

The Psychedelic Therapies Reimbursement Challenge

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A New Frontier in Mental Healthcare Facing Familiar Hurdles: The Challenge of Reimbursement

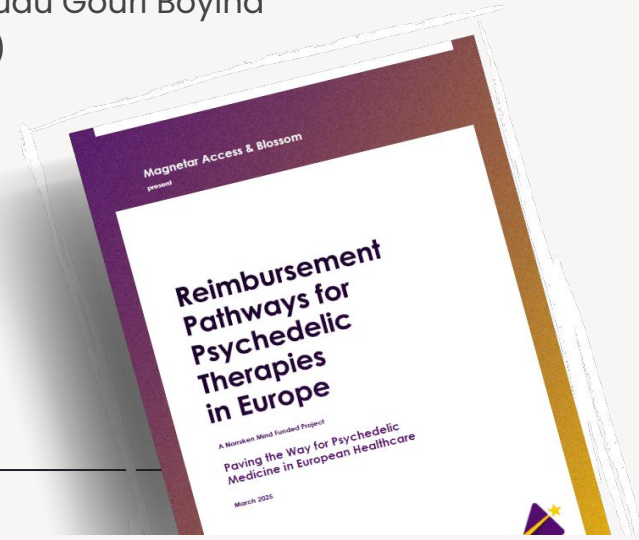


‘Reimbursement Pathways for Psychedelic Therapies in Europe’

- Multi-disciplinary authorship
- Supported by Norrsken Mind (project grant)
- First Europe-wide, payer-focused analysis of reimbursement and access pathways for psychedelics
- For developers, healthcare professionals, payers, policy makers and patients

Report Authors

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Report Objectives



Mapping the Reimbursement Landscape

Focusing on Germany, the Netherlands, the United Kingdom, and the Czech Republic



Identifying Challenges to Reimbursement and Solutions

Regulatory uncertainties, clinical evidence requirements, economic considerations, and infrastructural needs



Stakeholder Engagement to Collate Insights

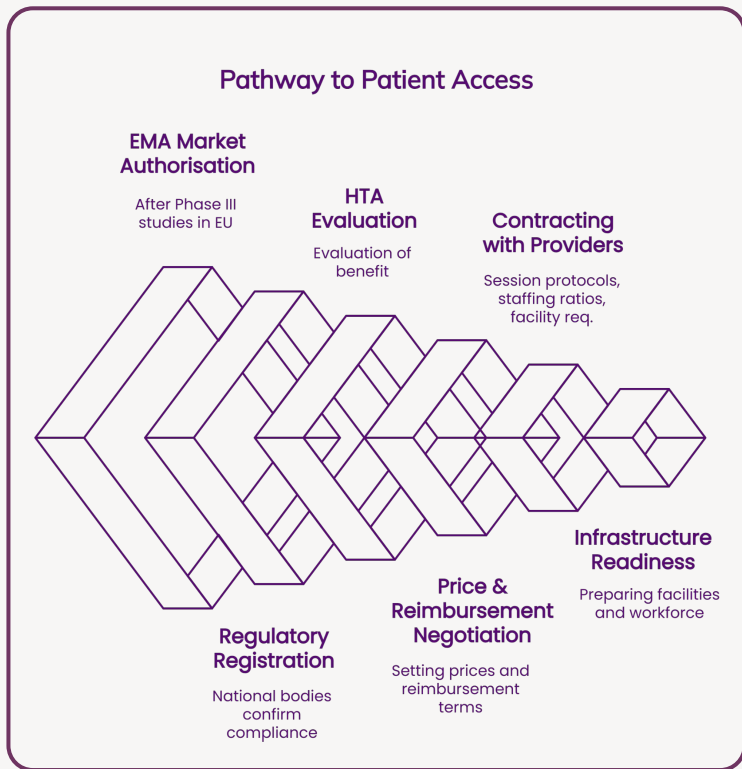
Payers, drug developers, healthcare professionals, patient advocacy groups



Facilitating Access to Psychedelic Therapies

Offering strategies to make psychedelic therapies accessible within existing healthcare frameworks

Reimbursement & Access Challenges for Psychedelics in Europe



Regulatory Complexity

- EMA authorisation
- Healthcare system approvals
- National drug controls

Evidence Challenges

- Non standard trial methodologies due to blinding difficulties
- Challenges in generating comparative effectiveness data
- Longer-term treatment effect

HTA Methodology Limitations

- Drug + psychotherapy combinations
- Comparative effectiveness
- Direct vs indirect value

Reimbursement & Access Challenges for Psychedelics in Europe

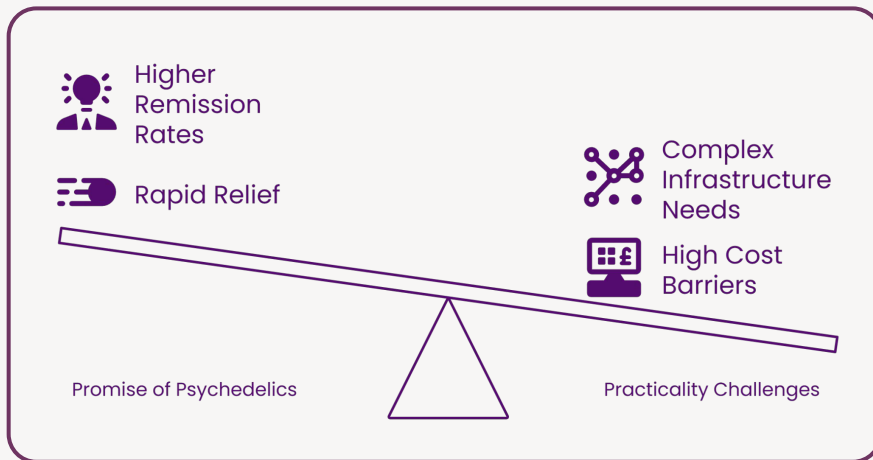
Economic Hurdles

- High upfront costs – patented compound pricing, specialised staffing and monitoring needs
- Especially when compared to low-cost standard of care treatments

Infrastructure Gaps

- Need for appropriate therapeutic spaces and trained professionals
- Healthcare systems face significant workforce shortages

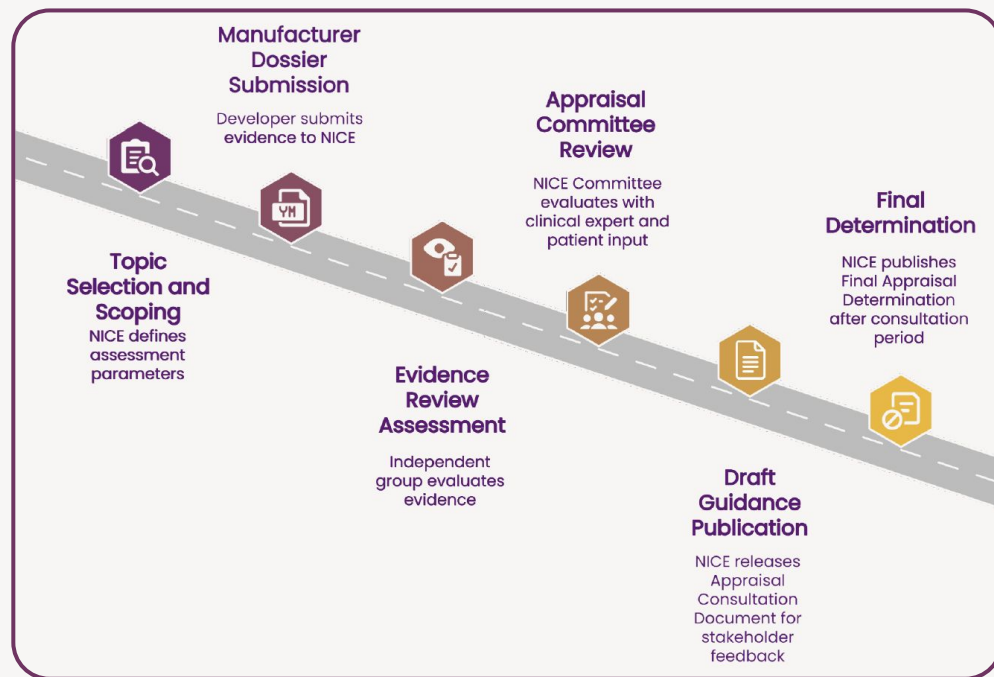
How can we balance promise vs. challenges and make psychedelics available to patients most in need?



The Route to National Reimbursement in the UK for Licensed Therapies Is Through National Health Technology Assessment

- As a default, all new medicinal products must be assessed by the National Institute for Health and Care Excellence (NICE) in England and Wales, and Scottish Medicines Consortium (SMC) in Scotland
- Health Technology Assessment (HTA) is a partly public process, following set methodologies and evidence standards
- Therapies must fall within a 'value for money' threshold
- NICE (and SMC) use cost-effectiveness modelling to determine the cost per quality adjusted life year (QALY)

Simplified HTA Process for England & Wales



Opportunities Specific to HTA in the UK for Psychedelics



Patient Quality of Life

Recognising improvements in patient well-being

NICE and SMC Policies

Allowing indirect treatment comparisons

Health Systems Benefits

Accepting long-term advantages for health system

Clinical Benefits

Demonstrating significant clinical advantages

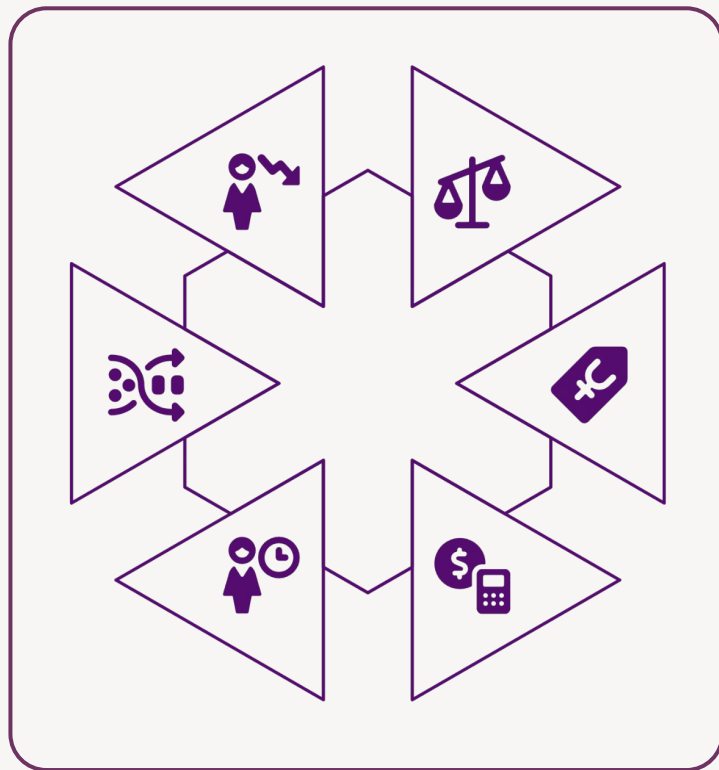
Cost Savings

Showing financial savings for the healthcare system

Drug and Therapy Eval.

Assessing combined treatment approaches

Challenges Specific to HTA in the UK for Psychedelics



Comparator Constraints

Need to benchmark against current standard of care

Full Cost Inclusion

New therapies must account for staff & setup costs

Cost Anchoring

Standard of care often inexpensive and entrenched

Clinic Time Intensity

Extended therapy sessions drive up hospital-based costs

Value Attribution Gaps

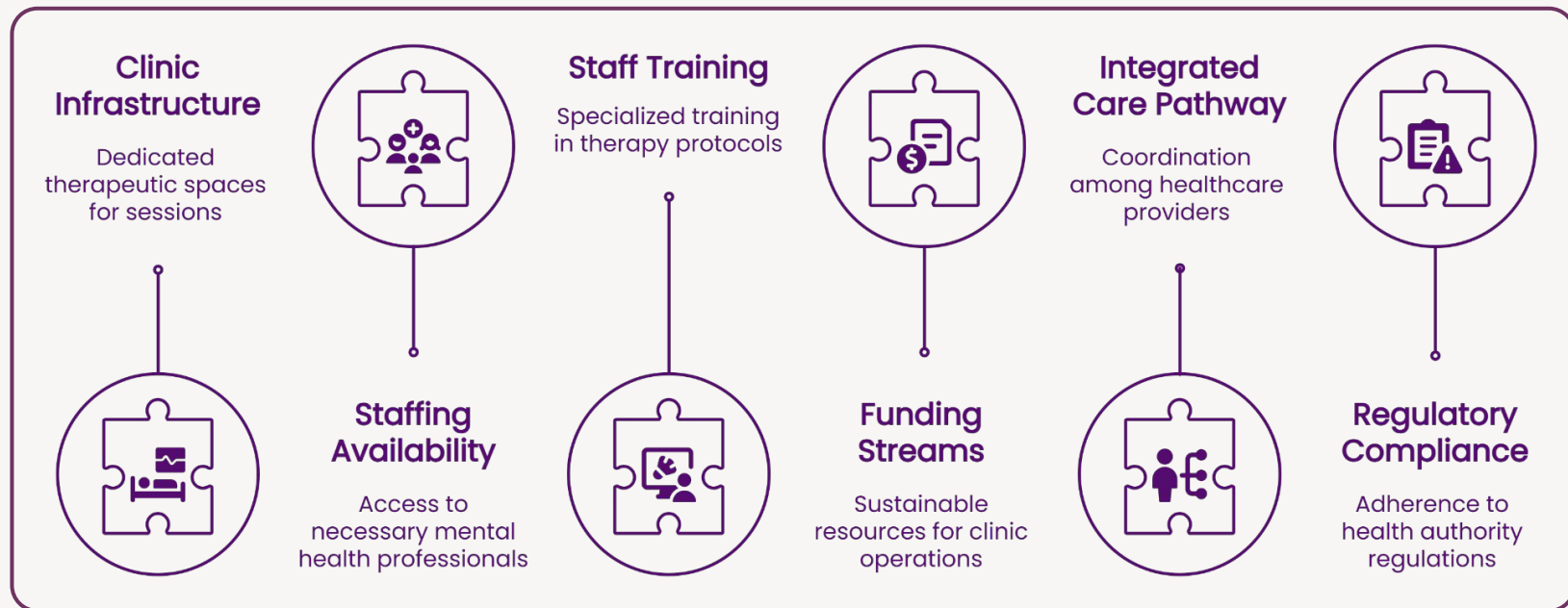
Indirect benefits to families and society often excluded

Economic Model Limits

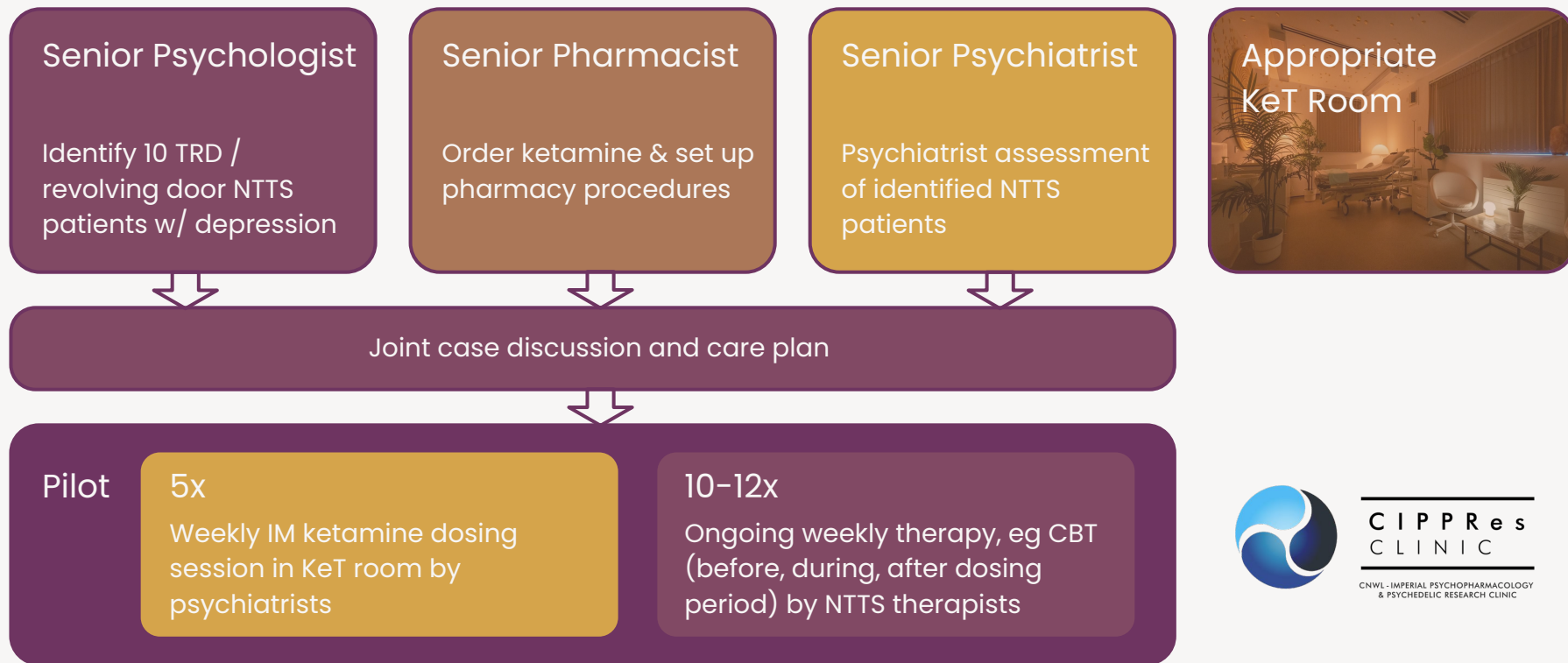
Existing frameworks struggle to capture novel treatment paradigms

From HTA Approval to Local Clinic Set Up and Patient Access

Key Considerations for Local Clinic Set Up and Patient Access



The CIM-KeT Model - A UK Ketamine Therapy Pilot With Potential for Scalability



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Key Advantages of the CIM-KeT Model That May Support Scalability

Existing Pathway Integration

Patients receive ketamine alongside an existing national care pathway, so no need to design a new care pathway

Targeted Patient Selection

Patients with confirmed treatment-resistant depression are already identified within the system

Therapy Resource Efficiency

Psychotherapy requirements are covered by existing services, avoiding additional staffing burdens

Community-Based Entry

Patients begin treatment within community programmes, reducing reliance on hospital infrastructure

Streamlined Discharge Process

Care pathway ensures smooth transition back to GP oversight after treatment concludes

Ongoing Outcome Monitoring

NTTS uses structured evaluations to continuously assess patient wellness and progress

Key Takeaways and Challenges for the UK for Reimbursement of Psychedelics

Mandatory HTA Navigation

Most licensed therapies must go through NICE or SMC HTA

Approval $\neq$ Access

HTA success doesn't ensure local implementation

HTA Method Mismatch

Psychedelics evidence package likely to clash with current HTA evaluation norms

Pathway Alignment Critical

Tied-in care pathways boost access and adoption chances

Lean Protocol Advantage

Lower-intensity protocols fit cost-effectiveness thresholds better

Stakeholder Dialogue Needed

Key barriers require early multi-stakeholder collaboration

What Can We Learn From Other Country Reimbursement Pathways?

Germany

Germany allows for immediate reimbursement, with pricing based on clinical benefit vs existing care

The Netherlands

Netherlands reviews direct and indirect benefits in HTA

NL & Czech Republic

Greater opportunity for innovative funding models between insurers and clinics in The Netherlands and Czech Republic

United Kingdom

From the case study countries in the report – Germany, The Netherlands, Czech Republic and the UK – It is England that stands out as the only country with no positive national recommendation for reimbursement of either ketamine or esketamine

Key Recommendations for Drug Developers for Optimising Reimbursement and Access of Psychedelics in the UK

Leverage Accelerated Pathways

e.g. Use of Innovative Licensing and Access Pathway (ILAP) to align with stakeholders



Engage Early With Evaluators

e.g. Use of NICE and SMC advice service to align on evidence package



Demonstrate comparative value

Conduct head-to-head trials where feasible



Incorporate long-term evidence

Need for longitudinal datasets to determine durability of treatment over time

Key Recommendations for Healthcare Stakeholder and Policy Makers

Review HTA Methodology for Psychedelics

NICE and SMC should review current methodology and determine readiness for psychedelic therapies



Invest in Facilities Development

NHS trusts should lead the creation of dedicated therapy rooms. Professional bodies should establish appropriate training programs



Pilot Scalable Models

Trusts and clinical networks should evaluate approaches such as group therapy or hybrid treatment protocols to manage costs and capacity



Develop Public-Private-Charity Partnerships

Stakeholders should consider collaborations to share the financial burden of infrastructure expansion and workforce scaling

Key Recommendations for Patient Groups and Clinical Groups

Participate in Therapy Evaluations

Identify and contribute to national HTA evaluations and treatment guidelines to provide critical perspectives on health conditions and the need for new therapeutic options



Create and Maintain Support Networks

Help design support networks for patients to share experiences and inform best practices for developers and health systems in psychedelic therapy

Many of the UK Challenges Require Multi-Stakeholder Discussions and Working Groups To Identify Practical Solutions – Starting Now

Consider Implementation Partnerships

NHS trusts, in collaboration with developers, should implement pilot programs to refine care pathways, generate real world data, inform economic models, and demonstrate real-world effectiveness



Consider Conditional Funding Mechanisms

NHS Commissioners and developers should explore the potential for temporary reimbursement mechanisms, such as the Innovative Medicines Fund, to enable early patient access while gathering additional real-world evidence



Develop Flexible Payments

Department of Health / NHS England and developers should collaborate on outcome-based pricing and risk-sharing agreements to alleviate payer concerns about high upfront costs and scalability

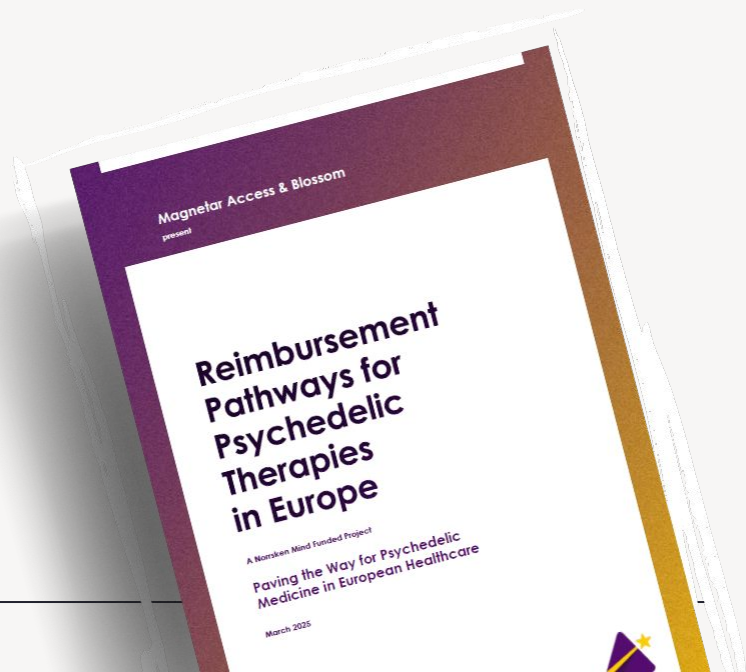
Let's turn reimbursement challenges into clear, actionable pathways

Read the full report for
detailed insights
& recommendations

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The Psychedelic Therapies Reimbursement Challenge

Breaking Convention

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