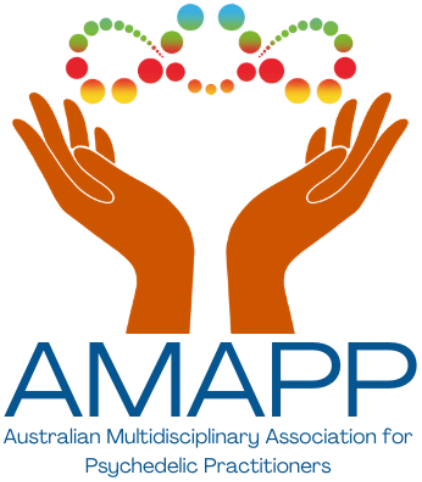

Critical Analysis of the Australian MDMA-Assisted Psychotherapy Guideline for PTSD

Authors:

Dr Martin Williams

Dr Lani Roy AMAPP Chair

Dr Simon Beck MD

Gianna Manzini

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Executive Summary

This critique examines the Australian clinical practice guideline for MDMA-assisted psychotherapy (MDMA-AP) for PTSD. The MDMA-AP guideline exhibits strengths, as well as key limitations. Overall, AMAPP emphasises that while the cautious stance minimises potential risk, it also risks constraining access, workforce development, and treatment innovation.

1. Introduction: Australian Mental Health Context

Post-traumatic stress disorder (PTSD) represents a substantial mental health burden in Australia and is a key target for emerging interventions such as MDMA-assisted psychotherapy (MDMA-AP).

1.1 Prevalence & Burden

Approximately 43% of Australians have experienced a mental illness in their lifetime, and around 22% experience one annually. Mental and substance use disorders account for approximately 15% of the total national disease burden.

1.2 PTSD Prevalence

The lifetime prevalence of PTSD is estimated at around 11% (≈14% women; ≈8% men), with approximately 75% of adults reporting at least one trauma exposure. Among high-risk groups, prevalence is even higher: retired first responders ~18%. Natural disaster–related PTSD contributes significantly to population mental health burden, with estimated costs such as ~$4.4 billion following the South-East Queensland floods of 2022.

1.3 Treatment Gap & Innovation Lag

Despite evidence-based therapies, around 30% of people with PTSD remain treatment-resistant. Translational lags for new treatments average ~17 years, and many promising innovations never reach patients.

1.4 Workforce & Access Gap

According to the Australian Institute of Health and Welfare (2022), the distribution of psychiatrists and clinical psychologists is heavily skewed toward urban areas. In rural and regional Australia, where rates of trauma, suicidality, and treatment-resistant mental illness are often higher, the availability of eligible and skilled practitioners is exceptionally limited. This uneven access poses serious challenges for delivering equitable mental health care (Kavanagh et al., 2023).

This context highlights the urgency of considering both the cautious evidence-based recommendations of the guideline and the operational innovations proposed by AMAPP, particularly competency-based workforce models, cultural responsiveness, and equity in access. Where the guideline adopts a conservative stance, operational design should nevertheless facilitate safe, equitable pilot programs and learning health-system feedback loops, rather than inadvertently restricting access or delaying the integration of novel but evidence-based interventions.

2. Strengths and Limitations of the MDMA-AP Guideline

2.1 Strengths of the guideline include:

- Methodological rigour - the use of GRADE and transparent certainty ratings aligns with best practice (Schünemann et al., 2019, pp. 143–151).
- Recognition of blinding challenges - functional unblinding is appropriately highlighted (e.g., high correct-guess rates), a recurrent issue in MDMA trials (Mithoefer et al., 2019, p. 7)
- Cautious positioning - a conditional recommendation against routine use is consistent with the current evidence and external regulatory concerns (Marks, 2024, pp. 963–964).
- Stated emphasis on evidence-based approaches.
- Consultation with a moderately broad range of experts and stakeholders.

2.2 Limitations of the guideline include:

- Lack of consultation with global researchers, practitioners and research participants.
- Informed primarily by reference to a very small number of systematic reviews and very limited reference to primary sources reporting clinical research.
- Factual error regarding the lack of research evidence on the long-term outcomes of MDMA-AP.
- Imbalance in efforts to avoid bias and CoI (exclusion of Guideline Development Group [GDG] members with perceived positive bias but inclusion of GDG members with clear negative bias).
- The GRADE methodology, despite its established strengths, was fundamentally misapplied in this guideline development process, undermining the validity of its conclusions. This includes: (1) The exclusion of individuals with relevant clinical expertise based on perceived conflicts of interest was excessive, resulting in the systematic exclusion of most Australian practitioners with substantive training and

clinical experience in psychedelic-assisted therapies. (2) The decision-making process relied on voting without implementing domain-based voting protocols, which represent international best practice for guideline development. Technical evaluations of clinical evidence (including effect size, heterogeneity, and risk of bias assessments) should involve only those with appropriate professional training to make such determinations. (3) While an expert advisory group provided input, the evaluation of this expert input was ultimately determined by individuals who may have lacked the requisite expertise for such assessments. (4) Critical transparency deficits exist regarding the expert group contributions, voting procedures, attendance records, the margin of decisions, and the authorship of the guideline itself.

- Lack of critical analysis of treatment-as-usual approaches, including currently approved psychotherapeutic and pharmacotherapeutic interventions.
- The one-month public consultation time period is very brief for a significant policy development, indicating inadequate stakeholder engagement.
- Insufficient consideration of the MAPS "non-directive therapy" approach within the evidence evaluation framework.
- Limited focus on workforce restrictions, equity, and feasibility. The guideline does not fully address how current workforce structures, training availability, and geographic distribution of clinicians will impact access.
- The guideline's design risks inadvertently raising costs and exacerbating rural inequity by mandating psychiatrist/clinical psychologist-led dyads without competency-based alternatives. The guideline acknowledges high costs but does not provide sustainable solutions.
- Geographic inequity is exacerbated under current recommendations: 82.9% of psychologists are in major cities, only 0.1% in very remote areas (Australian Institute

of Health and Welfare, 2022). AMAPP proposes tele-supervision and community clinic accreditation as solutions.

2.3 Additional considerations

Based on AMAPP's policy submission to the Therapeutic Goods Administration (TGA) Authorised Prescriber Scheme stakeholder review (Roy, 2025), additional considerations include:

- AMAPP's competency-based model (outlined in Appendix A), governance instruments, and Code of Conduct policy (AMAPP, 2024) provide concrete, proportionate pathways to address gaps while maintaining safety and quality.
- Equity, rural/remote access, and cultural safety require explicit operational design (e.g., accredited community clinics, tele-supervision, and culturally competent practice) rather than broad acknowledgement without solutions.
- Training and credentialing should be grounded in competencies (knowledge, skills, behaviours) with portfolio evidence, CPD, and supervision, instead of limiting eligibility by title.
- Including only AHPRA-registered professionals in dyads limits the workforce, minimises diversity, and raises costs; a competency-based model (outlined in Appendix A) instead expands safe and inclusive access. AMAPP recommends competency-based dyads with one AHPRA-registered clinician plus a trained co-therapist, consistent with MAPS Phase 2–3 dyads (e.g psychologist + counsellor/psychotherapist/nurse).
- Cost estimates (AU$20–30k per course) require Australian-specific health technology assessment, including potential cost-effectiveness in the context of disaster-related mental health burdens and treatment-resistant PTSD.

- Distinguishing clinical psychedelic-assisted therapy from ceremonial/traditional contexts and embedding cultural capability training avoids commodification and enables culturally informed practice.

3. Critical Analysis of MDMA-AP Guideline Recommendations

3.1 Recommendation 1 (Conditional recommendation against)

For people living with PTSD, the Guideline Development Group conditionally recommends against the routine use of MDMA-AP. If MDMA-AP is used, it should be limited to adults (≥18 years old) with PTSD symptoms for at least 6 months duration post-diagnosis, with moderate or severe PTSD symptoms in the past month (CAPS-5 total severity score ≥28), who have received an adequate trial of first-line evidence-based treatments, and who are not likely to be re-exposed to the index or other significant trauma during treatment.

AMAPP cannot endorse Recommendation 1 in its current formulation. While acknowledging the valid concern regarding insufficient evidence for first-line treatment in uncomplicated PTSD, the recommendation contains fundamental limitations that undermine its clinical utility and evidence-based foundation. Most critically, the recommendation fails to address the central question relevant to current Australian clinical practice: whether sufficient evidence exists to support MDMA-assisted therapy for treatment-resistant PTSD in adults within the existing TGA-authorised framework. The recommendation's predominantly negative framing appears inconsistent with both the available evidence base and the current regulatory environment for specialised psychiatric treatments. AMAPP would support a reformulated recommendation that specifically addresses treatment-resistant presentations

and employs more balanced language reflecting a nuanced appraisal of the available evidence.

The implication is that first-line evidence-based treatments are demonstrably superior to MDMA-AP in terms of their safety profile and tolerability, whereas this has not been shown in research. Although the FDA ultimately rejected Lykos' submission for medicine approval based on the recommendations of the Advisory Panel, the FDA did grant Breakthrough Therapy status to MDMA-AP (as developed and refined in the course of MAPS-sponsored research) in recognition of a medical need that was deemed by the FDA to be unmet by existing front-line interventions.

The restriction to individuals "who are not likely to be re-exposed to the index or other significant trauma during treatment" lacks adequate evidence-based justification. The guideline provides no clear rationale or supporting literature for this exclusionary criterion.

The requirement of ≥6 months' duration post-diagnosis is not consistent with PTSD treatment recommendations.

This requirement creates barriers to MDMA-AP access. By requiring symptoms to persist for at least 6 months "post-diagnosis" to be eligible for treatment, it fails to account for the often substantial time between symptom onset and formal PTSD diagnosis. This timing requirement excludes patients who have experienced prolonged symptoms before receiving their diagnosis.

Comparative effect size analysis reveals important context: The guideline notes SMD 0.86 (95% CI 0.42–1.31) for MDMA-AP (p. 16), while established therapies like EMDR (~0.99) and TF-CBT (~1.08) show similar or greater effect sizes (Lewis et al., 2020; Cusack et al., 2016). However, direct head-to-head comparisons remain absent from the literature.

Adolescent considerations: The safety and efficacy of MDMA-AP in individuals under 18 years remains unestablished (p. 21). Current pharmacological options for adolescents (SSRIs) demonstrate modest efficacy with notable safety considerations, particularly in this population (Ipser & Stein, 2012; Hetrick et al., 2012). Trauma-focused cognitive behavioural therapy and EMDR continue to represent first-line interventions. AMAPP emphasises the critical importance of future adolescent-specific research conducted under rigorous ethical oversight.

The requirement of moderate or severe PTSD symptoms in the past month (CAPS-5 total severity score ≥28) does not consider the nuances of PTSD symptoms.

Research indicates that subthreshold PTSD symptoms typically precede delayed-onset PTSD (Ellekilde Bonde, et al., 2022), highlighting the importance of early symptom monitoring and supporting consideration of intervention before symptoms reach severe thresholds. In addition, meta-analytic evidence demonstrates that longer duration since a traumatic event is associated with poorer treatment outcomes (Keyan, et al., 2024), reinforcing the importance of early intervention rather than waiting for symptom severity to increase.

While the rationale for positioning MDMA-AP as a second-line treatment is well understood, AMAPP respectfully suggests that this approach may not be optimal for all PTSD presentations.

While AMAPP acknowledges the current cautious approach to MDMA-AP and its proposed classification as a second-line treatment option, AMAPP respectfully submits that the regulatory framework should permit MDMA-AP as a first-line treatment for PTSD, determined through individualised patient case conceptualisation and clinical assessment (recommendations for inclusions are included in Appendix B).

The current MDMA guidelines, while prudent in establishing safety parameters, may inadvertently limit access for patients whose PTSD presentations are primarily relational in

nature and may not respond optimally to conventional first-line treatments such as pharmacotherapy (SSRIs, SNRIs) and evidence-based psychotherapies (CPT, EMDR, PE). For the patient cohort, the requirement to first trial these traditional treatments could result in prolonged symptom burden and potential deterioration.

AMAPP proposes that the current MDMA-AP guideline accommodates clinical discretion in treatment sequencing, allowing qualified practitioners to determine when MDMA-AP represents the most appropriate first-line intervention based on:

- Individual trauma presentation and etiology
- Previous treatment history and response patterns to conventional pharmacotherapy and psychotherapy
- Patient preference and informed consent
- Clinical contraindications to standard first-line treatments

Furthermore, there is no evidence to date to suggest that MDMA-AP is more harmful or risky than first-line treatments currently available. This approach aligns with evidence-based medicine principles while ensuring that regulatory processes do not create unnecessary barriers to optimal patient care for those who may benefit most from early access to MDMA-AP rather than sequential trials of conventional first-line treatments.

The requirement that patients must be unlikely to experience re-trauma during treatment in order to access MDMA-AP may be overly restrictive given the unpredictable nature of trauma exposure.

This requirement fails to account for the reality that trauma exposure, particularly for marginalised and vulnerable populations who may face ongoing systemic trauma, can be difficult to predict or control. This criterion could disproportionately exclude individuals

from marginalised communities who face higher baseline risks of trauma exposure due to systemic factors beyond their control. Therefore, predicting trauma exposure over a treatment period may be unrealistic, creating barriers to access. AMAPP recommends taking a person-centered case conceptualisation approach to assess individual risk. While immediate safety risks must be assessed and managed, the presence of ongoing trauma risk should not constitute grounds for exclusion given its prevalence across many populations. Rather, risks of trauma exposure should be identified and treatment tailored accordingly to the ongoing risk.

3.2 Recommendation 2 (Only in research settings)

Do not use MDMA-AP for the treatment of PTSD outside of clinical trials with appropriate ethical approval in people less than 18 years old.

AMAPP respectfully objects to the definitively prohibitive language “do not use” employed in this recommendation. In the absence of evidence demonstrating harm, more appropriate phrasing would state: "There is insufficient evidence to support the use of MDMA-AP for the treatment of PTSD in people less than 18 years old outside of appropriately approved clinical research settings." AMAPP would endorse a recommendation employing this more evidence-appropriate formulation. AMAPP notes that no clinical research studying the physiological, psychological, developmental or therapeutic effects of MDMA-AP on people less than 18 years old has been reported to date. In line with accepted medical practice, this intervention can only be administered to people under 18 in a clinical research setting with appropriate ethics committee oversight and responsibility until sufficient research evidence has been gathered and evaluated to enable informed decisions to be made by the TGA and other regulatory bodies. As per Recommendation 1, AMAPP reiterates that existing pharmacological options in adolescents (SSRIs) demonstrate modest effect sizes, and

trauma-focused psychotherapies should remain first-line. Future research could explore MDMA-AP only within ethically robust, developmentally sensitive protocols and registries.

3.3 Recommendation 3 (Only in research setting)

Do not use MDMA-AP for the treatment of PTSD outside of clinical trials with appropriate ethical approval in people who 1) have not had PTSD symptoms for at least 6 months duration post-diagnosis; 2) did not have at least moderate PTSD symptoms in the past month (CAPS-5 total severity score ≥28); 3) have not received an adequate trial of first-line evidence-based treatments; or 4) are likely to be re-exposed to the index or other significant trauma during treatment.

As per AMAPP's response to Recommendation 1, AMAPP cannot support Recommendation 3 (Only in research settings). AMAPP reiterates the concern that the persistent restriction against treating individuals with potential ongoing trauma exposure, for which the guideline provides insufficient evidence-based justification. AMAPP emphasises that while these criteria reflect the conservative approach adopted in clinical trials, clinical practice should apply eligibility criteria based on robust clinical evidence, patient welfare considerations, and informed consent principles, rather than rigid adherence to trial-based exclusions.

3.4 Recommendation 4 (Only in research setting)

For people living with PTSD, the Guideline Development Group strongly recommends against the use of MDMA-AP in patient groups who have been excluded from existing clinical trials for safety reasons. These patient groups include but are not limited to those who are pregnant or breastfeeding, with cardiovascular disease (e.g., uncontrolled hypertension, cardiac arrhythmia), psychotic disorder, suicide-related distress (i.e., currently experiencing

suicidal thoughts and/or behaviour), and people with current use of medications that may interact with MDMA.

AMAPP contends that this recommendation requires substantial revision to align with the available evidence base. The current formulation is overly restrictive given that many clinical trial exclusions were implemented as precautionary measures rather than in response to demonstrated adverse events. As currently expressed, the recommendation appears to override the clinical judgement of qualified, authorised medical practitioners including psychiatrists and cardiologists. AMAPP would conditionally support a recommendation emphasising the need for exceptional clinical caution in considering such patients, with treatment decisions made on an individual basis by appropriately authorised TGA prescribers in consultation with relevant specialist colleagues.

Safety contextualisation: Current evidence indicates that acute physiological effects of MDMA-AP are generally manageable through standard monitoring protocols in controlled clinical settings (Vizeli & Liechti, 2017). Nevertheless, cautious inclusion criteria remain clinically prudent.

4. Critical Analysis of MDMA-AP Guideline Good Practice Statements

4.1 Good Practice Statement 1

People living with PTSD have varying values, preferences, and lived experiences that should be central to the planning and delivery of MDMA-AP. Trauma-informed, participatory, and culturally responsive care should be planned using a shared decision-making approach between the clinicians and patients. Care should be responsive to the needs of individuals

from diverse cultural backgrounds, neurodivergent communities, and other priority populations.

AMAPP fully concurs with Good Practice Statement 1. AMAPP recommends establishing formal co-design processes incorporating lived experience advisory groups to ensure genuinely patient-centred care delivery.

Cultural competency training should be mandatory for all clinicians delivering MDMA-AP to prevent inadvertent harm to Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse patients, and other marginalised communities.

Psychedelic-assisted therapy dyads should include qualified practitioners who not only meet all regulatory, experiential, and training requirements but also represent diverse backgrounds that can enrich and culturally inform the therapeutic environment.

Given the longstanding Indigenous relationship with plant medicines and the critical importance of cultural safety, training pathways should integrate Indigenous healing practice standards, including the eight foundational domains outlined in PACFA's Indigenous Healing Practice Training Standards (PACFA, 2021).

4.2 Good Practice Statement 2

Prior to initiating MDMA-AP, appropriate medical, psychiatric, psychological, financial, and social screening should be conducted to maximise potential benefits and minimise potential harms. The screening process should be documented in appropriate records.

AMAPP agrees that comprehensive screening across the specified domains is critical for optimal outcomes, but emphasises that screening principles for clinical practice differ substantially from those applied in research settings. This differentiation reflects the distinct

objectives of therapeutic intervention versus research methodology. Clinical trial protocols typically accommodate factors such as confound elimination, placebo/nocebo effect minimisation, and avoidance of conditions that reflect the inherently conservative nature of academic medical research.

AMAPP proposes that clinical screening for MDMA-AP should employ eligibility criteria based on robust clinical evidence, overarching patient welfare and dignity considerations, and the therapeutic imperative to address mental illness optimally within current knowledge and experience parameters. Screening should encompass treatment outcome sustainability assessment, extending beyond access determination to integration capacity evaluation. To ensure practice consistency, AMAPP proposes standardised screening protocols and templates aligned with TGA standards and AMAPP Code of Conduct policy (AMAPP, 2024).

4.3 Good Practice Statement 3

Prior to initiating MDMA-AP, the treating psychiatrist is responsible for explaining to potential patients that the current evidence on the efficacy and safety of MDMA-AP is limited. The treating psychiatrist should also discuss the probability of treatment effectiveness and adverse events based on the clinical trial results. Potential patients should be provided with comprehensive information about what to expect before, during, and after treatment. Clinicians and people with lived experience of PTSD reported that some patients who have trialled established PTSD treatments without success may overestimate potential benefits and minimise potential risks.

AMAPP agrees that comprehensive patient education is essential, but questions whether psychiatrists are invariably the most appropriate professionals to deliver accessible patient

explanations that achieve optimal comprehension. Given that all MDMA-AP treatment team members require appropriate training, accreditation and experience, AMAPP proposes that educational responsibility should be distributed according to the professional competencies and patient-relationship skills of treatment team members.

AMAPP recommends developing patient-friendly educational materials, including multimedia resources (videos, infographics) co-designed with lived experience experts to optimise accessibility and comprehension.

4.4 Good Practice Statement 4

Prior to initiating MDMA-AP, the treating psychiatrist should obtain written informed consent from potential patients. This consent should address likely benefits and harms of treatment (including rare but serious adverse events); potential physical, psychological, and financial risks; and what to expect before, during, and after treatment. The psychiatrist is responsible for ensuring that any actual or potential conflicts of interest related to their association with companies that manufacture, market, or promote MDMA are declared to the patient. Obtaining informed consent should be treated as an ongoing process, with regular review and adaptation based on the patient's evolving needs and experiences. The consent should be documented in appropriate records.

AMAPP fully agrees with Good Practice Statement 4, recognising that comprehensive informed consent represents standard practice for psychiatric treatments and psychotropic medication prescription, including appropriate conflict of interest disclosure. AMAPP's informed consent guidelines are detailed in the AMAPP Code of Conduct policy (AMAPP, 2024).

AMAPP proposes that informed consent documentation should explicitly address considerations unique to psychedelic therapies, including potential media exposure, social stigma, and confidentiality challenges that may differ from conventional psychiatric treatments.

4.5 Good Practice Statement 5

Patients should be given the option to involve a support person (such as a next of kin, family member, carer, or advocate) before and after treatment, including during the process of obtaining informed consent.

AMAPP fully supports Good Practice Statement 5, emphasising that appropriate support person education is essential to optimise the care they can provide to MDMA-AP patients. AMAPP recommends developing structured "Support Person Guidelines" to prepare support persons for their roles during pre- and post-treatment phases. Additionally, practitioners require clear protocols for support person involvement, including guidance on when and how to appropriately include support persons while maintaining patient confidentiality and therapeutic boundaries. For example, allowing support persons during informed consent and potentially during sessions, developing separate informed consent process for support persons who will be present, and addressing confidentiality implications.

4.6 Good Practice Statement 6

Prior to initiating MDMA-AP, the treating psychiatrist should explore patient preferences around supportive touch. Evidence is lacking about the value of supportive touch during MDMA-AP. There are important ethical and clinical considerations related to supportive touch. MDMA may heighten suggestibility, increase the perceived pleasantness of touch, and impair a patient's capacity to provide or withdraw consent during dosing sessions. It is likely

that people living with PTSD have variable values and preferences in relation to supportive touch. Clear boundaries, guided by patient preference, should be established during the informed consent process. This should be followed by a dynamic and ongoing consent process throughout treatment. In situations where supportive touch is offered, therapists must have received appropriate training in its ethical and therapeutic application.

AMAPP broadly agrees with Good Practice Statement 6, while recommending amendment to specify that all MDMA-AP treatment team members should participate in patient consultation regarding supportive touch preferences. Specifically, AMAPP advises that patient preferences and informed consent should be revisited and documented at each treatment phase (preparation, dosing, and integration). Furthermore, psychedelic-assisted therapy training programs should incorporate scenario-based learning focused on supportive touch protocols, management, and ethics to ensure adequate practitioner preparation. In regard to informed consent for PTSD more broadly, AMAPP suggests future guidelines for informed consent include considerations for how different attachment styles and nervous system states can impact consent (see Appendix C for more information and recommendations).

4.7 Good Practice Statement 7

To ensure continuity of care, people who provide MDMA-AP should do so in consultation with the person's regular healthcare providers (e.g., general practitioners, psychologists, psychiatrists, therapists). MDMA-AP should be integrated into, rather than replace, a patient's broader treatment plan. Where possible, a designated provider (such as the patient's usual general practitioner) should remain primarily responsible for overall patient care.

AMAPP broadly agrees with Good Practice Statement 7, while recognising that regular healthcare providers may lack sufficient MDMA-AP knowledge to provide appropriate guidance, or may not support the patient's treatment choice. In such circumstances, AMAPP proposes establishing formalised protocols to accommodate patients who independently seek MDMA-AP and meet appropriate eligibility criteria. Additionally, AMAPP recommends developing standardised referral documentation and integration summaries to facilitate communication between MDMA-AP teams and mainstream healthcare providers, ensuring continuity of care regardless of referral pathway.

4.8 Good Practice Statement 8

All clinicians involved in the delivery of MDMA-AP should develop a strong therapeutic alliance with patients prior to and throughout MDMA-AP for building trust, ensuring emotional safety, and supporting the effectiveness of therapy.

AMAPP agrees with Good Practice Statement 8, emphasising that this underscores the importance of multidisciplinary MDMA-AP treatment teams to optimise therapeutic alliance establishment. If the treatment team determines that strong therapeutic alliance development proves problematic or impossible, the suitability of MDMA-AP for that patient requires careful, sensitive evaluation. AMAPP recommends that supervision protocols include relational dynamics monitoring and boundary maintenance to maximise therapeutic alliance potential.

4.9 Good Practice Statement 9

Safeguarding measures should be implemented during MDMA-AP sessions, including ensuring that only authorised personnel are present during dosing sessions, video-recording sessions where appropriate for accountability, and having two trained therapists in the room

during dosing sessions. The presence of two therapists is recommended as a risk mitigation strategy to provide a safeguard for both patients and therapists in the event of any concerns or allegations of misconduct.

AMAPP agrees with Good Practice Statement 9, which reflects current best practice based on two decades of global psychedelic-assisted therapy clinical research experience.

AMAPP recommends that safeguarding protocols be formally documented and regularly audited, with particular attention to secure storage of session recordings and establishment of independent oversight mechanisms.

4.10 Good Practice Statement 10

Clinics delivering MDMA-AP should ensure the presence of appropriately trained personnel, such as medical doctors, to oversee medical or pharmacological interventions in managing adverse events. Appropriate clinical support should be rapidly available in case of medical emergencies.

AMAPP broadly agrees with Good Practice Statement 10, noting that current TGA Authorised Prescriber scheme requirements mandate psychiatrist presence or availability during dose sessions. However, the statement does not address adverse events during preparation or integration sessions, where AP presence is not required. AMAPP recommends that each treatment site maintain comprehensive emergency preparedness protocols, including established local hospital pathways and regular simulation drills for dose-day emergency scenarios.

As indicated in AMAPP's policy submission to the TGA's AP Scheme Stakeholder Review (Roy, 2025), regarding the specific requirement for AP presence throughout dosing sessions,

this presence is not always required provided there is a trained on-site therapy team, including at least one clinician authorised to administer rescue medications (e.g., a registered nurse, nurse practitioner, authorised paramedic, or medical practitioner), and real-time telehealth access to the AP psychiatrist for immediate consultation and escalation if needed (MAPS, 2021; Johns Hopkins, 2018).

4.11 Good Practice Statement 11

Clinicians should advise patients that MDMA may impair the ability to drive or operate heavy machinery. Patients should be informed of, and comply with, relevant State legislation regarding not driving under the influence of MDMA.

AMAPP agrees with Good Practice Statement 11.

4.12 Good Practice Statement 12

Patients should only leave the treatment clinic once the acute effects of MDMA have fully worn off. This involves clinically assessing vital signs, level of awareness, mental stability, and ensuring a prearranged support person is available to accompany the patient home.

AMAPP supports Good Practice Statement 12. AMAPP additionally recommends implementing standardised discharge assessment protocols to ensure consistent application across treatment sites and optimise patient safety.

4.13 Good Practice Statement 13

A comprehensive communication plan should be developed to facilitate the patient's transition back to routine care after MDMA-AP treatment. People with lived experience report the importance of setting clear expectations from the outset of treatment. This includes

discussion around the possible option to continue care with the therapist from MDMA-AP with whom a strong therapeutic alliance has been established. Clinicians should discuss potential post-treatment care models (such as peer support groups, group integration sessions, or regular check-ins with clinicians) to provide patients with ongoing support after completing MDMA-AP.

AMAPP agrees with Good Practice Statement 13, acknowledging that strong therapeutic alliances established during MDMA-AP frequently lead patients to express interest in continuing treatment with dyad members.

AMAPP recommends establishing funded integration pathways, including peer-facilitated support groups and telehealth options specifically designed to address the needs of rural and remote patients.

4.14 Good Practice Statement 14

The Guideline Development Group recognises that evidence in relation to MDMA-AP is rapidly evolving and there is potential value in a living evidence approach to future guideline development. Clinicians and people living with PTSD should make themselves familiar with the current best available research about possible benefits and harms as the basis for treatment decision-making.

AMAPP strongly agrees with Good Practice Statement 14, emphasising the urgent need to establish a fully independent, curated registry of MDMA-AP clinical practice incorporating comprehensive databases of both positive and negative short- and long-term outcomes.

AMAPP proposes a collaborative model involving academic institutions, professional bodies, and government agencies to maintain this registry independently, with strong

commitment to open-access data availability for public transparency and research advancement.

4.15 Good Practice Statement 15

The Guideline Development Group concurs with the Royal Australian and New Zealand College of Psychiatrists (RANZCP) that the clinicians involved in the delivery of MDMA-AP should be registered with the Australian Health Practitioner Regulation Agency (AHPRA) or their equivalent governing body and operate within their recognised scope of practice.

AMAPP broadly agrees with Good Practice Statement 15, particularly emphasising the phrase "or their equivalent governing body." As a membership-based organisation representing diverse medical, mental health and allied health professionals, AMAPP has proposed in its TGA Consultation Review titled Expanding Clinical Recognition: a Policy Submission (Roy, 2025) that the Authorised Prescriber scheme be expanded to include:

- Non-psychiatrist medical doctors, palliative care physicians and addiction physicians with established mental health experience who complete accredited psychedelic-assisted therapy training and meet AMAPP credentialing standards (outlined in Appendix A).
- Multidisciplinary team models where prescribing doctors collaborate with fully credentialed multidisciplinary psychedelic therapists, ensuring comprehensive and holistic care delivery.
- Future inclusion of Paramedic Practitioners, Nurse Practitioners and Clinical Nurse Specialists, following framework and credentialing process finalisation, to support emergency preparedness and access equity.

AMAPP advocates for competency-based credentialing and supervision frameworks (outlined in Appendix A), multidisciplinary approaches, and comprehensive initiatives designed to implement optimal practice and achieve positive outcomes during the early implementation phase of MDMA-AP and other psychedelic-assisted therapies.

4.16 Good Practice Statement 16

Clinicians delivering MDMA-assisted psychotherapy (MDMA-AP) must complete specific, role-appropriate training. While psychiatrists should follow the RANZCP Psychedelic Training Framework, the multidisciplinary nature of MDMA-AP requires comprehensive national standards for all treatment team members.

AMAPP strongly supports the core recommendation of Good Practice Statement 16, whereby all practitioners of the treatment team must complete role-appropriate training as per comprehensive national standards. However, AMAPP emphasises that training standards currently exist only for psychiatrists through the RANZCP Psychedelic Training Framework, not for all other treatment team members, despite the multidisciplinary nature of MDMA-AP.

Central to AMAPP's position is the implementation of competency-based training standards that prioritise demonstrated skills over institutional affiliation. AMAPP advocates for training frameworks mapped to shared competency domains across disciplines, ensuring practitioners are evaluated on their individual capability to deliver MDMA-AP within the scope of their position and skillset. This competency-focused approach supports a training ecosystem that reflects the multidisciplinary nature of psychedelic-assisted psychotherapy, enabling all treatment practitioners to deliver effective patient care.

AMAPP's credentialing and supervision standards (included in Appendix A) exemplify this competency-based framework and provide guidance in lieu of national training standards. For

AMAPP's position and recommendations on expanding clinical recognition in psychedelic-assisted therapy to recognise its multidisciplinary nature, see AMAPP's submission to the TGA's Authorised Prescriber stakeholder review (Roy, 2025).

4.17 Good Practice Statement 17

Training should be available for the broader healthcare workforce to increase awareness and understanding of MDMA-AP, provide relevant and evidence-based information, and support making appropriate referrals. People with lived experience of PTSD emphasise the importance of clinician awareness, particularly among primary healthcare professionals who have an important role in providing evidence-based information to people with PTSD.

AMAPP agrees with this statement and proposes that training modules be co-designed with lived experience representatives, Aboriginal and Torres Strait Islander communities, and neurodivergent community representatives to ensure comprehensive cultural competency and accessibility.

AMAPP agrees that training for the broader healthcare workforce is essential to increase awareness and understanding of MDMA-AP, ensure access to relevant, evidence-based information, and support timely, appropriate referrals, especially in primary care where clinician awareness most directly benefits people with PTSD. To that end, AMAPP proposes a tiered, CPD-aligned professional development pathway, grounded in AMAPP's pillars of Peer Support, Advocacy, and Trust, and co-designed with people with lived experience of PTSD, Aboriginal and Torres Strait Islander communities, and neurodivergent representatives to ensure cultural safety and accessibility. Entry-level modules (for GPs, nurses, and allied health) focus on trauma-informed care, cultural competence, indications/contraindications, harm-reduction principles, and clear referral criteria and pathways. Intermediate modules

build skills in screening, risk assessment, shared-care planning, informed consent, and collaborative communication. Advanced modules for PAT practitioners include specialist group supervision, case consultation, and credentialing to uphold ethical and safe practice. Delivered through blended learning (e-learning, webinars, workshops, and supervised practice) with practical tools, checklists, and assessments, this pathway strengthens clinician confidence, standardises competencies across the system, and improves access to high-quality, evidence-informed MDMA-AP care.

AMAPP's credentialing framework has received endorsement from PACFA, and we are actively contributing to the development of an inter-agency psychedelic-assisted psychotherapy interest group that supports PACFA's specialist interest group while strengthening practitioner networks through coordinated supervision sessions and peer consultation.

4.18 Good Practice Statement 18

Patient information about MDMA-AP should be provided in a format that is accessible to different target populations, including culturally and linguistically diverse (CALD) communities, Aboriginal and Torres Strait Islander peoples, and emergency service workers. With permission, this information should also be made available to the patient's support person.

AMAPP emphasises the critical importance of safeguarding the therapeutic container while balancing scientific rigour with psychotherapeutic efficacy, and integrating Indigenous knowledge systems and cultural reciprocity obligations in service delivery.

5. Critical Analysis of MDMA-AP Guideline Research Recommendations

5.1 Research Recommendation 1

It should be mandatory for data on treatment outcomes, including adverse events, to be collected using a systematic and structured approach and recorded in an independently funded registry. With appropriate privacy safeguards in place, registry data should be made available for research, guideline development, and regulatory decision-making.

AMAPP strongly agrees with Research Recommendation 1 and actively seeks collaborators to implement an independently funded and managed registry. The registry currently managed by an Australian university operates under private funding with data unavailable for research, guideline development or regulatory decision-making.

AMAPP emphasises that registry data transparency and accessibility represent fundamental requirements for maintaining public trust and advancing evidence-based practice.

5.2 Research Recommendation 2

Further research is needed to determine the most appropriate psychotherapeutic approach to be used alongside MDMA in the treatment of PTSD. This includes evaluating whether MDMA can enhance the effectiveness of existing evidence-based psychotherapies, and identifying which therapeutic modalities or techniques are the safest and most effective when combined with MDMA.

AMAPP strongly agrees with Research Recommendation 2, recognising that evaluating currently recommended psychotherapeutic modalities for MDMA combination represents a

substantial long-term undertaking. Current international research includes MDMA-assisted CBT, CPT (NCT05067244), Cognitive-Behavioural Conjoint Therapy (CBCT, NCT02876172 and NCT05979844), Exposure Therapy (NCT05709353) and PE (NCT05709353), and Group Therapy (NCT05173831 and NCT05961527). Comparative studies examine individual versus group therapy (NCT05732155), MDMA-assisted CPT versus CPT alone (NCT05837845), MDMA-assisted CBCT versus CBCT alone (NCT06044675), and MDMA-assisted PE evaluation (NCT06117306).

5.3 Research Recommendation 3

Future research is needed to understand the extent to which symptoms may worsen before improving in people who receive MDMA-AP, and whether temporary worsening of symptoms is associated with significant distress or harm.

AMAPP agrees with Research Recommendation 3, noting that most MDMA-AP clinical trials have assessed symptom severity over time, from immediate post-integration sessions to long-term follow-up periods ranging from 18 weeks (MAPP-1 & MAPP-2) to an average of 42 months (MAP-1).

5.4 Research Recommendation 4

Evidence from current clinical trials relates to a single course (3 dosing sessions, 80–120 mg MDMA with supplemental half dose at each dosing) of MDMA-AP delivered over an 18-week period. There is a lack of safety and efficacy data on the use of MDMA for a longer or shorter term or at a different dosage. Further research is also needed into the benefits and harms of delivering more than one course of MDMA-AP.

AMAPP agrees with Research Recommendation 4, while noting inaccuracies regarding the absence of clinical trial data on (a) outcomes beyond 18 weeks and (b) quality of life, productivity, or health-related measures. Current research includes completed dose-response studies (NCT01793610) and ongoing investigations (NCT06418178), plus comparative 2- versus 3-dose protocols (NCT04784143). However, research on ongoing MDMA-AP sessions as-required remains absent.

AMAPP emphasises that longer-term studies should assess treatment impact on core PTSD symptoms and broader health, wellbeing, and quality of life outcomes, including associated risks. AMAPP acknowledges that outcome measures such as "productivity" may reflect socio-political-economic values potentially misaligned with patient-centred wellbeing approaches. Future research should prioritise meaningful health outcomes while examining community connection and peer support pathway effectiveness in sustaining long-term recovery beyond active treatment.

5.5 Research Recommendation 5

Future research is needed to investigate the safety and efficacy of MDMA-AP in people with PTSD who are re-exposed to their index or other significant trauma during the course of treatment. Current clinical trials have excluded people likely to be re-exposed to trauma.

AMAPP agrees with Research Recommendation 5, acknowledging the significant ethical challenges likely encountered in implementing such research. Phase 4 data from community-based clinical implementation will likely provide the most accessible information over time.

5.6 Research Recommendation 6

Future research is needed into the role of MDMA-AP in relation to other evidence-based treatments for PTSD, including whether earlier use of MDMA-AP may improve treatment outcomes.

The scope of Research Recommendation 6 requires clarification regarding whether it addresses MDMA-AP as implemented through the established MAPS treatment manual or broader psychotherapeutic approaches discussed in Recommendation 2. AMAPP fully supports evaluating MDMA-AP against approved pharmacotherapies, specifically SSRI/SNRI medications and psychotherapeutic interventions, including trauma-informed and somatic modalities (EMDR, Somatic Experiencing), multiplicity and relational models (IFS, Gestalt, Schema Therapy), mindfulness-based approaches (ACT, DBT), and culturally informed practices (narrative therapy, grief and loss counselling, Indigenous healing approaches).

5.7 Research Recommendation 7

Future research should explore the possible value of adapting treatment protocols according to the complexity of each patient's PTSD presentation. This may include variations in treatment duration, intervals between dosing sessions, number of dosing and integration sessions, or group integration sessions.

AMAPP agrees with Research Recommendation 7, suggesting that research commence with Phase 2 studies specifically recruiting participants with complex PTSD presentations and evaluating the variables specified in the recommendation.

5.8 Research Recommendation 8

Future research should investigate the safety and efficacy of MDMA-AP for PTSD in the context of specific comorbid conditions for which the therapeutic value of MDMA-AP is currently being evaluated (e.g., alcohol use disorders, eating disorders without active purging, substance use disorders).

AMAPP agrees with Research Recommendation 8, noting current clinical trials studying PTSD with alcohol use disorders (NCT05709353, NCT05943665 and NCT07118839).

5.9 Research Recommendation 9

Existing phase 3 clinical trial protocols for MDMA-AP in PTSD used fixed-dose regimens and excluded individuals who weighed less than 48 kg. Further research should be conducted into the possible value of weight-based dosing (e.g. concentration response, pharmacokinetic-pharmacodynamic simulations).

AMAPP respectfully disagrees with Research Recommendation 9, given extensive MDMA pharmacokinetic/pharmacodynamic data from Phase 1 trials excluded from the Evidence Review Team's analysis. MDMA produces reliable responses apparently independent of circulating concentration, possibly reflecting robust SERT activity rather than direct 5-HT receptor action. Body-habitus dose adjustments are rarely employed in psychedelic-assisted therapies, as clear correlations between body weight, dose level and experiential or therapeutic effects remain unestablished.

5.10 Research Recommendation 10

The Guideline Development Group recognises that people from different cultures might view MDMA-AP differently. Future research should investigate the acceptability of treatment

protocols for MDMA-AP in different cultural groups, including Aboriginal and Torres Strait Islander peoples.

AMAPP recognises that effective psychedelic therapy in Australia must acknowledge, support, and honour Indigenous models of care. Current regulatory frameworks fail to acknowledge Indigenous knowledge systems and longstanding relationships with plant medicines (Dudgeon et al., 2014; PACFA, 2022). AMAPP's accreditation standards recognise First Nations healthcare practitioners providing culturally informed trauma integration and community-led healing practices (AMAPP, 2025), contributing essential insights into holistic, place-based, and relational care models.

Excluding Indigenous practitioners with requisite clinical qualifications perpetuates cultural injustice and limits therapeutic possibilities in Indigenous contexts. Ethical and effective psychedelic-assisted therapy in Australia requires multidisciplinary perspectives within robust regulatory frameworks.

Aboriginal and Torres Strait Islander peoples experience significant intergenerational and cumulative trauma from historical and ongoing separation from family, land, and cultural identity, profoundly impacting social and emotional wellbeing (AIHW, 2018; Bendall et al., 2018).

AMAPP envisions coexistence between traditional and contemporary practices as distinct yet complementary domains. Maintaining clear boundaries promotes psychedelic-assisted therapy integrity and efficacy while preserving cultural heritage. AMAPP emphasises that psychedelic-assisted therapy represents contemporary clinical practice grounded in evidence-based psychotherapeutic approaches, distinct from ceremonial and shamanic uses occurring in Indigenous and traditional contexts with spiritual, communal, and cosmological dimensions.

AMAPP advocates respectful, reciprocal learning while maintaining appropriate boundaries to prevent cultural commodification and ensure both clinical effectiveness and cultural sovereignty preservation. This approach aligns with AMAPP's ethical policies regarding non-discriminatory practice and respect for patients and traditional psychedelic applications.

AMAPP agrees with Research Recommendation 10 and acknowledges culturally safe practice importance while noting that MDMA produces psychological responses less influenced by cosmological frameworks compared to classic psychedelics like psilocybin.

5.11 Research Recommendation 11

Future research should investigate whether there is a need for tapering or discontinuation of all other medications prior to MDMA-AP. People with lived experience report significant challenges in discontinuing other mental health medications prior to MDMA-AP.

AMAPP agrees with Research Recommendation 11, noting that medication interaction research represents an active area of clinical investigation and discussion in MDMA-AP research.

6. Conclusion

The Australian guideline on MDMA-assisted psychotherapy (MDMA-AP) for PTSD demonstrates methodological rigour and appropriate caution. However, its conservative stance risks delaying treatment innovation, constraining workforce development, and exacerbating access inequities, particularly affecting rural and marginalised communities.

In response to these concerns, AMAPP's proactive leadership and governance frameworks provide evidence-based solutions. AMAPP emphasises the importance of living evidence

frameworks, competency-based training, and equitable operational design. AMAPP's comprehensive credentialing standards (outlined in Appendix A) offer practical frameworks informed by internationally recognised clinical training domains, ethics, indigenous knowledge, somatic and trauma-informed practices, and multidisciplinary professional foundations. AMAPP remains committed to supporting practitioners and advancing the field through collaboration with regulatory organisations and peak bodies, ensuring that psychedelic-assisted psychotherapy in Australia evolves safely and equitably for all those we seek to serve.

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Appendix A: AMAPP Credentialing Standards

AMAPP credentials practitioners based on independent, policy-driven education standards informed by a systematic review of global competency frameworks for psychedelic-assisted therapy. Rather than being tied to any single university curriculum, our standards draw from internationally recognised clinical training domains, ethics, indigenous knowledge, somatic and trauma-informed practices, and a multidisciplinary professional base. This positions our accreditation around evidence-based knowledge and core competencies identified across contemporary research and professional models. This approach mitigates the risk of vested interests inherent in individual institutional programs and supports diverse learning pathways that reflect different practitioner strengths, cultural approaches, and regional contexts.

1. AMAPP Accreditation Guidelines

AMAPP Accreditation Guidelines (AMAPP, 2025) stipulate the following accreditation standards:

1.1 Core Training

Both Psychedelic-Assisted Therapists and Psychedelic Facilitators must have completed core training in Psychedelic-Assisted Psychotherapy with a minimum of 100 hours of theory/didactic learning demonstrating:

- Foundational knowledge: psychedelic history, the ‘Drug War’ and resurgence of research
- Indigenous wisdom: historical use of plant medicines and cultural context
- Pharmacology: psychedelic mechanisms and neuroscience
- Medical screening: contraindications, complexity, trauma-informed care

- Research: current Australian and global clinical evidence
- Ethics: safety, risk mitigation, relevant laws, professional guidelines
- Preparation and integration: clinical intake, set and setting, intention, mystical/transpersonal processes, somatic and trauma-informed integration, harm reduction, spiritual emergence, existential themes
- Space holding: non-directiveness, attunement, therapeutic touch, music and playlist curation
- Therapeutic relationship: boundaries, transference, counter-transference, therapist self-care

1.2 Experiential Training

- Minimum two years of clinical therapy experience
- Minimum 40 hours of experiential learning (breathwork, role play, dosing)
- Facilitation of at least two dosing sessions under supervision, e.g., clinical trials or community cannabis/ketamine work
- Supervision signed off by a PAT-experienced supervisor (minimum six hours) or confirmed by letter and peer reference verifying safe delivery across preparation, dosing, and integration.

1.3 Personal Development Work

Significant engagement in personal therapy, reflective practice, and legal non-ordinary state work (e.g., breathwork, meditation) to support therapist development.

1.4 Professional Registration

Registered with a governing body such as:

- Australian Health Practitioner Regulation Authority (AHPRA)
- Australian Association of Social Workers (AASW)
- Psychotherapy and Counselling Federation of Australia (PACFA)
- Australian Counselling Association (ACA)

1.5 Professional Insurance

All multidisciplinary psychedelic professionals must maintain their own professional indemnity insurance or be appropriately covered under the insurance policy of a licensed clinic, research institution, or university trial in which they are working.

1.6 Complementary Therapeutic Modalities

Background training in psychology, psychotherapy, or counselling plus capability with trauma-informed and somatic modalities, including:

- Somatic (e.g., EMDR, Hakomi, Sensorimotor Psychotherapy, Somatic Experiencing)
- Trauma-informed multiplicity models (e.g., Internal Family Systems, Structural Dissociation, Ego State Therapy, Resource Therapy, Gestalt, Jungian Depth Psychology, Schema Therapy, Transpersonal Psychology, Voice Dialogue, Emotion Focused Therapy)
- Mindfulness-based (e.g., ACT, DBT, MIBT)

1.7 Therapist Characteristics

Applicants must demonstrate:

- Good personal character and ethical integrity
- Professional registration
- Respect for Australian law regarding psychedelic use

- No outstanding allegations of abuse or misconduct
- Adherence to AMAPP Code of Conduct

1.8 Aboriginal and Torres Strait Islander Practitioners

AMAPP recognises Indigenous knowledge systems and supports culturally safe accreditation pathways, including practitioners and support workers using culturally informed healing practices such as:

- Narrative therapy
- Grief and loss counselling
- Indigenous counselling training
- Trauma integrated healing approaches

1.9 Continuing Professional Development

Ongoing professional development and supervision to maintain competency in psychedelic-assisted psychotherapy.

2. AMAPP Supervision Guidelines

AMAPP Supervision Guidelines (AMAPP, 2024) stipulate the following standards for supervisors:

Supervised practice may involve video-recorded sessions or co-therapy. To qualify as an AMAPP-Accredited Supervisor, an individual must have:

- Credentials in therapy (e.g., psychologist, psychiatrist)
- Minimum two years supervisory experience
- At least four dosing sessions delivered over 12 months

- Experience across all preparation, dosing, and integration phases

Once two dosing sessions and six hours of supervision are completed, the supervisor provides a letter confirming eligibility for full practitioner accreditation.

3. AMAPP Credentialing Processes/Framework

The credentialing requirements for these roles are rigorous. All accredited practitioners must complete a minimum of 100 hours of didactic learning, covering foundational topics such as psychedelic research history, ethno-medicine, pharmacology and neuroscience of psychedelic agents, trauma-informed screening, ethical guidelines, risk management, and core preparation and integration strategies. Additional instruction is provided in somatic and transpersonal approaches, symbolic processing, and therapeutic boundaries. These curricula draw on international sources, including MAPS (2022), BrainFutures (2023), and Fluence (2024), but are refined to reflect Australian clinical standards and cultural needs. For instance, AMAPP integrates modules on ethno-medicine, grief and loss in community, and ecological models of care, acknowledging the importance of local knowledge systems. Experiential learning is also a key requirement. Candidates must have at least two years of clinical therapy experience and complete more than 40 hours of experiential training through breathwork, role play, and supervised PAT sessions.

3.1 Full accreditation

Full accreditation requires participation in at least two supervised dosing sessions, such as those in clinical trials or community-based ketamine therapy, and six hours of one-on-one supervision with a PAT-experienced clinician. To confirm readiness, applicants must also submit a written endorsement from a supervisor or co-therapist attesting to their competence in preparation, dosing, and integration.

Ethical integrity and personal development form the final pillar of AMAPP's framework. All practitioners must be registered with a relevant professional body, such as:

- Australian Health Practitioner Regulation Agency (AHPRA)
- Psychotherapy and Counselling Federation of Australia (PACFA)
- Australian Association of Social Workers (AASW)
- Australian Counselling Association (ACA)

Candidates must also commit to ongoing personal reflection, therapy, and professional development. Regular supervision, ethical audits, and engagement with peer learning networks are not optional but foundational to maintaining accreditation.

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Appendix B: Case Conceptualisation and Assessment Framework

AMAPP acknowledges that there are a variety of assessment processes, theories, models and protocols for MDMA-AP. The following provides a snapshot of some key areas to consider for a comprehensive case conceptualisation and assessment framework.

Case Conceptualisation and Assessment Framework

By thoroughly understanding each patient's unique background, needs, and goals, practitioners can tailor diversity and inclusion considerations to individual cultural contexts, customise informed consent processes based on patient vulnerability factors, adapt the three-phase integration approach to personal healing timelines, and determine optimal support person involvement based on patient preferences and needs.

This individualised approach ensures that all protocol enhancements are applied thoughtfully and effectively, strengthening the overall scope and clinical utility of MDMA-assisted psychotherapy guidelines.

Comprehensive Patient Evaluation

- **Understand patient background** including trauma history, cultural context, and previous treatment experiences
- **Assess current psychological state** to establish baseline functioning and identify specific vulnerabilities
- **Assess clients' capacity for consent** based on a detailed assessment of their attachment style (avoidant, dismissive, secure), and what this means in relation to touch contracts, boundary violations, and potential risks due to freeze, flight, fight, fawn, and flock nervous system responses

- **Personalise safety protocols** by understanding how different attachment styles (secure, anxious-preoccupied, avoidant-dismissive, disorganized) impact consent capacity, boundary awareness, and vulnerability to touch-related triggers during altered states
- **Evaluate nervous system regulation** to identify clients who may experience freeze, flight, fight, fawn, or flock responses that could compromise their ability to maintain boundaries or communicate consent during treatment
- **Adapt informed consent processes** to account for attachment-related vulnerabilities, ensuring clients with insecure attachment patterns receive additional support in understanding touch protocols and boundary maintenance

Metacognitive Skills and MDMA Therapy

- **Assess and support metacognitive development** - Evaluate clients' current ability to navigate fluid boundaries between self, perception, and reality during altered states, while providing therapeutic support and psychoeducation to strengthen these skills (Millière et al., 2018)
- **Evaluate and enhance core metacognitive functions** - Assess current capacity for *monitoring* (observing mental processes as representations rather than reality) and *modification* (regulating cognitive operations through mindfulness and cognitive techniques), and provide therapeutic support and psychoeducation for skill development (Flavell, 1979; Wells, 2011)
- **Assess integration capabilities and provide psychoeducational support** - Evaluate clients' ability to recall and describe experiences, connect insights to habitual patterns, and distinguish useful revelations from altered-state distortions, while offering therapeutic interventions to strengthen these capacities

- **Evaluate behavioral translation skills and provide therapeutic support** - Assess clients' capacity to consciously implement new behaviors aligned with insights and navigate obstacles, while providing therapeutic guidance and psychoeducational resources
- **Assess readiness for neuroplasticity window and provide psychoeducation** - Evaluate clients' ability to intentionally direct enhanced brain flexibility toward desired changes during post-treatment recovery, while teaching therapeutic strategies to maximise this opportunity
- **Assess integration potential and provide ongoing therapeutic support** - Evaluate clients' capacity to translate temporary altered-state experiences into enduring personality and behavioral changes, while providing ongoing therapeutic support for this transformation process (Lysaker et al., 2020)

Treatment Planning and Goal Setting

- **Determine treatment fit** by evaluating how MDMA therapy aligns with the patient's overall treatment plan and therapeutic goals
- **Collaborate on goal-setting** to identify specific, measurable outcomes the patient hopes to achieve through therapy
- **Individualise treatment approach** by adapting protocols to address each patient's unique needs, circumstances, and presenting concerns
- **Integrate assessment findings** to inform all aspects of treatment planning, from informed consent to integration phases

Appendix C: Recommendations for Informed Consent

1. Consent, Boundaries, and Relational Safety Assessment

AMAPP emphasises the importance of collaboratively exploring relational, attachment and nervous system responses in relation to consent, boundaries and therapeutic processes, and co-creating strategies and resources within the client and therapy team.

1.1 Attachment Styles and Consent Capacity

Understanding how different attachment patterns impact a client's ability to provide meaningful informed consent and maintain therapeutic boundaries:

- **Secure Attachment**: Generally able to engage in balanced consent discussions and maintain appropriate boundaries
- **Anxious-Preoccupied**: May agree to treatment to maintain connection with therapist; require additional support in understanding risks and asserting needs
- **Avoidant-Dismissive**: May minimise vulnerability aspects of treatment; need encouragement to fully consider emotional and relational dimensions
- **Disorganised**: May have difficulty with consistent decision-making; require careful assessment of capacity and additional support structures

1.2 Nervous System States and Consent Considerations

1. Flight (Escape Response)

- **Definition:** The urge to flee or escape from real or perceived danger
- **Consent Considerations:** Clients may struggle to remain present for informed consent discussions or may avoid difficult material during preparation

2. Fight (Active Defence Response)

- **Definition:** Mobilisation of energy toward defending oneself through anger, aggression, or control
- **Consent Considerations:** May have unrealistic expectations or struggle to accept vulnerability inherent in treatment

3. Freeze (Shutdown Response)

- **Definition:** State of immobility, numbness, or disconnection with protective paralysis
- **Consent Considerations:** May have difficulty processing information or making informed decisions about treatment

4. Fawn (Appeasement Response)

- **Definition:** Survival strategy focused on people-pleasing, compliance, or appeasement
- **Consent Considerations:** May agree to treatment without fully understanding risks or may suppress concerns to maintain relational harmony

5. Flop (Submission Response)

- **Definition:** Total collapse, giving up, or complete submission to overwhelming threat
- **Consent Considerations:** May have passive expectations about treatment outcomes or difficulty advocating for their needs

6. Flock (Seek Safety in Groups)

- **Definition:** Tendency to seek safety and regulation through social connection and group belonging when threatened

- **Consent Considerations:** May defer decision-making to others or struggle with individual autonomy in treatment choices

1.2 Boundary and Touch Protocol Assessment

- **Assess clients' capacity for consent** based on attachment style and nervous system responses in relation to touch contracts, boundary violations, and potential risks during altered states
- **Personalise safety protocols** by understanding how different attachment styles impact consent capacity, boundary awareness, and vulnerability to touch-related triggers
- **Evaluate nervous system regulation** to identify clients who may experience responses that could compromise their ability to maintain boundaries or communicate consent during treatment
- **Adapt informed consent processes** to account for attachment-related vulnerabilities, ensuring clients with insecure attachment patterns receive additional support in understanding touch protocols and boundary maintenance