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New Treatments, New Barriers

Improving Mental Health Care in America



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Introduction

Mental health conditions affect millions of Americans, often disrupting work, relationships and daily life. Around one-quarter of Americans, or more than 60 million adults, experience a diagnosable mental health condition each year.[1] The consequences can be particularly severe for the 14.6 million Americans living with serious mental illness.[2] Without appropriate care, patients may experience worsening health that affects their ability to work and live independently and, in some cases, leads to hospitalization or increased suicide risk. Yet many struggle to get treatment because of cost, limited access to clinicians, network inadequacy or insurance barriers. These gaps also affect families and carry broader societal costs through greater health care use and lost productivity.

At the same time, advances in treatment are creating new possibilities for people with serious mental illness. Newer medications and emerging approaches, including psychedelic-assisted therapies, may help address needs that existing treatments have not fully met.

But innovation matters only if patients can access it. As mental health care evolves, coverage policies, provider networks and reimbursement systems must evolve with it so patients can receive clinically appropriate care when they need it.

Facing the Mental Health Treatment Gap

Mental illness can affect people across backgrounds and circumstances. Genetics, environmental stressors and lifestyle factors may influence mental health, but loneliness and loss of social connection can also play an important role. Addressing the treatment gap therefore requires more than improving medical access alone. Clinician shortages, insurance limitations and cost concerns, among other barriers, continue to prevent many people with mental illness from accessing treatment and support.

In fact, 62% of adults with mental illness, including 41% of those with a serious mental illness, receive no treatment.[3] Despite growing awareness and decreased stigma surrounding mental health challenges, too many patients still struggle to seek and access timely, appropriate care.

One particularly important issue is the shortage of clinicians, which is reaching crisis levels. According to the Bureau of Health Workforce, 40% of the U.S. population lives in what is known as a "mental health professional shortage area." It has been projected that in 2038, there will be a substantial shortages of addiction counselors, marriage and family therapists, mental health counselors, psychologists, mental health and substance use disorder social workers, adult psychiatrists, and child and adolescent psychiatrists.[4]

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Many communities, particularly rural and underserved low-income areas, face severe shortages of psychiatrists and behavioral health specialists. Patients may wait weeks or even months for appointments, often delaying diagnosis and treatment until symptoms become more severe. In many parts of the country, patients and families must travel long distances or rely on overextended health systems to access specialty care.

Furthermore, rising mental health treatment costs are emerging as a significant factor in patients with mental health reluctance to seek treatment. The National Alliance on Mental Illness reported that among people who have a mood disorder, about half say cost prevents them from trying a treatment they're interested in, a proportion that is much higher among the uninsured. The same study found that 61% of those without insurance reported stopping treatment because they could no longer afford it.[5]

These practical obstacles can be overwhelming for an individual living with mental illness, especially because the stigma still remains, even if attitudes have changed in recent decades.



Innovations in Mental Health Treatment

Improving patient outcomes starts with policies that embrace the latest innovations in treatment and ensure affordability and access.

Although important advances have been made for years in psychotherapy and community-based care, many psychiatric medications relied on mechanisms first introduced decades ago. Historically, "new" options typically offered only incremental improvements, leaving many patients cycling through medications that were ineffective, often difficult to tolerate, or challenging to maintain over time. That reality is beginning to change thanks to recent scientific breakthroughs.



Psychedelic Therapies

Researchers are exploring psychedelic-assisted therapies for some patients with treatment-resistant conditions, including depression, anxiety and PTSD. These treatments are not appropriate for everyone, particularly people with psychotic disorders, making careful patient selection essential.

Early research has shown promising results. In one study, 67% of patients with severe PTSD who received MDMA-assisted therapy no longer met diagnostic criteria for PTSD at the end of treatment, compared with 32% who received placebo.[6] A 2023 randomized clinical trial also found that a single 25-mg dose of psilocybin, combined with psychological support, reduced symptoms of major depressive disorder faster and by a greater amount than active placebo.[7]

Important questions remain about long-term safety, patient selection and how these treatments would work in clinical practice. Unlike traditional medications, psychedelic-assisted treatment relies heavily on specialized therapeutic support. Patients may undergo only one or two psychedelic experiences, followed by weeks or months of integration therapy with a trained clinician to help them process and apply the experience.

This model also raises regulatory and access questions. The FDA evaluates the safety and effectiveness of drugs, while psychedelic-assisted treatment includes a therapeutic component that extends beyond the medicine itself. As policymakers consider these treatments, access to appropriately trained clinicians and integration therapy should be considered alongside access to the medication.

It will also be important for regulators to ensure that Drug Enforcement Agency drug scheduling does not inappropriately limit access to FDA-approved medications—and that states update their drug schedules simultaneously with federal regulators.



New Mechanisms of Action

In 2024, the Food and Drug Administration approved xanomeline and trospium chloride, the first schizophrenia treatment in decades to use a new mechanism of action. Most existing medications rely primarily on dopamine receptor blockade, which can cause side effects that make long-term treatment difficult for some patients. Evidence suggests xanomeline and trospium chloride may improve symptoms with a different side-effect profile, offering another option for patients who have not responded well to or tolerated existing treatments.

> **Newer treatment approaches** may create additional options where few previously existed.





Long-Acting Injectable Antipsychotics

One of the clearest opportunities to improve outcomes for patients with serious mental illness involves FDA-approved long-acting injectable antipsychotics, commonly known as LAIs.

For patients living with schizophrenia and other serious mental illnesses, medication or treatment adherence can be difficult. Missed medications, inconsistent access to prescriptions and treatment interruptions may contribute to relapse, psychiatric hospitalization and worsening symptoms. These disruptions can also place significant strain on caregivers and emergency care systems.

Unlike oral medications taken daily, LAIs are administered on an extended schedule, sometimes every several weeks or months, helping patients maintain consistent treatment over time.

Studies have shown that LAIs were associated with 25% fewer hospitalizations and 89% higher odds of adherence.[8]

Yet despite their potential benefits, LAIs remain underused. Many patients are often unaware that these options exist, while clinicians may face workflow, reimbursement or administrative barriers that make implementation more difficult.

Some patients continue to encounter outdated assumptions that injectable therapies should be reserved only for people who have repeatedly failed treatment or experienced serious relapse. Earlier discussions about LAIs, shared decision-making and stronger support for administration may help more patients remain stable, avoid hospitalization and stay engaged in care.



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Current Challenges to Access

Innovation in mental health care may be accelerating, but patients continue to face many of the same barriers that have limited access for years. For patients living with serious mental illness, delays or disruptions in treatment can carry especially serious consequences. As the FDA continues to approve new treatments—and as promising therapies emerge—policymakers must ensure that outdated systems do not prevent patients from benefiting from progress.



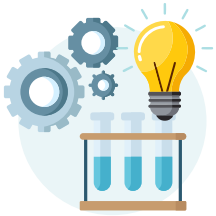
Utilization Management

Utilization management policies, including prior authorization and step therapy, continue to distort access to mental health treatment. Although these tools are often intended to manage costs, they may also delay care, interrupt treatment continuity and limit clinician flexibility. Patients and clinicians frequently report spending valuable time navigating paperwork, appeals and insurer requirements rather than focusing on treatment itself.

Prior authorization is one of the most persistent and disruptive barriers to timely treatment.[9] While historically used to control costs for high-priced drugs, the practice now applies to nearly all medications—even ones approved decades ago—let alone the potentially game-changing innovative treatments outlined above.

Another practice known as “step therapy” is also disruptive to accessing new, innovative treatments. To get the medicine prescribed by their clinician, patients must first prove that older, less expensive treatments on an insurer’s formulary do not work. The patient must try the insurer’s preferred alternatives and “fail first.” They are sometimes required to move through several “steps” before the insurer will cover the originally prescribed treatment.

Step therapy can be particularly harmful for people with serious mental illness. A person living with schizophrenia, severe depression or bipolar disorder may not have weeks or months to wait. The consequences of utilization management delays could be devastating, even deadly. Coverage policies should support clinically informed treatment decisions, not stand in the way of them.



Keeping Pace with New Treatments

Mental health innovation has historically lagged behind many other areas of medicine. Now, after years of limited progress, new mechanisms of action and new treatment approaches are beginning to emerge. Yet approval alone does not guarantee access. Patients often experience a gap between scientific progress and real-world availability.

It is important to recognize that a treatment with a new mechanism of action usually results in a very different side-effect profile for individual patients. A patient who has struggled with sedation, weight gain, metabolic complications or movement-related side effects may have a clinically appropriate reason to try a newer option, and insurers should value that fact in their coverage decisions.

Innovation only matters if patients can reasonably access it. Keeping pace with innovation means acknowledging that newer therapies are not simply "more expensive versions" of older medications. Decisionmakers should consider the broader value of maintaining stability—like reduced relapse, hospitalization and caregiver burden—for people living with mental illness.



Mental Health Parity in Practice

The Mental Health Parity and Addiction Equity Act of 2008 represented an important step toward improving access to mental health care. In principle, patients with mental health conditions should receive coverage that is equitable to patients seeking treatment for physical conditions. And although there have been efforts to improve enforcement of this act, parity still remains inconsistent.

Patients continue to report difficulty finding in-network behavioral health clinicians, long wait times for specialty care, and barriers associated with prior authorization. Stronger oversight and enforcement remain important to ensure that parity becomes meaningful in practice.





Medicaid and Continuity of Care

For many patients living with serious mental illness, Medicaid serves as a critical source of coverage. Yet patients and clinicians frequently report disruptions tied to changing formularies, utilization management requirements and coverage instability.

For a patient who has finally achieved stability on a medication regimen, a formulary change may create significant disruption. Forced non-medical switching, medication exclusions or new prior authorization requirements can interrupt care and create uncertainty for patients who may be struggling with current symptoms. These disruptions can place patients at increased risk of relapse, hospitalization or crisis care. For example, forced non-medical medication switches caused by formulary changes have been associated with a nearly five-fold increase in suicidal ideation or behavior, and a three-fold increase in adverse events.[10]

Patients who are stable should not be forced to restart the process of finding an effective therapy simply because coverage rules have changed. As Medicaid policies evolve, maintaining access to a broad range of treatment options will remain important for patients with mental illness. Coverage changes that narrow formularies or increase restrictions may reduce access to newer therapies and limit clinicians' ability to tailor treatment to individual patient needs. Policymakers should consider how coverage instability affects treatment adherence, long-term outcomes and overall health system costs.



Patient Cost

Of course, affordability for new treatments is a key to patient access. The Inflation Reduction Act of 2022 authorized Medicare drug price negotiation and capped annual Part D out-of-pocket spending, but some plan designs also shifted costs to beneficiaries.

This is a significant issue because a recent study found that out-of-pocket costs above $100 were associated with abandonment rates of up to 75% for some specialty drugs.[11] For mental illness, prohibitive costs can have life-or-death consequences, so it is critical for federal policymakers to manage such oversights carefully.



Valuing Patient and Clinician Perspectives

Conversations around mental health innovations and treatment value decisions should not be made in a vacuum. Patients and clinicians bring important perspectives to coverage decisions, particularly in serious mental illness, where lived experience, tolerability and long-term adherence play critical roles in outcomes.

Value discussions focused too narrowly on up-front treatment cost may overlook long-term financial and societal costs—and the human costs that matter most to patients and families. Treatment success should not be defined solely by symptom reduction. Stability, employment, housing security, relationships, caregiver burden and the ability to participate in daily life are also meaningful outcomes. Mental health care works best when policy reflects real-world patient experience.

Providing comprehensive mental health care also makes economic sense. When people with mental illness are supported in their daily lives, the benefits can extend beyond the health care system through greater workforce participation, fewer missed workdays, more independent living and reduced strain on families and society. Value decisions should account for these broader outcomes rather than focusing only on the immediate cost of treatment.



Mental health care works best when policy reflects **real-world patient experience.**

Opportunities for Advocacy

Mental health care is entering an important period of change, but innovation alone is not enough. Meaningful progress also requires sustained societal commitment to mental health, not simply greater awareness or public support in principle. For progress to occur, policy must help ensure that patients can access clinically appropriate care, remain engaged in treatment and avoid unnecessary disruptions that place recovery at risk.

Decisions about mental health coverage and value should not be made without the clinicians who treat these conditions and the people who live with them every day. Several advocacy opportunities may help improve access and strengthen mental health care for patients living with serious mental illness.



Include Patient and Clinician Perspectives in Coverage Decisions

Coverage decisions should reflect the clinical realities of mental health care. Formulary design, utilization management policies and coverage criteria should be informed by practicing clinicians and the patients they treat. As new treatment options become available, health plans should ensure they are incorporated into formularies in ways that preserve meaningful access rather than creating unnecessary barriers. When coverage policies are developed with input from those who understand the complexities of mental illness, patients are more likely to receive individualized care that aligns with clinical evidence and treatment goals.

Those living with mental illness also need spaces and opportunities to advocate for themselves by sharing their stories. Mental health treatment is deeply personal, and policymakers need to hear a multitude of perspectives. Patients and clinicians understand the real-world consequences of treatment disruption, medication side effects and gaps in access. Their experiences should help inform conversations around coverage, reimbursement and value. Policies work best when they reflect the realities patients and families face every day.

Patients can advocate for policies that improve access to treatment by sharing their lived experience, serving in peer advocacy groups, and engaging in community-based partnerships that reflect real-world needs.



Continued Support of Timely Access to Clinically Appropriate Care

Patients living with mental health challenges often require individualized treatment approaches. Because treatment response varies widely, clinicians should have the flexibility to make patient-centered decisions based on medical history, tolerability, adherence concerns and lived experience.

Advocates must continue to urge policymakers to evaluate whether utilization management practices are appropriately balanced against the needs of patients living with mental illness. Coverage systems should support timely access to clinically appropriate therapies rather than creating avoidable delays during periods of instability or crisis.



Strengthen Mental Health Parity in Practice

Mental health parity protections represented an important milestone, but implementation challenges remain. Policymakers should continue efforts to strengthen parity enforcement, improve network adequacy and ensure behavioral health care receives the same attention afforded to physical health conditions. Parity should be reflected not only in policy language, but also in real-world patient experience.



Protect Continuity of Care

For patients who have achieved stability, continuity of treatment matters. Abrupt changes in coverage, formulary exclusions or administrative disruptions may place patients at increased risk of relapse and hospitalization.

Coverage policies should consider the importance of maintaining treatment stability for patients living with serious mental illness and recognize the potential downstream consequences of interrupted care.



Support Mental Health Training Across Communities

Advocacy should also support programs that strengthen mental health knowledge among the people and institutions patients encounter every day. Training for primary care clinicians, teachers, law enforcement, high school peer counselors, legislators and health plans can help build a broader system of support for people living with mental illness. These efforts can reinforce the role of specialized mental health care while helping communities better understand and respond to mental health needs.



Conclusion

Mental illness continues to affect millions of Americans, yet access to timely, effective care remains out of reach for too many patients. At the same time, mental health treatment is evolving in promising ways. Long-acting injectable therapies and new treatment approaches are improving care for schizophrenia. Emerging psychedelic-assisted therapies may also create new options for some patients, but their promise depends on access to skilled facilitation and integrated psychotherapy, not psychedelic medicine alone.

While this paints a picture of hope, coverage barriers, workforce shortages, inconsistent parity enforcement and disruptions in continuity of care continue to shape treatment outcomes for many people living with mental illness.

With the personal, social and economic costs of untreated mental illness so high, now is the time to reduce administrative barriers, modernize coverage policies and ensure that innovation helps narrow the treatment gap.

The path forward should prioritize access, continuity and patient-centered care. By supporting clinically appropriate treatment, strengthening parity protections and ensuring coverage systems keep pace with scientific progress, policymakers can help create a mental health system that better serves patients, families and communities. Mental health innovation is evolving. The challenge is ensuring patients can benefit from it.

References

1. University of St. Augustine for Health Sciences. Mental Health Statistics [2026]. 31 March 2026. https://www.usa.edu/blog/mental-health-statistics/

2. Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2024 National Survey on Drug Use and Health. 2025. https://www.samhsa.gov/data/sites/default/files/reports/rpt56287/2024-nsduh-annual-national-report.pdf

3. Walker ER, Cummings JR, Hockenberry JM, Druss BG. Insurance Status, Use of Mental Health Services, and Unmet Need for Mental Health Care in the United States. Psychiatr Serv. 2015;66(6):578-584. doi:10.1176/appi.ps.201400248

4. Bureau of Health Workforce. State of the Behavioral Health Workforce, 2025. December 2025. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/Behavioral-Health-Workforce-Brief-2025.pdf

5. National Association on Mental Illness. Survey Finds Treatment Cost and Stigma Are Major Barriers to Accessing Care for Mood Disorders. 24 August 2021. https://www.nami.org/press-releases/survey-finds-treatment-cost-and-stigma-are-major-barriers-to-accessing-care-for-mood-disorders/

6. Mitchell JM, Bogenschutz M, Lilienstein A, et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med. 2021;27(6):1025-1033. doi:10.1038/s41591-021-01336-3

7. Raison CL, Sanacora G, Woolley J, et al. Single-dose psilocybin treatment for major depressive disorder: a randomized clinical trial. JAMA. 2023;330(9):843-853. doi:10.1001/jama.2023.14530

8. Lin D, Thompson-Leduc P, Ghelerter I, et al. Real-world evidence of the clinical and economic impact of long-acting injectable versus oral antipsychotics among patients with schizophrenia in the United States: a systematic review and meta-analysis. CNS Drugs. 2021;35(5):469-481. doi:10.1007/s40263-021-00815-y

9. Alliance for Patient Access. Mental Health Working Group 2025 Meeting Summary. 2025. https://allianceforpatientaccess.org/wp-content/uploads/2025/08/AfPA_Mental-Health-WG_-2025-Summary.pdf

10. West JC, Rae DS, Mojtabai R, et al. Clinically unintended medication switches and inability to prescribe preferred medications under Medicare Part D. J Psychopharmacol. 2012;26(6):784-793. doi:10.1177/0269881111406304

11. Ismail WW, Witry MJ, Urmie JM. The association between cost sharing, prior authorization, and specialty drug utilization: a systematic review. J Manag Care Spec Pharm. 2023;29(5):449-463. doi:10.18553/jmcp.2023.29.5.449

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