Requirements for seeking authorisation to prescribe ketamine for treatment resistant depression in Tasmania

These requirements are based on:

1. Legislative requirements for medical practitioners wishing to prescribe narcotic (Schedule 8) substances to seek authorisation under Section 59E of the Poisons Act 1971 and regulation 19 of the Poisons regulations 2008; and


Summary

- Treatment resistant depression (TRD) is defined as an insufficient response to at least two adequate antidepressant treatments and is associated with low rates of improvement. (i)
- The use of ketamine for TRD is an experimental treatment.
- Despite some clinical trials claiming rapid improvement in mood after ketamine infusion, there are still significant gaps in knowledge about dosage, formulations, treatment protocols and the effectiveness and safety of long term use.
- Ketamine is not currently recommended for use in clinical practice for the treatment of depression, and extensive, high quality research is needed to understand how to optimally use ketamine for TRD.
- Ketamine is listed in Regulation 19 of the Poisons Regulations 2008, it is a legal requirement that psychiatrists seek and gain authorisation under Section 59E of the Poisons Act 1971 before initiating treatment.
- as a substance that requires authorisation prior to issuing a prescription for treatment outside a medical facility.
- The authorisation process requires a psychiatrist wishing to prescribe ketamine to provide sufficient clinical information to demonstrate they have minimised (and adequately explained to the patient) the risks of harm from the experimental use of ketamine.
- These requirements will be subject to review as new clinical practice guidelines become available.
Background

- Ketamine is a narcotic (Schedule 8) substance and is only approved in Australia by the Therapeutic Goods Administration (TGA) for use as an anaesthetic.
- It is not approved by the TGA for treating depression.
- Ketamine has sedative, hallucinogenic and analgesic properties.
- It induces a state of dissociation, can be misused as a recreational drug and has addictive, psychosocial effects in humans.
- Ketamine is a common drug of abuse worldwide with the street name ‘K’ or ‘Special K’. (2, 3)
- In the past decade, ketamine has been researched as a potential antidepressant. (4, 5)
- This has resulted in some ‘off-label’ use by psychiatrists treating patients with TRD.
- Most researchers have only measured the effects of ketamine for 72 hours after infusion.
- The long term effects of ketamine prescribed in patients with TRD are unknown. (6)

Recommendation of the RANZCP Clinical Memorandum use of ketamine for treating depression (November 2017)

- The use of ketamine for the treatment of depression is considered a novel treatment. For more information refer to the RANZCP practice guideline The use of medication in dosages and indications outside normal clinical practice.
- Ketamine should be used under research trial conditions that includes oversight by an institutional research or clinical ethics committee and careful monitoring and reporting of outcomes.
- Psychiatrists should consider ketamine for TRD as a novel treatment when not used within the safeguards of a research trial.
- Psychiatrists who are considering prescribing ketamine for a patient with TRD, outside a research trial:
  - should ensure the patient is willing and able to consent.
AND at least ONE of the following:
  - should discuss this treatment with peer(s), preferably including a second opinion, and/or
  - seek institutional review by a Medicines Advisory Committee or equivalent, and/or
  - seek consideration by an institutional research ethics committee.
- People and their carers considering ketamine as a treatment for TRD should be provided with clear information and an explanation this is a unproven treatment. This should include a detailed explanation of the current evidence and potential risks, and be documented in the clinical notes.
- Practice outside of these recommendations should not occur.
Authorisation under Section 59E of the Poisons Act 1971

All applications to prescribe ketamine under Section 59E of the Poisons Act 1971 for TRD will be referred by the delegate to the Ketamine Advisory Panel (KAP) for assessment and advice. The KAP will consist of specialist psychiatrists, and where required an addiction medicine specialist.

Further information may be requested from applicants to enable the KAP to provide appropriate advice to the delegate. Initial authorities will be for a trial period of three months.

Subsequent applications will require a detailed report on the patient’s progress including the results of validated screening tools (e.g. Hamilton Depression Rating Scale) to measure and document any symptom change(s).

Essential requirements for all applications (to be provided to the Pharmaceutical Services Branch):

- The treating clinician (applicant) is a registered psychiatrist.
- The patient has been diagnosed with TRD as documented in the RANZCP clinical practice guidelines for mood disorders 2015.
- Informed patient consent has been performed and signed by the patient and the treating psychiatrist.

The applicant must also provide the following supporting documents for all patients:

- A comprehensive patient history; including diagnosis, concurrent medications, details of past unsuccessful therapeutic interventions (including pharmacological and psychological)
- Completed Ketamine s59E Application form
- Applications for patients who have current or past substance misuse must be accompanied by a recent report from an addiction medicine specialist or addiction psychiatrist providing a documented risk assessment and management plan.

- Detailed supporting information regarding the proposed treatment regimen including:
  - Proposed treatment regimen, timeframe and treatment goals, including withdrawal protocol in the case of treatment failure.
  - Objective measurements that will inform treatment success or failure.
  - Details of the formulation to be prescribed and the manufacturing facility/pharmacy preparing and dispensing ketamine.

Assessment Pathways

Path A - Patient is enrolled in a registered clinical research trial

The applicant must also provide:

- A copy of the research protocol and confirmation of human research or clinical ethics committee approval.
Path B – Patient is approved through a Medicines Advisory Committee

The applicant must also provide:

- A copy of the committee approval letter.

All patients being treated for TRD within the Tasmanian Health Service must follow either approval path A or B.

Path C – Patient not involved in a clinical trial and prescriber not able to access a Medicines Advisory Committee

The applicant must also provide:

- A written second opinion from a registered psychiatrist at the time of application clearly assessing the risks versus benefits of the proposed regimen.

It should be noted an authority to prescribe is not an endorsement of the need for a particular drug or dose.
Addiction psychiatrist is defined as a psychiatrist who has completed the relevant certificate of advanced training in addiction psychiatry.

* Clinical research trial that includes oversight by an institutional human research or clinical ethics committee

** Example includes the Tasmanian Medicines Access and Advisory Committee (TMAAC) for patients of the Tasmanian Health Service.

References


6. Zhang MWB, Ho RCM. Ketamine’s potential as a rapid antidepressant was overplayed2015 2015-08-19 09:25:44.