HSE Drugs Group – June 2023 Minutes

Meeting 2023.06: Tuesday 13th June 2023, 14.00 – 16.30

Via videoconference

1. Draft Minutes for Consideration

The minutes of the May 2023 meeting were considered and approved.

2. Matters arising / Update on Medicines considered at previous meeting

   i. The Chair welcomed Clare Mac Gabhann to the HSE Drugs Group as a newly appointed committee member.
   ii. An update on items previously considered by the Drugs Group was provided, including the number of items that had been considered in the first five meetings of the Drugs Group in 2023.
   iii. The remaining scheduled Drugs Group meeting dates were shared with the Group. Members were informed of the potential need to schedule additional meeting(s) beyond this in order to process the volume of applications for review in Q4 2023. The Group were made aware however that a full agenda for the next scheduled meeting had not yet been filled (as of June 2023).

3. Declaration of Interests / Nil Interest

One member declared a potential interest in relation to item i. Pegvaliase (Palynziq®) for phenylketonuria.

4. Medicines for Consideration

i. 23013 Pegvaliase(Palynziq®) for phenylketonuria (NCPE HTA ID: 21057)

The Drugs Group considered Pegvaliase (Palynziq®) for the treatment of patients with phenylketonuria aged 16 years and older who have inadequate blood phenylalanine control (blood phenylalanine levels greater than 600 µmol/L) despite prior management with available treatment options. The Group reviewed the clinical and economic evidence in detail along with the outputs of commercial negotiations, and the patient interest group submission received during the HTA process for Pegvaliase (Palynziq®).

The Drugs Group were unable to progress a recommendation that was supportive of reimbursement on the basis of the clinical and cost-effectiveness evidence available.

As the application was for a medicine for the management of a rare condition further Patient and Clinician Engagement input via the HSE Rare Diseases Technology Review Committee (RDTRC) would be sought. The Group committed to reviewing the output of the RDTRC at the earliest opportunity and would consider a reimbursement recommendation at that time.

ii. 23014 Olaparib (Lynparza®) in combination with bevacizumab for the maintenance treatment of adult patients with advanced ovarian, fallopian tube or primary peritoneal cancer (NCPE HTA ID: 21011)

The Drugs Group considered Olaparib (Lynparza®) in combination with Bevacizumab for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) 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 combination with Bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability. The Group reviewed the clinical and economic evidence in detail as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC), and the patient interest group submission received during the HTA process for Olaparib (Lynparza®).

The Group reviewed the pivotal evidence from PAOLA-1 (n=806), a Phase III randomised, double-blind, placebo-controlled, multicentre trial that compared the efficacy and safety of Olaparib in combination with Bevacizumab vs. placebo plus Bevacizumab for the maintenance treatment of advanced (FIGO Stage III-IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer following first-line platinum-based chemotherapy and Bevacizumab. The primary endpoint was progression-free survival (PFS).

The Drugs Group unanimously recommended reimbursement of Olaparib (Lynparza®) in this indication as it was considered to represent a cost-effective use of resources when taking into account conventional willingness to pay thresholds, when compared against Bevacizumab monotherapy in the HRD-positive population.

iii. 23015 Empagliflozin (Jardiance®) for symptomatic chronic heart failure (NCPE HTA ID: 22068)

The Drugs Group considered Empagliflozin (Jardiance®) in adults for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction >40%.

The Group reviewed the clinical evidence from EMPEROR-Preserved, a randomised, double-blind, placebo-controlled trial was conducted in 5,988 patients with chronic heart failure (NYHA II-IV) and preserved ejection fraction (LVEF >40%) to evaluate the efficacy and safety of Empagliflozin 10 mg once daily as adjunct to standard of care therapy. A total of 2,997 patients were randomised to Empagliflozin 10 mg (placebo: 2,991) and followed for a median of 26.2 months. The primary endpoint was the time to adjudicated first event of either cardiovascular (CV) death or hospitalisation for heart failure (HHF). CV death or HHF occurred in a lower proportion of patients in the Empagliflozin group (415 of 2997 patients, 13.8%) than in the placebo group (511 of 2991 patients, 17.1%), and the risk of CV death or HHF was significantly reduced with Empagliflozin treatment compared with placebo (HR Empagliflozin vs placebo 0.79; 95% CI 0.69 to 0.90, p = 0.0003).

The Group previously recommended reimbursement of Empagliflozin for the treatment of adults with symptomatic chronic HFrEF, which was considered to be a cost-effective use of HSE resources. The Drugs Group unanimously recommended reimbursement of Empagliflozin for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction >40% on the basis of the evidence presented, which was considered by the Group to be sufficiently robust to support extending use to the HFpEF subpopulation with HF.

iv. 23016 Lenvatinib (Kisplyx®) for 1L treatment of adults with advanced renal cell carcinoma (RCC), in combination with Pembrolizumab (NCPE HTA ID: 22057)

The Drugs Group considered Lenvatinib (Kisplyx®) in a combination regimen with Pembrolizumab for the first line treatment of adults with advanced renal cell carcinoma (RCC). The Group reviewed the clinical and economic evidence in detail as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC).

The Group noted that three other immuno-oncology/tyrosine kinase inhibitor (IO-TKI) combintations are licensed for advanced RCC, however none are yet reimbursed. Pembrolizumab and Lenvatinib are expensive medicines and greatly exceed the treatment costs associated with the current SOC. The Group considered the associated budget impact estimates were considered to be subject to a high level of uncertainty

The Drugs Group considered there was insufficient evidence presented to support a positive recommendation. The Group concluded that a full Health Technology Assessment should be conducted to assess the clinical effectiveness and cost effectiveness of Lenvatinib (Kisplyx®) in a combination regimen with Pembrolizumab compared with standard of care. The Group unanimously agreed that a robust deliberation could not take place in its absence.

v. 23017 Sacituzumab govitecan for the treatment of metastatic triple-negative breast cancer (mTNBC) (NCPE HTA ID: 22007)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the next scheduled 2023 meeting.

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	Apologies received
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)	Apologies received
Clare Mac Gabhann	Director of Nursing and Midwifery (Prescribing)	In attendance
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance*
Mr Michael Power	Public Interest Member	Apologies received
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Post Vacant	Acute Operations Division (Assistant National Director)	n/a
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

*parts of meeting and voting not attended

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

Secretariat:
Ellen McGrath, Chief I Pharmacist, Head of CPU PCRS
James Kee, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS