HSE Drugs Group – February 2024 Minutes
Meeting 2024.02: Tuesday 13th February 2024, 14.00 – 17.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the January 2024 meeting were considered and approved.

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

i. The Drugs Group wished to express their condolences to Professor Áine Carroll, HSE Drugs Group Chair, on the recent bereavement of a close family member. Dr. David Hanlon would chair the meeting in her absence.

ii. The Group were notified that Ellen McGrath had recently moved on from her role as the Head of the HSE Corporate Pharmaceutical Unit to a new professional opportunity external to the HSE. The Group acknowledged the loss of her significant experience and expressed their best wishes to Ellen in her new role.

iii. The Group acknowledged the current CPU resource constraints.

iv. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations from previous meetings had been progressed to the HSE Executive Management Team (EMT) and supported. This included EMT approval for Atidarsagene autotemcel (Libmeldy®), a medicine progressed via the Beneluxa initiative.

v. The Group previously reviewed Anifrolumab (Saphnelo®) at the January 2024 meeting, indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy. The applicant (AstraZeneca) was advised by CPU that a HTA should be submitted to the NCPE to progress this application.

vi. Daratumumab (Darzalex®) in combination with Cyclophosphamide, Bortezomib + Dexamethasone for the treatment of adult patients with newly diagnosed systemic light chain (AL) amyloidosis was previously considered by the Drugs Group at their May 2023 meeting, at which the Group made a conditional positive recommendation subject to an improved commercial offer. The applicant (Janssen) submitted a revised commercial offer which was considered by the Drugs Group at the February 2024 meeting. The Group maintained its May 2023 position and requested CPU to revert to the applicant regarding same.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Buprenorphine prolonged-release injection (Buvidal®) for opioid dependence (NCPE HTA ID: 22056)

The Drugs Group considered Buprenorphine prolonged-release solution for injection (Buvidal®) for the treatment of opioid dependence within a framework of medical, social and psychological treatment in adults and adolescents aged 16 years or over. The Drugs Group reviewed the entirety of the available clinical and economic evidence and the outputs of

commercial negotiations. The Group acknowledged that patients receiving treatment for opioid dependence can often include the most vulnerable in society and that current opioid agonist therapies have limitations. The advantages of Buvidal® as an additional treatment option were noted. The Drugs Group unanimously recommended pricing approval of Buvidal® for use within HSE Addiction Clinics including the National Drug Treatment Centre.

ii. **Nivolumab (Opdivo®) + chemotherapy for neoadjuvant treatment of NSCLC (NCPE HTA ID: 23050)**

The Drugs Group considered Nivolumab (Opdivo®) in combination with platinum-based chemotherapy for the neoadjuvant treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%. The Group reviewed the clinical and economic evidence, noting that Nivolumab represents the first immunotherapy to be licensed for neoadjuvant use in resectable NSCLC in adults. The Group acknowledged the impact of the commercial proposal on the cost per treatment course. Following deliberations, Nivolumab in combination with chemotherapy was unanimously recommended for reimbursement by the Group under the Oncology Drug Management System (ODMS) for this indication.

iii. **Avacopan (Tavneos®) for severe, active granulomatosis with polyangiitis or microscopic polyangiitis (NCPE HTA ID: 22009)**

The Drugs Group considered Avacopan (Tavneos®), in combination with a Rituximab or Cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA). The Group acknowledged that both GPA and MPA are rare, chronically debilitating conditions. In reviewing the clinical and economic evidence for Avacopan, the Group took into account a comprehensive patient interest group submission. The Group noted the serious side effects associated with current therapies. Limitations of the pivotal clinical trial were discussed. Treatment with Avacopan is associated with substantially higher costs than current standard of care. Taking into account the perspective of the applicant and the NCPE, the impact of the commercial offer does not result in an incremental cost effectiveness ratio (ICER) meeting conventional willingness to pay thresholds. The Drugs Group considered that the commercial offer was of insufficient magnitude to address the uncertainty related to cost-effectiveness. The Drugs Group agreed that it could recommend reimbursement under High Tech arrangements if [redacted]

iv. **Abemaciclib (Verzenios®) for adjuvant treatment of HR-positive, HER2-negative, node-positive early breast cancer (NCPE HTA ID: 22020)**

The Drugs Group considered Abemaciclib (Verzenios®) in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence. The Group reviewed the clinical evidence, noting that Abemaciclib represented the first licensed CDK4/6 inhibitor in this setting. In reviewing the economic evidence, the Group noted the substantial commercial offer and its impact on both the applicant's and the NCPE's cost-effectiveness estimates. The Group unanimously recommended in favour of reimbursement of Abemaciclib under High Tech arrangements for this indication.

v. **Daratumumab (Darzalex®) in combination with Lenalidomide and Dexamethasone for transplant ineligible newly diagnosed multiple myeloma (NCPE HTA ID: 22039)**

The Group considered Daratumumab (Darzalex®) in combination with Lenalidomide and Dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. The Group noted the rapidly evolving treatment landscape for multiple myeloma and the move towards Daratmumab usage in earlier lines of treatment. The Group reviewed the clinical and economic evidence in detail, the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC), a patient interest group submission and the outputs of commercial negotiations. The progression-free survival and overall survival (although immature) benefit for the Daratumumab arm of the pivotal MAIA trial was noted. Daratumumab in combination with Lenalidomide and Dexamethasone represents a high cost treatment option for this patient cohort. The Drugs Group noted the cost-effectiveness estimates and the very substantial budget impact. Following extensive and protracted deliberations, the Drugs Group were unable to make a recommendation for Daratumumab and requested additional information from the NCPE to inform further deliberations.

Appendix 1: Members Present on Microsoft Teams

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	Apologies received
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)	In attendance (Acting Chair)
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
Clare Mac Gabhann	Director of Nursing and Midwifery (Prescribing)	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Mr Michael Power	Public Interest Member	Apologies received
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Catherine Clarke	Strategy & Planning – Unscheduled Care (Assistant National Director)	In attendance
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

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

Secretariat:
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
James Kee, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS