of the trial and the lack of an active comparator. The Group noted the significant budget impact despite the commercial offer proposed. The Group did not support reimbursement.

v. 20008 Ustekinumab for ulcerative colitis

The Drugs Group deferred consideration of this therapy due to time constraints.

7. AOB / Members Time

The Drugs Group agreed that future meetings may need to take place via a suitable and secure videoconferencing facility.

**Appendix 1: Members Present**

| 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 | Apologies received |
| Dr David Hanlon | National Clinical Advisor and Group Lead Primary Care (General Practitioner) | In attendance |
| Ms Fiona Bonas | 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) | In attendance |
| Dr Roy Browne | Mental Health Division (Consultant Psychiatrist) | In attendance |
| 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) | 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)
Ms Kate Mulvenna (KM), Head of Pharmacy Function/ CPU, PCRS

Secretariat:
Ms Maria Daly (MD), Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan (FM), Senior Pharmacist, CPU PCRS