HSE Drugs Group – March 2022 Minutes

Meeting 2022.03: Tuesday 8th March 2022, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the February 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

There were currently no outstanding Drugs Group recommendations with the HSE EMT for consideration.

4. Declaration of Interests / Nil Interest

One member declared a conflict of interest for Dupilumab and abstained from the discussion and deliberations.

5. Medicines for Consideration

i. 22004 Blinatumomab for paediatric high risk first relapse ALL

The Drugs Group unanimously recommended in favour of reimbursement of Blinatumomab (Blincyto®) under the Oncology Drug Management System (ODMS) as monotherapy for the treatment of paediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome negative CD19 positive B-precursor ALL as part of the consolidation therapy. The Group reviewed study 20120215 which met its primary endpoint, demonstrating a statistically significant improvement in event-free survival (EFS) for patients treated with Blinatumomab compared to standard of care consolidation chemotherapy. Blinatumomab is currently reimbursed for a number of additional adult and paediatric indications. The Group recognised that this Blinatumomab indication represented an opportunity to treat a very small cohort of paediatric patients earlier in the treatment pathway. Following a review of the economic evidence, the Group considered the proposed commercial offer was sufficient to recommend in favour of reimbursement.

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

The Drugs Group unanimously recommended in favour of restricted reimbursement of Dupilumab (Dupixent®) under High Tech arrangements for the treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy (and who have not adequately responded to existing systemic treatments, who cannot tolerate them, or for whom their use is not clinically advisable). The Group reviewed the clinical and economic evidence for this patient population, including the commercial offer. It was noted that Dupilumab is currently reimbursed for adults and adolescents subject to a HSE Medicines Management Programme (MMP) managed access protocol. The Group agreed that Dupilumab represented a beneficial treatment option for a defined paediatric cohort for whom existing systemic therapies are not effective or tolerable. The Drug Group's positive recommendation was conditional on the establishment of a HSE MMP managed access protocol for this paediatric cohort.

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

The Drugs Group considered Nintedanib (Ofev®) for the treatment of other chronic fibrosing interstitial lung diseases with a progressive phenotype (PF-ILD). The Group noted that the term interstitial lung disease (ILD) encompasses a large group of pulmonary disorders. Nintedanib (Ofev®) is currently licensed and reimbursed for the treatment of idiopathic pulmonary fibrosis (IPF). The current pricing and reimbursement application pertains to a group of patients with different underlying clinical ILD diagnoses other than IPF who develop a progressive fibrosing phenotype during the course of their disease. The Group reviewed and discussed the clinical evidence for this indication in detail, noting that while the INBUILD trial met its primary endpoint (annual rate of decline in forced vital capacity), the analysis of time to death over 52 weeks suggested a similar risk of death between treatment groups in the overall population. Additionally, the trial was enriched with participants with a UIP-like fibrotic pattern and not all types of PF-ILDs were sufficiently represented in the study. A patient interest group submission was also considered by the Drugs Group in their deliberations. The Group reviewed the pharmacoeconomic evidence and despite the proposed commercial offer, the NCPE's adjusted base case incremental cost-effectiveness ratio (ICER) remained considerably higher than conventional willingness to pay thresholds compared to best supportive care. The Group considered there was significant uncertainty in the patient numbers and budget impact estimates due to the limited Irish epidemiological estimates and potentially underestimated market share projections. Following consideration of the totality of clinical and economic evidence, the Drugs Group unanimously agreed that the magnitude of the commercial offer was insufficient for the Group to support reimbursement. The Group unanimously agreed that it could recommend reimbursement if [redacted]

iv. 22007 Patiromer for the treatment of hyperkalaemia

The Drugs Group considered Patiromer (Veltassa®) for the treatment of persistent elevated potassium levels >5.4mEq/L in patients with chronic kidney disease (CKD), with or without heart failure, where continuation of renin angiotensin aldosterone system inhibitors (RAASi) therapy will have clear prognostic benefit. The Group noted this proposed cohort for reimbursement represented a defined subgroup of the full licensed population. The Drugs Group reviewed the evidence from the clinical development programme for Patiromer which encompassed a number of studies. The Drugs Group noted that while the clinical evidence demonstrated the efficacy of Patiromer in reducing serum potassium levels, the trials were not designed to assess clinical outcomes such as reduced mortality, rates of CKD progression or cardiovascular events. The Group considered that the cost-effectiveness estimates were not sufficiently robust for deliberations given the limitations of the clinical evidence and economic modelling. The Drugs Group considered that Patiromer would represent an additional, expensive step in the proposed treatment pathway if reimbursed. Optimal management of existing therapies was highlighted as being of key importance in this patient population. In the absence of the aforementioned clinical outcomes data, the Group unanimously agreed that it could not justify a positive reimbursement recommendation for Patiromer.

v. 22008 Entrectinib for ROS1-positive advanced NSCLC

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

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

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

6. AOB

20001 Darvadstrocel for the treatment of complex perianal fistulas in Crohn's Disease
The Drugs Group previously considered Darvadstrocel (Alofisel®) at their February 2020 meeting for the treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. On that occasion the Group unanimously did not support reimbursement and considered that a more robust clinical evidence base was required to support deliberations. The Group recommended that Darvadstrocel be referred to the Rare Diseases Technology Review Committee (RDTRC) when further clinical data became available.

At their March 2022 meeting, the Drugs Group reviewed a summary of recent developments for this Darvadstrocel application including additional clinical data. The Drugs Group requested that this additional clinical evidence be reviewed by the NCPE to determine whether there is sufficient clinical evidence to inform a robust review by the RDTRC, if referred.

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)	Apologies received
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	In attendance
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
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

*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