HSE Drugs Group – January 2023 Minutes

Meeting 2023.01: Tuesday 10th January 2023, 14.00 – 16.30

Via videoconference

1. Draft Minutes for Consideration

The minutes of the December 2022 meetings 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

Atidarsagene autotemcel (Libmeldy®) for metachromatic leukodystrophy (MLD) was considered by the Drugs Group at their December 2022 meeting. The HSE EMT supported the Drugs Group positive recommendation, which was to pursue specific terms on which a hospital pricing approval would be progressed, in joint negotiations between the applicant company and the relevant authorities in Ireland, the Netherlands and Belgium. The Drugs Group were notified that joint negotiations had since commenced.

4. Declaration of Interests / Nil Interest

None declared

5. Medicines for Consideration

i. 22007 Patiromer for the treatment of hyperkalaemia

In March 2022 the HSE Drugs Group did not recommend reimbursement of Patiromer 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 proposed cohort for reimbursement represented a defined subgroup of the full licensed population. The Group overall did not consider reimbursement could be supported given the uncertainty associated with both the clinical and cost-effectiveness evidence available.

In response to the proposed decision of the HSE EMT to refuse to make Patiromer available for reimbursement, the applicant (Vifor CSL) submitted representations, which were considered by the Drugs Group in January 2023.

The Group acknowledged the role of Patiromer in reducing serum potassium where indicated, and that treatment with potassium binders are recommended within specific international treatment guidelines related to management of CKD and cardiovascular disease. The clinical development programme for Patiromer encompassed a number of studies, which 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. Additional published evidence (DIAMOND study) was made available within the representations which was reviewed by the Drugs Group. While noting the general low number of clinical outcomes reported, and the non-statistical significance, numerically more patients on Patiromer experienced cardiovascular death or all cause death, and therefore the DIAMOND study was not considered by the Group to adequately address concerns related to clinical effectiveness. The Group also discussed at length the potential merits of restricting reimbursement in a managed access programme but overall did not consider there was sufficient justification for same.

Based on the totality of the supporting information and evidence submitted, the Drugs Group unanimously recommended that reimbursement of Patiromer under the High Tech arrangements is **not** supported.

ii. 22012 Pegylated liposomal Irinotecan for pancreatic adenocarcinoma

The Drugs Group considered pegylated liposomal Irinotecan (Onivyde® Pegylated Liposomal) for the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and Leucovorin (LV), in adult patients who have progressed following Gemcitabine based therapy.
In May 2022 the HSE Drugs Group did not recommend reimbursement of Onivyde® Pegylated Liposomal. While recognising the substantial unmet need for new and effective treatments for pancreatic cancer the Group overall did not consider reimbursement could be supported when taking into account the cost-effectiveness and considerable budget impact for the relatively modest outcomes as reported in the main NAPOLI-1 study. In response to the HSE EMT proposed decision to refuse reimbursement, the applicant (Servier) submitted representations, which were considered by the Drugs Group in January 2023. On the basis of the totality of the evidence submitted, the Drugs Group (by majority) maintained its position and did not recommend reimbursement.

iii. 22033 Vericiguat for long-term heart failure with reduced ejection fraction

The Drugs Group considered Vericiguat (Verquvo®) for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilised after a recent decompensation event requiring intravenous therapy. The group recognised that even with medical advances in the treatment of chronic heart failure with reduced ejection fraction (HFrEF), patients continue to experience worsening HF events and that there continues to be an unmet medical need for new therapies with that can provide a further reduction in mortality and morbidity and an improvement in quality of life.

The pivotal PIII Vericiguat Global Study in Subjects with Heart Failure with Reduced Ejection Fraction (VICTORIA) results were reviewed in full by the Drugs Group. This was a randomised, double-blind, placebo-controlled trial, which assessed the efficacy and safety of Vericiguat in patients with chronic heart failure and reduced ejection fraction following a recent decompensation event. The primary outcome was a composite of death from cardiovascular causes or first hospitalisation for heart failure. Over a median of 10.8 months, a primary outcome event occurred in 897 of 2526 patients (35.5%) in the Vericiguat group and in 972 of 2524 patients (38.5%) in the placebo group (hazard ratio (HR), 0.90; 95% confidence interval (CI), 0.82 to 0.98; p=0.02). There was no significant difference in death from any cause (secondary endpoint) which occurred in 512 patients (20.3%) in the Vericiguat group as compared with 534 patients (21.2%) in the placebo group (HR, 0.95; 95% CI, 0.84 to 1.07; p=0.38). There was no significant difference in quality of life between the Vericiguat and placebo groups as measured using the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score.

The clinical and pharmacoeconomic assessment conducted by the National Centre for Pharmacoeconomics (NCPE) reported that Vericiguat is more costly and less effective when compared to Dapagliflozin, Empagliflozin and Ivabradine (i.e. dominated by several relevant comparators) both at list price and the confidential price offering proposed by the applicant. On the basis of the evidence presented, the HSE Drugs Group would only recommend in favour of reimbursement of Vericiguat if the cost-effectiveness was further improved, which required [redacted]. A positive recommendation would also be subject to the establishment of a managed access protocol restricting reimbursement of Vericiguat to the licensed cohort of HF patients, which is currently defined as HFrEF.

iv. 22034 Mogamulizumab for mycosis fungoides (MF) or Sézary syndrome (SS)

The Drugs Group considered Mogamulizumab (Poteligeo®) indicated for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy. The Group reviewed the clinical evidence from the pivotal MAVORIC trial, noting the significant overall progression free survival (PFS) relative to Vorinostat. The median PFS 7.7 months versus 3.1 months, respectively; hazard ratio [HR] 0.53 (95% CI: 0.41, 0.69). The primary endpoint was further supported by favourable results for Mogamulizumab compared with Vorinostat in response rate (ORR, 28 vs 5%), duration of response (DoR, 14 months vs 9 months) and time to next line therapy (TTNT, 11 months vs 3.5 months). The Group acknowledged the substantial impact of the commercial offer on the cost-effectiveness estimates relative to list price. While acknowledging that there were some uncertainties in the clinical evidence available, including the confounding of the overall survival results, the Drugs Group voted in favour of reimbursement of Mogamulizumab for this indication.

v. 22036 Niraparib for 1L maintenance treatment of ovarian cancer

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the February 2023 meeting.

6. AOB

Two applications included on the agenda had representations submitted by practicing clinicians, which were shared in full with the Drugs Group. A discussion ensued on the appropriateness of the current processes and procedures. These processes will now be subject to review for further discussion at a future meeting of the Drugs Group.

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
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	In attendance
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

*part voting not attended

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

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