Oregon Prescription Drug
Affordability Board

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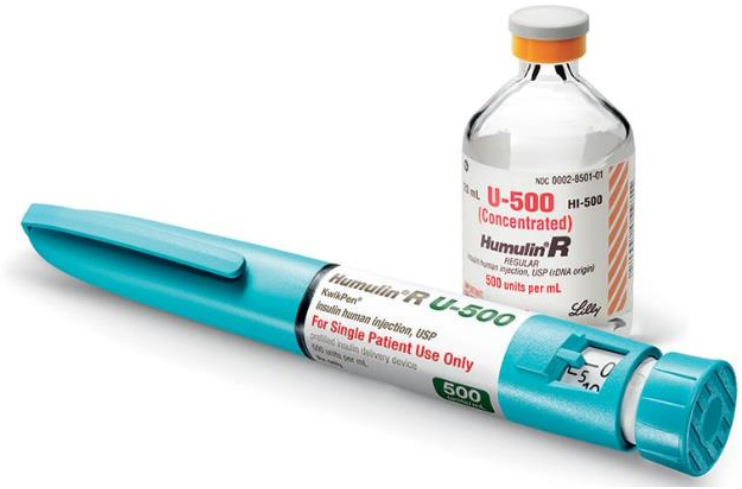
Humulin R U-500®

(*insulin regular*)[1]

Version 2.0



[1] Image source: https://www.medscape.com/viewarticle/857811?impID=%25%25JOBID%25%25&faf=1

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Document version history

Version	Date	Description
v1.0	6/9/2026	Original release
v2.0	6/15/2026	Updated health equity section with updated data. Updated the stakeholder section with information provided by the manufacturer.
v2.0	6/16/2026	Added web link to the public comment letter.

Review summary

Table 1 Review drugs

Insulin product	Non-proprietary name	Manufacturer	On the CMS Drug Price Negotiation List
Vial	*insulin regular*	Eli Lilly®	No
KwikPen	*insulin regular*	Eli Lilly®	No

Price history[2,3]

From 2019-2025, insulin products had a zero percent change in WAC.

Price concessions [4]

Based on data received from healthcare carriers, the **concentrated vial** had an average **gross spend of $994,601.** For the same product, the **net spend per enrollee was $3,532**, resulting in an **average price concession of 2.7 percent per claim**.

The **KwikPen** had a **gross spend of $819,677**. The **net spend per enrollee was $1,886**, resulting in an **average price concession of 20.9 percent per claim**.

Cost to the payers[5]

Table 2 2024 APAC payer annual total expenditure, claim, and cost per enrollee[6]

Insulin product	No. of enrollees[7]	No. of claims	Total payer paid	Cost per enrollee, mean	Cost per claim, median
Vial	139	541	$1,464,389	$10,535	$2,612
KwikPen	420	2,672	$4,886,424	$11,634	$1,328

[2] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[3] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[4] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. The data call includes information about the cost of the drug before and after price concessions in the commercial market.
[5] Based on Oregon's 2024 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[6] The totals for amounts paid, costs, and claims are from both medical and pharmacy reporting.
[7] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business, indicating that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Tables 7 and 8 as compared to other totals indicated in this report.

Cost to enrollees[8]

Table 3 2024 APAC annual enrollee out-of-pocket (OOP) cost[9]

Insulin product	Total paid by enrollees	OOP cost per enrollee, median	OOP cost per claim, mean	OOP cost per claim, median
Vial	$20,547	$30	$38	$0
KwikPen	$47,900	$2	$18	$0

Rubric considerations

Table 4 Rubric domains and scoring considerations

Domain	Vial	KwikPen
Number of enrollees	139	420
Price evaluation	0% average annual percent chang in WAC from 2019-2025	0% average annual percent chang in WAC from 2019-2025
Price concessions	2.7% claims receive rebates or price concessions	20.9% claims receive rebates or price concessions
System & payer costs	$1,464,389 payer paid	$4,886,424 payer paid
Enrollee burden	$148 mean of APAC OOP annual cost	$114 mean of APAC OOP annual cost
Equity impact	TBD	TBD
Access restrictions	Yes	Yes
Therapeutic alternative	N/A	N/A
Stakeholder input	Yes	Yes
Patent expirations	No	No
On CMS Maximum Fair Price List (MFP)	No	No

[8] Based on Oregon's 2024 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

[9] Total enrollee out-of-pocket costs is the sum of reported copayments, coinsurances, and deductibles.

Review background

This review incorporates supporting information from Medi-Span, FDA databases (e.g., Orange Book, Purple Book), and other publicly available data where applicable.

Two primary data sources inform this review: the Oregon All Payers All Claims (APAC) Reporting Program database and the Oregon commercial carrier data call. APAC aggregates claims data across all payer types in Oregon, including Medicaid, Medicare, and commercial plans, and presents gross cost estimates. In contrast, the data call reflects submissions from 11 commercial health insurers and reports primarily net costs after manufacturer rebates, PBM discounts, and other price concessions. As a result, APAC generally reflects larger total claims and cost figures due to broader reporting for more enrollees, while the data call offers insight into actual expenditures from private payers in the commercial market.

In 2023, APAC included data for approximately 3.5 million Oregonians. Approximately 27% of people in APAC had Medicare coverage, 33% of people had Medicaid coverage, and 39% of people had commercial coverage. APAC cannot require submission of claims and enrollment data from entities regulated under the Employee Retirement Income Security Act of 1974 (ERISA), so data for many self-insured plans are not included.[10,11] For these drug reviews, APAC data on people with Medicare coverage are limited to Medicare Advantage and Part D only and do not include claims for Traditional Medicare Part A or Part B.

The 2026 Oregon commercial carrier data call included data from commercial health plans providing coverage for approximately 800,000 Oregonians based on claims in 2024.[12] The data call is limited to fully-insured plans that are regulated by the state and does not include coverage regulated under ERISA.

This review addresses the affordability review criteria to the extent practicable. Due to limitations in scope and resources, some criteria receive minimal or no consideration.

In accordance with OAR 925-200-**0020**, PDAB conducted affordability reviews on prioritized prescription drugs selected under OAR 925-200-**0010**. The board selected ten drugs and two insulin products for affordability review in 2026. The selection process emphasized brand-name products with substantial cost impact and excluded antivirals, toxoids, vaccines, and products with available therapeutic equivalents or biosimilars as of February 2026. The board also

[10] Oregon All Payer All Claims Database (APAC) Data User Guide. Version 1.1 updated Nov 19, 2025. APAC-Data-User-Guide.pdf. The number of people represented in 2024 APAC data has not been published as of May 2026.
[11] For 2024, the DCBS Division of Financial Regulation reported that just under one million people in Oregon were enrolled in commercial health plans and slightly more than one million people in Oregon were enrolled in self-insured health plans. *2024 Quarterly enrollment report*, https://dfr.oregon.gov/business/reg/reports-data/annual-health-insurance-report/Pages/health-ins-enrollment.aspx, accessed June 1, 2026.
[12] The number of people covered by plans reporting to the commercial carrier data call was estimated using 2024 insurer data reported in 2025 to the Oregon Drug Price Transparency Program which receives reports on state-regulated health insurance plans.

removed from consideration products reviewed in 2025 and determined to possibly have potential system- or patient-level cost implications. To ensure broad relevance across Oregon's insured population, the board prioritized drugs reported by seven or more commercial health carriers.

For insulin products, the board focused on products with the highest end-of-year unit prices while excluding those with fewer than 100 covered enrollees. Insulin glargine products reviewed by the board in 2025 were also removed to maintain focus on products not yet evaluated. This approach ensured that the final selection aligned with statutory intent, reflected consistent application of rule-based selection factors, and supported a comprehensive assessment of products with meaningful affordability implications for Oregon's health care system and patients.

Visit the PDAB webpage for more information about purpose and statutory authority of the Oregon Prescription Drug Affordability Board (PDAB).

Drug information[13]

Table 5 Drug information

Drug proprietary name(s)	Humulin R U-500® concentrated vial and KwikPen
Non-proprietary name	*insulin regular*
Manufacturer	Eli Lilly and Company
Treatment	Improve glycemic control in adult and pediatric patients with diabetes mellitus requiring more than 200 units of insulin per day.
Strength	500 units/mL (U-500) • Vial: 20mL multidose vial containing 10,000 total units • KwikPen: 3 mL prefilled disposable pen containing 1,500 total units
Dosage	• Dosage is individualized and titrated based on metabolic needs, blood glucose monitoring, and glycemic control goals. • Usually administered two or three times daily approximately 30 minutes before meals. • KwikPen dosing: Doses in 5-unit increments with a maximum of 300 units per injection.
Form/route	Subcutaneous injection
Physician administered	No

[13] U.S. Food & Drug Administration. *Eliquis (apixaban) Prescribing Information*. Bristol-Myers Squibb Company, Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202155s034lbl.pdf.

Drug proprietary name(s)	Humulin R U-500® concentrated vial and KwikPen
NDCs reviewed	• Vial: 00002850101 • KwikPen: 00002882427

FDA approval

Table 6 FDA Approval

Insulin product	FDA approval date[14]	Expedited forms of approval	Orphan Drug Act[15]
Vial	March 1994	None identified through the available FDA materials	No
KwikPen	January 21, 2016	None identified through the available FDA materials	No

Health equity considerations

ORS 646A.694(1)(a) and OAR 925-200-0020 (1)(a) & (2)(a)(A-B). Limitations in scope and resources available for this statute requirement.

Claims data from APAC was evaluated for health equity considerations related to utilization in Oregon. The analysis included line of business (payer type), race, ethnicity, and gender where available and evaluated claim numbers, member counts, insurer paid amounts, and enrollee out-of-pocket costs. Equity data analysis using APAC is preliminary with additional data cleaning underway as of June 8, 2026. Claim counts and other metrics may change in future updates with improved data cleaning.

Humulin R U-500 claims were **observed among Medicare, Medicaid, and commercial enrollees**. Median and average claim costs were reviewed to understand typical and overall impacts. Median enrollee costs were generally similar across coverage categories, while average costs were higher in some groups, indicating a smaller number of higher-cost claims. Race and ethnicity information was included in the review; however, a substantial proportion of records were categorized as unknown, limiting interpretation of demographic differences.

[14] FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, staff used the earliest approval date across all related FDA applications.
[15] At time of review, the drug had no approved designations under the Orphan Drug Act.

Table 7 2024 APAC claim and enrollee count by line of business for Humulin R U-500 vial

Line of business	Claim count	Enrollee count[16]	Claims per enrollee
Commercial	196	57	3.4
Medicaid	110	36	3.1
Medicare	235	64	3.7
Total	**541**	**139**	**3.9**

Table 8 2024 APAC claim and enrollee count by line of business for Humulin R U-500 KwikPen

Line of business	Claim count	Enrollee count[17]	Claims per enrollee
Commercial	740	126	5.9
Medicaid	979	143	6.8
Medicare	953	221	4.3
Total	**2,672**	**420**	**6.4**

Table 9 2024 APAC payment by line of business for Humulin R U-500 concentrated vial

Line of business	Total payer paid	Mean payer paid/claim	Median payer paid/claim	Total enrollee OOP[18]	Mean enrollee OOP/claim	Median enrollee OOP/claim
Commercial	$571,701	$2,917	$2,650	$6,925	$35	$30
Medicaid	$237,572	$2,160	$1,457	$0	$0	$0
Medicare	$655,116	$2,788	$2,612	$13,622	$58	$5

Table 10 2024 APAC payment by line of business for Humulin R U-500 KwikPen

Line of business	Total payer paid	Mean payer paid/claim	Median payer paid/claim	Total enrollee OOP[19]	Mean enrollee OOP/claim	Median enrollee OOP/claim
Commercial	$1,328,709	$1,796	$1,145	$18,859	$25	$0
Medicaid	$1,502,246	$1,534	$1,132	$0	$0	$0
Medicare	$2,040,073	$2,141	$1,637	$28,910	$30	$0

[16] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business, meaning that an enrollee can be counted for each claim line of business. As a result, the difference in enrollment numbers may be different as compared to other totals indicated in this report.
[17] Ibid.
[18] Total enrollee out-of-pocket costs is the sum of reported copayments, coinsurances, and deductibles for all members in a line of business.
[19] Ibid.

Table 11 2024 APAC mean and median insurer and enrollee out-of-pocket costs per claim, Humulin R U-500 concentrated vial, by race

Race	Claims	Mean payer paid	Median payer paid	Mean enrollee OOP[20]	Median enrollee OOP
White	228	$2,194	$1,428	$19	$0
Black/African American	1	N/A	N/A	N/A	N/A
American Indian/Alaska Native	3	$3,356	$4,366	$0	$0
Asian	6	$3,306	$3,967	$0	$0
Native Hawaiian/Pacific Islander	0	N/A	N/A	N/A	N/A
Mix race	16	$2,501	$2,856	$0	
Other	12	$2,475	$1,044	$26	$45
Refused to answer	1	N/A	N/A	N/A	N/A
Unknown	274	$3,135	$2,863	$58	$20

Table 12 2024 APAC mean and median insurer and enrollee out-of-pocket costs per claim, Humulin R U-500 KwikPen, by race

Race	Claims	Mean insurer paid	Median insurer paid	Mean enrollee OOP[21]	Median enrollee OOP
White	1,523	$1,735	$1,213	$12	$0
Black/African American	69	$990	$864	$1	$0
American Indian/Alaska Native	34	$2,626	$1,755	$1	$0
Asian	45	$2,049	$1,645	$0	$0
Native Hawaiian/Pacific Islander	1	N/A	N/A	N/A	N/A
Mix race	54	$1,608	$1,279	$46	$0
Other	166	$1,537	$1,135	$5	$0

[20] The mean only includes claims paid from commercial and Medicare enrollees. Medicaid enrollees had $0 out-of-pocket costs.
[21] Ibid.

Race	Claims	Mean insurer paid	Median insurer paid	Mean enrollee OOP[21]	Median enrollee OOP
Refused to answer	47	$1,693	$1,099	$0	$0
Unknown	733	$2,122	$1,601	$33	$0

Table 13 2024 APAC claim counts and enrollee counts for Humulin R U-500, by ethnicity

Ethnicity	Claim count vial	Enrollee count vial	Claim count KwikPen	Enrollee count KwikPen
Hispanic	5	3	141	13
Non-Hispanic	259	60	1,783	259
Unknown	277	76	748	148

Table 14 2024 APAC claim counts and enrollee counts for Humulin R U-500, by gender

Gender	Claim count vial	Enrollee count vial	Claim count KwikPen	Enrollee count KwikPen
Female	274	75	1,387	189
Male	237	58	1,130	200
Unknown	30	6	155	31

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC.

Based on APAC claims, here are the number of Oregonians who filled a prescription for the review drugs in 2024:[22]

Table 15 Prescriptions filled for review drugs

Insulin product	Enrollees	Claims
Vial	139	541
KwikPen	420	2,672

[22]Number of 2024 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

Price for the drug

ORS 646A.694(1)(c) and OAR 925-200-0020(1)(c) & (2)(e), (f), & (g). Data source from Medi-Span, APAC, and carrier data call.

This section examines the pricing dynamics of insulin products, drawing on multiple data sources to characterize historical price trends and implications for affordability. It includes an analysis of the drug's wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC). Together, the data provides a comprehensive view of insulin list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

Price history

WAC per 30-day supply was calculated with unit WAC from Medi-Span and was reviewed as an indication of historic price trends for the drugs. However, WAC does not account for discounts, rebates, or other changes to the drug's cost throughout the supply chain.

Table 16 30-day supply for Review Drugs

	Vial	KwikPen
30-day supply[23]	600 U	600 U
Reference NDC	00002850101	00002882427

Table 17 2019-2025 WAC for review drugs per 30-day supply[24]

Year	Vial	KwikPen
2019	$89	$115
2020	$89	$115
2021	$89	$115
2022	$89	$115
2023	$89	$115
2024	$89	$115
2025	$89	$115
Avg. Annual % Change	0%	0%
% change 2019 and 2025	0%	0%

The WAC of the insulin products was based off two reported NDC's.

[23] 600 U refers to how many units a patient needs in 30 days.
[24] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.

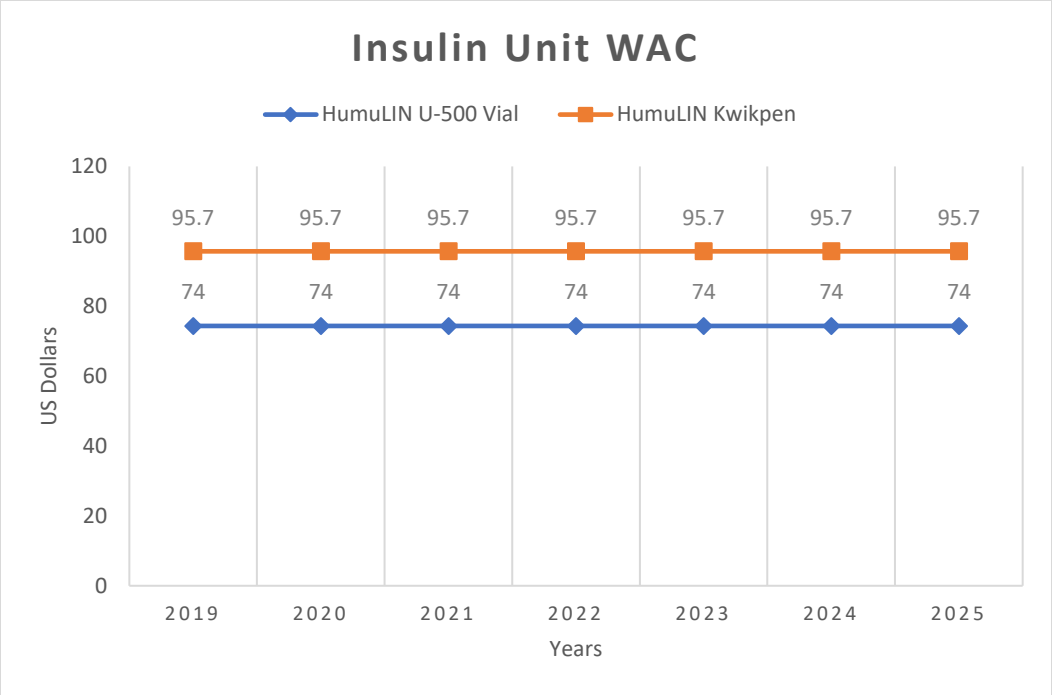


Figure 1 Unit WAC of insulins from 2019-2025

Table 18 Percent change of WAC of review drugs with CPI comparison

Year	Vial	KwikPen	CPI-U
2019-2020	0%	0%	0.7%
2020-2021	0%	0%	5.3%
2021-2022	0%	0%	9.0%
2022-2023	0%	0%	3.1%
2023-2024	0%	0%	3.0%
2024-2025	0%	0%	2.7%

Pharmacy acquisition costs

Two products were found in the AAAC data and are listed below.

While WAC provides a standardized benchmark of list price, it does not account for negotiated price concessions. In contrast, the AAAC offers a more representative estimate of the point-of-sale price incurred by Medicaid payers in Oregon, derived from regular pharmacy surveys conducted by the Oregon Health Authority. Monitoring these trends over time contextualizes drug price trajectory relative to inflation and affordability for public and private payers.

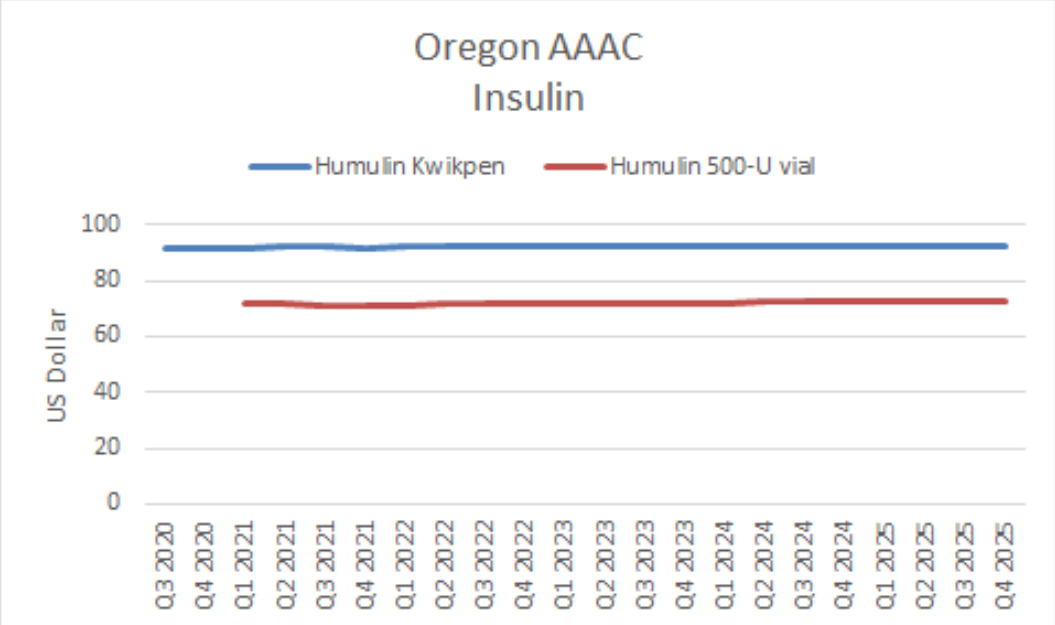
Table 19 2020-2025 AAAC Medicaid FFS quarterly purchase prices for Humulin R U-500 concentrated vial

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Unit WAC
2021	$72	$72	$71	$71	$71	$74
2022	$71	$71	$71	$72	$72	$74
2023	$72	$72	$72	$72	$72	$74
2024	$72	$73	$73	$73	$72	$74
2025	$73	$73	$73	$73	$73	$74

Table 20 2020-2025 AAAC Medicaid FFS quarterly purchase prices for Humulin R U-500 KwikPen

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Unit WAC
2020	-	-	$92	$92	$92	$96
2021	$92	$92	$92	$92	$92	$96
2022	$92	$92	$92	$92	$92	$96
2023	$92	$92	$92	$92	$92	$96
2024	$92	$92	$92	$92	$92	$96
2025	$92	$92	$92	$92	$92	$96

Figure 2 AAAC for insulin products from Q3 2020 to Q4 2025



Estimated average monetary price concession

ORS 646A.694(1)(d) and OAR 925-200-0020(1)(d) & (2)(d) & (2)(L)(A-B). Data source information provided from carrier data call.

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to insulin product claims in the commercial market. Drawing on data submitted through the carrier data call, it evaluates the extent to which these concessions reduced gross drug costs and estimates the average net costs to payers after adjustments. The analysis includes claim-level data on the proportion of claims with applied discounts, and the breakdown of the total concession amounts by type, offering insight into the reduced costs provided through manufacturer, PBM, and other negotiated price reductions.

Based on carrier-submitted data for 2024, the **average gross annual cost per enrollee in the commercial market for the concentrated vial was approximately $13,625 and $10,645 for the KwikPen**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **mean net cost per enrollee declined to approximately $13,257 for the vial and $8,425 for the KwikPen.** The **estimated mean discount for the vial was approximately 2.7 percent and 20.9 percent for the KwikPen** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Humulin R U-500 concentrated vial before concessions was $994,601**, with the total **price concessions amounting to approximately $26,824**. The **total cost of the KwikPen before concessions was $819,677**, with the total **price concessions amounting to approximately $170,919**, as detailed in Table 20.

Table 21 Net cost price concession estimates based on 2024 carrier-submitted data

	Vial	KwikPen
Total number of enrollees	73	77
Total number of claims	274	344
Total number of claims with price concessions applied	61	300
Percentage of claims with price concessions applied	22.3%	87.2%
Percentage of cost remaining after concessions	97.3%	79.1%
Percentage of discount	2.7%	20.9%
Manufacturer price concessions for all market types	$17,145	$135,173
PBM price concessions for all market types	$9,680	$35,745
Other price reductions for all market types	$0	$0

	Vial	KwikPen
Cost before price concessions across all market types	$994,601	$819,677
Total price concessions across all market types	$26,824	$170,919
Cost after price concessions across all market types	$967,777	$648,759
Mean cost per enrollee without price concessions	$13,625	$10,645
Mean cost per enrollee with price concessions	$13,257	$8,425

Including all market segments, the **highest gross average spend** of Humulin R U-500 products was **in the small group with $3,894 per claim for the concentrated vial** before any discounts, rebates, or other price concessions. For the same product, the **net cost per claim after** discounts, rebates, and other price concessions were **$3,822**. This resulted in only a **1.8 percent discount** on the reported price concession in the small group market segment as shown in Table 21.

Table 22 Mean price concessions across market types from data call[25]

Insulin product	Spending	Mean	Individual market	Large group	Small group
Vial	Spend per claim, gross	$3,630	$3,284	$3,629	$3,894
	Spending per claim, net	$3,532	$3,248	$3,521	$3,822
	Price concessions per claim	$98	$36	$109	$72
	Percent discount	2.7%	1.1%	3.0%	1.8%
KwikPen	Spend per claim, gross	$2,383	$3,233	$2,257	$2,099
	Spending per claim, net	$1,886	$2,637	$1,781	$1,606
	Price concessions per claim	$497	$596	$476	$494
	Percent discount	20.9%	18.4%	21.1%	23.5%

[25] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers.

Estimated total amount of the price concession to PBMs

ORS 646A.694(1)(e) and OAR 925-200-0020(1)(e) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source carrier data call.

This section is intended to quantify the total discounts, rebates, or other price concessions provided by the manufacturer of insulin products to each pharmacy benefit manager, expressed as a percentage of the drug price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market.

The statutory and regulatory criteria calls for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through improved reporting or additional disclosures from manufacturers, PBMs, and payers.

Estimated price for therapeutic alternatives[26]

ORS 646A.694(1)(f) and OAR 925-200-0020(1)(f), (2)(c) & (2)(m). Data source information provided from APAC.

This section is intended to present information on the estimated spending associated with insulin products and any therapeutic alternatives using data from APAC and the 2024 data call. At the time of this review, there are **no clinically appropriate therapeutic alternatives** to the insulin products under review. As a result, no comparative spending analysis for therapeutic alternatives could be conducted.

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to the absence of therapeutic alternatives for these insulin products, this analysis was not performed. Future reviews will incorporate comparative data if clinically recognized alternatives become available.

Estimated average price concession for therapeutic alternatives

ORS 646A.694(1)(g) and OAR 925-200-0020(1)(g) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement.

This section addresses the estimated average of discounts, rebates, or other price concessions associated with therapeutic alternatives to insulin products, as compared to the subject drug

[26] The definition of therapeutic alternative is 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. ORS 925-200-0020(2)(c).

itself. At the time of this review, there are no therapeutic alternatives available to assess the average price concessions in the Oregon market.

Estimated costs to health insurance plans

ORS 646A.694(1)(h) and OAR 925-200-0020(1)(h) & (2)(h) & (m). Data source information provided from APAC and data call.

This section quantifies the aggregate financial impact of insulin products on health insurance plans in Oregon, based on claims and expenditure data from APAC and the 2024 carrier data call. Costs are delineated by payer type—including commercial plans, Medicaid, and Medicare—as well as by net costs from market segment submitted by 11 commercial plans. These estimates highlight the distribution of expenditures across different types of health coverage and inform assessments of the drug's budgetary implications for public and private payers.

In 2024, the Oregon APAC database recorded **541 total claims for Humulin R U-500 concentrated vial for 157 total enrollees**, corresponding to a **total payer expenditure of nearly $1.5 million.** Across all payer types, **Medicare had the most enrollees and the largest spend at $655,116**.

The Humulin R U-500 KwikPen had **2,672 total claims** for **490 total enrollee**s and a **total gross payer paid nearly $4.9 million.** Across all payer types, **Medicare had the most enrollees and the largest spend at nearly $2.1 million**.

Table 23 Estimated concentrated vial 2024 APAC total annual gross payment, total enrollees, and total claims[27]

Payer line of business	Total enrollees	Total claims	Total payer paid	Percent of total payer spend by LOB
Commercial	57	196	$571,701	39.0%
Medicaid	36	110	$237,572	16.2%
Medicare	64	235	$655,116	44.7%
Totals[28]	**157**	**541**	**$1,464,389**	-

[27] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

[28] The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

Table 24 Estimated KwikPen 2024 APAC total annual gross payment, total enrollees, and total claims[29]

Payer line of business	Total enrollees	Total claims	Total payer paid	Percent of total payer spend by LOB
Commercial	126	740	$1,328,709	27.2%
Medicaid	143	979	$1,502,246	30.7%
Medicare	221	953	$2,055,469	42.1%
Totals[30]	**490**	**2,672**	**$4,886,424**	-

Table 26 compares the overall payer **cost per enrollee** of insulin products, distinguished by lines of business. **KwikPen has the highest mean cost per enrollee at $11,634,** across all lines of business, but has the lower median cost per enrollee at $8,385, compared to the concentrated vial's median per enrollee at $9,109.

Table 25 Estimated 2024 APAC payer annual gross cost per enrollee of the review drugs[31]

Insulin product	Vial	KwikPen
Commercial cost/enrollee	$10,030	$10,545
Medicaid cost/enrollee	$6,599	$10,505
Medicare cost/enrollee	$10,236	$9,301
Mean[32] cost/enrollee	**$10,535**	**$11,634**
Median cost /enrollee	$9,109	$8,385
Inter-quartile range (IQR)	$11,683	$13,418
Cost per enrollee, 75th percentile	$15,650	$16,876
Cost per enrollee, 95th percentile	$21,268	$31,866

Table 27 compares the overall payer cost per claim, distinguished by lines of business. **The concentrated vial has the highest mean cost per claim at $2,707,** and the **highest median cost per claim at $2,612**.

[29] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[30] The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.
[31] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[32] The overall mean cost per enrollee across commercial insurers, Medicaid, and Medicare.

Table 26 Estimated 2024 APAC payer annual gross cost per claim of the review drugs

Insulin product	Vial	KwikPen
Commercial cost/claim	$2,917	$1,796
Medicaid cost/claim	$2,160	$1,534
Medicare cost/claim	$2,788	$2,157
Cost per claim, mean	**$2,707**	**$1,829**
Cost per claim, median	$2,612	$1,328
IQR	$2,560	$1,302
Cost per claim, 75th percentile	$3,937	$2,239
Cost per claim, 95th percentile	$5,284	$5,161

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. Tables 28 through 33 examine the financial impacts of Humulin R U-500 insulin products through different metrics.

Table 28 provides **claims by commercial health insurance plans** for Humulin R U-500 products, distinguished by market. The **KwikPen has the most claims**, with a total of **344 claims** and large group has 244 reported claims.

Table 27 Estimated data call 2024 claims of review drugs [33]

Insulin product	Individual market claims	Large group market claims	Small group market claims	Total claims
Vial	24	218	32	274
KwikPen	52	244	48	344

Table 29 provides **enrollee count** across all market segments. **The KwikPen has the most enrollees in the large group market, with the total enrollees being at 77.**

Table 28 Estimated data call 2024 enrollees of review drugs

Insulin product	Individual market enrollees	Large group market enrollees	Small group market enrollees	Total enrollees
Vial	7	58	8	73
KwikPen	15	50	12	77

[33] Cost information from the data call is the cost of the drug after price concessions.

Table 30 shows the **overall annual spending** on Humulin R U-500 products by both plans and enrollees, distinguished by market segments. The **concentrated vial** has a **total annual spending of $981,175** with the **large group market being the biggest portion at $780,920**.

Table 29 Estimated 2024 data call annual net spending of the review drugs from all markets

Insulin product	Individual market annual spending	Large group market annual spending	Small group market annual spending	Total net annual spending
Vial	$77,951	$780,920	$122,304	$981,175
KwikPen	$155,727	$501,377	$85,229	$742,333

Table 31 shows the **overall health plan expenditure** on Humulin R U-500, excluding enrollee out-of-pocket payments, distinguished by market segments. The **concentrated vial** has the highest **total health plan expenditure of $972,517** with **the large group market** having the highest enrollment and highest costs.

Table 30 Estimated 2024 data call annual health plan net expenditures of the review drugs from all markets

Proprietary name	Individual market plan paid	Large group market plan paid	Small group market plan paid	Total annual plan paid
Vial	$76,281	$775,182	$121,054	$972,517
KwikPen	$153,007	$493,731	$82,814	$729,552

Table 32 shows the **total enrollee out-of-pocket** distinguished by market segments. The **KwikPen** has the highest **total enrollee OOP cost of $12,781** with **the large group market being the biggest portion at $7,646**.

Table 31 Estimated 2024 data call annual enrollee out-of-pocket cost of the review drugs from all markets

Proprietary name	Individual market enrollee OOP cost	Large group market enrollee OOP cost	Small group market enrollee OOP cost	Total annual enrollee OOP cost
Vial	$1,670	$5,738	$1,250	$8,658
KwikPen	$2,720	$7,646	$2,415	$12,781

Table 33 details the **net average (mean) spend per claim and per enrollee** in total and the amounts paid by enrollees and by health plans across all market segments.

Table 32 Estimated 2024 data call net mean spending in total and by plans and enrollees per claim and per enrollee (annual total) in all markets

Proprietary name	Market	Avg. total paid/ claim	Avg. plan paid/ claim	Avg. enrollee paid/claim	Avg. total paid/ enrollee	Avg. plan paid/ enrollee	Avg. enrollee OOP/ enrollee
Vial	Individual	$3,248	$3,178	$70	$11,136	$10,897	$239
	Large group	$3,582	$3,556	$26	$13,464	$13,365	$99
	Small group	$3,822	$3,783	$39	$15,288	$15,132	$156
KwikPen	Individual	$2,995	$2,942	$52	$10,382	$10,200	$181
	Large group	$2,055	$2,023	$31	$10,028	$9,875	$153
	Small group	$1,776	$1,725	$50	$7,102	$6,901	$201

Impact on enrollee access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

This section summarizes information reported by carriers regarding plan design features that relate to coverage of insulin products, including prior authorization requirements, step therapy protocols, and formulary placement. The data describes how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the following plan design features were observed for Humulin R U-500 products. Approximately **25 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **zero percent of plans required step therapy**.

For formulary placement, **zero percent of plans** indicated Humulin R U-500 products were on a non-preferred formulary and **1.4 percent of plans did not cover the concentrated vial**.

Table 33 Plan design analysis from 2024 data call

Insulin products	Required prior authorization	Required step therapy	On a non-preferred formulary	Not covered
Vial	25.0%	0.0%	0.0%	1.4%
KwikPen	24.6%	0.0%	0.0%	0%

Note: percentages can equal over 100 percent as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in the small group market that require prior authorization but two other plans in the small group market that do not require prior authorization.

Relative financial impacts to health, medical or social services costs

ORS 646A.694(1)(j) and OAR 925-200-0020(1)(j) & (2)(i)(A-B). Limitations in scope and resources available for this statute requirement.

This section addresses the extent to which the use of insulin injection products may affect broader health, medical, or social service costs, as compared to alternative treatments or no treatment. At the time of this review, there was no quantifiable data available to PDAB to assess these relative financial impacts in the Oregon population.

The statutory and regulatory criteria calls for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through carrier reporting, manufacturer disclosures, or other sources.

Future reviews may incorporate findings from real-world evidence, health technology assessments, or economic modeling as such data become available.

Estimated average enrollee copayment or other cost-sharing

ORS 646A.694(1)(k) and OAR 925-200-0020(1)(k) & (2)(j)(A-D). Data source information provided from APAC and carrier data call. Data limitations with patient assistance programs

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for insulin products in Oregon, as reported in 2024 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Tables 35 and 36 presents the average annual enrollee OOP costs derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-enrollee and per-claim and OOP gross costs. For example, **Medicare enrollees recorded higher average annual OOP costs**.

Table 34 Annual out-of-pocket cost per enrollee by line of business (light green table header) and descriptive statistics for total market (dark green table header) [34]

Insulin product	Commercial	Medicare	Medicaid	Mean[35]	Median[36]	IQR	75th percentile	95th percentile
Vial	$121	$213	$0	$148	$30	$140	$140	$420
KwikPen	$150	$131	$0	$114	$2	$105	$105	$442

Table 35 Annual out-of-pocket cost per claim by line of business (light green table header) and descriptive statistics for total market (dark green table header)[37]

Insulin product	Commercial	Medicare	Medicaid	Mean[38]	Median	IQR	75th percentile	95th percentile
Vial	$35	$58	$0	$38	$0	$40	$40	$105
KwikPen	$25	$30	$0	$18	$0	$0	$0	$85

Clinical information based on manufacturer material

ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L). Information provided from manufacturers and information with sources from contractor(s).

Drug indications[39]

- FDA approved: Humulin R U-500 is a concentrated human insulin indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus requiring more than 200 units of insulin per day.

- Limitation of use:
    - Safety and efficacy when used in combination with other insulins has been determined.

[34] Based on 2024 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[35] Includes summation of copay, coinsurance, and deductible across all from all markets across all claims.
[36] Median represents the middle value of the data set when arranged in ascending order.
[37] Based on 2024 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[38] Includes summation of copay, coinsurance, and deductible across all from all markets across all claims.
[39] U.S. Food & Drug Administration. Humulin R U-500 prescribing information. Revised 12/2015. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/018780s135s152lbl.pdf.

    - Safety and efficacy when delivered by continuous subcutaneous infusion has been determined.

- Dosage and route:
    - 500 units/mL concentrated human insulin
    - Available as a 3 mL single-patient-use KwikPen containing 1,500 units of insulin and a 20 mL multiple-dose vial containing 10,000 units of insulin.
    - Administered subcutaneously, usually two or three daily approximately 30 minutes before meals.

Clinical efficacy

Humulin R U-500 is a concentrated human insulin product used in patients with diabetes who require more than 200 units of insulin per day. Insulin lowers blood glucose by stimulating peripheral glucose uptake by skeletal muscle and fat and inhibiting hepatic glucose production. It also inhibits lipolysis and proteolysis and enhances protein synthesis.[40]

In pharmacodynamic data from an euglycemic clamp study of 24 healthy obese subjects, single doses of Humulin R U-500 had a mean onset of action of less than 15 minutes and a mean duration of action of 21 hours, with a reported range of 13 to 24 hours. The FDA label states the time-action characteristics reflect both prandial and basal activity, attributed to the high concentration of the preparation.[41]

The dose is individualized and titrated based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal. Dose adjustments may be needed with changes in physical activity, meal patterns, renal or hepatic function, medications, or acute illness to reduce the risk of hypoglycemia or hyperglycemia.

Clinical safety

- FDA safety warnings and precautions:
    - Hyperglycemia, hypoglycemia, or death due to dosing errors with the vial presentation.
    - Never share insulin syringe between patients
    - Hyperglycemia or hypoglycemia with changes in insulin regimen
    - Hypersensitivity reactions
    - Hypokalemia
    - Fluid retention and heart failure with concomitant use of PPAR-gamma agonists, including thiazolidinediones.

- Contraindications:
    - During episodes of hypoglycemia

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[40] U.S. Food & Drug Administration. Humulin R U-500 prescribing information. Revised 12/2015. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/018780s135s152lbl.pdf.
[41] Ibid.

    - Hypersensitivity to Humulin R U-500 or any excipients

- Common or reported adverse reactions:
    - Hypoglycemia
    - Allergic reactions, including severe generalized allergies and anaphylaxis
    - Lipodystrophy
    - Localized cutaneous amyloidosis
    - Injection site reactions
    - Weight gain
    - Peripheral edema
    - Anti-insulin antibody development

- Safety considerations for specific populations:
    - Pediatric use is supported for patients requiring more than 200 units of insulin per day, based on evidence from studies with other human insulin products in pediatric patients with type-1 diabetes and studies in adults with diabetes.
    - Conservative dosing is advised in geriatric patients to avoid hypoglycemia.
    - Frequent glucose monitoring and insulin dose reduction may be required in renal or hepatic impairment.

Comparative clinical efficacy

The FDA label does not provide head-to-head comparative clinical efficacy data between Humulin R U-500 concentrate and Humulin R U-500 KwikPen. The products contain the same concentration of insulin, 500 units/mL, and differ by delivery presentation: prefilled KwikPen or multiple-dose vial.

The KwikPen presentation dials in 5-unit increments and delivers a maximum dose of 300 units per injection. No dose conversion is required when using the KwikPen or the U-500 insulin syringe with the vial presentation. The label specifically warns not to transfer Humulin R U-500 from the KwikPen into any syringe due to the risk of overdose and severe hypoglycemia.

The FDA label also states that the safety and efficacy of Humulin R U-500 used in combination with other insulins or delivered by continuous subcutaneous infusion has not been determined.

Input from specified stakeholders

ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

See Appendix for all stakeholder comment letters.

Survey-style feedback forms were posted on the PDAB website from April to August 2026, to collect voluntary information about drugs under review from stakeholders including patients, caregivers, and advocacy groups; individuals with scientific or medical training; safety net providers; pharmaceutical manufacturers; pharmacy benefit managers; and health insurers. This

section summarizes the input received for specific drugs. The 2026 community outreach report summarizes additional general input about drug prices and patient experiences.

Patients and caregivers

Note: The information presented is based on self-reported survey responses from individuals prescribed certain medications. Participation in the survey was voluntary, and the responses reflect the individual's personal understanding and interpretation of the question asked. As such, the data may contain inconsistencies or inaccuracies due to varying levels of comprehension, recall bias, or misinterpretation of question intent. These limitations should be considered when interpreting the responses.

Limited patient/caregiver feedback was received for Humulin R U-500, consisting of one caregiver response regarding the KwikPen formulation. The respondent reported long-term daily use of the medication (>3 years) with coverage through an employer-sponsored insurance plan.

The respondent reported affordability and access concerns despite insurance coverage, including increase out-of-pocket costs over the past year, insurance related barriers, and medication shortages/backorders. The respondent also indicated delaying prescription fills and reducing medication use due to cost concerns, though the medication had not been discontinued.

While limited in number, the feedback suggests that ensured patients using concentrated insulin products may still experience barriers related to insurance coverage and continuity of access, particularly during periods of insurance transition or supply disruption.

"Most of our issues with this medication came during a change in insurance coverage. Why does a medication that costs less than $5 to manufacture per 10 ml vial cost over $1700.00 for a month's supply of 2-4 packs of pens? Regardless of whether insurance covers all or most of that cost isn't the issue. The issue is how did we build a system that cares so little about people's health in comparison to the profit margin and yearly bonuses."

Individuals with scientific or medical training

One individual with scientific or medial training provided feedback. The respondent reported that Humulin R U-500 provides substantial clinical benefit for patients with high insulin requirements and indicated that the supporting evidence for its use is strong and guideline-supported. However, the respondent also noted that utilization management requirements, including step therapy and quantity limits, frequently delay patient access and create significant administrative burden for providers and pharmacies.

The respondent reported that patient costs frequently result in delayed or declined treatment and have a major negative impact on medication adherence. While the medication was viewed as having moderate overall value relative to its cost, affordability concerns were identified as an important barrier to patient access. Additional comments emphasized concerns regarding

insurance-related barriers, healthcare access challenges, and the need for greater investment in prevention and health education efforts.

Safety net providers

No survey information has been received from safety net providers about this drug as of the last update of this document.

Manufacturers

One manufacturer response was received regarding Humulin R U-500 concentrated insulin products. The manufacturer provided information for both the KwikPen and the concentrated vial. According to the manufacturer, the Humulin R U-500 concentrated vial is currently not marketed in the United States, while the KwikPen remains commercially available in Oregon.

The manufacturer reported that no generic or biosimilar versions of either product have been approved and that the products do not currently have FDA-recognized market exclusivity. They indicated that multiple FDA-approved therapeutic alternatives are available. The manufacturer also noted that rebates and discounts are offered to pharmacy benefit managers, health insurers, wholesalers, and other health care entities, as well as patient financial assistance programs, including copay assistance, patient assistance programs, and free or replacement drug programs.

According to the survey information, Humulin R U-500 products are commonly subject to utilization management requirements, and current pricing is aligned with their clinical value. Additional comments highlighted Lilly's insulin affordability initiatives, including manufacturer-sponsored programs intended to reduce patient out-of-pocket costs and improve access to insulin therapy.

Pharmacy benefit managers

No survey information has been received from PBMs about this drug as of the last update of this document.

Health insurers

No survey information has been received from health insurers about this drug as of the last update of this document.

Appendix

Stakeholder feedback:

Table 36 Feedback

Name of writer	Association to drug under review	Drug	Format	Date	Exhibit website link
Rachel Dolan	Manufacturer	Humulin R U 500	Letter	6/15/2026	Click to view the letter.