HSE Drugs Group – July 2024 Minutes
Meeting 2024.06: Tuesday 9th July 2024, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

The minutes of the June 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 progressed to the HSE Senior Leadership Team (SLT) for consideration from previous meetings had been supported.

ii. The Group agreed to hold an additional meeting in August 2024 providing sufficient members are available for a quorum.

iii. It was noted that suitable replacements were being sought for the current Drugs Group vacancies.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Trastuzumab deruxtecan (Enhertu®) for HER2-positive breast cancer (NCPE HTA ID 22050)

The Group considered Trastuzumab deruxtecan (Enhertu®) as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens. The Group noted the progression-free survival and overall survival benefit reported in the pivotal DESTINY-Breast03 study. The Group acknowledged the impact of the commercial proposal and the substantial improvement in the cost effectiveness estimates. Following consideration of the clinical and pharmacoeconomic evidence, the Drugs Group, by majority, recommended in favour of reimbursement of Trastuzumab deruxtecan under the Oncology Drug Management System (ODMS). The Group noted this majority positive recommendation was against the backdrop of a very substantial and challenging budget impact for the HSE.

ii. Vosoritide (Voxzogo®) for achondroplasia in patients aged two years and older (NCPE HTA ID 22028)

The Drugs Group considered Vosoritide (Voxzogo®) for the treatment of genetically confirmed achondroplasia in patients aged two years and older whose epiphyses are not closed.
The Group reviewed the clinical and economic evidence in detail along with the outputs of commercial negotiations, and the patient interest group submission received during the HTA process for Vosoritide (Voxzogo®). The Drugs Group were unable to progress a recommendation that was supportive of reimbursement on the basis of the clinical and cost-effectiveness evidence available. As the application was for a medicine for the management of a rare disease, further patient and clinician engagement input via the HSE Rare Diseases Technology Review Committee (RDTRC) would be sought. The Group committed to reviewing

the output of the RDTRC at the earliest opportunity and would consider a reimbursement recommendation at that time.

iii. Difelikefalin (Kapruvia®) for moderate to severe pruritus associated with chronic kidney disease in adult patients on haemodialysis (NCPE HTA 23001)

The Drugs Group considered Difelikefalin (Kapruvia®) for the treatment of moderate to severe pruritus associated with chronic kidney disease in adult patients on haemodialysis. The Group acknowledged that patients undergoing haemodialysis have a reduced quality of life and a shortened life expectancy, with both further reduced in those with chronic kidney disease associated pruritus (CKD-aP). The Group noted the use of off-label therapies in CKD-aP patients, which are not always well tolerated and lack robust evidence of their antipruritic efficacy, underscoring a significant unmet need in this patient cohort. The Group acknowledged the substantial commercial proposal and its impact on cost-effectiveness estimates. Having considered the unmet need for a licensed & effective therapy, the strengths and limitations of the clinical evidence, and the considerable improvement in cost-effectiveness, the Drugs Group unanimously recommended hospital pricing approval of Difelikefalin (Kapruvia®) in this indication.

iv. Ibrutinib (Imbruvica®) in combination with Venetoclax, for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) (NCPE HTA ID 22054)

The Drugs Group considered Ibrutinib (Imbruvica®) in combination with Venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). The Group reviewed the clinical and economic evidence, the outputs of commercial negotiations, the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC) as well as the patient interest group submission received during the HTA process. The Group noted that Ibrutinib in combination with Venetoclax represents the first all-oral, once daily, chemotherapy-free, fixed-duration regimen in this disease area. In reviewing the clinical evidence, the Group noted a number of limitations. The control arm of the GLOW trial was not considered to represent standard of care in Ireland. The CAPTIVATE trial lacked a control arm and was open-label in design with non-blinded investigator assessment. The Group noted the ongoing Study CLL17 evaluating Ibrutinib monotherapy v fixed-duration Venetoclax + Obinutuzumab v fixed-duration Ibrutinib + Venetoclax in patients with previously untreated CLL may provide further clinical evidence for Ibrutinib + Venetoclax in this CLL setting. The Group acknowledged that the limitations in the comparative effectiveness evidence informing the model rendered the cost effectiveness evidence subject to considerable uncertainty. Given the lack of evidence in certain subpopulations and limitations in the indirect treatment comparisons (ITCs) presented by the applicant, the NCPE were unable to undertake a NCPE-adjusted base case analysis. On the basis of the limitations in the clinical and pharmacoeconomic evidence, the Drugs Group by majority did not recommend in favour of reimbursement of Ibrutinib + Venetoclax in this indication.

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)	Apologies received
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 Mary Ruth Hoban	Assistant Director of Nursing and Midwifery (Prescribing) HSE West	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Position vacant	Public Interest Member	N/A
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Ms Carol Ivory for Ms Catherine Clarke	General Manager, Specialist Acute Services, Acute Operations, HSE for Strategy & Planning – Unscheduled Care (Assistant National Director)	In attendance
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	Apologies received
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
Louise Walsh, Senior Pharmacist, CPU PCRS