July 13, 2026

VIA ELECTRONIC SUBMISSION

Oregon Prescription Drug Affordability Board
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RE: Oregon Prescription Drug Affordability Board (PDAB): July 15, 2026 Meeting Materials — Draft Drug Review Report for Verzenio® (abemaciclib)

Eli Lilly and Company ("Lilly") appreciates the opportunity to provide our perspective on the Oregon PDAB ("the Board") meeting materials, which include the Draft Drug Review Report ("the Report") for our product Verzenio® (abemaciclib).[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology companies, committed to equitable and affordable access to our medicines so that our innovations can transform more people's lives.

Lilly shares the Board's goal of improving patient outcomes by making effective treatments accessible. However, price controls do not make medicines more affordable for patients, and any actions to meaningfully address affordability will require targeting underlying incentives in the pharmaceutical supply chain in need of reform, rather than misguided and unlawful[2] policies such as upper payment limits (UPLs). We continue to have serious concerns about the data and methodology underpinning the Board's affordability review process. To that end, Lilly urges the Board to take into consideration the recommendations and concerns outlined below in its review of Verzenio®.

Lilly is Committed to Patient Affordability

Throughout our 150-year history, Lilly has worked to address some of the most pressing health challenges facing humanity, including diabetes, depression, cancer, and obesity. Today, more than 71 million people are estimated to use a Lilly medicine. Our commitment to patients and society goes beyond the medicines we make: we are committed to equitable and affordable access to our medicines so that our breakthrough treatments can transform more people's lives.

Verzenio® is Affordable for Oregon Patients

The primary focus of any cost review by the Board should be on patients, and the Board's own data show that Verzenio® is broadly affordable for Oregon patients. Across all payer types in the All Payer All Claims (APAC) dataset, the median enrollee out-of-pocket (OOP) cost is $0 per claim and the median annual OOP cost per enrollee is $0, and Medicaid enrollees have $0

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[1]Oregon Prescription Drug Affordability Board. Verzenio® (abemaciclib), Draft Drug Review Report, Version 1.0, July 7, 2026. https://dfr.oregon.gov/pdab/Documents/Verzenio-2026.pdf.

[2]See Amgen Inc. *v. Mizner*, No. 1:25-cv-03452, 2026 U.S. Dist. LEXIS 148973, __ F.Supp.3d __ (D. Colo. July 1, 2026) (granting preliminary injunction against Colorado UPL).

OOP costs.[3] Every reporting plan covers Verzenio® (0% "not covered"), and no plan requires step therapy.[4] Real-world data confirm this: approximately 60 percent of insured patients pay $0 per Verzenio® prescription, and approximately 90 percent pay less than $200.[5]

Health plans design formularies that determine patients' out-of-pocket obligations. According to the Board's data, 100 percent of reporting plans require prior authorization for Verzenio® and approximately 48.5 percent place it on a non-preferred tier.[6] Non-preferred placement and utilization-management requirements can raise what patients pay and delay access. Where affordability challenges arise, they are most likely a function of restrictive plan benefit designs—such as high upfront deductibles or adverse formulary placement—rather than the medicine itself.

The cost of Verzenio® to payers can be well below list price. Based on the Board's commercial carrier data, Verzenio® claims received an average price concession of approximately 14.1 percent, and roughly 74.9 percent of claims received some form of manufacturer rebate, pharmacy benefit manager (PBM) discount, or other concession.[7] Of note, Verzenio® had the *highest* percent discount of products reviewed in the class.[8]

In addition, Lilly helps reduce patient out-of-pocket costs directly. Lilly offers a variety of affordability solutions through patient support programs and copay assistance for eligible commercially insured patients.[9] Lilly also donates medicines to charitable organizations such as the Lilly Cares Foundation, a separate 501(c)(3) tax-exempt Indiana nonprofit corporation, which provides Verzenio® at no cost to qualifying patients in households with annual adjusted gross incomes up to 500 percent of the federal poverty level.[10] In 2025, Lilly Cares provided $37.17 million in medication value to 1,179 patients served in Oregon.[11]

Verzenio® Provides Value to Patients and the Health System

An affordability review should also weigh a medicine's clinical value and the medical costs that effective treatment prevents. Breast cancer has the highest overall economic burden of any cancer in the United States, and that burden is growing: aggregate costs are estimated to

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[3]Verzenio® Report, Tables 3, 28, and 29 (2024 APAC enrollee out-of-pocket cost).
[4]Verzenio® Report, Table 27 (Plan design analysis from 2024): 100% of reporting plans required prior authorization, 0% required step therapy, 48.5% placed the product on a non-preferred formulary tier, and 0% did not cover it.
[5]Based on HealthVerity®-sourced real-world data - Verzenio® Patient Out of Pocket Cost per Script by Channel (January - December 2024). Accessed on September 20, 2025.
[6]Id., Verzenio® Report, Table 27 (100% of reporting plans required prior authorization; 48.5% placed the product on a non-preferred formulary tier).
[7]Verzenio® Report, Tables 14 and 15 (net cost price-concession estimates from the commercial carrier data call). The Report states an average discount of 14.1% and that 74.9% of claims received some form of price concession.
[8]Verzenio® Report, Table 18 (price concessions for therapeutic alternatives), reflecting a 14.1% average discount for Verzenio® compared with 4.6% and 3.1% for the two therapeutic alternatives; see also Tables 14 and 15.
[9]Lilly. How much should I expect to pay for Verzenio® (abemaciclib)? pricinginfo.lilly.com/verzenio.
[10]Lilly Cares Foundation, a separate 501(c)(3) tax-exempt Indiana nonprofit corporation, provides Lilly medications at no cost to qualifying patients. lillycares.com/how-to-apply.
[11]Lilly Cares Foundation, 2025 state-level data. lillycares.com.

have roughly doubled, from about $16.5 billion in 2010 to about $32.7 billion in 2024.[12] Verzenio® treats hormone receptor-positive (HR+), HER2-negative breast cancer in both early-stage and advanced disease, and national clinical guidelines recommend it as a standard-of-care therapy in these settings.[13]

In early breast cancer, Verzenio® is added to endocrine therapy to lower the risk that a high-risk cancer returns and spreads. In the Phase 3 monarchE trial, this combination kept more patients cancer-free through seven years than standard-of-care endocrine therapy alone: it reduced the risk that invasive cancer returned by 26.6 percent (a roughly 6.5 percentage-point improvement) and the risk of distant recurrence by about 25.4 percent (a roughly 5.1 percentage-point improvement).[14] Patients also lived longer. After about 76 months of follow-up, adding Verzenio® reduced the risk of death by about 15.8 percent compared with endocrine therapy alone, and fewer patients were living with metastatic disease at seven years (about 6.4 percent versus 9.4 percent).[15]

Verzenio® is the only CDK4/6 inhibitor to demonstrate a statistically significant improvement in overall survival in early breast cancer, a clinical advancement not shared with therapeutic alternatives. This survival improvement is achieved over a two-year course of treatment resulting in shorter patient exposure and lower per-patient total cost versus other treatments with a longer treatment duration.[16] In early breast cancer, Verzenio® further addresses an unmet need through its combinability with either an aromatase inhibitor (AI) or tamoxifen. Up to 30 percent of patients will be intolerant of, or have contraindications to, AIs, resulting in tamoxifen plus Verzenio® as the only other endocrine therapy – CDK4/6 inhibitor combination approved in the early breast cancer setting.

In advanced or metastatic disease, Verzenio® combined with endocrine therapy roughly doubled median progression-free survival versus endocrine therapy alone in the Phase 3 MONARCH 3 trial (approximately 29 months versus approximately 15 months).[17] These outcomes carry direct cost implications for purchasers in addition to health benefits for patients. When breast cancer progresses into metastatic disease, treatment costs and

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[12]Mariotto AB, et al. J Natl Cancer Inst. 2011; National Cancer Institute, Cancer Trends Progress Report.
[13]National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Breast Cancer; and Burstein HJ, et al. ASCO endocrine and targeted therapy guidance for HR+, HER2- breast cancer, J Clin Oncol. 2024. PMID: 38478799.
[14]Johnston SRD, Harbeck N, Hegg R, et al. Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2-, Node-Positive, High-Risk, Early Breast Cancer (monarchE). J Clin Oncol. 2020;38(34):3987-3998. PMID: 32954927. Seven-year invasive disease-free survival and distant relapse-free survival benefits are reported in the monarchE overall-survival analysis (PMID: 41110697).
[15]Johnston S, Martin M, O'Shaughnessy J, et al. Overall Survival with Abemaciclib in Early Breast Cancer (monarchE). Ann Oncol. 2025 (Epub ahead of print). PMID: 41110697. Hazard ratio for death 0.842 (95% CI, 0.722–0.981; two-sided p=0.027) in the intent-to-treat population at approximately 76 months' median follow-up.
[16]Verzenio® monarchE budget impact model. Data on file.
[17]Goetz MP, Toi M, Huober J, et al. Abemaciclib plus a nonsteroidal aromatase inhibitor as initial therapy for HR+, HER2- advanced breast cancer: final overall survival results of MONARCH 3. Ann Oncol. 2024;35(8):718-727. PMID: 38729566. Median progression-free survival approximately 29 months versus approximately 15 months with endocrine therapy alone; the overall-survival difference (median 66.8 vs. 53.7 months) did not reach statistical significance.

healthcare resource utilization can increase dramatically, with lifetime costs estimated to be in the range of $587,000 - $935,000.[18,19] As an oral therapy that can be taken at home, Verzenio® can also reduce the travel, clinic, and administration burden associated with infusion-based regimens. By reducing recurrence and delaying progression to metastatic disease, Verzenio® can avert these costs while also reducing administrative costs and burden of care. These advantages provide value that a gross-spending view of the medicine alone does not capture.

Cancer Care Must Be Individualized, and Patients Need Access to a Range of Treatment Options

More women are diagnosed with breast cancer than any other non-cutaneous cancer in the United States, and an estimated 42,170 U.S. women were projected to die from the disease in 2025 alone.[20] Behind that number are individual patients whose disease, circumstances, and priorities may differ widely. Breast cancer is not a single disease. It varies by stage, tumor biology, hormone-receptor and HER2 status, genomic features, and how it behaves over time.[21] Even among the hormone receptor-positive, HER2-negative patients for whom Verzenio® is indicated, the right treatment depends on whether the disease is early or advanced, the patient's menopausal status, prior therapies, and the specific characteristics of the tumor.

Every patient's cancer journey is unique, and treatment decisions should reflect individual priorities, lifestyles, and goals. The needs of patients also change over time. A regimen that is appropriate at diagnosis may not be appropriate if the disease progresses or a patient develops resistance, and patients frequently move through several lines of therapy over the course of their care. Individual circumstances shape what is tolerable and effective—for example, comorbidities such as cardiac or liver conditions, the burden of managing many medications at once in older patients, the ability to tolerate a particular endocrine partner, the difference between a pill taken at home and an infusion that requires travel to a clinic, and personal considerations around work, caregiving, and quality of life. Two individuals may face the same diagnosis and the same events yet experience them in entirely different ways.

There is no one-size-fits-all approach to cancer care. National guidelines reflect this by recommending a range of options and leaving the treatment choice to shared decision-making between patients and their treating physicians, rather than prescribing a single therapy for

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[18]Chang SH, et al. Cost-effectiveness of early vs delayed use of abemaciclib combination therapy for HR+/HER2- early breast cancer. *J Manag Care Spec Pharm.* 2024;30(9):942-953.
[19]Sheffield KM, et al. A real-world US study of recurrence risks in HR+, HER2- early breast cancer. Future Oncol. 2022;18(21):2667-2682.
[20]National Cancer Institute, Surveillance, Epidemiology, and End Results (SEER) Program, Cancer Stat Facts: Female Breast Cancer (2025 estimates).
[21]Howlader N, Altekruse SF, Li CI, et al. US incidence of breast cancer subtypes defined by joint hormone receptor and HER2 status. J Natl Cancer Inst. 2014;106(5):dju055. PMID: 24777111 (HR+, HER2- is the most common invasive subtype, approximately 66–73% of breast cancers); see also DeSantis CE, et al. Breast cancer statistics, 2019. CA Cancer J Clin. 2019;69(6):438-451. PMID: 31577379.

everyone.[22] For these reasons, patients and providers need the flexibility to access the full range of appropriate, guideline-recommended treatments—including Verzenio®—across multiple lines of care. Policies that narrow that range, whether through upper payment limits, restrictive formulary placement, step therapy, or nonmedical switching, risk putting the right treatment out of reach at the moment a patient needs it most. The stakes of that constraint are especially high in oncology, because a delayed or inappropriate change in therapy can allow disease to progress to incurable metastatic cancer. We urge the Board to weigh these clinical and personal realities and to avoid actions that would limit Oregon patients' access to the treatment options their care requires.

Data Quality Concerns Undermine the Board's Affordability Review Process

We remain concerned about the data underlying the Board's affordability review, independent of any ultimate affordability conclusion, and we address our principal concerns below. Some errors are identical to ones identified previously in both the Humulin® and Mounjaro® reports[23], which raises concerns and suggests that the Board has not addressed previously identified problems.

Key inputs are drawn from a limited carrier-submitted dataset that may be unrepresentative. The commercial carrier data call captured approximately 1,201 Verzenio® claims across 189 enrollees, compared with 2,891 claims across 355 enrollees in APAC—roughly 40 percent of statewide claims.[24] That subset is limited to fully insured commercial plans and excludes ERISA self-insured plans (covering roughly one million Oregonians), Medicaid, and Medicare. Yet the price-concession and formulary/access parameters that feed the Board's scoring rubric appear to be derived solely from this smaller dataset. Drawing rubric scores from a non-representative sample risks bias and inaccuracy and, at a minimum, warrants validation before the data inform the Board's determination.

The Report's rubric mislabels the price-concession statistic. The "Price concessions" domain of the rubric (Table 4) is described as the share of claims that "received rebates or price concessions" and reports "14.1%." However, 14.1 percent is the average percent discount per the Board's data, not the share of claims; the Report's own data show that approximately 74.9 percent of claims received a concession.[25] Because the rubric is a structured input to the Board's affordability determination, this error understates how broadly concessions apply and risks skewing the Board's conclusions.

The Report contains internal inconsistencies and errors. First, the "Residents prescribed" section states that Verzenio® had "2,981 claims," while every other table in the Report uses

[22]National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Breast Cancer (recommending therapy individualized to disease stage, tumor biology, and patient factors through shared decision-making rather than a single therapy for all patients).
[23]See Eli Lilly comment letter to the Oregon PDAB regarding the Humulin® and Mounjaro® reviews, June 15, 2026.
[24]Verzenio® Report, Tables 6 and 19 (APAC: 2,891 claims across 355 enrollees) compared with Table 14 (commercial carrier data call: 1,201 claims across 189 enrollees).
[25]Verzenio® Report, Table 4 (Rubric domains) compared with Table 14 (net cost price-concession estimate).

2,891 claims.[26] Second, the Medicare total payer-paid figure is reported as $8,577,880 in one table and $8,663,103 in another; only the latter reconciles with the stated $38,491,663 total.[27] Third, the mean net cost per enrollee is reported as $77,063, but the Report's own totals imply approximately $74,063.[28] Fourth, the Report states that 74.9 percent of claims received a concession while simultaneously stating that this leaves "82.9 percent at full gross cost"—figures that cannot both be correct.[29] Fifth, the Report is internally inconsistent on the drug's approval year, listing 2017 in one table and February 26, 2018 in another.[30] These errors should be corrected before the review proceeds.

Small-cell demographic reporting raises patient-privacy concerns. While the Report states: "In this review, cell values with enrollee counts derived from APAC data are suppressed to protect confidentiality when the cell has 30 or fewer individuals,"[31] Table 8 includes multiple cells with counts as low as four or five claims, which necessarily correspond to a handful of enrollees, lower than the Board's stated threshold. For comparison, CMS suppresses Medicaid State Drug Utilization Data cells with fewer than eleven prescriptions, citing the Federal Privacy Act and the HIPAA Privacy Rule. We encourage the Board to apply consistent small-cell suppression throughout the Report.[32]

Methodological Concerns Remain Unaddressed

As in prior comments[33], we reiterate our concerns about the methodology the Board employs to measure and define affordability.

The Board has not meaningfully defined "affordability." It remains unclear whether the primary focus of the review is patient cost-sharing or system cost. Without a consistent definition, reviews risk being applied in an arbitrary and inconsistent manner, stakeholder input is inhibited, and it becomes virtually impossible to determine whether a medicine creates an "affordability challenge."[34] As noted at the outset, patient affordability should be the focus of any cost review. A meaningful definition should also account for a medicine's clinical value

[26]Verzenio® Report, "Residents prescribed" section (stating "2,981 claims") compared with Tables 2, 6, 16, 19, 20, and elsewhere (2,891 claims).
[27]Verzenio® Report, Table 7 (Medicare total payer paid of $8,577,880) compared with Table 19 (Medicare total payer paid of $8,663,103). Only the latter reconciles with the stated total payer expenditure of $38,491,663.
[28]Verzenio® Report, Table 14. The stated mean net cost per enrollee of $77,063 is inconsistent with the Report's own figures: total cost after concessions of $13,997,923 divided by 189 enrollees is $74,063, and a 14.1% discount applied to a $86,225 gross per-enrollee cost likewise yields $74,063.
[29]Verzenio® Report, "Estimated average monetary price concession" section, which states that 74.9% of claims received a concession while also stating that this leaves "82.9 percent at full gross cost"—figures that cannot both be correct.
[30]Verzenio® Report, Table 1 ("Year approved 2017") compared with Table 5 ("First approved by the FDA Feb. 26, 2018").
[31]Verzenio® Report, Version 1.0, at 7.
[32]Verzenio® Report, Table 8 (2024 APAC costs by race), reporting cell counts of four and five individuals. For comparison, CMS suppresses Medicaid State Drug Utilization Data cells with fewer than eleven prescriptions, citing the Federal Privacy Act and the HIPAA Privacy Rule. cms.gov.
[33]See Letter from Lilly to Board (October 13, 2025); Letter from Lilly to Board (January 19, 2026); Letter from Lilly to Board (June 15, 2026).
[34]Oregon Administrative Rule (OAR) 925-200-0020, conducting an affordability review; OAR 925-200-0010, drug selection.

and the broader value it delivers, which a superficial analysis of gross spending cannot capture.

The Board's reliance on total gross spending conflates cost with utilization. Using total gross spending obscures the difference between a medicine's unit price and the volume of patients who need it. For an oncology therapy like Verzenio®, aggregate spending reflects the number of Oregonians living with HR+, HER2- breast cancer as much as it reflects price. Affordability determinations should reflect estimated net spending on a per-patient basis, inclusive of any medical-cost offsets attributable to the drug that ultimately accrue to state purchasers.

Wholesale Acquisition Cost (WAC) is a flawed measure. Although the Board may consider WAC, its statutory directive is to identify whether a drug may create affordability challenges for health care systems or high out-of-pocket costs for patients—a determination that cannot reasonably rest on list price.[35] Affordability should focus on affordability to the patient, which WAC does not provide a measure of. In addition, WAC does not represent the final net cost of a drug, because rebates and other price concessions can reduce the net cost incurred by payers, including state payers. The Board's own data confirm this for Verzenio®, which carried an average price concession of approximately 14.1 percent in the commercial market and shows that 75 percent of claims received a price concession.[36] It is unclear how a change in WAC could increase the cost to the health care system when WAC does not measure a net price paid by a payer nor affordability to patients.

The Board Provides Insufficient Timelines for Meaningful Public Comment

The Board must also allow sufficient time for meaningful public and stakeholder participation before rendering decisions.[37] The practice of setting unreasonably short comment periods continues to raise significant concerns about the ability of stakeholders—including patients, caregivers, and treating providers—to meaningfully review materials and provide comment. Treating physicians have voiced serious concerns about the impact of PDABs on patient care, including the risks of nonmedical switching, which are well documented and include increased likelihood of adverse events, reduced adherence, and long-term complications.[38]

The Board Should Continue to Promote Policies that Actually Address Patient Affordability

As outlined in our previous letter[39], Lilly is pleased that some of the policy recommendations adopted in the Board's 2025 Report would meaningfully address issues in the pharmaceutical payment system without inviting the unintended consequences inherent in price-setting schemes.[40] The Board should continue to recommend reforms that address the warped

[35]OAR 925-200-0010 (drug selection); OAR 925-200-0020 (affordability review).
[36]Verzenio® Report, Tables 14 and 15 (mean price concessions across market types).
[37]OAR 925-200-0020(k); Or. Rev. Stat. § 646A.694(3); OAR 925-200-0020(2)(k)(A).
[38]Value of Care Coalition. Specialty Doctor Survey Reveals Concerns about PDABs. valueofcarecoalition.org.
[39]Letter from Lilly to Board (June 15, 2026).
[40]Oregon Prescription Drug Affordability Board, 2025 Annual Report, at 30. dfr.oregon.gov.

supply-chain incentives that expose patients to higher cost-sharing obligations, which would enable lower costs at the point of sale and create the conditions for list- and net-price parity.

Lilly appreciates the opportunity to respond to the Board's materials. We value the Board's shared commitment to improving prescription drug access and patient affordability, and we believe Verzenio® positively contributes to the health and well-being of patients in Oregon.

Sincerely,

Rachel Dolan

Rachel Dolan
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Eli Lilly and Company