NSW Health

NSW GOVERNMENT

POISONS AND THERAPEUTIC GOODS REGULATION 2008

AUTHORITY

Authority to issue prescriptions or supply esketamine

I, Andrew Hargreaves, Director Pharmaceutical Operations, a duly authorised delegate of the Secretary, NSW Health, make this instrument pursuant to section 170 of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) (the Regulation) for the purposes of section 28(5) of the *Poisons and Therapeutic Goods Act 1966* (the Act) and sections 84AA and 98A of the Regulation. Pursuant to clause 171(1) of the Regulation, this authority is granted subject to conditions.

Andrew Hargreaves
Director, Pharmaceutical Operations
(Delegation Numbers PH380 & PH381)

31 March 2026

Authorisation to a class of persons to issue a prescription for, or supply, esketamine without an authority under section 29 of the Poisons and Therapeutic Goods Act 1966

1 Authorisation

This authority authorises a person within the Authorised Class of Persons (an Authorised Person) to issue a prescription for, and to supply, esketamine intended for administration by spray or application to mucous membranes to a person for the purpose of treating the person for treatment-resistant depression (TRD) without an authority under section 29 of the Act.

2 Authorised Class of Persons

A medical practitioner who is a specialist psychiatrist.

3 Conditions

3.1 The Authorised Person may only issue a prescription for, or supply, a substance under this authority if the substance is esketamine nasal spray that is registered on the Australian Register of Therapeutic Goods (ARTG).

3.2 The Authorised Person must take reasonable steps to ensure that esketamine prescribed and/or supplied under this authority is administered to the patient (including self-administration by the patient) under the direct medical supervision of the Authorised Person. Administration must occur only in an appropriately supervised healthcare setting that:

(a) has documented clinical governance arrangements;

(b) has established medication administration and patient monitoring procedures and protocols; and

(c) is adequately equipped to manage behavioural and/or medical emergencies arising from the administration of esketamine.

3.3 The Authorised Person must regularly review SafeScript NSW for any relevant information, including approvals, prescribed and dispensed events, for any patient the Authorised Person intends to prescribe or supply to under this authority.

3.4 The Authorised Person must not issue a prescription for, or supply:

(a) to a drug dependent person; or

(b) to a person under the age of 18; or

(c) more than 84mg of esketamine to a person for use in a single day

under this authority.

3.5 The Authorised Person must issue a prescription for, or supply, esketamine under this authority only within their lawful scope of practice, in accordance with all applicable standards, codes and guidelines, and within treatment protocols substantiated by scientific evidence and approved product information.

4 Duration

This authority commences on 31 March 2026 and expires on 31 March 2028 or the date that the authority is revoked, whichever is earlier.