

Prices for Leading Insulins Will Likely Not Be Negotiated Under New Drug Pricing Package

The prices for leading insulins used by hundreds of thousands, if not millions, of Medicare beneficiaries are unlikely to be negotiated in the mechanism outlined in the new reconciliation drug price reform package.¹ Unlike the Build Back Better Act, the new package excludes insulin-specific negotiation requirements and, instead, treats insulin like other drugs.

Under the new bill, negotiations are limited to single-source drugs that do not have generic or biosimilar competition.² Three popular insulins—insulin glargine (Lantus); insulin aspart (Novolog); and insulin lispro (Humalog)—either already have or are expected to have biosimilar competition before the negotiation mechanism is set to apply (Table 1). All three insulins would thus likely fail to qualify as single source drugs eligible for negotiation.

Table 1: Competition for leading insulin brands

Brand Name	Insulin Name	Competitive Landscape ³
Lantus	Insulin glargine	Interchangeable biosimilar (Semglee) ⁴ and follow-on biologic (Basaglar)
Novolog	Insulin aspart	Mylan/Biocon biosimilar candidate subject to regulatory authorization ⁵
Humalog	Insulin lispro	Follow-on biologic approved (Admelog); biosimilars in clinical pipeline ⁶

While competition is helpful, the limited competition expected (one or two competitors) may not deliver the significant price reductions typically associated with more competitors. Further, in the case of insulin, both prescription drug corporations and pharmacy benefit managers have incentives to keep prices high. A combination of biosimilar competition and price negotiation would be more effective in delivering significant price reductions.

In 2020, Medicare spent billions of dollars before rebates purchasing huge volumes of these leading insulins for many beneficiaries (Table 2). To protect insulin users, Congress can restore the requirement to negotiate insulin product prices in the reconciliation drug price reform package.

Table 2: Spending and use of leading insulin brands (2020)⁷

Brand Name	Part D Spending	Part D Total Claims	Part D Total Beneficiaries
Insulin Glargine (Lantus)			
Lantus Solostar	\$2,663,360,231.80	4,583,923	1,002,500
Lantus	\$1,055,722,607.00	1,821,215	378,001

¹ Because insulin users may use multiple products in combination, the number of total Medicare beneficiaries using the three insulin products is not immediately clear.

² “A qualifying single source drug” must be a biologic that is not “not the reference product for any biological product that is licensed and marketed under section 351(k).” There are also other eligibility restrictions.

³ The bill excludes negotiations for products with biosimilars licensed using a 351(k) application. Whether and how CMS will interpret the introduction of follow-on biologics (which represent 351(a) applications) remains unclear.

⁴ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes>

⁵ <https://www.cnbc.com/healthcare/us-fda-asking-for-more-data-on-insulin-aspart-see-no-commercial-impact-of-application-rejection-biocon-12069932.htm>

⁶ <https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/biosimilars-page/sgs-biosimilars-usmarketlandscape-053122.pdf>

⁷ <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data>. We categorize products based on brand name, but CMS may interpret products in a different way.

Insulin Aspart (Novolog)			
Novolog Flexpen	\$1,844,084,368	2,265,569	585,300
Novolog	\$595,182,275	851,731	202,965
Novolog Mix 70-30 Flexpen	\$421,364,939	373,649	78,223
Insulin Aspart Flexpen	\$30,872,498	126,542	56,064
Insulin Aspart	\$11,784,405	53,350	24,803
Novolog Mix 70-30	\$112,025,124	120,938	24,734
Insulin Aspart Prot-Insulin Asp	\$5,499,159	14,916	5,805
Insulin Aspart Penfill	\$136,607	381	241
Insulin Lispro (Humalog)			
Humalog Kwikpen U-100	\$1,053,915,810	1,276,804	384,871
Humalog	\$449,251,292	759,810	192,852
Insulin Lispro Kwikpen U-100	\$141,621,808	454,776	153,626
Insulin Lispro	\$55,755,528	194,851	66,303
Humalog Mix 75-25 Kwikpen	\$277,054,166	258,489	53,831
Humalog Kwikpen U-200	\$154,533,157	116,218	30,870
Humalog Mix 75-25	\$89,208,218	103,461	19,228
Insulin Lispro Protamine Mix	\$9,342,252	18,372	6,802
Humalog Mix 50-50 Kwikpen	\$24,113,084	20,412	4,241
Humalog Junior Kwikpen	\$6,145,479	10,392	3,832
Humalog Mix 50-50	\$10,144,997	11,129	1,932
Insulin Lispro Junior Kwikpen	\$325,269	1,167	664
Lyumjev Kwikpen U-100	\$326,193	390	299
Lyumjev	\$193,210	196	123
Lyumjev Kwikpen U-200	\$49,352	41	26