

# Evidence Review Standards for Qualifying Conditions

Adopted: 4-20-2026

## Purpose:

To ensure that recommendations for new qualifying conditions under the Medical Psilocybin Program are based on credible scientific evidence, clinical relevance, and patient safety considerations.

## Scope:

This policy governs the evaluation of potential qualifying conditions by the Patient Qualification and Safety Committee.

## Standard of Evidence

Randomized controlled trials shall be considered the strongest and most reliable form of evidence for evaluating therapeutic benefit and shall be prioritized when available.

In the absence of sufficient randomized controlled trial data, the Committee may consider high-quality observational studies, open-label trials, and other emerging evidence, provided that:

- Limitations are clearly acknowledged; and
- The totality of evidence supports a reasonable expectation of benefit and safety.

Systematic reviews and meta-analyses may be used to evaluate consistency and overall trends in the evidence. The Committee shall ensure that such analyses are not given duplicative weight where they rely on the same underlying studies already under review

In applying the standard of evidence, the Committee shall consider:

- The strength and consistency of findings across studies
- The size and clinical relevance of observed effects
- Known or potential risks associated with treatment
- The severity of the condition and availability of alternative treatments