HSE Drugs Group – July 2026 Minutes
Meeting 2026.07: Tuesday 14th July 2026, 14.00 – 17:00
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the June 2026 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 Management Team (SMT) for consideration following the June 2026 meeting had been supported.

3. Declaration of Interests / Nil Interest

None raised

4. Medicines for Consideration

i. Risdiplam (Evrysdi®) for the treatment of 5q spinal muscular atrophy (SMA) in adult patients with a clinical diagnosis of SMA Type 2 or Type 3 or with one to four SMN2 copies (HSE Pricing and Reimbursement Application tracker ID: HSE100076, NCPE HTA ID: 25062)

The Drugs Group considered risdiplam (Evrysdi®) for the treatment of 5q SMA in patients with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies. The applicant sought reimbursement approval in a subpopulation of the licensed population, in respect of patients aged 18 years and older with a clinical diagnosis of SMA Type 2 or Type 3 or with one to four SMN2 copies, who have not previously been treated with a Disease Modifying Therapy (DMT). Following risdiplam review by the Drugs Group in April 2026, the Group requested its referral to the HSE Rare Diseases Technology Review Committee (RDTRC) for further patient and clinician engagement, to assist in their deliberations. Upon completion of the RDTRC process, the Drugs Group, at the July 2026 meeting, reviewed the totality of clinical and economic evidence for risdiplam, including the statement from the RDTRC as well as the outputs of commercial negotiations. The Group recognised that SMA is a rare and highly variable disease which can lead to impaired motor function and reduced life expectancy. The Group recognised that there is a cohort of patients in Ireland aged 18 years or older who do not have access to any DMT and receive best supportive care only. In reviewing the available evidence, the Group acknowledged the uncertainties in the clinical efficacy data, the high unmet need for this cohort of patients, and noted the impact of the commercial proposal and the associated budget impact. Following lengthy deliberations, the Group, by majority, recommended in favour of reimbursement of risdiplam (Evrysdi®) for the above indication under High Tech arrangements subject to the establishment of a Managed Access Protocol (MAP).

ii. Levodopa (Inbrija®) for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease (HSE Pricing and Reimbursement Application tracker ID: HSE100057, NCPE HTA ID: 25044)

The Drugs Group previously considered levodopa (Inbrija®) for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease treated with a levodopa/dopa-decarboxylase inhibitor at the February 2026 meeting. The Group unanimously did not recommend reimbursement at this meeting. Following consideration by the HSE Senior Leadership Team (SLT), the Drugs Group recommendation was subsequently supported.

In response to the written Notice of Proposal of the HSE's intention not to reimburse levodopa (Inbrija®) for this indication, the applicant submitted representations, which were considered by the Drugs Group at the July 2026 meeting. The Group recognised that Parkinson's disease is a chronic, progressive, neurodegenerative disorder and that motor fluctuations (OFF episodes) have a significant impact on quality of life. The Group acknowledged that Inbrija®, a powder for inhalation (PFI), offers an alternative route of administration for levodopa, independent of the gastrointestinal route. The Group also noted that the use of Inbrija® PFI requires patients to be capable of preparing the inhaler and educated in correct inhalation technique. The Group noted uncertainties in the available clinical efficacy data and the lack of direct comparative evidence against existing treatments. The Group acknowledged that levodopa PFI is an alternative formulation of an established drug that is already reimbursed by the HSE, and noted the significant cost differential between levodopa PFI and oral dispersible levodopa, notwithstanding the improved proposed commercial offer. The Group noted that budget impact estimates were subject to considerable uncertainty. Following deliberations, having considered the totality of clinical and economic evidence, the HSE Drugs Group maintained their February 2026 position and unanimously recommended against reimbursement of levodopa (Inbrija®) under the Community Drugs Schemes for this indication.

iii. Omaveloxolone (Skyclarys®) for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older (NCPE HTA ID: 24033)

The Drugs Group considered omaveloxolone (Skyclarys®) for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. The Group recognised that Friedreich's ataxia is a rare, genetic, rapidly progressive, debilitating, and degenerative neuromuscular disorder. The Group discussed the profound impact that Friedreich's ataxia has on quality of life and life expectancy. The Group acknowledged that current treatment of Friedreich's ataxia focuses on symptom management and best supportive care and that omaveloxolone, an orphan medicine, is the first licensed therapy for Friedreich's ataxia. The Group reviewed evidence from the MOXIe Part 2 trial and the MOXIe Open-label Extension study. The Group considered the limitations and uncertainties associated with the available clinical efficacy data. The Drugs Group considered patient organisation submissions from Friedreich's Ataxia Research Alliance (FARA) Ireland and Ataxia Foundation Ireland, as well as a clinician representation, in its deliberations. After protracted deliberations, the Group were unable to progress a recommendation that was supportive of reimbursement on the basis of the available clinical evidence, noting the substantial budget impact. As the application was for a medicine for the management of a rare disease, further patient and clinician engagement input via the HSE RDTRC would be sought. The Drugs Group committed to reviewing the output of the RDTRC at the earliest opportunity. The Drugs Group would further consider the application for omaveloxolone, taking account of the RDTRC statement alongside the available evidence, before determining whether a reimbursement recommendation could be made.

iv. Osilodrostat (Isturisa®) for the treatment of endogenous Cushing's syndrome in adults (NCPE HTA ID: 22023)

The Drugs Group considered osilodrostat (Isturisa®) for the treatment of endogenous Cushing's syndrome in adults. The Group recognised that Cushing's syndrome is a rare and heterogeneous endocrine condition and that the clinical consequences of excess endogenous cortisol exposure can be severe. The Group reviewed the clinical evidence and noted the lack of direct comparative evidence against relevant comparators. The Group considered the impact of the commercial offer on treatment costs and budget impact. Whilst acknowledging

that osilodrostat, an orphan medicine, represents an alternative treatment option for patients with endogenous Cushing's syndrome, the Group [redacted] The Group unanimously agreed that it could support reimbursement of osilodrostat subject to an improved commercial offering of [redacted]

v. **Glofitamab (Columvi®) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (NCPE HTA ID: 23055)**

The Group considered glofitamab (Columvi®) as monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy. The Group acknowledged the poor prognosis for this patient cohort and the evolving treatment landscape for DLBCL, noting the reimbursement of epcoritamab (Tepkinly®) in this setting since November 2025. The Group noted glofitamab (Columvi®) to be a Bispecific T-Cell Engager with a fixed treatment duration. Advice from the National Cancer Control Programme Technology Review Committee (NCCP TRC) was also considered by the Group in its deliberations. The Group reviewed the impact of the commercial proposal on treatment costs and budget impact estimates, [redacted]. Having considered the clinical and pharmacoeconomic evidence (incorporating the commercial proposal), the Group unanimously recommended in favour of reimbursement of glofitamab (Columvi®) under the Oncology Drug Management System (ODMS) for this indication.

vi. **Enfortumab vedotin (Padcev®), in combination with pembrolizumab (Keytruda®), as first-line treatment of adult patients with unresectable or metastatic urothelial cancer (NCPE HTA ID: 24038)**

The Group considered enfortumab vedotin (Padcev®), in combination with pembrolizumab (Keytruda®), as first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy. The Group acknowledged the poor prognosis for this patient cohort and the need for additional therapies to improve treatment outcomes. The Drugs Group noted the placement of enfortumab vedotin, in combination with pembrolizumab, in international guidelines. The Group noted the promising overall survival and progression free survival outcomes in the available clinical evidence. Advice from the NCCP TRC was also considered by the Group in its deliberations. The Group noted the impact of the commercial proposal on cost-effectiveness estimates and the budgetary impact. Following deliberations, considering the clinical and cost-effectiveness evidence and unmet need, the Drugs Group unanimously recommended in favour of reimbursement of enfortumab vedotin (Padcev®), under the ODMS, notwithstanding the substantial budget impact.

5. AOB

i. The Chair and Drugs Group acknowledged the departure of Dr Cliona McGovern from her role as a Drugs Group member. The Chair and Group warmly thanked Dr Cliona McGovern for her input 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.

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 Position vacant	Assistant National Director, National Cancer Control Programme for National Director of the National Cancer Control Programme (Medical Consultant)	In attendance
Dr Eimear Brannigan	Consultant in Infectious Diseases and General Internal Medicine	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
Position vacant	Public Interest Member / Ethicist	N/A
Position vacant	Public Interest Member	N/A
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Ms Carol Ivory	Assistant National Director, Specialist Services, Access and Integration	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	Apologies received
Dr Kevin Kelleher	Lay member	Apologies received
Prof. Atif Awan	Consultant Paediatric Nephrologist and Clinical Lead - National Rare Diseases Office	In attendance
Dr Turlough Bolger	Consultant in Paediatric Emergency Medicine	Apologies received
Ms Ciara Kirke	Clinical Lead - National Medication Safety Programme	In attendance

In attendance (non-voting):
Prof. Michael Barry (NCPE)

Secretariat:
Linda Fitzharris, Head of Pharmacy Function and Corporate Pharmaceutical Unit, PCRS
Aoife O'Reilly, Chief II Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Chief II Pharmacist, CPU PCRS
Ciara Berry, Senior Pharmacist, CPU PCRS
Ciara Regan, Senior Pharmacist, CPU PCRS
Katarzyna Deren, Senior Pharmacist, CPU PCRS