

PATIENT INFORMATION

Last Name: _____ First Name : _____ Second Name(s): _____
Personal Health Number (PHN): _____ Province or Territory: _____
Birthdate (YYYY / MM / DD) : _____

MEDICAL PRACTITIONER INFORMATION

Last Name: _____ First Name: _____ College ID: _____
Medical Specialty: _____ Province or Territory: _____
List Other Medical & Mental Health Professionals Involved: _____

This assessment form may be completed by a licensed healthcare practitioner, authorized to prescribe in their respective province (i.e Medical Doctor or Nurse Practitioner). The assessing medical practitioner is to make these determinations independently, summarize their findings below and document completed form in the patient’s health record. The criteria for patient inclusion below strongly emulates those used by the Johns Hopkins research group in their landmark 2016 clinical study on psilocybin for end-of-life distress.

Medical Inclusion Criteria

- Age: Over 18 years old.
 - ★ Other age ranges may be considered on an individual basis.
- Has, or has had, a serious illness, disease or disability.

Indicate nature of illness:
- Has a performance status of between 100% - 50%.
 - ★ A performance status below 50% is not considered an absolute contraindication but may be considered on an individual basis.
 - 100% Fully active, able to carry on all pre-disease performance without restriction
 - 90% Fully active but performance slightly restricted
 - 80% Fully active but restricted in physically strenuous activity
 - 70% Active but unable to work. Ambulatory and able to carry out work of a light or sedentary nature
 - 60% Ambulatory and capable of all self-care but unable to carry out any work activities
 - 50% Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
 - 40% Requiring help with ambulation and self care
 - 30% Completely disabled, cannot carry on any self-care, totally confined to bed or chair
- NOT receiving chemotherapy, hormonal therapy, radiation therapy, biologic therapies.
- If receiving chemotherapy, hormonal therapy, radiation therapy, biologic therapies: Tolerating the therapy or treatment in a sufficient fashion to allow administration of oral psilocybin.
 - ★ Patients receiving chemotherapy, hormonal therapy, radiation therapy, biologic therapies may participate while receiving those therapies. Continuing hormonal therapy, chemotherapy, or radiation treatment is acceptable if the patient is tolerating the therapy or treatment in a sufficient fashion to allow administration of oral psilocybin.
- If Cancer: Cancer has NO central nervous system involvement.
 - ★ Special attention needs to be paid to cancer with known intracranial involvement. Any evidence of intracranial involvement, such as focal deficit, visual disturbance and/or gait disturbance warrants a medical consult.
- NOT in treatment in a clinical trial where psilocybin therapy would disqualify them from their treatment trial.
- NO severe hepatic dysfunction.

- ★ The following values may serve as guides but are not considered absolute contraindications. Elevated hepatic enzymes warrant a medical consult.
 - GGT > 3 x ULN (upper limit of norm)
 - AST > 3 x ULN
 - ALT > 3 x ULN
 - Tot Bili > 50 umol/L
- NO severe renal insufficiency (eGFR < 20 ml/min)
 - ★ Renal insufficiency is not an absolute contraindication and warrants a medical consult.
- NO paraneoplastic syndrome or a tumor with ectopic hormone production which may place the patient at risk for hypercalcemia, Cushing's syndrome, or SIADH secretion.
 - ★ If a paraneoplastic syndrome exists or if the threat of hypercalcemia exists, but the lab work indicates that it is not a problem currently and if the patient is clinically stable, then psilocybin therapy is worthy of consideration and warrants a medical consult.
- NO uncontrolled cardiovascular conditions: uncontrolled hypertension, uncontrolled angina, a clinically significant ECG abnormality (e.g. atrial fibrillation).
 - ★ Cardiovascular conditions present are not an absolute contraindication and warrants a medical consult.
- NO uncontrolled vascular disease (such as TIA in the last 3-6 months, stroke with loss in mental status, peripheral or pulmonary vascular disease with active claudication).
 - ★ Vascular conditions present are not an absolute contraindication and warrants a medical consult.
- NO active uncontrolled epilepsy.
 - ★ A history of a remote seizure should not be an absolute contraindication and warrants a medical consult.
- NO unstable Insulin-dependent diabetes; If taking oral hypoglycemic agent, then NO recent history of hypoglycemia or instability.
- Is NOT pregnant (positive pregnancy test), NOT nursing, and practicing an effective means of birth control (e.g. hormonal agents or double barrier method: i.e. spermicide & condom).
- NOT currently taking on a regular (e.g., daily) basis:
 - investigational agents,
 - medications that are MAO inhibitors.
 - ★ Patients taking MAO-A inhibitors (especially the irreversible inhibitors) should be assessed on a case by case basis. These will require a minimum 2 week washout period. The possible concern over serotonin syndrome with these agents is not well documented in the literature, however the long interval before MAO is replenished may warrant a cautious approach based on the patient's risk factors and warrants close medical oversight.
 - ★ Patients taking MAO-B inhibitors should be assessed on a case by case basis as there is a potential for a heightened response and warrants close medical oversight.

- ❑ NOT currently taking benzodiazepines.
 - ★ Use of benzodiazepines is not a contraindication. Patients taking benzodiazepines should be assessed on a case by case basis. Abrupt withdrawal of benzodiazepines is dangerous and may precipitate seizures and cardiovascular issues. Remaining on these compounds MAY blunt the psychedelic effect of psilocybin, but the literature is mixed on this topic.
 - ★ Any PRN benzodiazepines, taken in the 24 hours before the psilocybin session, must be reported to and assessed by the practitioner providing medical oversight.

- ❑ NOT currently taking Trazodone, Mirtazapine, Buspirone, Atypical antipsychotics, SSRI's, SPARI's, SNRI's, TCA's.
 - ★ Trazodone + Mirtazapine + Atypical antipsychotics are antagonists of the 5HT2A receptor and Buspirone is a competitive agonist for 5HT2A and 1A receptors - these agents are more likely to cause a blunt experience and may be tapered if the practitioner providing medical oversight considers it safe to do so.
 - ★ SSRIs, SPARI's, TCA's and SNRI's may be tapered if the practitioner providing medical oversight considers it safe to do so. The concern over possible serotonin syndrome with these agents is not well founded in the literature. Antidepressants may blunt the psychedelic effect.
 - ★ It is recommended that reducing dosages at intervals of 5 half-lives is the best way to taper. Depending on the urgency of the situation, a drug free week following the taper is ideal.

- ❑ NOT currently taking opioid pain medications.
 - ★ Use of opioid pain medications is not a contraindication.
 - ★ Any PRN medications for treating breakthrough pain, taken in the 24 hours before the psilocybin session, must be reported to and assessed by the practitioner providing medical oversight.
 - ★ Any opioid agonist therapy must be reported to and assessed by the practitioner providing medical oversight.

- ❑ NOT currently taking any UGT 1A10 or 1A9 inducers or inhibitors (ex: Diclofenac and Canagliflozin).
 - ★ Use of UGT 1A10 or 1A9 inducers or inhibitors is not a contraindication.
 - ★ As described elsewhere, any PRN medications must be reported to and assessed by the practitioner providing medical oversight.

Psychiatric Inclusion Criteria

- ❑ Patient emotional distress has not successfully responded to other treatments:
 - ★ other treatments failed, could not tolerate other treatments, unable to access other treatments, or refused other treatments for reasons acceptable to the medical practitioner conducting assessment.

- ❑ Patient demonstrates sufficient comprehension for understanding potential implications, limitations, risks, benefits and processes for utilizing psilocybin therapeutically.

- ❑ NO severity of depression or anxiety symptoms warranting immediate treatment with antidepressant or daily anxiolytic medication (e.g., due to suicidal ideation).

- NO current or past history of meeting DSM-5 criteria for:**
 - Schizophrenia;
 - Psychotic Disorder (unless substance-induced or due to a medical condition);
 - Borderline Personality Disorder;
 - Bipolar I Disorder;
 - Bipolar II Disorder;
 - ★ Borderline Personality Disorder, Bipolar I Disorder and Bipolar II Disorder may be considered after a psychiatric consult.

- Does NOT **currently** meet DSM-5 criteria for:**
 - Dissociative Disorder

- NO first and second degree relatives meeting DSM-5 criteria for:**
 - Schizophrenia;
 - Psychotic Disorder (unless substance-induced or due to a medical condition);
 - Bipolar I Disorder;
 - Bipolar II Disorder.
 - ★ Patients with first and second degree relatives with Bipolar Disorder may be considered after a psychiatric consult.

- NO current active Substance Use Disorder**
 - ★ Current substance use disorder is not a contraindication.
 - ★ Active substance use disorder warrants additional consideration and a medical consult.
 - ★ Substance use on the day of the psilocybin session is a contraindication.

- NO other psychiatric conditions judged to be incompatible with establishment of rapport or safe exposure to psilocybin.**

Provide details if any inclusion criteria is not met and/or any referral to specialist for further assessment.

SIGNATURE

COMPLETION DATE

Maintained by:	TheraPsil Clinical Intake Director and Medical Consult					
Issuing Authority:	TheraPsil Medical Consult					
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