HSE Drugs Group – January 2022 Minutes

Meeting 2022.01: Tuesday 11th January 2022, 14.00 – 16.30

Via videoconference

1. Draft Minutes for Consideration

The minutes of the December 2021 meeting 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 meetings

An update on items previously considered by the Drugs Group was provided. The Group's relevant recommendations from the December 2021 meeting had since been progressed to the HSE EMT for deliberation.

4. Declaration of Interests / Nil Interest

5. Medicines for Consideration

i. 20024 Axicabtagene Ciloleucel for the treatment of relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL)

The Drugs Group previously considered Axicabtagene Ciloleucel (Yescarta®) at its April 2021 meeting for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy. The Drugs Group did not support reimbursement on that occasion.

The Drugs Group noted the additional clinical evidence and enhanced commercial proposal submitted by the applicant for consideration. Following a comprehensive review and deliberation upon the totality of evidence including the substantial opportunity cost, the Drugs Group agreed, by majority, to support reimbursement of Axicabtagene Ciloleucel for this indication.

ii. 22001 Venetoclax in combination with Obinutuzumab for previously untreated chronic lymphocytic leukaemia (CLL)

The Drugs Group unanimously recommended in favour of reimbursement of Venetoclax (Venclyxto®) in combination with Obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). The Group noted the evolving role of Venetoclax in the CLL treatment pathway. The Group reviewed the clinical evidence from the pivotal, phase III study (CLL14). Overall survival data is currently immature but improvements in progression-free survival with Venetoclax in combination with Obinutuzumab were supported by improved objective response rates, complete response rates and minimal residual disease rates versus the control arm. At list price, the Group noted the cost-effectiveness of Venetoclax in combination with Obinutuzumab was predominantly favourable versus comparators. The commercial proposal further improved the cost-effectiveness of this treatment regimen. The Group agreed that reimbursement of Venetoclax in combination with Obinutuzumab be recommended.

iii. 20007 Risankizumab for plaque psoriasis

Risankizumab (Skyrizi®) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy was considered by the Drugs Group. The Group reviewed the clinical and economic evidence, noting the number of biological comparators available for plaque psoriasis. The Group recommended restricted reimbursement under the High Tech arrangements whereby Risankizumab be reserved for use as a subsequent line of therapy following treatment with a lower cost biological disease modifying anti-rheumatic drug (bDMARD).

iv. 22002 Cabotegravir in combination with Rilpivirine for HIV-1 infection

The Drugs Group considered Cabotegravir (Vocabria®) in combination with Rilpivirine (Rekambys®) for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/ml) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class. The Group noted that this treatment regimen represented the first 2-drug long acting injectable regimen for the maintenance of viral suppression in HIV-1 patients. At list price, this treatment regimen represented a price premium relative to oral HIV treatment regimens. Following consideration of the commercial proposal, the Group considered that this regimen was now [redacted]

v. 21022 Gilteritinib for acute myeloid leukaemia

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the February 2022 meeting.

vi. 21017 Semaglutide for type II diabetes mellitus

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the February 2022 meeting.

6. AOB

i. The Drugs Group discussed the possibility of members voting in absentia in the event a member may be unable to attend a meeting. The value and merit of the broader Group inputs and deliberations informing each Drugs Group recommendation was recognised. The Group agreed it was important to maintain the current voting process at this time.

ii. The Drug Group noted that a total of 52 new medicines were approved by the HSE in 2021 (29 new medicines, 21 new uses of existing medicines, and expanded reimbursement of a further 2 medicines). Despite a 5 year investment exceeding €477m by the HSE for these 52 medicines, approximately €400m in additional costs over the next 5 years will be avoided on these new medicines following price reductions as a result of assessments (carried out by the National Centre for Pharmacoeconomics), commercial negotiations (led by the Corporate Pharmaceutical Unit of the Primary Care Reimbursement Service) and the deliberative processes followed by the Drugs Group and the HSE Executive Management Team.

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	In attendance
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)	Apologies received
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	In attendance*
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance*
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	In attendance	In attendance
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
Ms Angela Fitzgerald	Acute Services Division (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*

*Parts of meeting and voting not attended

In attendance (non-voting):
Ms Kate Mulvenna
Dr. Lesley Tilson (NCPE)

Secretariat:
Ms Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Ms Fiona Mulligan, Chief II Pharmacist, CPU PCRS