Application for Approval to Prescribe or Supply a Schedule 8 Medicine – Esketamine or Ketamine for Treatment Resistant Depression

as required under the Poisons and Therapeutic Goods Act 1966 (NSW)

This application form is to be used for any Australian Register of Therapeutic Goods (ARTG) registered esketamine nasal spray or ketamine injectable products for Treatment Resistant Depression.

Application to prescribe or supply any unregistered or extemporaneously compounded esketamine or ketamine product is to be made using the Application for Approval to Prescribe or Supply an Unregistered or (Pharmacy) Extemporaneously Compounded Schedule 8 Product for Human Therapeutic Use

Practitioners can apply online through the SafeScript NSW portal. Applying via the portal allows a practitioner to receive real-time approval or a notification if an application needs to be reviewed by the NSW Ministry of Health. Practitioners can also monitor the progress of their online application.

If you are a **psychiatrist** please complete this application. All other prescribers please refer the patient to a psychiatrist for prescribing and supply of esketamine or ketamine for Treatment Resistant Depression.

Esketamine and ketamine medicines are to be administered under direct medical supervision, in a healthcare setting which has established administration and patient monitoring procedures and protocols.

Before starting the application:

- If the patient is currently enrolled on the Opioid Treatment Program (OTP), please make sure that you have obtained written agreement from the authorised OTP prescriber for the proposed treatment.
- Please make sure you have sought a review (within 12 months) from a psychiatrist if the maximum dose exceeds 84mg for esketamine or 400mg for ketamine. Doses exceeding the maximums specified above are considered to be high dose. You may be required to provide supporting documentation and will be notified if additional documentation is required.

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Clinical Advice and Support

The NSW Ministry of Health recommends the use of **SafeScript NSW** to assist practitioners to make informed clinical decisions https://www.safescript.health.nsw.gov.au/. Consider checking **SafeScript NSW** for evidence of alerts or other issues related to the prescribing and supply of high-risk monitored medicines.

The NSW Ministry of Health recommends that all prescribing and supply is in accordance with the approved **Product Information (PI)** and with published recommendations.

Applicants are advised to consider if the patient would benefit from a review by an **addiction medicine specialist** to manage any perceived drug dependence concerns.

Applicants can contact experienced clinical advisors and addiction medicine specialists to obtain general clinical advice and support when managing patients with drug and alcohol issues, by calling the free **Drug & Alcohol Specialist Advisory Service (DASAS)** in the Metropolitan Area: (02) 8382-1006; in Regional, Rural & Remote NSW areas: 1800 023 687, available 24/7. This advice line cannot provide support for an application for an approval.

Privacy Statement: The information set out in this form is required by the NSW Ministry of Health for the issuance of an approval to prescribe or supply a Schedule 8 medicine as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. Information collected as part of the application process may be used and disclosed as part of assessing the application. Medicare numbers may be used for the purpose of patient identification. Practitioner information, and data regarding the number of patients for whom they hold approvals to prescribe or supply a Schedule 8 medicine, may also be used and disclosed for policy and planning purposes. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety or where required or authorised by law. The application may not be processed if all information and all declarations requested on the form are not completed. For further information on privacy, visit http://www.health.nsw.gov.au/patients/privacy

☐ **I confirm that I have read and understood the information contained in 'Clinical Advice and Support' and the 'Privacy Statement'**

(This declaration is mandatory and must be completed)

Enquiries:

Please direct any enquiries to the Pharmaceutical Services Unit: Tel: **(02) 9424 5923**
or email: MOH-S8Auth@health.nsw.gov.au

Submitting the application:

Fax completed form to the Pharmaceutical Services Unit: Fax: **(02) 9424 5889**
or email: MOH-S8Auth@health.nsw.gov.au

Practitioners can apply online through the SafeScript NSW portal and in many cases receive real time approval.

Processing Time:

Please allow up to **7 business days** for the processing of applications.

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SECTION A – PRESCRIBER DETAILS

Prescriber Name: (as displayed in AHPRA)

First Name: _____ Middle Name(s): _____

Family Name: _____

Name of Practice: _____

Address: _____ Suburb/town: _____

Postcode: _____ Telephone: _____ Fax: _____

Mobile: _____

Email: _____ (please note this email address will be used for all correspondence)

AHPRA Registration No.: _____ PBS Prescriber No.: _____

SECTION B – PATIENT DETAILS

Patient Name: (as shown on Medicare card)

First Name: _____ Middle Name(s): _____

Family Name: _____

Patient also known as: (if applicable)

First Name: _____ Middle Name(s): _____

Family Name: _____

Address: _____ Suburb/town: _____

Postcode: _____ Medicare number: (if applicable) _____ Ref no.: _____

DVA number: (if applicable) _____

DOB: _____ (dd/mm/yyyy) Sex: ☐ Male ☐ Female ☐ Another term

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SECTION C – PRE-QUESTIONS

1. IS THE PATIENT CURRENTLY ENROLLED ON THE OPIOID TREATMENT PROGRAM (OTP)?

☐ **No**. Go to **question 2**

☐ **Yes**. I am the authorised OTP prescriber. Go to **question 2**

☐ **Yes. I am NOT the authorised OTP prescriber.** Has the patient been reviewed by the authorised OTP prescriber and written agreement to the proposed treatment obtained?

- ☐ **Yes**. Go to **question 2**
- ☐ **No**. Contact the authorised OTP prescriber and obtain written agreement before submitting this application. **This application cannot proceed** and will not be considered until written agreement is obtained**.**

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2. DO YOU CONSIDER THIS PATIENT TO BE DRUG DEPENDENT?

A 'drug dependent person' means a person who has acquired, as a result of repeated administration of:

(a) a drug of addiction, or

(b) a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985,

*an overpowering desire for the continued administration of such a drug (**section 27 of the Poisons and Therapeutic Goods Act 1966**).*

☐ **Yes.** Go to **Section D Esketamine or Section E Ketamine**

☐ **No.** Go to **question 3**

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3. IF THE PATIENT IS NOT CONSIDERED TO BE DRUG DEPENDENT, HAVE THEY USED OR ARE THEY EXPECTED TO USE AN ARTG REGISTERED ESKETAMINE OR INJECTABLE KETAMINE PRODUCT OR ANY OF THE LISTED SCHEDULE 8 MEDICINES BELOW, CONTINUOUSLY FOR MORE THAN TWO MONTHS?

- any Schedule 8 medicine intended for administration by injection
- any Schedule 8 medicine for inhalation, or for spray or application to mucous membranes
- buprenorphine (except transdermal preparations)
- hydromorphone
- methadone
- alprazolam
- flunitrazepam

☐ **Yes**. **Approval required.** Go to **Section D Esketamine or Section E: Ketamine**

☐ **No**. **Approval is NOT required** for this patient at this time. Prescribing may continue without approval from NSW Ministry of Health

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SECTION D – ESKETAMINE

Only complete if using an ARTG registered esketamine product. If applying for approval to use an extemporaneously-compounded product, please use Application for Approval to Prescribe or Supply an Unregistered or (Pharmacy) Extemporaneously-Compounded Schedule 8 Product for Human Therapeutic Use

Maximum dose: _____ mg

If the maximum dose exceeds 84mg: Has the patient been reviewed by a second, independent psychiatrist and do you have support for treatment at a **high dose**?

☐ **Yes**. Go to **Section F: Declaration**

☐ **No**. Refer the patient to a psychiatrist and obtain support for treatment at a high dose.
Go to Section F: Declaration

SECTION E – KETAMINE

Only complete if using an ARTG registered ketamine product. If applying for approval to use an extemporaneously-compounded product, please use Application for Approval to Prescribe or Supply an Unregistered or (Pharmacy) Extemporaneously-Compounded Schedule 8 Product for Human Therapeutic Use

Maximum dose: _____ mg

If the maximum dose exceeds 400mg: Has the patient been reviewed by a second, independent psychiatrist and do you have support for treatment at a **high dose**?

☐ **Yes**. Go to **Section F: Declaration**

☐ **No**. Refer the patient to an independent psychiatrist and obtain support for treatment at a high dose.
Go to **Section F: Declaration**

SECTION F – DECLARATION

☐ **I confirm that the information I have provided in this application is true and complete to the best of my knowledge.**

Please tick the option which applies:

☐ **I confirm, where required, that I have sought a review and obtained support from another psychiatrist for the proposed treatment.**

☐ **I confirm I will seek specialist review and obtain support from another psychiatrist to support this application.**

☐ **I confirm that I do not require independent review and support.**

Print and Sign

Signature: _____ Date: _____ (*dd/mm/yyyy*)

SHPN (LRS) 240174