



Health

POISONS AND THERAPEUTIC GOODS REGULATION 2008

AUTHORITY

Authority to issue prescriptions or supply esketamine

I, Bruce Battye, Director Pharmaceutical Operations, a duly authorised delegate of the Secretary, NSW Health, make this instrument pursuant to clause 170 of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) [the Regulation] for the purposes of Section 29 of the *Poisons and Therapeutic Goods Act 1966*. Pursuant to clause 171(1) of the Regulation, the authorisation is granted subject to conditions.

Bruce Battye
Director Pharmaceutical Operations
(Delegation Numbers PH380 & PH381)

Date: 1/4/25

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

1 Authorisation

This authority authorises a medical practitioner in an Authorised Class of Persons to supply and issue a prescription for the Type B drug of addiction 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 *Poisons and Therapeutic Goods Act 1966* (the Act).

2 Definitions

In this instrument:

- *Treatment-resistant depression (TRD)* means a diagnosis meeting the criteria in the:
 - *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition (DSM-5) published by the American Psychiatric Association
- *drug dependent person* has the same meaning as in the Act, section 27.

3 Authorised Class of Persons

Medical practitioners registered in the following fields of specialty practice within a specialty:

Specialty	Field of specialty practice
Psychiatry	N/A

4 Conditions

4.1 The medical practitioner in the Authorised Class of Persons must issue a prescription for the Australian Register of Therapeutic Goods (ARTG) registered esketamine nasal spray only for the purpose of the treatment of a person for treatment-resistant depression.

4.2 Esketamine must be provided by the Authorised Class of Persons for patients to administer under their direct medical supervision. This must occur in an appropriately supervised healthcare setting with good clinical governance practices, established administration and patient monitoring procedures and protocol. This setting must be equipped to manage any behavioural and/or medical emergencies.

4.3 This authority does not authorise issue of a prescription for, or supply to, drug dependent persons.

4.4 This authority does not authorise issue of a prescription for, or supply to persons under the age of 18.

4.5 This authority does not authorise issue of a prescription for, or supply to, a person above the following daily dose limits.

Drug	Daily dose limit
esketamine	84 milligrams

4.6 The medical practitioner in the Authorised Class of Persons must issue a prescription or supply esketamine 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 any approved product information.

5 Duration

This authority commences on 01 April 2025 and expires on 1 April 2026, or otherwise on a date that this authority is earlier cancelled.