



Manufacturer feedback submission

Drug under review	Humulin R U-500 KwikPen (insulin regular)
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.

Humulin R U-500 KwikPen (insulin regular)

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

Standard

Question 3. Year of the first FDA approval

1994

Question 4. Is the drug currently marketed in Oregon?

Yes

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

More than 5

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?

No



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

No response provided.

Question 10. Earliest known expiration of exclusivity or patent protection

No response provided.

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?

Yes

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):

Pharmacy benefit manager; Health insurers; 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):

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

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

Medicare Part D patients benefit from the Inflation Reduction Act's \$35/month insulin copay cap (effective automatically), which Lilly worked with the federal government to help secure, but they are not eligible for manufacturer copay savings cards. The Lilly Cares Foundation PAP may assist qualifying Medicare patients who meet income thresholds.

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.

At Lilly, We are proud of our insulin affordability solutions, which have made a real impact for Oregonians and all Americans. Lilly has been working for years to reduce insulin out-of-pocket costs for people with diabetes. Lilly was the first company to cap what patients pay at \$35 per month for all of our insulins, regardless of the number of pens or vials they are prescribed in a month. In 2024, the average monthly out-of-pocket cost for Lilly insulin was less than \$15.