HSE Drugs Group – December 2020 Minutes

Meeting 2020.10: Tuesday 8th December 2020, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the November 2020 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

CPU provided the members with an update in relation to items previously considered. The group were made aware that EMT approved one license extension (new use) from December 2020.

Updates / reports from TRCs

The National Cancer Control Programme Technology Review Committee's (NCCP TRC) recommendations in relation to Liposomal Daunorubicin and Cytarabine as well as Niraparib were available for the HSE Drugs Group and considered in the discussions for both medicines.

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 20025 Lanadelumab for the routine prevention of recurrent attacks of hereditary angioedema (HAE)

Lanadelumab is a potentially life long prophylactic treatment to prevent angioedema attacks, that can be life threatening, in patients diagnosed as having hereditary angioedema (HAE). The Drugs Group noted that HAE was a rare disease and that there was an unmet need for effective treatments to reduce the frequency and severity of attacks that would positively impact on patients' quality of life.

The Drugs Group considered the clinical and cost-effectiveness evidence that was available for Lanadelumab.

HELP-03 was the pivotal PIII trial, which was a multicenter, randomised, double-blind, placebo-controlled parallel-group study in 125 (including 10 adolescents) patients with symptomatic type I or II HAE. During the study run-in period, the mean attack rate was 3.7 attacks/month with 52% (65/125) of subjects experiencing ≥3 attacks/month. After 26 weeks treatment all three Lanadelumab treatment arms produced statistically significant reductions in the mean monthly HAE attack rate compared to placebo across all primary and secondary endpoints in the Intent-to-Treat population (ITT). All Lanadelumab treatment groups also observed an improvement in Angioedema Quality of Life Questionnaire (AE-QoL) total and domain scores compared to the placebo group. Further evidence, where patients were followed up for 30 months was also available from an open label extension study HELP-04. Final analysis from this study showed that [redacted].

[redacted]

[redacted]

The Drugs Group recommended reimbursement conditional on a managed access programme and clinical guideline being in place that would ensure patients who meet the eligibility criteria were reviewed at appropriate intervals and maintained on the lowest effective dose. The positive recommendation was also conditional on the applicant [redacted] proposed in a patient access scheme [redacted].

ii. 20026 Liposomal Daunorubicin and Cytarabine for the treatment of acute myeloid leukaemia (AML)

The Drugs Group unanimously recommended in favour of reimbursement of Liposomal Daunorubicin and Cytarabine (Vyxeos Liposomal®) under the Oncology Drug Management System (ODMS) for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

In the pivotal PIII study, Study 301 (n=309) Vyxeos Liposomal demonstrated superiority in overall survival (primary endpoint) in the ITT population compared with the comparator 7+3 treatment regimen.

The applicant proposed [redacted] which resulted in an incremental cost effectiveness ratio of [redacted] (applicant) and [redacted] (NCPE perspective) compared with standard of care. At the confidential price, the Drugs Group accepted that reimbursement of Vyxeos Liposomal®, an orphan drug meeting a significant unmet need in AML, could be supported.

iii. 20027 Upadacitinib for rheumatoid arthritis

The Drugs Group recommended reimbursement of Upadacitinib under High Tech arrangements, which was conditional on a managed access programme being in place that would ensure patients with moderate to severe rheumatoid arthritis (RA) were first adequately treated with the lowest cost biological disease modifying anti-rheumatic drug (bDMARD) currently available for reimbursement and that Upadacitinib would be reserved for use as a subsequent line of treatment where required i.e. for inadequate responders.

The Drugs Group noted that the HSE currently reimburses two alternative JAK inhibitors for the treatment of RA. [redacted]

iv. 20004 Niraparib for ovarian cancer

The application for Niraparib was previously considered by the Drugs Group in March 2020. The Drugs Group requested that the CPU engage with the applicant with the view to enhancing the confidential pricing proposal. A new commercially confidential proposal was available and considered at the December meeting.

The Drugs Group, in the majority, recommended in favour of reimbursement of Niraparib (Zejula®) under High Tech arrangements as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

The NOVA study was a pivotal phase III, double blind, comparative, randomised international study conducted in 553 patients with relapsed, predominantly high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who were platinum sensitive, defined by complete response (CR) or partial response (PR) for more than six months to their penultimate platinum-based therapy. Niraparib was associated with a statistically significantly improved progression free survival (PFS) compared with placebo in the gBRCA mutation cohort as well as in the overall non-gBRCA mutation cohort. In both cohorts the superiority of the Niraparib arm over the placebo arm was observed in all predefined subgroups and the highest efficacy was observed for the BRCA2 mutation.

The Drugs Group noted that the revised commercial proposal meant that in the gBRCA mutation population [redacted]. In the non-gBRCA mutation population the final ICER ranged from [redacted] (applicant preferred assumptions) to [redacted] (NCPE preferred assumptions) vs. routine surveillance. The HSE currently reimburses Olaparib for the gBRCA mutation population (similar licensed indication) but there is no PARP inhibitor approved for the non-gBRCA mutation population leaving a significant unmet need in a patient group with a very dismal prognosis. The Drugs Group (in the majority) therefore supported reimbursement for both cohorts on the basis of the unmet need as well as the clinical and cost-effectiveness evidence presented.

v. 20005 Dupilumab for atopic dermatitis (adult)

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

vi. 20006 Dupilumab for atopic dermatitis (adolescent)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the January 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	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)	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)	Apologies received
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	Apologies received
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance
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

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

Secretariat:
Ms Fiona Mulligan, Senior Pharmacist, CPU PCRS
Ms Maria Daly, Chief II Pharmacist, CPU PCRS
Ms Ellen McGrath, Chief II Pharmacist, CPU PCRS