HSE Drugs Group – April 2022 Minutes

Meeting 2022.04: Tuesday 12th April 2022, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the March 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

The March 2022 Drugs Group recommendations were under consideration by the HSE EMT.

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 22008 Entrectinib for ROS1-positive advanced NSCLC

The Drugs Group considered Entrectinib (Rozlytrek®) as monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors. The Group reviewed the clinical evidence for this indication. The Group noted that although the available Entrectinib evidence on intracranial activity is limited and uncontrolled, there is a paucity of intracranial evidence for established ROS1-positive advanced NSCLC therapies. The Group considered the economic evidence including the small eligible patient population. The Group unanimously recommended in favour of reimbursement on the basis of the commercial offer.

ii. 22009 Roxadustat for symptomatic anaemia associated with chronic kidney disease

The Drugs Group unanimously recommended in favour of reimbursement of Roxadustat for the treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD). The Group reviewed the evidence for Roxadustat from the clinical development program for non-dialysis dependent (NDD) and dialysis-dependent (DD) CKD patients with anaemia. The Group noted that the correction and maintenance of haemoglobin levels with Roxadustat was greater than with placebo in the NDD population and comparable to the correction achieved with erythropoiesis-stimulating agents (ESA) in both the NDD and DD populations. The merits of an oral treatment option were acknowledged. The Group reviewed the commercial offer for Roxadustat, in the context of the range of available ESA comparators, noting that Roxadustat [redacted]

iii. 22010 Daratumumab in combination with Bortezomib, Thalidomide and Dexamethasone for newly diagnosed multiple myeloma

The Drugs Group recommended in favour of reimbursement of Daratumumab (Darzalex®) in combination with Bortezomib, Thalidomide and Dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. The Group acknowledged the evolving role of Daratumumab in the multiple myeloma treatment pathway and noted that a number of indications are currently reimbursed. The Group reviewed the impact of the enhanced commercial offer on the cost-effectiveness estimates, and noted its extension across all

currently reimbursed indications. The Drugs Group unanimously voted in favour of reimbursement having considered the totality of clinical and economic evidence.

iv. 22011a Bempedoic Acid and 22011b Bempedoic Acid in combination with Ezetimibe for primary hypercholesterolaemia or mixed dyslipidaemia

The Drugs Group considered Bempedoic acid (Nilemdo®) and Bempedoic acid in combination with Ezetimibe (Nustendi®) for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet, for statin intolerant patients or patients on maximally tolerated statin therapy. The Group reviewed and considered the available clinical evidence in detail. The limited evidence on the efficacy of Bempedoic acid in patients with heterozygous familial hypercholesterolemia was noted. Additionally, the effect of Bempedoic acid on cardiovascular outcomes has not yet been determined. The Group noted the Bempedoic acid cardiovascular outcomes trial, CLEAR Outcomes, is ongoing and will determine whether Bempedoic acid reduces the incidence of adverse cardiovascular events in high CV risk patients with statin intolerance and elevated LDL-C. The primary outcome is a composite of the time to first cardiovascular death, non-fatal myocardial infarction, non-fatal stroke or coronary revascularisation. The estimated primary completion date is December 2022. The Group considered the clinical evidence and cost of currently reimbursed therapies and agreed that a reimbursement recommendation for Bempedoic acid could not be made on the basis of the current evidence. The Drugs Group unanimously agreed that the results from the ongoing CLEAR Outcomes trial were required to inform further deliberations.

v. 22012 Pegylated liposomal Irinotecan for pancreatic adenocarcinoma

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

vi. 22013 Larotrectinib for solid tumours with a NTRK gene fusion

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 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)	In attendance
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
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
Post Vacant	Acute Services Division (Assistant National Director)	n/a
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	Apologies received
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:
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS