HSE Drugs Group – April 2021 Minutes

Meeting 2021.04: Tuesday 13th April 2021, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the March 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

The National Service Plan (NSP) made a provision of €50m for new drugs in 2021. There are currently no outstanding applications with the HSE EMT awaiting a decision with the most recent Drugs Group recommendation for Talazoparib being approved by the EMT for reimbursement.

Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations in relation to Tisagenlecleucel (both indications), Axicabtagene Ciloleucel and Atezolizumab in combination with nab-paclitaxel for the treatment of TNBC were available for the HSE Drugs Group and considered in the discussions for these medicines.

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 20023 Tisagenlecleucel for the treatment of relapsed and/or refractory diffuse large B cell lymphoma (DLBCL)

Tisagenlecleucel for the treatment of r/r DLBCL was previously considered by the Drugs Group in November 2020. At that meeting the Drugs Group was unable to support reimbursement (in the majority) on the basis of the application submitted.

In response to the Drugs Group position on reimbursement in November 2020 the applicant submitted a revised commercial proposal for the DLBCL indication [redacted] Further efficacy data was also made available from the pivotal JULIET study. The commercial proposal improved the cost-effectiveness to a level that was considered acceptable by the Group for this application [redacted] Given the improved terms in the commercial offer, the unmet need, and potential for CAR-T to offer a prolonged response and survival in some patients the unanimous decision of the Drugs Group was to support a positive reimbursement recommendation for this indication.

ii. 20022 Tisagenlecleucel for the treatment of relapsed and/or refractory B-cell acute lymphoblastic leukaemia (ALL)

The pricing and reimbursement application for Tisagenlecleucel for the treatment of relapsed and/or refractory B-cell acute lymphoblastic leukaemia (ALL) had previously been reviewed by the Drugs Group at its meeting in October 2020. In previous deliberations it was broadly recognised that relapsed

and/or refractory paediatric ALL (pALL) is a rare condition with a high unmet need but there were also uncertainties noted by the Group in terms of the clinical benefits obtained from Tisagenlecleucel in pALL arising from a lack of comparative data in the single-arm designed pivotal studies and overall survival (OS) data that remained immature.

The Drugs Group request for further engagement with the company on the matter of the identified uncertainties in both the evidence for clinical and cost-effectiveness led to a revised commercial offer being deliberated on at the April 2021 meeting. In addition more mature clinical data emerging from the ELIANA study was reviewed by the Group. The developing data continued to demonstrate that treatment with CAR-T could offer transformative survival outcomes for some patients with r/r ALL with an otherwise known poor prognosis. The revised commercial offer also resulted in an improvement in cost-effectiveness to a level that was considered acceptable by the Group. The totality of the further supporting information submitted by the applicant was sufficient for unanimous support of a positive recommendation for reimbursement.

iii. 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 main efficacy data submitted as part of the pricing and reimbursement application for Axicabtagene Ciloleucel was derived from one single arm PI/II open-label multicentre study ZUMA-1. The primary endpoint was objective response rate (ORR). In the 24-month follow-up analysis, based on the mITT population (n=101), the ORR and the CR rate based on the independent review committee were 74% and 54%, respectively. Median duration of response and median overall survival had not been reached. The main outcomes results including survival observed in the ZUMA-1 study compared favourably to the results observed in SCHOLAR-1, a retrospective, patient-level, pooled analysis of outcomes in refractory aggressive NHL (n = 636) that provided historical context for interpreting the ZUMA-1 results.

The results of the Health Technology Assessment conducted by the National Centre for Pharmacoecomics (NCPE) compared treatment with Axicabtagene Ciloleucel versus standard of care in Irish clinical practice which consists of salvage chemotherapy regimens. The Drugs Group noted that at list price the incremental cost-effectiveness ratios were high and subject to number of uncertainties, which was demonstrated by a 0% probability of cost effectiveness based on a willingness to pay threshold (WTP) of €45,000/QALY.

When reviewing the commercially confidential offer submitted by the applicant the Drugs Group considered that there was a lack of evidence to support the price [redacted]

The Drugs Group concluded that it would support reimbursement of Axicabtagene Ciloleucel if a commercial offering emerged [redacted] when clinicians select to treat r/r DLBCL patients with one CAR-T product over another.

iv. 21007 Atezolizumab for triple negative breast cancer (TNBC)

The Drugs Group, in the majority, did not support reimbursement of Atezolizumab (Tecentriq®) in combination with nab-paclitaxel for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death ligand-1

(PD-L1) expression ≥ 1%, and who have not received prior chemotherapy for metastatic disease. The Group considered the magnitude of unmet need and the overall survival evidence in the context of the costs that would have to be funded. Notwithstanding the submission of a confidential commercial offer the application could not be considered to be a cost-effective use of resources. Using the applicant preferred base case the final approximated ICERs remain substantially above conventional willingness to pay thresholds.

v. 21008 Atezolizumab for extensive stage small cell lung cancer (SCLC)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 2021 meeting.

vi. 21009 Atezolizumab for 1L urothelial carcinoma (UC)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 2021 meeting.

vii. 21010 Tafamidis for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy(ATTR-CM)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 2021 meeting.

viii. 21011 Ozanimod for relapsing remitting multiple sclerosis (RRMS)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 2021 meeting.

ix. 21012 Dabrafenib + Trametinib for adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 2021 meeting.

x. 21013 Delafloxacin antibiotic therapy for the treatment of infection

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the May 2021 meeting.

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)	Apologies received
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
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	Public Interest Member	In attendance*
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance*
Ms Angela Fitzgerald	Acute Services Division (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

*Parts of meeting and voting not attended

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

Secretariat:
Ms Fiona Mulligan, Senior Pharmacist, CPU PCRS
Ms Ellen McGrath, Chief I Pharmacist, CPU PCRS
Ms Jennifer McCartan, Chief II Pharmacist, CPU PCRS