Schedule

Supporting access to eflornithine (difluoromethylornithine (DFMO)) for public hospital patients with high-risk neuroblastoma

FEDERATION FUNDING AGREEMENT – HEALTH

Table 1: Formalities and operation of schedule	
Parties	Commonwealth New South Wales Victoria
Duration	This Schedule is expected to expire on 30 June 2025
Purpose	This Schedule provides time-limited funding to states and territories (States) to reimburse the cost of purchasing and transporting the medicine eflornithine (otherwise referred to as Difluroromethylornithine or DFMO) for eligible patients. The funding is intended to provide adequate time for the Australian sponsor, Norgine Pty Ltd, to establish a compassionate access scheme or expanded access program (which became available on 7 October 2024), and to pursue regulatory consideration by the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Scheme (PBS) subsidy consideration by the Pharmaceutical Benefits Advisory Committee (PBAC).
Estimated financial contributions	The Commonwealth will provide an estimated total financial contribution to the States of up to $20.0 million in respect of this Schedule. The specific amount that will be paid to States for each financial year will be demand driven and will depend on the number of eligible patients for which the medicine is prescribed in the jurisdiction, recommended dosage and other clinical factors. The Commonwealth will reconcile reimbursement claims from States in January 2025 and make payments in February 2025.
Additional Terms	The Commonwealth will reimburse States through this Schedule solely for the purchase costs of DFMO incurred between 10 July 2024 and 6 October 2024 for the treatment of eligible patients through Tanner Pharma Group.[1] In circumstances where Tanner Pharma Group is required to supply between 7 October 2024 (when the

[1] Reimbursement is provided to the supply public hospitals, which may not always be in the residing States of the patients.

	expanded access program became available) and 31 October 2024, these purchase costs will also be reimbursed. For the purpose of this Schedule, eligible patients include children and young people with high-risk neuroblastoma being treated through public hospitals who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy as reflected in the 13 December 2023 US Food and Drug Administration's approval of DFMO. When considering suitability for treatment, clinicians should consider the 23 August 2024 ANZCHOG Solid Tumour Group position statement on Eflornithine (DFMO) for patients with high-risk neuroblastoma in Australia and New Zealand. The States will ensure that access to DFMO is: • judicious, appropriate, safe and evidence-based. • prescribed at no cost to the patient. This includes not charging these patients a co-payment for the provision of DFMO, such as is allowed by clause G1(f) of the 2020-2025 Addendum to the NHRA (or the equivalent section in any future Addendum). • prescribed by the practitioner in line with the patient's treating pathway and overseen by hospital-based or state-based Drug and Therapeutics Committees (or equivalent) to ensure its judicious, appropriate, and safe evidence-based use. • accessed through the Australian Government's Special Access Scheme or Authorised Prescriber pathway prior to Therapeutic Goods Administration approval and that all relevant terms are adhered to. • sourced through Tanner Pharma Group, operating on behalf of US WorldMeds. To obtain reimbursement for the purchase costs of DFMO for eligible patients States will provide reports (a 'Reimbursement Claim Report') to the Commonwealth at the times indicated in Table 2. The reports must include: • evidence of the purchase cost of DFMO, such as an invoice to the State from the supplier. • information confirming that the purchase of the medicine relates to the provision of access to an eligible patient. • confirmation that access to DFMO was overseen by a hospital-based or state-based Drug and Therapeutics Committees (or equivalent).

	The Parties agree that supply of the medicine for existing[2] and new eligible patients must be pursued through Norgine's expanded access program from 7 October 2024. The National Health Reform Agreement provides that the Commonwealth will not fund a service where the same service, or any part of the same service, is otherwise funded by the Commonwealth. The Parties acknowledge that the Commonwealth's financial support for the pharmaceutical costs associated with the treatment of eligible patients under this Schedule (a public hospital service) constitutes an explicit exemption from these arrangements and that the non-pharmaceutical (and other) costs associated with provision of public hospital services to eligible patients may be otherwise addressed through the existing NHRA arrangements. The States will maintain appropriate records to identify the episodes of care associated with DFMO prescriptions reimbursed under this Schedule when reporting to the Administrator of the National Health Funding Pool and the Independent Health and Aged Care Pricing Authority. This is to allow the additional cost of the DFMO to be excluded from future NHRA price setting determinations.

[2] Norgine's expanded access program will cover all patients who have accessed DFMO through this Schedule, regardless of whether they meet the EAP's eligibility criteria.

Table 2: Performance requirements, reporting and payment summary			
Output	**Performance milestones**	**Report due**	**Payment**
Access to eflornithine where clinically recommended for eligible public hospital patients being treated for high-risk neuroblastoma	Provision of a Reimbursement Claim Report by the states and territories seeking reimbursement containing the evidence outlined in this Schedule between 10 July 2024 and 31 October 2024 for the treatment of eligible patients.	10/1/2025	100% of reimbursement of DFMO purchase cost, up to a total program expenditure of $20.0 million over the duration of the schedule.
Note: While Norgine's expanded access program became available from 7 October 2024, States would be eligible to seek reimbursement until 31 October 2024 for the purchase costs of DFMO sourced through Tanner Pharma Group to support the transition of existing patients where required. This is to ensure no interruption to treatment during transfer onto the EAP.			

The Parties have confirmed their commitment to this schedule as follows:

Signed *for and on behalf of the Commonwealth of Australia by*

The Honourable Mark Butler MP
Minister for Health and Aged Care

25 November
[Day] [Month] 2024

Signed *for and on behalf of the State of New South Wales by*

The Honourable Ryan Park MP
Minister for Health
Minister for Regional Health

18 12 24
[Day] [Month] 2024

Signed *for and on behalf of the State of Victoria by*

The Honourable Mary-Anne Thomas MP
Minister for Health
Minister for Health Infrastructure
Minister for Ambulance Services

[Day] [Month] 2024