

# Why Insulin Is So Expensive For Some and Not For Others

In early 2021, the United States Senate Finance Committee released a report examining the factors that have led to the significant rise in Insulin drug prices over the course of the 21<sup>st</sup> century<sup>1</sup>. This paper summarizes the key findings from the Committee report and describes the motivations and outcomes for the main stakeholders in the U.S. pharmaceutical supply chain.

### **Drivers of the Increase in Insulin Prices**

When discussing the cost increases of any drug, there are two different prices to consider:

- Wholesale Acquisition Cost (WAC) The WAC, or list price, is the price the drug manufacturer sets for the drug. The WAC price, however, is not the amount the manufacturer receives, nor is it the amount paid by the Federal government, health insurers, or employers. The WAC price is the starting point that manufacturers use to negotiate with stakeholders further down the pharmaceutical supply chain.
- 2. <u>"Net" Price</u> This is the price the manufacturer actually receives after reductions for rebates and other types of discounts and guarantees. Unlike the WAC, the net price can vary by payer or even within different product lines for the same payer.

Over the course of the 21<sup>st</sup> century, the WAC and net prices for Insulin drugs have increased significantly<sup>2</sup>. In the early 2010s, a substantial growth in rebates brought the net price down from its peak levels, even as the WAC continued to grow. This dynamic of WACs increasing at a much higher rate than net prices creates more variation of payments made by different stakeholders, and brings greater disparity between the winners and losers of the Insulin supply chain. Figures 1, 3, and 4 show the WAC and net price changes for the Insulin drugs Humalog, Lantus, and Levemir.

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<sup>&</sup>lt;sup>1</sup> Grassley-Wyden. *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug.* January 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

<sup>&</sup>lt;sup>2</sup> Grassley-Wyden Page 6.

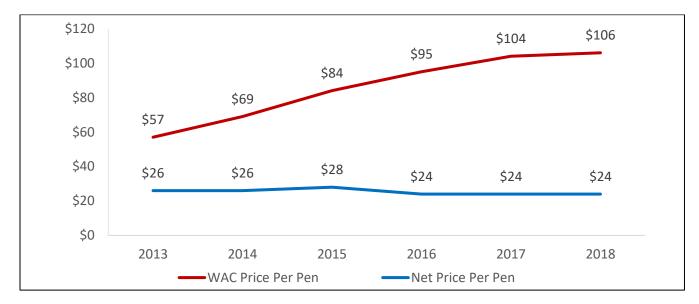


Figure 1: U.S. Humalog U-100 KwikPen WAC and Net Prices by Year, 2013 to 2018<sup>3</sup>

As described in the Committee report, the increase in Insulin WAC is primarily driven by the following factors:

- 1. Pharmaceutical manufacturers have significant control over setting the WAC for their products. With this freedom, manufacturers have increased prices in order to lock in a higher price point for their new Insulin product launches and also to mirror or track competitor price changes (a practice known as "shadow pricing")<sup>4</sup>.
- 2. Competing for preferred formulary placement, manufacturers utilize a pricing strategy of higher WAC and higher rebates (while maintaining similar net prices) to appease Pharmacy Benefit Managers (PBMs)<sup>5</sup>. PBMs administer prescription drug benefits and negotiate with manufacturers for rebates and discounts off the WAC on behalf of health insurers and other payers. PBMs typically collect a portion of the rebate revenue and are paid administrative fees based on a percentage of the WAC. Thus, the PBMs are financially incentivized to work with the manufacturers that offer higher WACs and higher rebates, and PBMs maximize these incentives by giving such drugs better placement on their clients' formularies. See Figure 2 below for an illustration of these dynamics. As shown in this example, the PBM earns more with the "Higher WAC and Rebate" pricing strategy. From the payer's perspective, the cost is essentially the same in both scenarios, lessening the payer's motivation to push for lower WAC drugs.

<sup>&</sup>lt;sup>3</sup> Grassley-Wyden Page 45.

<sup>&</sup>lt;sup>4</sup> Grassley-Wyden Page 6.

<sup>&</sup>lt;sup>5</sup> Grassley-Wyden Page 7.

Figure 2: WAC vs. Net Price Cost Dynamics

	Higher WAC and Rebate	Lower WAC without Rebate
WAC	\$100.00	\$53.50
Rebate – Flows to Payer	\$47.50	\$0.00
Rebate – Retained by PBM	\$2.50	\$0.00
Net Price (Price Manufacturer Receives) <sup>6</sup>	\$50.00	\$53.50
PBM Fees (e.g., 2% of WAC + 5% of Rebate)	\$4.50	\$1.07
Payer Allowed Cost (Net Price – PBM Retained	\$54.50	\$54.57
Rebates + PBM Admin Fees)	\$54.50	\$54.57

From a clinical perspective, most consider Insulins to be interchangeable in their safety, efficacy, and kinetics<sup>7</sup>. Additionally, there are currently no generic Insulin products available to consumers. Without clinical differences or generic disruptors, manufacturers will continue to be able to set WACs at their discretion and compete for formulary placement based on WAC and rebate dynamics.

## **Outcomes for Key Stakeholders**

- Manufacturers As described in the Finance Committee report, the revenue pharmaceutical
  manufacturers are receiving for Insulin is significantly higher than in the early 2000s, even with
  the net price decreasing in recent years.
- PBMs The PBM industry has significantly consolidated in recent years with the three top
  companies serving over 80% of the Medicare Part D and commercial markets<sup>8</sup>. Through this
  consolidation, PBMs command significant negotiation power and have been able to use this
  leverage to steer the Insulin pricing dynamics to their direct advantage.
- Health Plans and Other Private Payers Health plans pay the net price of the drug and thus are generally shielded from increases to WAC alone. However, the final outcome for private payers can vary depending on which PBM is used and what rebates or discounts are negotiated. Payers with more bargaining power (more covered members) can command higher rebates than payers with less bargaining power. In some cases, different books of business at the same company can receive different levels of rebates<sup>9</sup>. For plans aligned with larger PBMs that have more bargaining power, the net price for Insulin will likely be less than what other plans pay.

<sup>&</sup>lt;sup>6</sup> In this example, the manufacturer gives up \$3.50 per script of revenue in return for the drug to receive preferred pharmacy placement on the PBM's formularies.

<sup>&</sup>lt;sup>7</sup> Grassley-Wyden Page 36.

<sup>&</sup>lt;sup>8</sup> Grassley-Wyden Page 31.

<sup>&</sup>lt;sup>9</sup> Grassley-Wyden Page 44.

Health plans operating in Medicare Part D can particularly benefit from the higher WAC and higher rebate dynamics. In the coverage gap and catastrophic zones, the portion of the rebate kept by the plan can be larger than the plan's share of the claim cost.

- Consumer In general, rebates are not shared at the point-of-sale and are not used to reduce the price consumers pay for their specific drugs. However, the impact to consumers can vary depending on the insurance the consumer has. The impact to consumers is very important as both the growing cost and the increased use of formulary exclusions can contribute to poor member adherence and result in avoidable complications and higher costs for the U.S. health care system overall.
  - Copays vs. Coinsurance Consumers subject to cost sharing in the form of copays would likely not feel the impact of higher Insulin WACs as much as consumers who are charged a percentage of the WAC.
  - Larger vs. Smaller Payers As discussed above, smaller payers may not be able to command as favorable a net price as organizations with greater market share. These plans may need to collect more member cost sharing or premiums to make up the cost difference.
  - Medicare Part D While the benefit designs of Medicare Part D plans can vary significantly, prior to the implementation of the Senior Savings Model in 2021, most beneficiaries were at least subject to 25% coinsurance for all drug costs in the coverage gap benefit phase. The higher WACs for Insulin will bring Part D beneficiaries to the coverage gap quicker and subject the members to more spending in this phase. See Appendix Figure 6 for additional detail.
  - No Insurance Consumers without any form of insurance would be liable for the entirety
    of the WAC increase unless the manufacturer offers a direct coupon for the uninsured.

#### Government Programs

- Medicare Part D Based on data provided by Centers for Medicare and Medicaid Services (CMS), annual Part D spending on Insulin has increased by billions of dollars from 2010 to 2020 prior to rebates<sup>10</sup>. See Appendix Figure 5 for additional detail. Medicare does share in some of the higher rebates, but given Medicare's 80% liability in the catastrophic benefit phase, Medicare typically will pay higher net costs as WAC increases.
- Medicaid (Medicaid Drug Rebate Program (MDRP)) Manufacturers seek to avoid triggering Medicaid "best price" when developing their bids for commercial plans. Higher net prices flow through to the "best price" relevant to the MDRP.

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<sup>&</sup>lt;sup>10</sup> Grassley-Wyden Page 47.

## **Future Changes to Insulin Supply Chain**

The rise of Insulin prices has generated a lot of attention, resulting in reform proposals from both government and private stakeholders. We have highlighted below a few areas that have started and may continue to drive change in the Insulin pricing dynamics.

- Medicare Part D Senior Savings Model (PDSSM) The PDSSM was introduced to Medicare Part
  D for the 2021 payment year by CMS in order to reduce beneficiary spending for Insulin drugs.
  The new model is designed to limit the cost sharing for beneficiaries in all Part D benefit phases
  to \$35 or less per script. Shifting more of the cost to the manufacturers and the Part D plan
  sponsor. The model saw broad participation from all three major Insulin manufacturers and many
  Part D plans.
- 2. Rebates at the Point of Sale (POS) Proposed rules to bring rebates to the POS in Medicare have been introduced by HHS several times. While not currently law, requirements to offer rebates at the POS would allow Insulin patients to more directly share in the rebates and align the price the plans pay with the price paid by other stakeholders. See the Wakely white paper for more detail on the impact of moving rebates to the POS.
- 3. <u>Biosimilars</u> While there are still no Insulin generics, the FDA approved the first interchangeable biosimilar Insulin product for the treatment of diabetes in late July 2021<sup>12</sup>. If offered with a WAC less than the brand biologic net price, the biosimilars can bring the opportunity for significant savings to consumers by increasing competition and driving net cost savings.

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<sup>11</sup> https://www.wakely.com/sites/default/files/files/content/return-pos-rebates\_0.pdf

<sup>&</sup>lt;sup>12</sup> https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-Insulin-product-treatment-diabetes

## **Appendix**

The following tables are included in the Appendix:

- Figure 3: WAC Price of Sanofi's Lantus and Novo Nordisk's Levemir (2014 2019) The WACs of Lantus and Levemir pens increased by over \$100 from March 2014 to January 2019. The price increases of the two drugs occurred at similar times.
- <u>Figure 4: Lantus Price Evolution</u> The Lantus WAC increased by 245.2% from 2007 to 2016. The net price of Lantus peaked at a 94.8% increase from 2007 levels in 2014, but was eventually lowered to a 42.9% increase from 2007 levels in 2016.
- Figure 5: Medicare Spending on Insulin by Brand Gross of Rebates (2010 2018) Medicare Part D spending on Insulin drugs, prior to rebate reductions, has increased by over \$11B from 2010 to 2018.
- Figure 6: Out-of-Pocket Costs for Beneficiaries Enrolled in Medicare Part D MAPD and PDP Plans
   (Insulin Only) In 2010, less than 5% of Medicare Part D Beneficiaries taking Insulin had out of
   pocket costs for their Insulin drugs over \$5,000. In 2018, nearly 30% of Beneficiaries taking Insulin
   were spending over \$5,000 on their Insulin drugs.

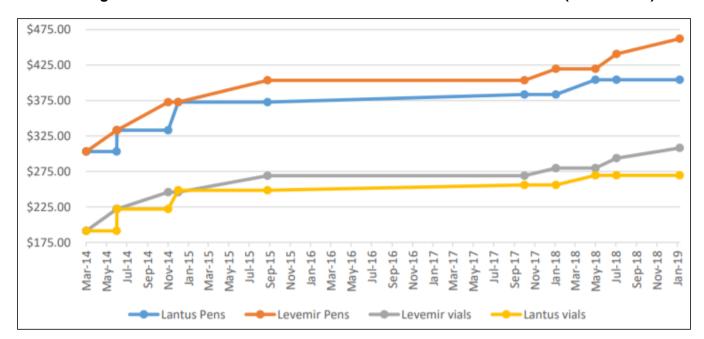


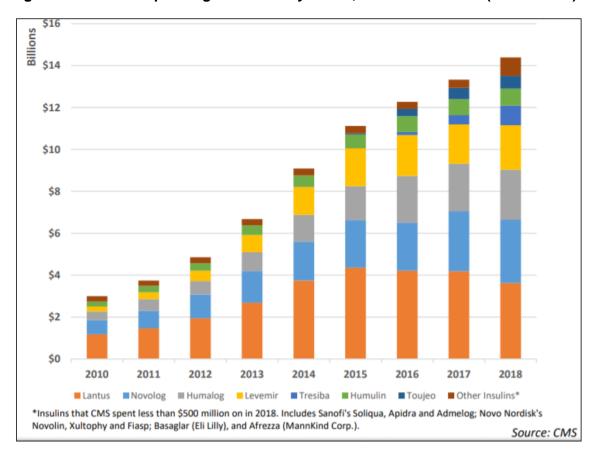
Figure 3: WAC Price of Sanofi's Lantus and Novo Nordisk's Levemir (2014 - 2019)<sup>13</sup>

<sup>&</sup>lt;sup>13</sup> Grassley-Wyden Page 43.

CPI Act NS VOL Price WAC GTN Δ WAC Net Growth vs 2007 Growth Growth 2005 3% 57.35 2006 40% 19% 20% 15% 5% 3% 29 184 155 64.67 54.97 2007 30% 167 71.96 61.22 WAC NET 17% 13% 13% 0% 3% 35 132 2008 31% 14% 4% 236 174 83.04 68.81 15.4% 12.4% 16% 18% -3% 62 2009 24% 14% 10% 12% -3% 0% (9) 207 215 91.95 74.66 27.8% 22.0% 2010 7% 4% 3% 10% -7% 2% 76 34 100.64 76.72 39.9% 25.3% 42 2011 15% 11% 4% 10% -6% 3% 91 109 18 109.98 79.37 52.8% 29.7% 2012 22% 6% 16% 19% -4% 2% 68 508 439 130.05 91.03 80.7% 48.7% 2013 26% 19% 25% -6% 2% 59 754 694 107.27 122.6% 75.2% 7% 160.16 2014 12% 1% 11% 35% -24% 2% 80 563 484 215.74 119.28 199.8% 94.8% 2015 -20% 1% -21% 15% -37% 0% 6 (1,202)(1,208)248.41 93.97 245.2% 53.5% 2016 -13% -6% -6% 0% -7% 1% 45 (290)(334)248.45 87.48 245.2% 42.9% \$ 304 731 \$ 428

Figure 4: Lantus Price Evolution<sup>14</sup>

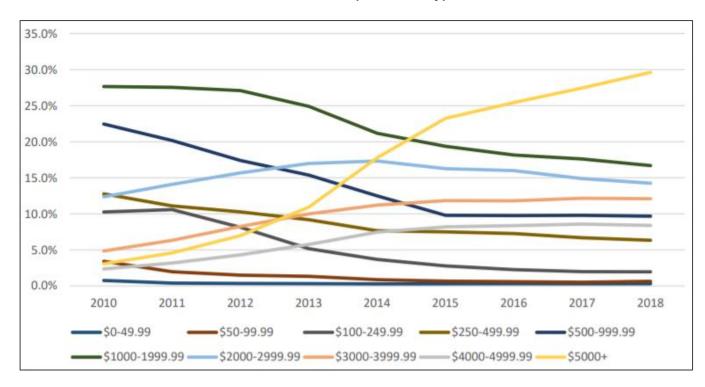
Figure 5: Medicare Spending on Insulin by Brand, Gross of Rebates (2010 - 2018)<sup>15</sup>



<sup>&</sup>lt;sup>14</sup> Grassley-Wyden Page 46.

<sup>&</sup>lt;sup>15</sup> Grassley-Wyden Page 47.

Figure 6: Out-of-Pocket Costs for Beneficiaries Enrolled in Medicare Part D MAPD and PDP Plans (Insulin Only)<sup>16</sup>



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<sup>&</sup>lt;sup>16</sup> Grassley-Wyden Page 49. This table shows the percent of Medicare Part D Beneficiaries taking Insulin Drugs (Y-Axis) at different Out-Of-Pocket spending points (X-Axis). For example, in 2010, between 25%-30% of Part D Beneficiaries taking Insulin Drugs has Out-Of-Pocket spending in the \$1,000-\$1,999.99 range.