HSE Drugs Group – February 2025 Minutes
Meeting 2025.02: Tuesday 11th February 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the January 2025 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 for consideration from previous meetings had been supported.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Ropeginterferon alfa-2b (Besremi®) for polycythaemia vera (NCPE HTA ID: 23004)

The Drugs Group considered ropeginterferon alfa-2b (Besremi®) as monotherapy in adults for the treatment of polycythaemia vera (PV) without symptomatic splenomegaly. The Group acknowledged that PV is a rare, debilitating and life-threatening condition for which there is a number of licensed therapies (one of which is currently experiencing a global supply issue). Ropeginterferon alfa-2b represents an additional treatment option for PV patients, enabling a fortnightly administration schedule. The applicant anticipates that ropeginterferon alfa-2b may be used for adult patients over 60 years, with PV without symptomatic splenomegaly, who are intolerant, resistant to or who demonstrate an incomplete response to treatment with Hydroxycarbamide and require a subsequent treatment option, as an alternative to ruxolitinib. This proposed place in therapy was noted by the Group as not fully aligning with NCPE sought clinical opinion. Clinical evidence from the PROUD-PV and CONTINUATION-PV trials was reviewed by the Group. Several methodological issues and uncertainties of the trials were noted. The Group also noted the absence of direct comparative evidence for ropeginterferon alfa-2b versus ruxolitinib or pegylated interferon alfa-2a. A patient organisation submission of evidence from MPN Voice was considered by the Group. Further information was also reviewed by the Group from the National Cancer Control Programme Technology Review Committee (NCCP TRC). At list price the pharmacoeconomic analysis demonstrated that the comparator ruxolitinib dominated ropeginterferon alfa-2b (i.e. was less costly and more effective). The applicant (AOP Pharma) proposed a [redacted] This rendered [redacted] than ruxolitinib under the applicant's base case. An NCPE Review Group adjusted base case was not presented given the limitations of the model structure and the supporting assumptions. The Group agreed there was insufficient evidence to justify the price premium of ropeginterferon alfa-2b relative to existing therapies. On the basis of the totality of currently available evidence, the Group unanimously recommended against reimbursement of ropeginterferon alfa-2b.

ii. Lipegfilgrastim (Lonquex®) in children 2 years of age and older for neutropenia (NCPE HTA ID: 23080)

The Drugs Group considered lipegfilgrastim (Lonquex®) in children 2 years of age and older for reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). The application for lipegfilgrastim in paediatric patients also incorporated a new vial presentation for consideration. Lipegfilgrastim was approved for

reimbursement under High Tech arrangements for adult patients in 2013. Lipegfilgrastim is the first long-acting granulocyte-colony stimulating factor (G-CSF) licensed for paediatric cancer patients, the potential patient benefits of which were acknowledged by the Group. Following consideration of the clinical and economic evidence, the Group by majority recommended in favour of reimbursement of lipegfilgrastim under High Tech arrangements.

iii. Tafasitamab (Minjuvi®) for relapsed/ refractory DLBCL (NCPE HTA ID: 22008)

The Drugs Group considered tafasitamab (Minjuvi®) in combination with lenalidomide followed by tafasitamab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT). The Group acknowledged the rapidly evolving DLBCL treatment landscape and considered that tafasitamab represented an additional treatment option for patients. The Group reviewed the clinical evidence from the L-MIND trial, noting the objective response rate and overall survival data but also the associated uncertainties of a single-arm, open-label, phase II study. In reviewing the pharmacoeconomic evidence, the Group acknowledged the impact of the substantial commercial proposal in mitigating some of the uncertainty relative to existing therapies. Following deliberations, the Group, by majority, recommended in favour of reimbursement of tafasitamab (Minjuvi®) under the Oncology Drug Management System (ODMS).

iv. Fruquintinib (Fruzaqla®) for metastatic colorectal cancer (NCPE HTA ID 24031)

The Drugs Group considered fruquintinib (Fruzaqla®) as monotherapy for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib. The aim of treatment for mCRC is to prolong survival while maintaining the best possible quality of life. Following exhaustion of available standard therapies, an unmet medical need prevails. Clinical evidence from the pivotal FRESCO-2 trial was reviewed alongside the NCCP TRC recommendation. In the FRESCO-2 trial, fruquintinib demonstrated an absolute increase in median OS of 2.6 months relative to placebo. The Group acknowledged that whilst modest, the OS benefit is considered clinically relevant in this cohort of patients with refractory disease. The Group reviewed the substantial commercial proposal and its budgetary impact. Having considered the unmet need, the strengths and limitations of the available evidence, and the impact of the commercial proposal, the Drugs Group recommended (by majority) in favour of reimbursement of fruquintinib under High Tech arrangements.

5. AOB

i. The Chair and Drugs Group acknowledged the imminent departure of Professor Ellen Crushell from her role as a Drugs Group member. The Chair and Group warmly thanked Professor Crushell for her dedication and insightful contributions over the years and wished her every success in her new role. A suitable replacement would now be sought to fill the vacated position.

ii. The Group was notified that the HSE was currently working with the HSE National Patient and Service User Forum to seek expressions of interest from members of the public interested in becoming a public interest member of the HSE Drugs Group.

Appendix 1: Members Present via videoconference

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 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 Position vacant	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	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance*
Dr Kevin Kelleher	Lay member	In attendance

*Parts of meeting and/or some voting not attended

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

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