HSE Drugs Group – February 2022 Minutes

Meeting 2022.02: Tuesday 8th February 2022, 14.00 – 16.15

Via videoconference

1. Draft Minutes for Consideration

The minutes of the January 2022 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

An update on items previously considered by the Drugs Group was provided. All of the relevant positive recommendations from the December 2021 and January 2022 meetings had been approved by the HSE EMT.

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 21022 Gilteritinib for acute myeloid leukaemia

The Drugs Group previously considered Gilteritinib (Xospata®) at its October 2021 meeting as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. The Drugs Group unanimously agreed that it would recommend reimbursement if [redacted] on that occasion.

Following a comprehensive review and protracted deliberation on the totality of clinical and economic evidence, including the impact of a revised commercial offer, the Drugs Group, by majority, did not recommend in favour of reimbursement of Gilteritinib. The Group noted the poor prognosis for this patient cohort and the limited treatment options for patients with a FLT3 mutation in this setting. The Group recognised that the revised commercial offer improved the cost-effectiveness of Gilteritinib versus comparators. Notwithstanding this, Gilteritinib remained a very high cost medicine that provided modest survival benefit over salvage chemotherapy in the pivotal ADMIRAL trial. The potential opportunity cost of reimbursing Gilteritinib was discussed in depth by the Group, with the majority agreeing that reimbursement of Gilteritinib for this indication was not an optimum use of limited HSE resources.

ii. 21019 Oral Semaglutide for type II diabetes mellitus

The Drugs Group previously considered oral Semaglutide (Rybelsus®) at its September 2021 meeting for the treatment of adults with insufficiently controlled Type II diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise: as monotherapy when Metformin is considered inappropriate due to intolerance or contraindications; or in combination with other medicinal products for the treatment of diabetes. The Drugs Group unanimously agreed that a price premium over oral comparators such as Empagliflozin could not be supported.

Following an extensive review of the application at their February 2022 meeting, the Drugs Group recommended that Semaglutide (Rybelsus®) not be reimbursed on the basis of the revised commercial

proposal. Semaglutide (Rybelsus®) remained at a premium to oral Empagliflozin and other oral comparators considered within the NCPE Health Technology Assessment. The Group recognised that subcutaneous Semaglutide (Ozempic®) was already reimbursed under the Community Drugs Schemes, alongside a number of alternative subcutaneously administered GLP-1 analogues. The Group noted that although Semaglutide demonstrated non-inferiority versus placebo in terms of MACE (major adverse cardiovascular events) in the PIONEER 6 trial, superiority versus placebo was not confirmed. The Health Technology Assessment detailed a five year gross budget impact exceeding €91m at the original list price, and despite the revised commercial proposals considered by the Drugs Group, reimbursement of oral Semaglutide (Rybelsus®) still represented a substantial multi-million euro investment. The Group noted that HSE expenditure on Type II Diabetes in Ireland was on an upwards trajectory. Following a thorough deliberation, the Drugs Group unanimously reaffirmed their September 2021 recommendation, namely that a price premium for oral Semaglutide over oral comparators such as Empagliflozin could not be supported.

iii. 22003 Olaparib for metastatic castration resistant prostate cancer

The Drugs Group considered Olaparib (Lynparza®) for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent. The Group reviewed the clinical and economic evidence in detail. The key evidence informing this indication came from the PROfound trial in which patients were randomised to receive Olaparib or investigator's choice of new hormonal agent (Enzalutamide or Abiraterone plus Prednisolone). The Group noted that the NCPE identified Docetaxel as the most relevant comparator and that the comparator arm in the PROfound trial may not be reflective of Irish clinical practice. Patients enrolled in the trial were required to have failed prior treatment with a new hormonal agent (NHA) and sequencing with a subsequent NHA was unlikely in Irish clinical practice. The Drugs Group acknowledged the lack of direct comparative evidence for Olaparib versus either Docetaxel or Cabazitaxel. The Group considered that Olaparib was priced at a significant premium compared to all comparators considered in the NCPE Rapid Review Assessment. In the absence of relevant comparative evidence, the Group agreed that the value of Olaparib treatment versus relevant comparators in this patient population was unclear. Following a lengthy deliberation, the Group agreed that further data was required to inform the Drugs Group deliberations.

iv. 22004 Blinatumomab for paediatric high risk first relapse ALL

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the March 2022 meeting.

v. 22005 Dupilumab for atopic dermatitis (6-11 years)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the March 2022 meeting

vi. 22006 Nintedanib for chronic fibrosing interstitial lung diseases with a progressive phenotype

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the March 2022 meeting.

6. AOB

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)	In attendance
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	Apologies received
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	Apologies received
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
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	In attendance*

*Parts of meeting and voting not attended

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

Secretariat:
Ms Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan, Chief II Pharmacist, CPU PCRS