HSE Drugs Group – October 2022 Minutes

Meeting 2022.09: Tuesday 11th October 2022, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the September 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 meeting

i. The September 2022 Drugs Group relevant recommendations had been progressed to the HSE Executive Management Team (EMT) for consideration.

ii. Following initial feedback from Drugs Group members regarding further meeting capacity in 2022, it was agreed that an additional meeting should be arranged. Members would be asked to confirm their preferred meeting date with the HSE CPU.

4. Declaration of Interests / Nil Interest

One member declared a potential interest in relation to item 5. vi (Delta-9-tetrahydrocannabinol/Cannabidiol for multiple sclerosis related spasticity) and would abstain from voting on this medicine.

5. Medicines for Consideration

i. 22022 Fedratinib for myelofibrosis

The Drugs Group considered Fedratinib (Inrebic®) for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with Ruxolitinib. The Drugs Group noted that this particular application involved two distinct populations. Firstly, Fedratinib (a JAK2-selective inhibitor) provides an additional licensed treatment option in a JAK inhibitor naïve population. Fedratinib also addresses an unmet need as a licensed treatment option in patients previously treated with Ruxolitinib, for whom the prognosis has been acknowledged as poor. The Group considered the clinical evidence from the JAKARTA and JAKARTA2 trials. It was noted that Fedratinib represented [redacted] Following deliberations, the Drugs Group unanimously recommended in favour of reimbursement of Fedratinib under High Tech arrangements.

ii. 22023 Apalutamide for mHSPC

The Drugs Group considered Apalutamide (Erleada®) for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT). The Drugs Group considered the totality of clinical and economic evidence for Apalutamide at length. The Group acknowledged the significant overall survival and radiographic progression-free survival benefit observed in the primary analysis of the pivotal TITAN trial for Apalutamide + ADT relative to placebo +ADT. The absence of direct comparative evidence versus other potential comparators + ADT was noted by the Group including Docetaxel, Abiraterone, and Enzalutamide, all of which are detailed in international

guidelines (ESMO and NCCN) as potential treatment options for mHSPC (depending on disease burden and diagnosis). A patient interest group submission was also considered by the Drugs Group. The pharmacoeconomic analysis was informed by a network meta-analysis which suggested that Apalutamide had a similar effect on overall survival compared to Abiraterone and a numerically favourable (but not statistically significant) effect versus Docetaxel and Enzalutamide. The Group considered the impact of the commercial offer for Apalutamide on the cost-effectiveness estimates versus these comparators. Due to the incremental QALY (0.02) for the comparison with Abiraterone + ADT, minor changes in the drug acquisition costs had a large impact on the incremental cost-effectiveness ratio (ICER). The Group noted the loss of exclusivity for Abiraterone and the imminent associated price reduction. Following protracted discussion, the Group recommended in favour of reimbursement of Apalutamide (by majority) subject [redacted]

iii. 22024 Dupilumab for severe asthma

The Drugs Group considered Dupilumab (Dupixent®) for adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. The Group recognised that Dupilumab, a recombinant human IgG4 monoclonal antibody that inhibits IL-4 and IL-13 signalling, represented an alternative biologic treatment option for patients with severe asthma. The Group reviewed the impact of the Dupilumab commercial offer relative to currently reimbursed alternative biologic treatment options. The Drugs Group unanimously recommended in favour of reimbursement of Dupilumab (Dupixent®) under High Tech arrangements for severe asthma subject to the establishment of a managed access protocol restricting reimbursement to a defined cohort of the licensed population (in line with other currently reimbursed biologic therapies for severe asthma).

iv. 22025 Empagliflozin for chronic heart failure with reduced ejection fraction

The Drugs Group considered Empagliflozin (Jardiance®) for the treatment of adults with symptomatic chronic heart failure with reduced ejection fraction. The Group reviewed the clinical evidence from the pivotal EMPEROR-Reduced trial, noting that Empagliflozin versus placebo, as an adjunct to standard of care heart failure therapy, was statistically significantly superior in reducing the risk of the primary composite endpoint of cardiovascular death or hospitalisation for heart failure. The ICER for Empagliflozin as an add-on therapy to the standard of care was estimated at €3,879/QALY. Reviewing the deterministic sensitivity analyses, the Drugs Group noted that the ICER for Empagliflozin plus standard of care remained below €11,000/QALY across all parameter variations of interest. The Group considered Empagliflozin for the treatment of adults with symptomatic chronic heart failure with reduced ejection fraction to be a cost-effective use of HSE resources and unanimously recommended in favour of reimbursement under the Community Drugs Schemes.

v. 22026 Ozanimod for ulcerative colitis

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

vi. 22027 Delta-9-tetrahydrocannabinol/Cannabidiol for multiple sclerosis related spasticity

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the November 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	In attendance
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	Apologies received
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)	Apologies received
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Post Vacant	Office of Nursing & Midwifery Services (Director of Nursing)	n/a
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Mr Michael Power	Public Interest Member	In attendance
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

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

Secretariat:
Ellen McGrath, Chief I Pharmacist, Head of CPU PCRS
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS