



Manufacturer feedback submission

Drug under review	Verzenio (abemaciclib)
Manufacturer	Eli Lilly

Publication note: The information below was submitted by the manufacturer through the Oregon Prescription Drug Affordability Board manufacturer feedback form. Responses are presented as submitted, with minor formatting changes. Blank survey fields are identified as “No response provided.” Contact and other form fields identified as not for public posting have been omitted. Manufacturer-submitted statements have not been independently verified unless otherwise stated in the drug review packet.

Manufacturer Responses

Question 1. Select the name of the drug.

Verzenio (abemaciclib)

Question 2. FDA approval pathway (select all that apply)

Breakthrough therapy; Priority review

Question 3. Year of the first FDA approval

2017

Question 4. Is the drug currently marketed in Oregon?

Yes

Question 5. Number of FDA-approved therapeutic alternatives for the primary indication

1-2

Question 6. Are generic or biosimilar versions FDA-approved?

No

Question 7. Is the drug considered first-in-class for its primary indication?

No

Question 8. Does the drug currently have FDA recognized market exclusivity?

Yes



Question 9. Type of exclusivity (select all that apply)

No response provided.

Question 10. Earliest known expiration of exclusivity or patent protection

More than 3 years

Question 11. Does the drug have orphan drug designation from the FDA to prevent, diagnose or treat a rare disease or condition?

No

Question 12. Does the drug have FDA approval to prevent, diagnose or treat diseases or conditions that are not considered rare diseases?

No

Question 13. Does the manufacturer provide price concessions (rebates, discounts, etc.) for the drug in the U.S. market?

Yes

Question 14. Types of price concessions offered (select all that apply):

Rebates; Discounts

Question 15. Primary entities that receive price concessions (select all that apply):

Health insurers; Pharmacy benefit manager; Wholesalers

Question 16. Does the manufacturer offer patient financial assistance programs related to this drug?

Yes

Question 17. Types of patient assistance offered (select all that apply):

Free or replacement drug program; Patient assistance program (PAP); Copay assistance

Question 18. Are patients with public coverage (Medicare, Medicaid) eligible for any assistance?

No

Question 19. Are patients without public or private insurance eligible for any assistance?

Yes

Question 20. Is the drug commonly subject to utilization management (e.g., prior authorization or step therapy)?

Yes

Question 21. Which factors most influence the drug's list price over time? (select up to two)

No response provided.



Question 22. Does the manufacturer believe the drug's current pricing aligns with its clinical value?

Yes

Question 23. Any additional information the manufacturer chooses to provide.

Verzenio has been approved across multiple settings within the indication for Breast cancer (HR-positive, HER2-negative): (a) in combination with fulvestrant for advanced/metastatic disease after endocrine therapy progression; (b) as monotherapy for advanced/metastatic disease after endocrine therapy and chemotherapy; (c) in combination with an aromatase inhibitor for initial advanced/metastatic treatment; and (d) in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of node-positive, high-risk early breast cancer. Verzenio also uniquely carries NCCN Compendium-endorsed on and off-label uses across five disease areas, some of which have very low incidence rates.

On patient affordability: Lilly is proud of our affordability programs. Lilly offers a variety of affordability solutions through patient support programs and copay assistance for eligible commercially insured patients. 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. In 2025, Lilly Cares provided \$37.17 million in medication value to 1,179 patients served in Oregon.

Lilly urges the Board to consider that 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 everyone. 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.