Peaceful Mind Psychiatric Services

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Date: 11/21/2025

To Whom It May Concern,

My name is Michelle Giddings, I am a board-certified nurse practitioner and hold a Doctor of Nursing practice degree with a focus on psychiatry. I specialize in in-patient and outpatient treatment and treat pediatric and adult patients. Patients with Attention-Deficit Hyperactivity Disorder may have poor responses to their treatment necessitating treatment that includes newer nonstimulant options. Qelbree has been a beneficial medication to help with my client's ADHD symptoms, improving their motivation, focus/concentration, hyperactivity, and allowing them improvement in their quality of life with Qelbree. Having access to Qelbree allows our patients to achieve and maintain stabilization of their ADHD symptoms.

Sincerely,

Michelle Giddings, DNP, APRN, PMHNP-BC

Peaceful Mind Psychiatric Services

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From: Philip Malinas <pmalinas@psychplus.com>
Sent: Monday, November 24, 2025 9:54 AM
To: Pharmacy Services <rxinfo@nvha.nv.gov>
Subject: Qelbree

This is a letter of support for putting/keeping Qelbree (viloxazine) as a first-line treatment for children, adolescents and adults on the NV Medicaid formulary.

It is one of two norepinephrine reuptake inhibitors available for ADHD and is more efficacious than the other, atomoxetine.

It is the only non-stimulant that can be taken by patients who cannot swallow pills or capsules (such as small children or developmentally disabled patients) as its' capsules can be opened up and sprinkled.

It also does not provoke mood-swings in Bipolar patients that I am treating for comorbid ADHD.

Philip Malinas, M.D.
Board-certified Child, Adolescent and Adult Psychiatrist
Reno, NV

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November 13th, 2025

Nevada Medicaid Pharmacy and Therapeutics Committee

To the Members of the Committee,

I am writing to request that Qelbree be placed on Tier 1 for all Nevada Medicaid plans. This request is based on clear changes in the clinical landscape and on the day-to-day challenges that physicians across our state now face when treating children, adolescents, and adults with ADHD.

The current federal position toward controlled substances has created new pressure on prescribers. The heightened DEA oversight has made ADHD management far more complex, and insurance challenges have limited medication access for many of my patients. This shift has not reduced the need for effective ADHD care. It has only narrowed the tools that clinicians can use.

We have long relied on the nonstimulant options that precede Qelbree, but they do not meet the treatment needs of most patients. Their onset is slow. Their side effect profiles are difficult for patients to tolerate. Their effectiveness is often limited. I have tried each of these options in my practice for many years, and I can say plainly that they do not fill the gap left when restricting stimulant access.

Qelbree is the only nonstimulant I have used that performs reliably and safely without the complications tied to controlled substances. It offers strong symptom control, it does not create

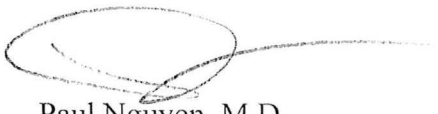
diversion risk, and it protects the long-term safety of both the patient and the community. Its practical advantages are significant. Families adhere to treatment plans more consistently. My practice has changed because finally, I have an option that works without putting them through the strain of the older nonstimulants or controlled substances.

The cost of Qelbree to the Medicaid system is low compared to the burden created by undertreated ADHD and other medications. When patients do not receive effective care, they return to clinics and performance drops. Family stress rises. Early intervention with a safe and reliable option is far less costly in the long run.

Tier 1 placement would allow clinicians to use Qelbree at the appropriate point in care, without unnecessary delays and failures of other medications. It would also help cut down the costs of the clinic overall. Prior authorizations, phone calls looking for out-of-stock medications, and trials and failures cost both the provider and patient time and money.

I respectfully ask the committee to review the evidence and the need in our community. Qelbree is the most practical, safe, and effective nonstimulant available, and the current regulatory climate makes access more important than ever. Tier 1 placement would bring Nevada Medicaid in line with the needs of both patients and prescribers. Should you have any questions regarding this case, please feel free to contact my office. I am licensed by the state of Nevada to practice clinical psychiatry.

Thank You,



Paul Nguyen, M.D.

LIC# 12178

- **Hello and good afternoon my name is Patrick Harvey, I am a Pharmacist with Supernus Pharmaceuticals, Field Medical Affairs.**
- **Thank you for the opportunity to update you on the latest Qelbree Research.**

- QELBREE has been preferred on the Nevada PDL since 2022 and I wanted to start out by thanking the committee for making this important medication available to providers and patients in Nevada.

- Qelbree offers patients a non-addictive, efficacious, safe treatment alternative that is readily available and with a unique MOA not found in other ADHD medications.

- Preclinical studies have expanded our understanding of viloxazine's pharmacology and have shown that viloxazine not only selectively inhibits norepinephrine reuptake transporters (Ki=0.13 nM), but it also binds directly to and exhibits partial agonism at the serotonin 5-HT2C receptor.[2-7] This data provides evidence that the pharmacology of viloxazine is multimodal and differs from other nonstimulant medications indicated for ADHD. In January, the FDA added new information to the pharmacodynamics (Section 12.2) to the Qelbree label and they also added results of our lactation study which Qelbree is the only ADHD medication studied under the current FDA guidelines. Qelbree resulted in a RID of ~1% of the mother's dose.

- We completed a phase 4 study in pediatric patients treated with a stimulant who were still experiencing clinically meaningful ADHD symptoms. With the addition of Qelbree to the stimulant, patients experienced significant improvements in ADHD symptoms, and in parent ratings of morning behavior (before stimulant medications "kick in"), evening behavior (after the effects of stimulant medications "wear off"), and sleep disturbance.

- Decentralized REAL WORLD EVIDENCE trial of QBE in adults with ADHD and clinically significant depression and anxiety... In addition to significant improvements in ADHD symptoms, participants experienced greater than 50% improvement in patient and clinician reported outcome measures of depression and anxiety, as well as improvements in sleep and executive functioning. This was a real-world study in complex patients taking a number of concomitant psychiatric medications. No new safety signals were identified.

- In an Independently funded head-to-head sequential cross over study published in CNS Drugs, comparing atomoxetine to Qelbree in peds and adult ADHD patients.**:** Qelbree showed statistically significant ADHD symptom improvements, faster onset of response, and better tolerability compared to atomoxetine during the 4 weeks trial. Post trial 96% of patients preferred Qelbree. Atomoxetine may take several weeks to demonstrate if will be a viable treatment option delaying effective treatment if failure is required to prescribe Qelbree.

I would like to conclude by asking the committee to continue to make QELBREE available as a preferred option for providers and patients in Nevada.

- I am happy to answer any questions you may have.
- Thank you for your attention.

From: Dr. Sam Zand <drzand@anywhereclinic.com>
Sent: Friday, December 5, 2025 5:15 PM
To: Pharmacy Services <rxinfo@nvha.nv.gov>
Cc: Joey Cousins <joey@anywhereclinic.com>
Subject: Public Comments

Dear Silver State Scripts Board Members and Nevada Medicaid Leadership,

My name is Dr. Sam Zand, a Nevada psychiatrist providing Spravato (esketamine) treatment to Medicaid members. Thank you for the opportunity to submit public comment for the December 11, 2025 meeting.

I am writing to highlight three policies that are unintentionally restricting access to care and to share real examples of how they affect patients in our community:

1. PAR requirements tied to a single treating provider limit access and disrupt continuity of care

Current policy allows only one named provider on the PAR. In multidisciplinary clinics, different clinicians cover different days and must be able to supervise safely.

Real patient example:

A patient with severe treatment-resistant depression was stable and improving on Spravato. When our authorized provider had an unexpected medical leave, the patient's treatment was abruptly paused because the covering provider was not listed on the same PAR, even though

they were fully credentialed and part of the same Spravato team. The patient lost two consecutive weeks of treatment and clinically regressed, increasing their suicidal thinking.

Request: Allow PARs to list multiple qualified providers or approve Spravato at the program/ clinic level rather than tied to a single clinician.

2. Monthly psychiatrist visits and 30-day limits are unrealistic during a psychiatry shortage

Because approvals are limited to 30 days, patients must re-establish care with a psychiatrist every month for ongoing medical necessity, even when a PA/NP is fully capable of managing stable follow-ups under supervision.

Real patient example:

A patient who works full-time and cares for two children missed a single psychiatrist appointment due to work schedule constraints. Although they consistently met with our NP, their Spravato treatments were suspended because only the psychiatrist visit counted for renewal. Their depressive symptoms worsened, and they landed in the ER after a panic and suicidal ideation episode, an outcome that was avoidable with more reasonable continuity-of-care rules.

Request: Allow PAs/NPs to perform monthly ongoing-necessity assessments under collaborative psychiatric oversight and approve 60–90 days for stable patients.

3. 99215 and 99417 unit limitations conflict with FDA-mandated Spravato monitoring

Spravato sessions require significant clinician time, prolonged monitoring, medical decision-making, and the ability to intervene in dissociation, nausea, hypertensive episodes, or emotional crises. Unit limits on 99215 and 99417 force clinics into billing that doesn't match mandated care.

Real patient example:

One patient experiences prolonged dissociation requiring extended monitoring well beyond two hours, which is fully aligned with REMS guidelines. However, once prolonged service units hit their monthly cap, our clinic was unable to bill for that necessary supervision. This created a scenario where continuing care was financially unsustainable—even though the treatment was working and medically required.

Request: Create a Spravato-specific exception or expanded allowance for 99215 and 99417 to meet REMS and package-insert requirements without penalty.

In closing, Spravato is one of the most effective treatments available for our most vulnerable, treatment-resistant patients. These policy constraints, while likely not intended, are causing delays, treatment interruptions, and preventable psychiatric deterioration.

Thank you for considering these comments and for your ongoing commitment to improving patient access and safety. I plan to virtually attend the Dec 11 meeting, and I am happy to participate in further discussion or provide detailed case summaries if helpful.

Regards,

Dr. Sam Zand

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Medicaid Public Testimony for Tyvaso DPI (treprostinil) Inhalation Powder for the Nevada Medicaid P&T Meeting on December 11th, 2025.

Good afternoon, my name is **Brock Bizzell** and I am a **Sr. HEOR Liaison** with United Therapeutics Corporation.

In May 2022, The FDA approved Tyvaso DPI for the treatment of patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension due to interstitial lung disease (PH-ILD) to improve exercise ability.[1] Tyvaso DPI is a new formulation and inhalation device for Tyvaso, and is the only dry powder inhaler approved by the FDA for use in PAH and PH-ILD.

Tyvaso DPI was evaluated in the BREEZE study. The primary objective was to evaluate the safety and tolerability of Tyvaso DPI during a three-week treatment phase in 51 PAH patients on a stable regimen of Tyvaso inhalation solution who were transitioned to Tyvaso DPI.[1,2]

Patients who transitioned from Tyvaso to Tyvaso DPI demonstrated safety and tolerance. Ninety-six percent of patients completed the three-week treatment phase, while two subjects discontinued due to treatment-related adverse events. Adverse events were consistent with studies of inhaled treprostinil in patients with PAH, and there were no study drug-related serious AEs.[1,2]

Significant improvements in secondary study objectives were also observed at week three, including: [2]

- six-minute walk distance of 11.5 meters compared to baseline (p=0.0217).
- overall patient satisfaction with the Tyvaso DPI inhaler as measured using the Preference Questionnaire for Inhaled Treprostinil Devices (PQ-ITD) (p<0.0001)
- PAH-SYMPACT patient reported outcome questionnaire were observed in physical impacts (p=0.0438) and cognitive and emotional impacts (p=0.0048).

The 49 patients who completed the treatment phase of BREEZE opted to continue in an optional extension phase. Improvements in 6MWD compared to baseline were sustained in the optional extension phase through the data cutt-off date up to 51 weeks.[2]

Given these findings, we ask that you consider also making Tyvaso DPI Preferred on the Nevada Medicaid Preferred Drug List for both PAH and PH-ILD patients that rely on your services for their medications.

Thank you for your attention and I am happy to take any questions.

References:

1. TYVASO DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2022.
2. Spikes LA, Bajwa AA, Burger CD, et al. BREEZE: Open-label clinical Study to Evaluate the Safety and Tolerability of Treprostinil Inhalation Powder as Tyvaso DPI™ in Patients With Pulmonary Arterial Hypertension. *Pulm Circ. 23 March 2022. https://doi.org/10.1002/pul2.12063.*