HSE Drugs Group – March 2024 Minutes
Meeting 2024.03: Tuesday 12th March 2024, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

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

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

i. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations from the previous meeting had been progressed to the HSE Executive Management Team (EMT) for consideration.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Finerenone (Kerendia®) for the treatment of chronic kidney disease (Stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults (NCPE HTA ID: 22012)

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ii. Finerenone (Kerendia®) for the treatment of chronic kidney disease (with albuminuria i.e. stage 1 and 2) associated with type 2 diabetes in adults (NCPE HTA ID: 23077)

The Drugs Group noted two individual Finerenone applications were scheduled for successive consideration and, given their overlap, agreed to review the totality of clinical and pharmacoeconomic evidence for each application before commencing deliberations.

The Group acknowledged the increasing prevalence of CKD associated with type 2 diabetes in adults. The treatment landscape for CKD associated with type 2 diabetes has evolved considerably in recent years with a number of landmark trials demonstrating the cardiorenal protective benefits of SGLT2 inhibitors. The Group noted international guidelines now recommend initiation of a SGLT2 inhibitor in patients with type 2 diabetes, CKD and an eGFR ≥20 ml/min/1.73 m^2. The Group noted that Finerenone (a novel, selective, non-steroidal mineralocorticoid receptor antagonist) is anticipated to be used as an add-on therapy to SGLT2 inhibitors in the treatment pathway for this cohort of patients. Clinical evidence from the FIDELIO-DKD, FIGARO-DKD, and the FIDELITY pooled analysis was reviewed in detail by the Group. 4.6% and 8.4% of the overall FIDELIO-DKD and FIGARO-DKD trial populations were receiving treatment with a SGLT2 inhibitor as a baseline medication, respectively. The Group noted the considerable uncertainty associated with the magnitude of additional clinical benefit to be gained from the introduction of Finerenone. In the context of a recently evolved treatment pathway, the Group considered the currently available clinical evidence in relation to the incremental benefit of Finerenone over and above international standard of care (i.e. ACEi/ARB + SGLT2 inhibitor treatment) to be limited and insufficient to support a positive reimbursement recommendation at this time. On the basis of the limitations of the currently available clinical evidence, the Group unanimously recommended against reimbursement of Finerenone.

iii. Venetoclax (Venclyxto®) for acute myeloid leukaemia (NCPE HTA ID: 22001)

The Drugs Group considered the reimbursement of Venetoclax (Venclyxto®) in combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy. The Group acknowledged the rare and aggressive nature of AML and the need for additional treatment options for newly diagnosed patients without actionable mutations, deemed unfit for intensive chemotherapy. The significant overall survival advantage demonstrated by the Venetoclax +

Azacitidine arm versus the Azacitidine monotherapy arm in the pivotal VIALE-A trial was noted. The Drugs Group considered the cost effectiveness evidence in depth, including the impact of the commercial offer. The Drugs Group noted the ICER for Venetoclax + Azacitidine versus Azacitidine still exceeded conventional willingness to pay thresholds from both the applicant and the NCPE's perspective. Following deliberations, the Group, by majority, recommended in favour of reimbursement under High Tech arrangements having carefully weighed up the clinical and economic evidence including the rarity of the disease, the bleak prognosis, the limited treatment options in this cohort, and the overall survival benefit observed in the clinical trial.

iv. **Odevixibat (Bylvay®) for progressive familial intrahepatic cholestasis (NCPE HTA ID: 21058)**

The Drugs Group considered Odevixibat (Bylvay®) for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. The Group acknowledged the severe impact of this disease, typically affecting young children. Patients not undergoing surgical biliary diversion or liver transplant have a very bleak prognosis. Pharmacological treatment options are limited to unlicensed symptomatic medical therapies. A patient interest group submission informed the Drugs Group deliberations. The evidence from the pivotal phase III clinical trials was reviewed. The Group noted that PEDFIC1 (a randomised, double-blind, placebo-controlled trial) met its primary endpoint with significantly greater proportions of Odevixibat treated patients achieving the specified reduction in fasting serum bile acid levels. The impact of Odevixibat on pruritus and the improvements in z-scores for height and weight in actively growing children treated with Odevixibat was also noted. Despite a substantial commercial offer from the applicant, the Drugs Group noted that the cost effectiveness estimates far exceeded conventional willingness to pay thresholds. Notwithstanding this, following deliberations, the Drugs Group recommended in favour of reimbursement of Odevixibat for PFIC, under High Tech arrangements, in patient 6 months and older subject to the establishment of a managed access protocol. This positive recommendation took into account the high unmet need for this debilitating orphan disease, the supporting PIII clinical trial evidence, the detail outlined in the patient interest group submission, and the impact of the commercial offer on the cost effectiveness and budget impact for Odevixibat.

5. AOB

i. The Drugs Group Chair proposed an in person meeting be considered by the Group in the near future, if feasible for members.

ii. The Drugs Group Chair proposed extending an invite to the HSE Medicines Management Programme to provide a brief overview of Health Technology Management, specifically the impact of Drugs Group recommended managed access protocols for medicines previously considered. It was agreed this would be of value to the Group.

iii. The Group agreed, in line with the Terms of Reference, that a second alternate cannot attend a Drugs Group meeting in the event a Drugs Group member or their nominated, accepted alternate are not in a position to attend.

iv. The membership of the Drugs Group was discussed including the current vacancy and the potential expansion of the membership to include further specialities.

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)	Apologies received
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)	Apologies received
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	Apologies received
Catherine Clarke	Strategy & Planning – Unscheduled Care (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	In attendance

In attendance (non-voting):
Dr Lesley Tilson (NCPE)

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