February 19, 2026

VIA ELECTRONIC MAIL

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405
Email: pdab@dcbs.oregon.gov

Re: Comment on Affordability Review of VRAYLAR (cariprazine)

Dear Members of the Oregon Prescription Drug Affordability Board:

AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, and neuroscience. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

As a threshold matter, AbbVie believes that the Oregon Prescription Drug Affordability Board ("PDAB") statute is bad public policy that will not result in improving patient affordability. Moreover, we believe that the Board's implementation of the PDAB statute is unconstitutional, including potentially implicating the Due Process Clause. Additionally, the Board's implementation and administration of the Oregon PDAB statute is inconsistent. Among other examples, AbbVie is writing regarding our concerns about the PDAB's ongoing lack of transparency, clarity, and methodological rigor in both the determination of affordability and the assessment processes it employs, which has resulted in an inappropriate affordability review determination conducted by the PDAB for our product VRAYLAR (cariprazine). VRAYLAR is a once-daily, oral dopamine D3/D2 and serotonin 5-HT1A partial agonist and serotonin 5-HT2A antagonist atypical antipsychotic (AA). VRAYLAR is the only FDA-approved dopamine D3-preferring antipsychotic. It is used to treat schizophrenia and other serious mental illnesses, including bipolar I disorder (both poles) and bipolar I depression, and as an adjunctive therapy for major depressive disorder (MDD).

The selection of VRAYLAR and application of the review criteria by the PDAB in its affordability review report (the "Report") under O.R.S. § 646A.694 and O.A.R. § 925-200-0020 was unsupported by clinical evidence and utilization data and arbitrary. For example, the PDAB focused on VRAYLAR's high utilization as indicative of affordability challenges, without considering the critical health benefits of appropriate use of antipsychotic medications. The PDAB's focus on patient out-of-pocket ("OOP") costs suffered both from factual inaccuracies and a failure to identify and consider the role of benefit design in driving high patient OOP costs. The PDAB's comparison to "therapeutic alternatives" also failed to either articulate a defensible definition of a therapeutic alternative or to accurately reflect clinical guidelines and current clinical practice. Given these flaws, AbbVie respectfully requests that the PDAB reverse its determination that VRAYLAR may create

affordability challenges for the Oregon health care systems or patient out-of-pocket costs pursuant to O.R.S. §646A.694.

1. **Lack of Clarity and Methodology in Determining Affordability**

Over the past several months, the PDAB has been engaged in extensive internal debate surrounding the very definition and process of assessing affordability, resulting in prolonged uncertainty and lack of consensus. This ambiguity has significantly impaired the PDAB's ability to carry out its mandate effectively and predictably. Most recently, this internal discord culminated in the resignation of Vice Chair Amy Burns. These difficulties accentuate the urgency of establishing a clear and transparent framework to assess affordability, as well as a predictable and transparent methodology of drug selection.

It is imperative that the PDAB fully accomplishes this foundational work by **establishing reliable criteria and a predictable, transparent process before any prescription drugs are selected for review or any affordability determinations are made**. Moving forward without a robust methodology risks arbitrary decision-making and undermines both stakeholder confidence and the PDAB's credibility.

2. **Report's Consideration of VRAYLAR Utilization Discounts Importance of Appropriate Antipsychotic Use**

With respect to the substance of the report, AbbVie's broadest concern is that the Report provides a recitation of data points that fail to adequately account for the clinical importance of VRAYLAR. As an initial matter, the Report is based on data that is, by the PDAB's own admission, incomplete – for example, see the following Board member's remarks from the October 15, 2026, Board meeting[1]:

Michele Yoder [46:06]:
"And so I think there are some limitations with the APAC data and some of the other data that this committee has, and so that's really where my comments are centered around."

Chair Shelley Bailey [48:50]:
"And then, miss Coder, just, as a follow-up to your comment related to APAC and things, I do I do want to reference that, you are correct that we do have limitations in some of the data that we have, but we, staff has certainly worked very hard to, provide us with data."

Chair Shelley Bailey [1:52:58]:
"I mean, I just wanna reference, you know, a, just kinda reinforcing, there's limitations with what we had from the data call in 2023 to help us better populate line item three on there. But number but the second point I wanted to make was even though we may not be able to pull that information from the data calls, to me still keeping it, you know, in the rubric is something that I think is really

[1] Oregon Division of Financial Regulation. (n.d.). *Oregon Prescription Drug Affordability Board Meeting of Oct. 15, 2025*. YouTube. https://www.youtube.com/watch?v=pWLLdMtLE0A

valuable even if the board members are just using that as they think through things when we get to a vote."

Cortnee Whitlock [2:30:44]:
"And then kind of following up with you what you're saying, John, I know the challenge with part of what the PDAB does is the set your requirements to look at the drugs from the year before, unfortunately, how the data has to come in through various other programs and how it's set up, we're actually kinda, like, eighteen months to two years behind in showing what's actually going on currently to what the data that we have is representing. And I just wanna remind the board that I know that's one of the biggest challenges...."

Dan Hartung [2:42:35]:
"Well, I have a lot I mean, I have a lot of concerns with this dataset, the carrier data, because it's a only it's just a subset of the commercial payers."

Cortnee Whitlock [2:45:14]:
"And I again, we understand that the data call information is based off of only 11 carrier submissions and, you know, that it doesn't capture the whole universe of what's happening in Oregon because it's it doesn't capture Medicaid or Medicare."

The absence of complete information taints the results of the PDAB's affordability review, even before considering its manifold other flaws.

Moreover, the incompleteness of the data is compounded by an absence of clinical and policy context. Nowhere is this clearer than in the Report's treatment of VRAYLAR total expenditure and utilization. The Report cites the Oregon 2023 All Payer All Claims ("APAC") data, which shows total expenditure of approximately $37 million on VRAYLAR in the state and that 3,897 Oregonians filled a prescription for VRAYLAR in 2023, with 29,623 total claims.[2] The Report notes that VRAYLAR has higher utilization than the listed "therapeutic alternatives."[3]

This discussion of total expenditure and utilization appears to be intended to align with the affordability review factors at O.A.R. §§ 925-200-0020(1)(b) ("The number of residents in this state prescribed the prescription drug") and (1)(j) ("The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives"). Nowhere in the Report, however, is there any depth of discussion or analysis of the impact of the utilization of VRAYLAR on the Oregon health care system or Oregonians suffering from serious mental illness. Such nuanced treatment is required by § 925-200-0020(1)(j), and is certainly required by subsection (1)(i), which requires the PDAB to consider "[t]he impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state."

A. <u>Clinical and Policy Considerations Accentuate Importance of Access to and Appropriate Utilization of Antipsychotics</u>

[2] VRAYLAR Affordability Review Report (hereinafter, "Report") at 5, 9.
[3] Report, at 18-19.

Applicable data make clear that the use of VRAYLAR is positive for the vulnerable populations for whom it is prescribed. These include patients with schizophrenia, MDD and bipolar disorder, and populations at severe risk of adverse outcomes. For example, the estimated average life lost is 28.5 years for patients with schizophrenia in the United States.[4] Nearly 5% of patients with schizophrenia die by suicide.[5] Similarly, people living with MDD and bipolar disorder often have the comorbidity of substance use disorder.[6, 7] Fully 31% of persons with MDD will attempt to take their own lives,[8] and 20% of persons with bipolar disorder ***will*** take their own lives.[9] Selection of and adherence to the clinically appropriate antipsychotic is literally a matter of life and death for some of the most vulnerable Oregonians.

It is widely recognized among policymakers that the appropriate balancing between support for appropriate utilization and avoidance of inappropriate utilization is an analysis that differs depending on the specific type of drug in question. Given the clinical importance of antipsychotics like VRAYLAR, federal and state policymakers have unequivocally made the determination that considerations of access are paramount for antipsychotics, given the unique vulnerability of patients who receive these medications.

On the federal level, the Centers for Medicare & Medicaid Services ("CMS") includes antipsychotics as one of the six Medicare Part D protected classes. Indeed, the agency has expressly recognized that appropriately treating these patients is more important than achieving cost savings, stating in a 2019 Part D rulemaking that "the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to [prior authorization] or [step therapy] requirements outweighs the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility."[10]

CMS has also established quality measures that reward providers for helping their patients adhere to antipsychotic therapies. These include an adherence to antipsychotics quality measures for patients with schizophrenia under both the Medicaid Certified Community Behavioral Health Clinics demonstration program[11] and the Medicare Quality Payment Program's Merit-Based

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[4] Olfson M, Gerhard T, Huang C, Crystal S, Stroup TS. *JAMA Psychiatry*. 2015; 72(12):1172-81.
[5] AMA. The Lifetime Risk of Suicide in Schizophrenia. https://jamanetwork.com/journals/jamapsychiatry/fullarticle/208392.
[6] Hunt GE, Malhi GS, Lai HMX, Cleary M. Prevalence of comorbid substance use in major depressive disorder in community and clinical settings, 1990-2019: Systematic review and meta-analysis. J Affect Disord. 2020 Apr 1;266:288-304. doi: 10.1016/j.jad.2020.01.141. Epub 2020 Jan 26. PMID: 32056890.
[7] Loftus J, et al. J Affect Disord. 2020;267:258–63. https://doi.org/10.1016/j.jad.2020.02.035
[8] Dong M, Zeng L-N, Lu L, Li X-H, Ungvari GS, Ng CH, et al. Prevalence of suicide attempt in individuals with major depressive disorder: a meta-analysis of observational surveys. Psychological Medicine. 2019;49(10):1691–704. doi:10.1017/S0033291718002301.
[9] Wahid AW. Medication nonadherence high in people with bipolar disorder. Healio Psychiatry News. 2023 May 8. https://www.healio.com/news/psychiatry/20230508/medication-nonadherence-high-in-people-with-bipolar-disorder.
[10] CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," Final Rule, 84 Fed. Reg. 23832, 23840 (May 23, 2019), https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf.
[11] https://aspe.hhs.gov/sites/default/files/documents/1faadf771e9567b0926e33739341cb50/ccbhc-report-congress-2020.pdf

Incentive Payment System for physicians.[12] VRAYLAR would be eligible for both of these measures as it is FDA-approved and used for the treatment of schizophrenia.[13]

Oregon policymakers have come to a similar conclusion. For example, O.R.S. § 414.325(5)(b)(B) prohibits the Oregon Health Authority from requiring prior authorization for "[a]ny mental health drug prescribed for a medical assistance recipient if: (i) The claims history available to the authority shows that the recipient has been in a course of treatment with the drug during the preceding 365-day period; or (ii) The prescriber specifies on the prescription "dispense as written" or includes the notation 'D.A.W.' or words of similar meaning." Certain mental health drugs are also carved out from the requirement to obtain prior authorization for non-Preferred Drug List medications in Oregon Medicaid.[14]

Indeed, **VRAYLAR is on Oregon Medicaid's Mental Health "Carve Out" list.** It is reimbursed on a Fee-for-Service basis and there are no step edits or prior authorization requirements for Oregon Medicaid patients to access VRAYLAR. This coverage speaks to the clinical merits of the drug and to a policy decision by the State of Oregon that utilization of VRAYLAR in the state is positive when appropriately prescribed given the clinical benefit VRAYLAR provides to so many patients suffering from bipolar disorder, schizophrenia, and MDD. Indeed, elsewhere the Report seems to agree that access to and appropriate utilization of VRAYLAR is a positive, expressing concern that "access restrictions [on VRAYLAR], coupled with historical patterns of under prescribing newer agents in Black and Latino populations, contribute to treatment gaps and reinforce cycles of under-treatment in marginalized communities."[15]

B. Health Economic Data Support Appropriate Antipsychotic Utilization

Under O.A.R. § 925-200-0020(2)(i), the PDAB must consider, when conducting an affordability review, "[i]n addition to the criteria in subparagraph (1)(j): (A) To the extent such information can be quantified, the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment. (B) To the extent such information can be quantified, the total cost of the disease and the drug price offset."

Clinical and health economic comparisons of state Medicaid programs with open versus restricted access to antipsychotics supports the proposition that ensuring access to, and appropriate utilization of, antipsychotic drugs like VRAYLAR likely saves the health system money. A 2025 article in the Journal of Health Economics and Outcomes Research compared the impact of open access policies to antipsychotics in Michigan Medicaid to more restrictive policies in California, Colorado, Florida, Illinois, and Wisconsin. This study found that "patients prescribed atypical [antipsychotic] medications experienced significantly poorer outcomes in states without [open access] policies. Specifically, ***these patients faced an increased risk of both overall and Serious Mental Illness (SMI)-related hospitalizations, as well as higher overall and SMI-related medical***

[12] https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2024_Measure_383_MIPSCQM.pdf
[13] U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.
[14] O.A.R. § 410-121-0040(8); *see* https://www.oregon.gov/oha/hsd/ohp/pages/policy-pharmacy.aspx
[15] Report, at 9.

costs."[16] The study showed that "even in states that experienced modest savings in pharmacy costs [associated with more restrictive access to antipsychotics], these savings were outweighed by increased expenditures in inpatient, outpatient, and emergency care services."[17] It is worth noting that an analysis of the total societal cost of schizophrenia in 2024 showed that barely 10% of such costs are attributable to health care,[18] meaning that the costs of inadequate access to clinically appropriate antipsychotics are likely substantially higher than the health care costs alone.

The Report also did not address the implications of data comparing VRAYLAR with other antipsychotics. For example, when compared to CAPLYTA, VRAYLAR patients experienced 27% fewer all-cause and mental health-related inpatient hospitalizations during treatment and 22% fewer all-cause ER visits and 26% fewer mental health-related ER visits. VRAYLAR was also associated with 13% fewer all-cause outpatient visits and 12% fewer mental health-related outpatient visits.[19] In addition to the all-important benefits for patients' health and well-being, the improvement in hospitalizations and ER visits associated with VRAYLAR relative to CAPLYTA has major implications for expenditures by the Oregon health care system.

Altogether, these data further accentuate that the Report's focus on VRAYLAR utilization and overall expenditure is flawed and unintentionally deceptive. Any consideration of these data points must reflect a nuanced recognition that promoting access to and appropriate utilization of VRAYLAR when prescribed by a physician is an evidence-based policy choice to protect patients and health system resources.

3. OOP Costs Driven by Payer Benefit Design

The regulations at O.A.R. § 925-200-0020(1)(k) require consideration of "[t]he estimated average patient copayment or other cost-sharing for the prescription drug in this state." In the Report, the PDAB's discussion of OOP costs for VRAYLAR included noticeable inaccuracies. For instance, both the Report and Vice Chair Hartung listed the OOP cost per commercial claim at $282.[20] In reality, the OOP cost for Oregonians with commercial insurance is $69 per month[21], before any cost sharing assistance savings are applied, which may further reduce the cost to $0 per month for eligible patients. Additionally, the OOP cost for Oregonians with Medicare is $16 per month[22], significantly lower than the $69 per month listed in the Report[23]. Using incomplete data mischaracterizes the affordability of VRAYLAR for patients in Oregon.

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[16] Patel R, Baser O, Waters HC, et al. Open access to antipsychotics in state Medicaid programs: effect on healthcare resource utilization and costs among patients with serious mental illness. JHEOR. 2025:12(1):222-229. doi:10.36469/jheor.2025.137909.

[17] *Id.*

[18] Krasa H, Baumgardner J, Brewer I et al. National and State Societal Costs of Schizophrenia in the US in 2024. JAMA Psychiatry. doi: 10.1001/jamapsychiatry.2025.4383.

[19] Ta J, Hambrick A, Zanardo E et al. Healthcare Resource Utilization With Cariprazine Versus Lumateperone Among Patients With Bipolar I Depression. Presented at the Neuroscience Education Institute (NEI) Congress, November 6-9, 2025, Colorado Springs, CO (DV-016921).

[20] Report, at 24; Oregon Division of Financial Regulation. (n.d.). *Oregon Prescription Drug Affordability Board Meeting of Dec. 17, 2025*. YouTube https://www.youtube.com/watch?v=zTyUMuPgpOs

[21] Data on file

[22] Data on file

[23] Report, at 24.

AbbVie agrees that it is important to keep down the OOP cost of VRAYLAR to ensure access to the drug and adherence to medication regimens. Notably, though, the regulations at § 925-200-0020(2)(j) require the PDAB to consider, "[i]n addition to the criteria in subparagraph (1)(k): Patient copayment or other cost sharing data, across different health benefit plan designs." These regulations reflect the fact, which the Report does not address, that amount paid by the patient at the pharmacy counter generally has more to do with benefit design decisions made by insurers than with list pricing decisions made by manufacturers. This is the case for **VRAYLAR, which saw increases in WAC between 2018 and 2024 which were <u>below</u> the increase in CPI-U during this period.**[24] In contrast, the Report notes that almost all plans (96.6%) categorized VRAYLAR as a non-preferred drug[25], which can have substantial implications for cost sharing.

A more effective approach to address OOP costs for innovative and medically necessary drugs like VRAYLAR, is for Oregon to focus on the impact of insurer practices on these costs.[26] Oregon regulators must ensure that insurers and pharmacy benefit managers' cannot use programs such as accumulator adjustment programs and copay maximizers to block manufacturer efforts to limit patients' cost sharing obligations through patient assistance programs. As an important first, the Oregon legislature recently passed legislation requiring that "an insurer offering a health plan that provides pharmacy benefits and a pharmacy benefit manager shall include all amounts paid by an enrollee or paid by another person on behalf of an enrollee toward the cost of a covered prescription drug when calculating the enrollee's contribution to an out-of-pocket maximum, deductible, copayment, coinsurance or other cost-sharing requirement applied to the drug."[27] Oregon regulators have a responsibility to carefully scrutinize plan documents to ensure that plans are not violating this law by implementing accumulator adjustment programs or utilizing copay maximizers in excess of the Affordable Care Act's annual out-of-pocket maximum under 42 U.S.C. § 18022.

4. **<u>List of Purported Therapeutic Alternatives is Incorrect and Not Reflective of Clinical Practice</u>**

Lastly, AbbVie believes that the Report's list of purported therapeutic alternatives to VRAYLAR is incorrect and does not reflect clinical practice guidelines or real-world physician experience. This may be attributable, in part, to the problematic definition of "therapeutic alternative" adopted by the PDAB and set forth in O.A.R. § 925-200-0020(2)(c): "A drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose."

The Report provides little clarity on how the PDAB implements this vague definition. AbbVie believes that a therapeutic alternative must be a branded therapy that shares the same mechanism of action and is medically appropriate for the same group of patients in each of the FDA-

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[24] AnalySource; Federal Reserve Bank of St. Louis https://fred.stlouisfed.org/series/CPIAUCSL
[25] Report, at 22.
[26] *See* O.R.S. § 646A.680 *et seq.*
[27] 2004 HB 4113, *available at* https://olis.oregonlegislature.gov/liz/2024R1/Downloads/MeasureDocument/HB4113/Enrolled.

approved indications as the selected drug. Differences in efficacy and safety outcomes between the selected drug and a therapeutic alternative treatment should be small and not clinically meaningful.

Specifically, the Report fails to recognize that VRAYLAR is clinically distinct from the PDAB-identified therapeutic alternatives in several key respects. **None of the therapeutic alternatives share VRAYLAR's mechanism of action and none are approved for all of the same indications as VRAYAR, which is used to treat not only MDD, but also the full spectrum of bipolar-I (depression and mixed/mania) and schizophrenia.**

Further, the Report completely disregards significant differences in clinical outcomes and in safety profiles between VRAYLAR and the purported therapeutic alternatives. VRAYLAR has a unique pharmacological profile. It is the only dopamine D_3-preferring D_3/D_2 receptor partial agonist. D_3 receptors are associated with cognition, affect, motivation, and reward regulation. And partial agonism allows for modulation of dopamine in relation to the surrounding neurotransmitter levels, rather than dopamine antagonists, which completely block their targeted receptors. VRAYLAR also has the longest half-life among the oral atypical antipsychotics, which is important in these intermittently adherent populations. Also, VRAYLAR has a more neutral metabolic profile with low risk of weight gain and sedation. This is particularly important because patients with many of the conditions these drugs treat are at an increased risk for early mortality caused by cardiovascular disease. Additionally, weight gain is a common reason for discontinuation with other atypical antipsychotics. Turning to directly comparative data, in several real-world studies comparing persistence and healthcare resource utilization (HCRU) between VRAYLAR and Caplyta, patients taking VRAYLAR were significantly more likely to be persistent to treatment relative to comparators, staying on VRAYLAR almost two months longer during the study period. Patients initiating VRAYLAR also had fewer hospitalizations and emergency department visits. In sum, the list of therapeutic alternatives identified by the PDAB is incorrect and underappreciates the clinical distinctions that sets VRAYLAR apart.

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For the reasons set forth above, AbbVie respectfully submits that the VRAYLAR Report is highly flawed, with superficial analyses of VRAYLAR utilization, patient OOP spending, and proposed therapeutic alternatives that fail to incorporate relevant evidence as required by O.A.R. § 925-200-0020, or to adequately consider the importance of appropriate antipsychotic use and the role of benefit design in OOP expenditure. **Accordingly, we urge the PDAB to reverse its determination that VRAYLAR may create affordability challenges for the Oregon health care systems or patient out-of-pocket costs.**

Furthermore, we reiterate our strong recommendation that the PDAB prioritize the development and implementation of a transparent and predictable methodology for drug selection, affordability review, assessment, and determination. No prescription drugs should be selected for review, nor should any affordability determinations be made, until such a framework is firmly in place. Establishing clear and consistent criteria is essential to ensure fair, evidence-based, and accountable decision-making that maintains stakeholder trust and upholds the PDAB's integrity.

We look forward to working collaboratively with the PDAB to identify and implement affordability solutions that lower patients' out-of-pocket costs and ensure continued access to innovative medicines.

Thank you for the opportunity to provide this feedback. Please feel free to contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Kim Fitpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc.