# Documents Produced by Novo Nordisk



RAPHAEL ADAM PROBER

March 8, 2019

#### VIA HAND DELIVERY

The Honorable Charles E.Grassley Chairman

The Honorable Ron Wyden Ranking Member

Committee on Finance United States Senate 219 Dirksen Senate Office Building Washington, DC 20515

Dear Chairman Grassley and Ranking Member Wyden,

On behalf of Novo Nordisk Inc. ("NNI"), we write in response to your letter dated February 22, 2019 (the "Letter"), in which you requested information and data related to prescription drug prices. As a company dedicated to improving the lives of people with diabetes and other chronic diseases, NNI shares your concerns about affordability and appreciates your commitment to addressing the complicated landscape of laws, regulations, market forces, and supply-chain entities that impact the price of prescription drugs. As discussed with staff, we continue to gather information and data relevant to the requests in your Letter, and will thereafter supplement this initial response.

By way of background, NNI has already taken meaningful steps to address patient access and affordability. In November 2016<sup>1</sup>, NNI issued its position on pricing and affordability, outlining the three tenets below:

 Limit any potential list price increases on medicines to no more than single digit percentages annually;

<sup>&</sup>lt;sup>1</sup> For more information on NNI's position on pricing and affordability, please see https://www.novonordisk-us.com/whoweare/about-novo-nordisk/our-position-on-pricing-and-affordability.html#



- Work with all involved to simplify and transform the healthcare system, a system currently driven by a complex web of varying insurance and payment models, rebates, discounts, administrative fees, co-pays, and deductibles; and,
- Find ways to lower the out-of-pocket cost to patients as a result of high-deductible health plans or lack of insurance through partnerships, collaborations, or by NNI on its own.

Consistent with these tenets, in March 2017, NNI jointly announced with CVS Health that the pharmacy network would offer Novolin® brand human insulin for \$25/vial through its Reduced Rx savings program in 68,000 pharmacies. Similarly, in April 2017, NNI began offering its Novolin® line of human insulin in ESI's Inside Rx program – accessible at approximately 40,000 pharmacies nationwide – for \$24/vial. For both of these programs, any commercially eligible patient can enroll, regardless of whether they have a benefit or insurance plan through CVS or ESI.

In addition, for over 15 years, NNI has contracted with Walmart to make Novo Nordisk human insulin available at Walmart pharmacies under the ReliOn® brand, which Walmart sells for less than \$25/vial for cash paying patients with or without insurance coverage. In 2018, NNI expanded the Walmart ReliOn® offering to include Novo Nordisk human insulin (Novolin® 70/30) in a pen device. Today, NNI estimates that approximately 500,000 Americans are using Novo Nordisk's human insulin medicines through these types of partnerships.

Since 2003, NNI has had in place the Novo Nordisk Patient Assistance Program ("PAP"), which provides free medicines, including insulins, to lower-income patients who qualify. In 2018, NNI provided free insulin medicines to nearly 60,000 patients through the PAP. NNI also helps patients afford their medicine with co-pay assistance programs, which help lower a commercial patient's out-of-pocket expenses, and provided over \$200 million in co-pay assistance in 2018.

For the Medicaid program, NovoLog<sup>®</sup>, NovoLog<sup>®</sup> Mix, and Levemir<sup>®</sup> insulins are essentially free to the states (rebates are at the 100% cap) and to Medicaid beneficiaries. NNI also provides voluntary supplemental Medicaid rebates for Tresiba<sup>®</sup> in many states. For covered entities under the 340B program, NovoLog<sup>®</sup>, NovoLog<sup>®</sup> Mix, and Levemir<sup>®</sup> are at "penny" pricing, meaning they are effectively free to the 340B entity.



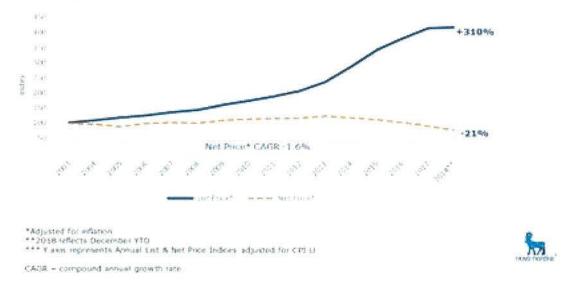
While NNI has been able to reach many patients struggling to afford insulin through these programs, NNI recognizes that more needs to be done. NNI looks forward to being part of the solution, along with all stakeholders in the complex healthcare system, including pharmaceutical companies, pharmacy benefit managers ("PBMs"), insurance companies, employers, patient organizations, and policy makers.

Question 1 of your Letter inquires about, among other things, list and net price for NNI's insulin medicines. By way of background, news reports and other commentary on drug pricing have at times left the incorrect impression that increases in list prices directly correlate to companies like NNI realizing higher profits. The reality is far more complex. In fact, a list price increase by a certain percentage does not lead to a one-for-one corresponding increase in profit for NNI. Rather, after NNI sets the list price, NNI negotiates discounts, rebates, and other price concessions with the payers (these include intermediaries such as PBMs, who negotiate on behalf of employers and health insurers and determine whether NNI's medicines are covered on formulary, and health insurers with whom NNI negotiates directly). Some contracted entities receive a discount up front, when the medicine is purchased, while other payers receive a rebate after NNI's medicines are dispensed. Because of these significant rebates and other price concessions, NNI only realizes a portion of any list price increase. In fact, net prices for NNI's insulin medicines (the amount realized after rebates, discounts, fees and terms provided to payers) have declined year over year for every year from 2015 through 2018, and experienced double-digit declines in 2017 and 2018 as a result of increasing payer demands for higher rebates for formulary access.

By way of example, the following graph shows list and net prices dating back to 2003 for NovoLog® FlexPen.



### NovoLog® FlexPen



As this graph demonstrates, list price increases (factoring in the negotiations and concessions described above), have translated year over year to a -1.6% overall decline in NovoLog® FlexPen net price when adjusted for inflation. Although the price for each of NNI's insulin medicines is unique, the trajectory of flat or declining net prices is consistent across NNI's insulin portfolio.

With specific reference to Question 7, the names and titles of NNI voting members of the Pricing Committee responsible for insulin products are listed in the attached document. For identification and reference, this document has been labeled as NNI-FINANCE-001.

Question 3 of your letter asks about negotiations with PBMs, rebates, and formulary placement. As described above, one of the drivers of the disparity between list prices and net prices is the demand for higher rebates by payers, including PBMs. Rebates are typically calculated not as a fixed amount, but as a percentage of list price, and these percentages have increased significantly in recent years. Moreover, for Part D plans, the rebates NNI provides to



payers for claims dispensed to non-low-income-subsidy patients are on top of mandatory government rebates or discounts, such as the 70% manufacturer liability in the coverage gap discount program. In 2018, across all of NNI's medicines, rebates and discounts consumed 68% of gross sales in the U.S. – up from 64% in 2017, 59% in 2016, 56% in 2015, and 48% in 2014. In other words, in the aggregate, for every dollar in gross sales for NNI's products in 2018, sixty-eight cents was given to payers in the form of rebates and discounts.

Despite the increasing demands from payers, rebates allow NNI, like other manufacturers, to maintain and expand formulary positions and coverage, which in turn ensures that a large portion of patients in the United States, including those covered under Medicare Part D, have broad access to NNI's medicines. As a company, NNI believes that making medicines available to patients is the single most important investment it can make in improving the lives of people with diabetes and other chronic illnesses. Unfortunately, NNI has no ability to control whether the rebates it pays to enable broader access to medicines result in lower out-of-pocket costs for patients. Since employers are under financial pressure to manage the costs of health benefits, they pressure payers (health plans and PBMs) to keep the costs down or at least to moderate the cost growth rate. As a consequence, payers have stated that they pass down portions of the manufacturer rebates to employers, who use them to lower *all* of the plan's premiums and do not necessarily pass along these savings to the patients who depend on NNI's insulin medicines – including those patients with high-deductible plans who are left to pay list prices.

It is also important to recognize that manufacturers do not determine what an individual insured patient pays for their prescriptions. That determination is a function of benefit design. As benefit designs have evolved, there have been unintended consequences of intensified cost management – in particular, higher patient out-of-pocket costs.

Unfortunately, NNI expects that, absent meaningful change to the current healthcare system, rebate pressures will continue to pose challenges due to payer demands and increasing competition to maintain and expand formulary positions and coverage. Although net prices may continue to decline as a result of these pressures, uninsured and underinsured patients are unlikely to realize lower out-of-pocket costs.



With regard to advances in insulin medicines, an issue addressed in Question 2 of your Letter, it is critical to understand that there has been significant and ongoing innovation – including extensive research and development – in this therapeutic space.

For diabetes patients, effective management of blood glucose levels is critical. This effective management for all patients with type 1 diabetes and many with type 2 diabetes requires a significant degree of diligence in order to monitor glucose levels while balancing carbohydrate intake along with appropriate insulin doses. Advances in insulin purification and stability during the mid-20<sup>th</sup> century allowed many patients to dose insulin more accurately, and advances in use of recombinant DNA technology in the 1980s meant that patients requiring insulin would no longer have to depend on bovine or porcine sources in order to control their glucose levels. These human insulin medicines have been effective and affordable options for people who require insulin to lower blood glucose for decades, and are used by millions of Americans and others around the world to help manage their diabetes. However, recent advancements in modern insulin medicines designed by modifying the amino acid structure of human insulin have made it possible for patients to dose their insulin medicines much more closely to what the pancreas would deliver in a person without diabetes. These advancements are particularly important for type 1 diabetes patients or those on intensive insulin regimens. They have allowed patients to dose with fewer or more convenient injection times, and have made it easier for patients to avoid the number one risk of using insulin: low blood glucose or hypoglycemia.

NNI has a continued focus on innovation. In just the last three years, NNI has developed new drugs like Tresiba®—a next-generation, long-acting insulin that has shown improved glucose control benefits alongside a reduction in risk of hypoglycemia—and Fiasp®, a new short-acting insulin that offers quicker onset. These two recent advances specifically have allowed those patients requiring insulin to more safely and effectively control their glucose both overnight as well as around mealtime when the glucose rises quickly after eating. NNI has also created new, more accurate and convenient delivery systems that permit patients to take insulin through pen devices with smaller and less invasive pen needles, rather than with a traditional vial and syringe. NNI continues to invest in research to explore further advances for diabetes patients such as glucose sensitive insulin and oral delivery of insulin. NNI is actively working to integrate dosing data from Bluetooth-connected pen devices into digital platforms to further improve quality of care for insulin-dependent patients.



Innovations like those just described, which allow patients to more safely and effectively manage their diabetes, benefit the individual patient and also lower overall healthcare costs by preventing serious and expensive complications that typically accompany uncontrolled diabetes.<sup>2</sup>

It is important to recognize that, for every medicine that is approved and launched, there are significant financial resources expended on the many other drug candidates studied in clinical trials that do not progress and ultimately come to market. For that reason, investment in research and development cannot be measured only by the costs of bringing drugs to market. As a company committed to finding new therapies to improve patients' lives, NNI has multiple research and development and production sites across multiple therapeutic areas throughout the U.S. (including in New Jersey, Washington, Indiana, New Hampshire, and a new Stem Cell research center in California). NNI is also currently investing over 2 billion dollars in a new production facility in North Carolina. Investments like these make continued innovation possible, contribute to the economy, and create high quality jobs throughout the country.

NNI recognizes the difficulties patients face today affording their insulin and, as described above, NNI is committed to helping find solutions. Despite the challenges of the complicated U.S. healthcare system, NNI has taken steps to make its medicines more accessible and affordable. With respect to Question 8 of your Letter, which asks about internal and external programs NNI uses to assist patients purchasing insulin or obtaining it at no cost, please refer to the Novo Nordisk Patient Assistance Program, co-pay assistance programs, and partnerships with Walmart, CVS, and ESI described above. As previously noted, NNI believes that, within the constraints of the current healthcare system, maintaining and expanding formulary coverage – even where it means providing its medicines at steep discounts – is crucial to affordability as formulary coverage allows a large portion of the U.S. population to access NNI's medicines, including insulin, through reasonable co-pays.

NNI is also actively involved in advocating for policies it believes will help patients who require medication for chronic diseases such as diabetes. NNI joins patient advocacy organizations

<sup>&</sup>lt;sup>2</sup> In Question 2, you request information concerning patents applicable to NNI's insulin medicines. NNI includes a list of product patents on its website. Although this list may not be exhaustive, it references many patents that apply to NNI's insulin medicines, including patents that cover the active ingredient and formulations of its insulin medicines. That page may be found here: https://www.novonordisk-us.com/products/product-patents.html.



and stakeholders across the supply chain to call on Congress to reintroduce and pass the *Chronic Disease Management Act* (H.R. 4978/S.2410 from the 115<sup>th</sup> Congress), to allow for first dollar coverage of medicines that prevent chronic disease progression or complications, such as insulin, on the IRS preventive drug list. This would allow patients with high deductible plans to access their insulin without first having to reach their deductible. In all efforts to address the challenges of the complex U.S. healthcare system, NNI believes that coordination and collaboration among all the players in the supply chain—including payers, PBMs, insurance companies, manufacturers, employers, patient organizations, and policymakers—is critical.

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Production of this and future information and data is not intended to constitute a waiver of the attorney-client, attorney work product, or any other applicable rights or privileges in this or any other forum. NNI expressly reserves its rights in this regard. In addition, certain information responsive to the Committee's requests, and in particular in future submissions, may contain highly sensitive information – potentially including confidential, proprietary, trade secret, and/or material non-public information. Accordingly, NNI requests that such information be kept confidential by the Committee and its staff. Notwithstanding our request that such information be kept confidential, we would ask that staff provide us with notice and an opportunity to be heard before the Committee discloses any such information or data to third parties.

We appreciate our recent conversations with your staff on these matters and look forward to engaging further with the Committee to continue addressing the questions in your Letter. As discussed with your staff, and as described above, certain of these questions may call for sensitive information, and we will raise such issues with staff as appropriate. NNI is committed to working with the Committee to respond to its inquiry and to addressing the complicated issues surrounding drug pricing more broadly. We look forward to working cooperatively with you and your staff in this regard.



Sincerely,

Raphael A. Prober Steven R. Ross

Counsel for Novo Nordisk Inc.

Enclosure



**RAPHAEL ADAM PROBER** 

May 10, 2019

#### VIA HAND DELIVERY

The Honorable Chuck Grassley Chairman

The Honorable Ron Wyden Ranking Member

Committee on Finance United States Senate 219 Dirksen Senate Office Building Washington, DC 20515

Dear Chairman Grassley and Ranking Member Wyden:

On behalf of Novo Nordisk Inc. ("NNI"), we write in further response to your letter dated February 22, 2019 (the "Letter"), in which you requested information and data related to prescription drug prices. As a company dedicated to improving the lives of people with diabetes and other chronic diseases, NNI shares your concerns about affordability and appreciates your commitment to addressing the complicated landscape of laws, regulations, market forces, and supply-chain entities that impact the price of prescription drugs. As discussed with staff, we continue to gather information and data relevant to the requests in your Letter, and will supplement this further response.

With respect to Request 1 of your Letter, please find enclosed at Bates numbers NNI-FINANCE-000002 through NNI-FINANCE-000003 a chart showing all insulin medicines and dosages/delivery systems currently sold by Novo Nordisk, and their historical Wholesale Acquisition ("WAC") price dating back to January 1, 2014. Please note that not all insulin medicines and dosages/delivery systems have been available for the entire period. For those products that were not available on January 1, 2014, WAC prices are shown dating back to the time of the product's launch.

# Akin Gump STRAUSS HAUER & FELD LLP

The Honorable Chuck Grassley The Honorable Ron Wyden May 10, 2019 Page 2

With respect to Request 2 of your Letter, please find enclosed at Bates Numbers NNI-FINANCE-000004 through NNI-FINANCE-000009 a list of patents and statutory exclusives for Novo Nordisk's insulin products. This list shows patents for the active ingredients, formulations, approved methods of use, and applicable devices for all insulin medicines that are currently on the market. Please note that this list includes patents that were sought and approved before January 1, 2014, as well as after.

With respect to Request 4 of your Letter, and per our conversation with your staff on April 25, 2019, please find enclosed at Bates Numbers NNI-FINANCE-000010 through NNI-FINANCE-000036 a template contract with a Pharmacy Benefit Manager ("PBM"). As we described to your staff, many of NNI's larger contracts are based on templates provided by the PBM or plan and thus do not follow this precise form.

In Request 8 of your Letter, you have asked about NNI's patient assistance programs. NNI has a number of such programs and also provides product donations to organizations committed to supporting patients with diabetes.

First, Novo Nordisk offers a Diabetes Patient Assistance Program ("PAP" or "Diabetes PAP"), which is an internal program that provides free insulin and other diabetes medicine to eligible patients. It has been administered through Conduent, a third party vendor since 2014. To be eligible for Novo Nordisk's Diabetes PAP, a patient must be a U.S. citizen or legal resident who does not have private prescription drug coverage; VA benefits; or any federal, state, or local program benefits such as Medicare and Medicaid. There are exceptions for Part D patients who have spent more than \$1,000 on prescription medicine in the calendar year; patients who are Medicare eligible but do not have Part D coverage and have been denied for an Extra Help/Lowincome subsidy; and patients who are Medicaid eligible that have applied for and been denied Medicaid. In order to participate, the patient's income must be at or below 400% of the poverty line, which is about \$103,000 for a family of four or \$49,960 for an individual. NNI's Diabetes PAP provides free insulin to tens of thousands of patients each year.

Novo Nordisk also offers a copay savings card program, which is a discount or coupon card that patients can download from Novo Nordisk's website, or obtain through their medical provider and activate by phone or Novo Nordisk's website. This program was administered by McKesson from 2014 through 2018, and ConnectiveRx from 2018 through the present. In order to redeem the offer, a patient must have a valid prescription for the brand being filled. A patient



is not eligible if he or she participates in, seeks reimbursement for, or submits a claim for reimbursement to any federal or state healthcare program with prescription drug coverage. Additionally, the patient must be enrolled in, and must seek reimbursement from or submit a claim for reimbursement to, a commercial insurance plan, and the brand and the prescription being filled must be covered by the patient's commercial insurance plan.

Novo Nordisk also offers an automatic electronic discount voucher, which is administered electronically and automatically through RelayHealth pharmacy solutions technology. Eligible patients purchasing medication (NovoLog®, Tresiba®, and Xultophy® among insulins) at participating pharmacies will automatically have an e-voucher applied, thereby lowering the patient's out of pocket cost. RelayHealth is the vendor for this program.

In addition, Novo Nordisk partners with Walmart, CVS Health, and ESI to offer human insulin (Novolin®) at participating pharmacies and Walmart stores for approximately \$25 per vial. NNI has partnered with Walmart in this effort for over 15 years (with Novolin® sold under the Walmart brand ReliOn®) and began its partnerships with CVS and ESI in 2017. In 2018, Novo Nordisk extended one \$25 human insulin offerings to a pen device, which is available at Walmart for a few dollars more for the equivalent dose.

Novo Nordisk also donates products to a non-profit organization that serves underserved patients in South Carolina. Welvista, the vendor for this program, sets the criteria for eligibility. Finally, Novo Nordisk donates products to summer camps serving patients with diabetes. A licensed practitioner associated with the camps verifies the camps' non-profit status. In some years, Novo Nordisk has also provided free medicine to patients affected by natural disasters, such as Hurricane Katrina.

With respect to the number of patients served by these programs, please see the chart enclosed at Bates Number NNI-FINANCE-000037.<sup>2</sup> Please note, with respect to co-pay cards, we have broken down the numbers by medicine because some patients likely receive more than one Novo Nordisk medicine, such that simply adding up totals for each medicine will likely not

<sup>&</sup>lt;sup>1</sup> This limitation is largely based on the government's legal interpretations of 42 U.S.C. § 1320a-7b(b) and interpretations of similar state statutes.

<sup>&</sup>lt;sup>2</sup> NNI does not collect information on the number of patients served by products donated through Welvista, or through diabetes summer camps. For that reason, the enclosed chart is limited to NNI's Diabetes PAP, co-pay assistance program, and human insulin partnerships.



provide an accurate count of patients served by the program. NNI does not have visibility into the exact number of patients assisted by the e-voucher program, only the number of prescriptions for which assistance was provided, and the amount spent to reduce eligible patients' out-of-pocket costs.

With respect to NNI's human insulin partnerships, please note that these numbers are drawn from the number of vials and pens sold each year. For that reason, the numbers are approximate; because some patients may use more than one vial each month (or equivalent dose in pen form), it is difficult to estimate the number of unique patients who utilize this affordable option. Please note further that, because NNI's collaborations with CVS and ESI began in 2017, the number of patients served in prior years reflect only the partnership with Walmart.

For the costs of these programs, please see the enclosed chart at Bates Number NNI-FINANCE-000038. Please note that, for NNI's Diabetes PAP, the numbers reflect the WAC price of medicines provided to patients free of charge, and do not reflect the additional costs of administering the program. NNI continues to collect information on administrative costs and will supplement this production when it becomes available.

For the co-pay assistance and e-voucher programs, the numbers reflect both the amount Novo Nordisk contributed to patient co-pays at the pharmacy counter and the costs of administering the program (with the exception of the co-pay assistance program in 2014<sup>3</sup>). Please note that, because the e-voucher program was initiated in 2015 (and for that year was limited to Tresiba®), program costs are provided for 2015, 2016, 2017, and 2018.

For donations through Welvista, and donations to diabetes camps, the numbers in the chart reflect only the WAC price of the medicines NNI provided. NNI does not pay the costs of administering those programs.

The human insulin partnerships with Walmart, ESI, and CVS are differently situated with regard to costs and revenue than other affordability initiatives. We continue to gather that information and will supplement this production when it becomes available.

<sup>&</sup>lt;sup>3</sup> As shown in the chart, the administrative costs for co-pay assistance in 2014 are not available. For that reason, the total for that year reflects only the amount expended to reduce patients' co-pay.



In Request 11, you have asked about the proposed rule from the Department of Health and Human Services ("HHS"), Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Novo Nordisk is fully supportive of the proposed rule and believes that it will lower patient out of pocket costs if successfully implemented. Novo Nordisk is also supportive of an eventual transition to the commercial market, but believes the rebate policy should first be implemented in Medicare Part D to reduce the potential for disruption in the market, which could adversely impact patients.

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Production of this and future information and data is not intended to constitute a waiver of the attorney-client, attorney work product, or any other applicable rights or privileges in this or any other forum. NNI expressly reserves its rights in this regard. In addition, certain information responsive to the Committee's requests includes highly sensitive information — including confidential, proprietary, trade secret, and/or material non-public information. Accordingly, NNI requests that such information be kept confidential by the Committee and its staff. Notwithstanding our request that such information be kept confidential, we would ask that staff provide us with notice and an opportunity to be heard before the Committee discloses any such information or data to third parties.

We appreciate our recent conversations with your staff on these matters and look forward to engaging further with the Committee to continue addressing the questions in your Letter. As discussed with your staff, and as described above, certain of these questions may call for sensitive information. We understand that the Committee is subject to Senate Rule 29.5 and will treat the confidential information produced accordingly. We appreciate that consideration and we will raise issues regarding sensitive information with staff as appropriate. NNI is committed to working



with the Committee to respond to its inquiry and to addressing the complicated issues surrounding drug pricing more broadly.

We look forward to working cooperatively with you and your staff in this regard.

Sincerely,

Raphael A. Prober MB
Raphael A. Prober
Steven R. Ross

Counsel for Novo Nordisk Inc.

Enclosure

#### HISTORIC WAC PRICE FOR INSULIN PRODUCTS

Product Name	NDC/UPC/HRI	History Price Type	History Effective Date	History Package Price	WAC Current Package Price	WAC Current Effective Date	Package Description	Qty 5	Size	Package SUM
Fiasp FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-3204-15	WAC	07/03/2018			07/03/2018		5		3 ML
Fiasp FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-3204-15	WAC	09/29/201			07/03/2018		5		3 ML
Fiasp Subcutaneous Solution 100 UNIT/ML	00169-3201-11	WAC	07/03/201					1		0 ML
Fiasp Subcutaneous Solution 100 UNIT/ML	00169-3201-11	WAC	09/29/201					1		0 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC WAC	01/08/2019		7.00.00	01/08/2019		5	-	3 ML 3 MI
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10 00169-6438-10	WAC	07/03/2018 01/03/2018		\$462.21 \$462.21			5 5	-	3 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	08/25/201					5		3 MI
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	11/18/2014					5	-	3 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	05/31/2014	\$333.12	\$462.21	01/08/2019	Pen	5	-	3 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	05/21/2014	\$303.12	\$462.21	01/08/2019	Pen	5		3 ML
Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	01/08/2019	1		. ,		1		0 ML
Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	07/03/2018		7000.2	,,		1		0 ML
Levemir Subcutaneous Solution 100 UNIT/ML Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12 00169-3687-12	WAC WAC	01/03/2018 08/25/2019					1		0 ML 0 ML
Levemir Subcutaneous Solution 100 UNIT/ML Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	11/18/201					1		0 ML
Levenir Subcutaneous Solution 100 UNIT/MI	00169-3687-12	WAC	05/31/2014	,		,,		1		0 MI
Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	12/19/201		7000.0	,,		1		0 ML
NovoLIN 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3007-15	WAC	10/08/2018					5	-	3 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	07/06/2010	\$137.70	\$137.70	07/06/2016	Vial	1	1/	0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	11/25/201		7-0			1		0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	05/19/201					1		0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	11/18/2014	,	\$137.70	. ,		1		0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11 00169-1837-11	WAC WAC	05/28/2014 12/03/201			. ,		1		0 ML 0 MI
NovoLIN N Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1834-11	WAC	07/06/201		7-0	,,		1		0 MI
NovoLiN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	11/25/201					1		0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	05/19/201					1		0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	11/18/2014	\$109.56	\$137.70	07/06/2016	Vial	1	1/	0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	05/28/2014	\$99.65	\$137.70	07/06/2016	Vial	1	1/	0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	12/03/201		\$137.70			1		0 ML
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC	07/06/2010					1		0 ML
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC	11/25/201	,		. ,		1		0 ML
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC WAC	05/19/201			. ,		1		0 ML 0 ML
NovoLIN R Injection Solution 100 UNIT/ML NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11 00169-1833-11	WAC	11/18/2014 05/28/2014					1		0 MI
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC	12/03/201					1		0 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	07/03/2018					5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	02/23/201		\$558.83	07/03/2018	Pen	5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	07/06/2010	\$493.25	\$558.83	07/03/2018	Pen	5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	11/25/201					5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	05/19/201			. , ,		5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	11/18/2014					5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10 00169-6339-10	WAC WAC	05/28/2014 12/03/2013			. , ,		5 5	-	3 ML 3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	07/03/201			07/03/2018		5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	02/23/201					5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	07/06/2010			07/03/2018		5	-	3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	11/25/201	\$457.10	\$558.83	07/03/2018	Pen	5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	05/19/201			07/03/2018		5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	11/18/2014					5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC WAC	05/28/2014					5		3 ML 3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3696-19 00169-3685-12	WAC	12/03/201 07/03/201					5 1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 ONT/ML  NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	02/23/201					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	07/06/2010					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	11/25/201	\$245.50	\$300.12	07/03/2018	Vial	1	1/	0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	05/19/2019	\$231.75	\$300.12	07/03/2018	Vial	1	10	0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	11/18/2014					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	05/28/2014					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	12/03/2013		\$300.12			1		0 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12 00169-3303-12	WAC WAC	07/03/2018 02/23/201			07/03/2018 07/03/2018		5 5		3 ML 3 MI
Novol OG PenFill Subcutaneous Solution Cartridge 100 UNIT/MI	00169-3303-12	WAC	07/06/201			07/03/2018		5	-	3 MI
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	11/25/201		++++++	07/03/2018		5		3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	05/19/201					5		3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	11/18/2014	\$377.56	\$537.47	07/03/2018	Cartridge	5	3	3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	05/28/2014		++++++	07/03/2018		5		3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	12/03/201					5		3 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	07/03/2018					1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML NovoLOG Subcutaneous Solution 100 UNIT/MI	00169-7501-11	WAC WAC	02/23/201 07/06/201					1		0 ML 0 MI
NovoLOG Subcutaneous Solution 100 UNIT/ML NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	11/25/201		7-00.00	,,		1		0 MI
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	05/19/201					1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	11/18/2014					1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	05/28/2014	, , , , , , , , , , , , , , , , , , , ,	7-00.00	,,		1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	12/03/201		7-00.00	,,		1		0 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-2660-15	WAC	01/08/2019	\$508.43	\$508.43	01/08/2019	Pen	5	3	3 ML

#### HISTORIC WAC PRICE FOR INSULIN PRODUCTS

Tresiba FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-2660-15	WAC	07/03/2018	\$484.68	\$508.43	01/08/2019 Pen	5	3 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-2660-15	WAC	01/03/2018	\$461.60	\$508.43	01/08/2019 Pen	5	3 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-2660-15	WAC	10/23/2015	\$443.85	\$508.43	01/08/2019 Pen	5	3 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 200 UNIT/ML	00169-2550-13	WAC	01/08/2019	\$610.11	\$610.11	01/08/2019 Pen	3	3 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 200 UNIT/ML	00169-2550-13	WAC	07/03/2018	\$581.62	\$610.11	01/08/2019 Pen	3	3 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 200 UNIT/ML	00169-2550-13	WAC	01/03/2018	\$553.92	\$610.11	01/08/2019 Pen	3	3 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 200 UNIT/ML	00169-2550-13	WAC	10/23/2015	\$532.62	\$610.11	01/08/2019 Pen	3	3 ML
Tresiba Subcutaneous Solution 100 UNIT/ML	00169-2662-11	WAC	01/08/2019	\$338.95	\$338.95	01/08/2019 Vial	1	10 ML
Tresiba Subcutaneous Solution 100 UNIT/ML	00169-2662-11	WAC	12/21/2018	\$323.12	\$338.95	01/08/2019 Vial	1	10 ML
Xultophy Subcutaneous Solution Pen-injector 100-3.6 UNIT-MG/ML	00169-2911-15	WAC	01/08/2019	\$1,039.88	\$1,039.88	01/08/2019 Pen	5	3 ML
Xultophy Subcutaneous Solution Pen-injector 100-3.6 UNIT-MG/ML	00169-2911-15	WAC	01/03/2018	\$991.31	\$1,039.88	01/08/2019 Pen	5	3 ML
Xultophy Subcutaneous Solution Pen-injector 100-3.6 UNIT-MG/ML	00169-2911-15	WAC	03/03/2017	\$953.18	\$1,039.88	01/08/2019 Pen	5	3 ML

CONFIDENTIAL & PROPRIETARY NNI-FINANCE- 000003

#### **Insulin Patents and Exclusivities**

#### NovoLog® FlexPen® and NovoLog® Mix 70/30 FlexPen®:

The following patents have been identified by Novo Nordisk to claim aspects of NovoLog® FlexPen® and NovoLog® Mix 70/30 FlexPen®:

- RE41956
- 9265893
- 7762994
- 8579869

There are no unexpired regulatory exclusivities for NovoLog® FlexPen® or NovoLog® Mix 70/30 FlexPen®.

#### <u>Levemir®</u>

The following patents have been identified by Novo Nordisk to claim aspects of Levemir®:

- 5,750,497
- 6,899,699
- RE46,363
- 7,762,994
- 8,579,869
- 8,672,898
- 8,684,969
- 8,920,383
- 9,108,002
- 9,132,239
- 9,457,154
- 9,486,588
- 9,616,180
- 9,687,611
- 9,775,953
- 9,861,757
- 7,686,786
- 10,220,155

There are no unexpired regulatory exclusivities for Levemir®.

#### **Tresiba®**

The following patents have been identified by Novo Nordisk to claim aspects of Tresiba®:

- 7,615,532
- 6,899,699
- 7,762,994
- 8,579,869
- 8,672,898
- 8,684,969
- 8,920,383
- 9,108,002
- 9,132,239
- 9,457,154
- 9,486,588
- 9,687,611
- 9,775,953
- RE 46,363
- 9,616,180
- 9,861,757
- 10,220,155

The following regulatory exclusivities are applicable to Tresiba®:

- New Chemical Entity, expires 2020/09/25
- New Patient Population, expires 2019/12/16

#### **Xultophy®**

The following patents have been identified by Novo Nordisk to claim aspects of Xultophy®:

- 6,268,343
- 6,899,699
- 7,615,532
- RE46,363
- 8,672,898
- 8,684,969
- 8,846,618
- 8,920,383
- 8,937,042
- 9,108,002
- 9,132,239
- 9,457,154
- 9,486,588
- 8,579,869
- 9,687,611
- 9,775,953
- 9,616,180
- 9,861,757
- 7,762,994
- 10,220,155

The following regulatory exclusivities are applicable to Xultophy®:

- New Chemical Entity, expires 2020/09/25
- New Combination, expires 2019/11/21

#### Fiasp® FlexTouch®

The following patents have been identified by Novo Nordisk to claim aspects of Fiasp® FlexTouch®:

- 8,324,157
- 6,899,699
- RE46,363
- 7,762,994
- 8,579,869
- 8,672,898
- 8,684,969
- 8,920,383
- 9,108,002
- 9,132,239
- 9,457,154
- 9,486,588
- 9,616,180
- 9,687,611
- 9,775,953
- 9,861,757
- 10,220,155
- 7,686,786

The following regulatory exclusivities are applicable to Fiasp®:

• New Product, expires 2020/09/29

#### Novolin® 70/30, Novolin® N, and Novolin® R:

Novo Nordisk does not have unexpired patents that claim aspects of Novolin® 70/30, Novolin® N, and Novolin® R.

There are no unexpired regulatory exclusivities applicable to Novolin® 70/30, Novolin® N, and Novolin® R.

# PHARMACY BENEFIT MANAGEMENT (PBM) REBATE AGREEMENT

This Rebate Agreement ("Agreement"), dated \_\_\_\_\_\_\_, is by and between Novo Nordisk Inc. ("Novo Nordisk"), having its principal offices at 800 Scudders Mill Road, Plainsboro, NJ 08536, and <Customer Full Name> ("Customer"), having its principal offices at <Insert Customer Address>.

#### **RECITALS**

WHEREAS, Novo Nordisk is, among other things, engaged in the business of developing, manufacturing, and marketing prescription pharmaceutical products;

WHEREAS, Customer is, among other things, engaged in the business of providing pharmacy benefit management services on behalf of such entities as self-insured employers, employee groups, exclusive provider organizations, health maintenance organizations, indemnity plans, health insurance companies, preferred provider organizations, and/or other organizations;

WHEREAS, Novo Nordisk desires that its products be available to individuals receiving health care coverage or benefits through such organizations;

WHEREAS, this Agreement is intended to set forth the terms and conditions upon which Novo Nordisk will provide Customer with discounts on Products in the form of Rebates, and Customer has represented to Novo Nordisk that the Rebates described herein are necessary discounts to Novo Nordisk's prices for its Products to enable Novo Nordisk to compete with prices offered by manufacturers of competing products; and

WHEREAS, the Agreement is intended to set forth the terms and conditions upon which Novo Nordisk will pay Administrative Fees to Customer with respect to Products.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises set forth herein, the parties agree as follows:

- 1. **Term**. The Term of this Agreement shall commence on **<Insert Date>**, and shall continue in effect through **<Insert Date>**.
- 2. **Definitions**. As used herein, the following terms are defined as set forth below:
  - 2.1. "Administrative Fees" means the administrative fees set forth in Section 12.
  - 2.2. "Biosimilar" means an FDA-approved biological which received approval via the 505(b)(2) New Drug Application pathway or Section 351(k) of the PHS Act (42 U.S.C. 262(k)). Customer shall treat any Biosimilar as a brand Competitive Product.
  - 2.3. "Competitive Product" means an FDA-approved prescription pharmaceutical or biological (including any Biosimilars) which is within the same Therapeutic Class as a Product covered by this Agreement. All Products and their respective related Competitive Products shall be categorized in groups of Therapeutic Classes. In the event that the FDA approves additional prescription pharmaceuticals or biologicals within the Therapeutic Classes of the Products during the Term of this Agreement, such newly approved pharmaceuticals or biologics shall be considered to be Competitive Products and added within the appropriate Therapeutic Class.

- Competitive Utilization for all Products in **Exhibit A** must be submitted as a condition for Rebates to be paid.
- 2.4. "Contract Quarter" means each full three (3) month calendar period, beginning January 1, April 1, July 1 and October 1, that this Agreement remains in full effect.
- 2.5. "<u>Data</u>" means information concerning Product and Competitive Product Utilization, the description of Pharmacy Controls implemented by Customer and its Eligible Plans, and other information provided to Novo Nordisk by Customer for each Eligible Plan.
- 2.6. "<u>Disincentives</u>" means any communications to Pharmacies, providers or others, which discourage the use of a Product in a manner inconsistent with a Product's status on Formulary, including but not limited to prior authorization, counter-detailing, or any financial disincentive, unless it is an approved Novo Nordisk exception.
- 2.7. "Eligible Plan (Plan)" means any health care plan, program, or other arrangement of any self-insured employer, employee group, exclusive provider organization, health maintenance organization, preferred provider organization, third party payor, union or other organization which (i) has appointed Customer to manage its Pharmacy Benefit, (ii) has appointed Customer to provide administrative and Formulary management services by written contract, and (iii) is identified in the list attached hereto in **Exhibit D** or is hereafter added to such list in accordance with this Agreement. The term "Eligible Plan" specifically excludes entities:
  - 2.7.1. for which Customer provides only "claims processing" services;
  - 2.7.2. which offer "consumer card" or similar business arrangements;
  - 2.7.3. which are located outside the United States;
  - 2.7.4. which maintain no eligibility criteria for Pharmacy Benefits;
  - 2.7.5. which have transferred Pharmacy Benefit risk management to any third party through capitation or otherwise;
  - 2.7.6. which receive discounts directly or indirectly through another agreement with Novo Nordisk on the same Product Utilization;
  - 2.7.7. which are not in compliance with applicable laws including but not limited to those referenced with the **General Provisions** of this Agreement; or
  - 2.7.8. Managed Medicaid or fee-for-service organizations, unless expressly agreed to elsewhere in this Agreement; and.
  - 2.7.9. plans with a deductible phase prior to coverage in excess of \$750.
- 2.8. "Formulary" (individually or "Formularies" collectively) means a listing of prescription pharmaceutical or biological products covered under a Plan that is (a) developed, maintained, and adopted by Customer and/or Plans, (b) approved by a Plan's or Customer's P&T Committee (defined below), and (c) provided to Members, Pharmacies, and/or physicians for the purposes of guiding the reimbursement of pharmaceutical products.

# PHARMACY BENEFIT MANAGEMENT (PBM) REBATE AGREEMENT

This Rebate Agreement ("Agreement"), dated \_\_\_\_\_\_\_, is by and between Novo Nordisk Inc. ("Novo Nordisk"), having its principal offices at 800 Scudders Mill Road, Plainsboro, NJ 08536, and <Customer Full Name> ("Customer"), having its principal offices at <Insert Customer Address>.

#### **RECITALS**

WHEREAS, Novo Nordisk is, among other things, engaged in the business of developing, manufacturing, and marketing prescription pharmaceutical products;

WHEREAS, Customer is, among other things, engaged in the business of providing pharmacy benefit management services on behalf of such entities as self-insured employers, employee groups, exclusive provider organizations, health maintenance organizations, indemnity plans, health insurance companies, preferred provider organizations, and/or other organizations;

WHEREAS, Novo Nordisk desires that its products be available to individuals receiving health care coverage or benefits through such organizations;

WHEREAS, this Agreement is intended to set forth the terms and conditions upon which Novo Nordisk will provide Customer with discounts on Products in the form of Rebates, and Customer has represented to Novo Nordisk that the Rebates described herein are necessary discounts to Novo Nordisk's prices for its Products to enable Novo Nordisk to compete with prices offered by manufacturers of competing products; and

WHEREAS, the Agreement is intended to set forth the terms and conditions upon which Novo Nordisk will pay Administrative Fees to Customer with respect to Products.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises set forth herein, the parties agree as follows:

- 1. **Term**. The Term of this Agreement shall commence on **<Insert Date>**, and shall continue in effect through **<Insert Date>**.
- 2. **Definitions**. As used herein, the following terms are defined as set forth below:
  - 2.1. "Administrative Fees" means the administrative fees set forth in Section 12.
  - 2.2. "Biosimilar" means an FDA-approved biological which received approval via the 505(b)(2) New Drug Application pathway or Section 351(k) of the PHS Act (42 U.S.C. 262(k)). Customer shall treat any Biosimilar as a brand Competitive Product.
  - 2.3. "Competitive Product" means an FDA-approved prescription pharmaceutical or biological (including any Biosimilars) which is within the same Therapeutic Class as a Product covered by this Agreement. All Products and their respective related Competitive Products shall be categorized in groups of Therapeutic Classes. In the event that the FDA approves additional prescription pharmaceuticals or biologicals within the Therapeutic Classes of the Products during the Term of this Agreement, such newly approved pharmaceuticals or biologics shall be considered to be Competitive Products and added within the appropriate Therapeutic Class.

- Competitive Utilization for all Products in **Exhibit A** must be submitted as a condition for Rebates to be paid.
- 2.4. "Contract Quarter" means each full three (3) month calendar period, beginning January 1, April 1, July 1 and October 1, that this Agreement remains in full effect.
- 2.5. "<u>Data</u>" means information concerning Product and Competitive Product Utilization, the description of Pharmacy Controls implemented by Customer and its Eligible Plans, and other information provided to Novo Nordisk by Customer for each Eligible Plan.
- 2.6. "<u>Disincentives</u>" means any communications to Pharmacies, providers or others, which discourage the use of a Product in a manner inconsistent with a Product's status on Formulary, including but not limited to prior authorization, counterdetailing, or any financial disincentive, unless it is an approved Novo Nordisk exception.
- 2.7. "Eligible Plan (Plan)" means any health care plan, program, or other arrangement of any self-insured employer, employee group, exclusive provider organization, health maintenance organization, preferred provider organization, third party payor, union or other organization which (i) has appointed Customer to manage its Pharmacy Benefit, (ii) has appointed Customer to provide administrative and Formulary management services by written contract, and (iii) is identified in the list attached hereto in **Exhibit D** or is hereafter added to such list in accordance with this Agreement. The term "Eligible Plan" specifically excludes entities:
  - 2.7.1. for which Customer provides only "claims processing" services;
  - 2.7.2. which offer "consumer card" or similar business arrangements;
  - 2.7.3. which are located outside the United States;
  - 2.7.4. which maintain no eligibility criteria for Pharmacy Benefits;
  - 2.7.5. which have transferred Pharmacy Benefit risk management to any third party through capitation or otherwise;
  - 2.7.6. which receive discounts directly or indirectly through another agreement with Novo Nordisk on the same Product Utilization;
  - 2.7.7. which are not in compliance with applicable laws including but not limited to those referenced with the **General Provisions** of this Agreement; or
  - 2.7.8. Managed Medicaid or fee-for-service organizations, unless expressly agreed to elsewhere in this Agreement; and.
  - 2.7.9. plans with a deductible phase prior to coverage in excess of \$750.
- 2.8. "Formulary" (individually or "Formularies" collectively) means a listing of prescription pharmaceutical or biological products covered under a Plan that is (a) developed, maintained, and adopted by Customer and/or Plans, (b) approved by a Plan's or Customer's P&T Committee (defined below), and (c) provided to Members, Pharmacies, and/or physicians for the purposes of guiding the reimbursement of pharmaceutical products.

- 2.9. "Government Program" means Medicare, Medicaid, TRICARE, the 340B program, or any or other state or federal (as defined in 42 U.S.C. § 1320a-7(h) and § 1320a-7b(f)) health care program, entitlement program or public assistance program.
- 2.10. "<u>Health Care Exchange</u>" (Exchange)" means a set of government-regulated and standardized health care plans in the United States, from which individuals may purchase health insurance eligible for federal subsidies.
- 2.11. "Incentives" means any communications to Pharmacies, providers or others, encouraging or requiring use of a Competitive Product or competing non-Formulary product in a manner inconsistent with a Product's status on the Formulary.
- 2.12. "Managed Medicaid" means the Medicaid benefit as administered by a private health care insurer under contract with the relevant state Medicaid department.
- 2.13. "Market Share" means for each Eligible Plan for each Therapeutic Class listed in **Exhibit A** (expressed as a percentage), the calculation as defined in **Exhibit C** for each respective Rebate eligible Unit of Product dispensed through Pharmacies within such Eligible Plan.
- 2.14. "Material Breach" means any breach that is central to the object or purpose of this Agreement, including, but not limited to, providing Incentives for a Competitive Product or Disincentives for Products.
- 2.15. "Maximum Allowable Cost" or "MAC" means a reimbursement level to Pharmacies established by Customer for Products where there is more than one manufacturer.
- 2.16. <u>"Maximum Quantity"</u> means the maximum number of units to be dispensed in a given prescription based upon days' supply and maximum units per day (as defined in **Exhibit E**).
- 2.17. "Member" means any person who is enrolled in or covered by a Plan for his or her primary Pharmacy Benefits and any such person's dependents who are covered by a Plan for Pharmacy Benefits. "Member" specifically excludes individuals who are not eligible for Pharmacy Benefits, and any cash-paying customers who are not enrolled in or covered by a Plan having an agreement with Customer to manage Pharmacy Benefits.
- 2.18. "National Market Share" means the Market Share of each respective Product and Competitive Product, defined as Product (or Competitive Product) Units or Rx's (as defined in **Exhibit C**) compared to the IMS Health total United States Units or Rx's for all products within the same respective Therapeutic Classes.
- 2.19. "Own Use" means lawful consumption of the dispensed pharmaceutical product by a Member. Own Use expressly excludes the distribution or dispensing of Units to non-members or to any person or entity for resale or other purposes.
- 2.20. "Pharmacy" (individually or "Pharmacies" collectively) means any one or more retail pharmacies which are properly licensed to dispense prescription drugs which have a written agreement with Customer or a Plan to provide pharmacy services to Plan Members.

From time to time upon request by Novo Nordisk, Customer shall provide Novo Nordisk with a current list of the Pharmacies permitted to dispense Products and Competitive Products under the Plans. Customer's agreements with Pharmacies shall prohibit Pharmacies from counter-detailing or other dis-incentivizing activities

against Products on Formularies, subject to Pharmacies' professional obligations relating to good clinical practice.

Upon execution of this Agreement, Customer shall provide Novo Nordisk with a listing of all owned or affiliated mail order pharmacies and shall update such list from time to time should the information no longer be complete or current.

- 2.21. "Pharmacy Benefits" means a drug reimbursement program under which the delivery and dispensing of pharmaceutical or biological products, including Novo Nordisk's Products, by Pharmacies is managed in accordance with Customer's Formulary and Pharmacy Controls, and under which the Member is not at risk for the net amount paid to the Pharmacy.
- 2.22. "Pharmacy Controls" means pharmacy benefit design and effective compliance programs that have been determined and established between Customer and each Plan with regards to Pharmacies, Members, physicians and other health care providers. Pharmacy Controls shall include Formulary design and development by a Pharmacy and Therapeutics Committee ("P&T Committee"), and three (3) or more of the following:
  - 2.22.1. routine communications to physicians to ensure awareness of the products' availability on Formulary, and physician education with respect to such Formulary products;
  - 2.22.2. a Member drug co-payment structure which encourages the use of Formulary products;
  - 2.22.3. drug utilization evaluation;
  - 2.22.4. drug step-therapy protocol; and/or provides utilization management tools such as Step Edit, Prior Authorization, NDC Block, etc.
  - 2.22.5. physician education with respect to Formulary products.
- 2.23. "Prescription Drug Benefit" means the prescription drug program, which is subject to Pharmacy Controls and implemented through a participating Pharmacy as a Plan Benefit solely for eligible Members.
- 2.24. "Product(s)" or "Novo Nordisk Product(s)" means the pharmaceutical products sold by Novo Nordisk and listed in **Exhibit A** attached hereto, as the same may be amended. Products shall <u>not</u> include any Product which is listed (a) on a Formulary but indicated as "Non-Formulary" or "NF", (b) disadvantaged in any way versus a Competitive Product, (c) with mandatory generic substitution required, or (d) with prior authorization required. Upon thirty (30) days written notice to Customer, Novo Nordisk may add, modify, or delete Products from this Agreement.
- 2.25. "Protected Health Information" means personally identifiable, confidential, sensitive health information obtained by Customer and utilized in connection with this Agreement as defined by the Health Insurance Portability and Accountability Act ("HIPAA").
- 2.26. "Rebate(s)" are set forth in **Exhibit B** and mean, for any period, all rebates or other discounts provided for under this Agreement with respect to the Utilization of Products which Rebates shall be collected by Customer on behalf of the Eligible Plans.

- 2.27. "Therapeutic Class" means the product market universe for Products set forth on Exhibit A. Novo Nordisk retains the sole and exclusive right to redefine the product market universe set forth on Exhibit A based upon: (i) the entry (including a new dosage form, strength, size, reformulation or other product line extension from the market), removal or discontinuance of a product in the market; (ii) a change in the indication of any product; (iii) a modification by Novo Nordisk of Novo Nordisk's view of the competitive products against which a Product competes. Any such change in Therapeutic Class will be communicated in writing to Customer.
- 2.28. "<u>United States</u>" means the fifty (50) United States, Puerto Rico, U.S. Territories, and the District of Columbia.
- 2.29. "<u>Unit(s)</u>" means individual capsules, tablets, milliliters, or grams dosage forms (or such other standard pharmacy unit of measure as the parties may agree to) of Products or Competitive Products dispensed to members through Pharmacies.
- 2.30. "<u>Utilization</u>" means the number of Units of Products or Competitive Products (where applicable) dispensed to Members of Eligible Plans through Pharmacies for which reimbursement is made by Customer on behalf of Eligible Plans, but shall <u>not</u> include:
  - 2.30.1. Units dispensed to Members of Eligible Plans which have not included the Novo Nordisk Products on the Formulary applicable to such Eligible Plan, in the Formulary position set forth on **Exhibit B**;
  - 2.30.2. Units dispensed to Members other than for Members' Own Use, or to non-Members or any other person or entity for resale;
  - 2.30.3. Units dispensed but not reimbursed by Customer;
  - 2.30.4. Any Units excluded in **Exhibit E** of this Agreement.
- 2.31. "WAC" means Novo Nordisk's Wholesale Acquisition Cost for a Product as published by Novo Nordisk from time to time.

#### 3. Authority to Do Business

- 3.1. Customer shall enter into lawful written agreements with each Plan included in **Exhibit D** to manage its Pharmacy Benefits, provide administrative and Formulary management services, and negotiate and collect Rebates from Novo Nordisk with respect to the Products on their behalf.
- 3.2. Customer shall represent and warrant that it has the legal authority to enter into, carry out the purpose of, and conduct business necessary to, this Agreement.

#### **CUSTOMER OBLIGATIONS**

#### 4. Formulary Placement

4.1. In order to receive Rebates and Administrative Fees with respect to a Novo Nordisk Product and Plan, Customer shall include such Novo Nordisk Product on the Plan's Formulary within thirty (30) days of the effective date of this Agreement and shall maintain such Product on the mutually agreed upon Formulary status for such Plan for the duration of the Agreement.

- 4.2. Customer shall provide Novo Nordisk with a copy of its Formulary listings, and any amendments thereto, applicable to each Therapeutic Class, within thirty (30) days of the effective date of this Agreement or within thirty (30) days of any amendments to the applicable Formulary. Copies of amendments to Formulary may be submitted with Customer's invoice, according to section 7.1, if within the applicable timeframe.
- 4.3. When Novo Nordisk Products are placed on Formulary pursuant to the terms of this Agreement, Customer shall notify all network physicians through print or electronic medium or an e-prescribing aggregator of such placement within thirty (30) days of placement.
- 4.4. Customer will not place a Novo Nordisk Product on its Formularies unless the P&T Committee has reviewed such Novo Nordisk Product from a clinical perspective and has determined that the Novo Nordisk Product is appropriate for the Formulary Classifications assigned to it.
- 4.5. As a condition of receiving Rebates and/or Administrative Fees for a Product and Plan, Customer agrees that it will not provide Incentives for competing products or Disincentives for such Formulary Product and such Plan.
- 4.6. Nothing in this Agreement shall prevent Customer and/or a Plan from removing any Product from any of its Formularies or changing the Formulary status of a Product, provided Customer promptly notifies Novo Nordisk of such removal or change in status; however, in such event no Rebate shall be payable for such Product from and after the effective date of such removal or change in status with respect to the Plan(s) to which the removal applies.
- 4.7. The offer of any Rebates and/or Administrative Fees under this Agreement shall not affect clinical decisions made by any P&T Committee concerning the safety or efficacy of any Product or the clinical integrity of the Formulary process.

#### 5. Plan/Member Communications

- 5.1. Customer shall, as part of its agreements with Plans and through written communications with Plans during the term of this Agreement, disclose to the Plans the terms under which Novo Nordisk will pay Rebates, including the amounts thereof, and shall advise such Plans to disclose such Rebates to any third party who is financially at risk for the cost of the Products.
- 5.2. Customer shall regularly distribute copies and current updates of its Plans' Formularies listing Novo Nordisk Products to its Members, Pharmacies, physicians and other health care providers providing services to Members under the Plans. The specific Formulary name used for each Plan for each Novo Nordisk Product is specified at **Exhibit D**.
- 5.3. Subject to good pharmacy and medical practice and applicable laws, Customer shall not restrict or discourage the use of the Formulary Products in any way nor take any actions which will adversely affect the utilization of the Formulary Products, except as expressly permitted herein.
- 5.4. Unless otherwise required by law or good clinical practice, Customer shall take no action, including but not limited to telephone calls or written communication to

physician providers or pharmacies regarding a specific Product prescription that will adversely affect Utilization of such Product without the prior written consent of Novo Nordisk.

5.5. During the Term hereof, subject to applicable laws and regulations regarding patient confidentiality, Customer will supply Novo Nordisk with representative copies of any communications to Members or Pharmacies regarding the Products or their Therapeutic Classes contemporaneously with their delivery to such persons or entities.

#### 6. Plan Maintenance

6.1. All Plans listed in **Exhibit D** are eligible to participate in this Agreement. From time to time during the Term of this Agreement, if Customer wishes to add a new plan to be included in the list of Eligible Plans hereunder, Customer shall so advise Novo Nordisk in writing and provide Novo Nordisk with the information necessary to add such plans to **Exhibit D**.

Such new plan shall be added to the list of Eligible Plans hereunder unless Customer receives an objection to the addition of such plan from Novo Nordisk within ten (10) business days of Novo Nordisk's receipt of new plan information from Customer; provided, however, Novo Nordisk reserves the right in its sole discretion to determine to remove plans from the list of Eligible Plans based upon the information supplied to or otherwise obtained by Novo Nordisk.

If Novo Nordisk decides not to include or to remove any plan from eligibility hereunder, it shall so notify Customer of such decision, which notice shall specify the reasons for Novo Nordisk's non-acceptance or removal. Any plan added to the list of Eligible Plans shall be eligible for Rebates as of the first day of the first full month following the date Novo Nordisk adds such plan to the list of Eligible Plans.

- 6.2. In the event that Customer ceases to provide pharmacy benefit management services to a plan listed in **Exhibit D** during the term of this Agreement, Customer shall notify Novo Nordisk within fifteen (15) days of such deletion.
- 6.3. All updates will be provided to Novo Nordisk by Customer according to the contact information provided.

#### 7. Utilization Reporting

7.1. Within ninety (90) days of the end of each Contract Quarter, Customer shall furnish Novo Nordisk with complete electronic data files in National Council for Prescription Drug Programs (NCPDP) flat file standard at the "PP" data level (to include all mandatory NCPDP fields) or such other format as is mutually agreed upon in writing by both parties (collectively the "Utilization Reports"). The Utilization Reports shall indicate the extent to which Products were paid for by Customer on behalf of its Plans during such Contract Quarter.

All Utilization Reports shall (i) provide prescription level data, including pharmacy identifier, Prescription Origin Code, Formulary ID, Formulary Status, prescriber identifier, date of service, prescription number, quantity dispensed, days supply, refill indicator, requested rebate amount, invoiced amount fields, claim number, coordination of benefits indicator, and retail or mail service indicator for each Product; (ii) provide the National Drug Codes and proprietary names of each Product and each other product within the same Therapeutic Class as set forth on

**Exhibit A**; (iii) provide formulary code, description, tier, plan reimbursement and patient liability for Products; (iv) summarize the Units and prescriptions for each Product and each other pharmaceutical or biological product within the same Therapeutic Class, Product Market Share Data and requested Rebate amount as set forth on **Exhibit B**; and (v) indicate the total number of Units sold and dispensed by participating Pharmacies to Eligible Plans during the respective Contract Quarter.

Customer shall furnish all applicable Formularies with each invoice submitted to Novo Nordisk; Formularies must be legible and up-to-date for each invoice period Customer is requesting Rebates. All Formularies must be defined as a formal PDL or PDF; emails shall not constitute proof of Formulary compliance.

As a condition to paying Rebates for Health Care Exchange Utilization under the Agreement, Customer shall provide a separate invoice, applicable Formulary and Utilization Report to Novo Nordisk which identifies Health Care Exchange Utilization. Such Report shall be provided to Novo Nordisk at the same time that the standard Utilization Report identifying commercial Utilization is due to Novo Nordisk.

If no claim is received within ninety (90) days of the end of a Contract Quarter, Novo Nordisk reserves the right to not pay Rebates on the sale or Utilization of such Products.

- 7.2. Any additional data that relates to a Rebate claim which was not submitted within the time specified in Section 7.1 above may only be submitted as a "Supplemental Rebate" request within the next immediately following Contract Quarter submission. Such Supplemental Rebate request must contain all appropriate Utilization and Competitor Product data as required or such claim will be denied. Data for the Supplemental Rebate will be included with the new Contract Quarter's rebate claim data for Rebate calculation purposes. Any claim for Rebate(s) not submitted as provided in this Section shall be deemed waived and no Rebate will be due or owing. No claims for Rebates may be submitted other than those based on payments made for Products dispensed during the preceding quarter.
- 7.3. All Utilization Reports not otherwise submitted electronically must be submitted to the following address:

Novo Nordisk Inc.			
800 Scudders Mill Road			
Plainsboro, NJ 08536			
Attention: Rebate Management			
Phone:			
Facsimile:			
Email:			

7.4. To assist Novo Nordisk with the coordination of any Data submitted to it from Customer, Customer's responsible contact person is listed below:

Name:	
Title:	
Address:	
Phone:	
Facsimile:	

Email: _	
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#### 8. Additional Customer Rights and Obligations

- 8.1. Customer agrees that Product(s) for which Customer seeks Rebates hereunder have been, to the best of its knowledge, used for the "Own Use" of its Members. The delivery of each Utilization Report shall be deemed a recertification to Novo Nordisk that Products for which Customer receives a Rebate shall have been dispensed only in accordance with the warranty in the preceding sentence.
- 8.2. Except to the extent permitted by Customer's agreements with the Plans, Customer shall distribute all Rebates payable under this Agreement to the Plans.
- 8.3. Customer agrees that it will not enter into any agreement which would materially and adversely affect its ability to perform its obligations under this Agreement.

#### **NOVO NORDISK OBLIGATIONS**

#### 9. **Rebate Payments**

- 9.1. Subject to Customer fulfilling its obligations and all of the terms and conditions set forth in this Agreement, Rebates will be paid to Customer by Novo Nordisk on a quarterly basis within ninety (90) days of receipt of the complete Utilization Reports required under Section 7 above.
- 9.2. Novo Nordisk shall pay Rebates for a partial Contract Quarter, in the event 1) of an early termination of this Agreement set forth in Section 13, Termination, or due to a new generic/Biosimilar that causes the removal of a Product from this Agreement, as set forth in Section 10.3, or 2) the effective date or termination date of this Agreement does not start or end on a Contract Quarter; all terms and conditions of this Agreement shall apply.
- 9.3. Rebates are paid on eligible Utilization and will be calculated and paid as a percentage off Product Unit WAC. The per Unit percentage Rebates are defined in **Exhibit B**.
- 9.4. For the purposes of Rebate calculation, WAC shall be the WAC in effect at the beginning of the Contract Quarter for each Product during the relevant Contract Quarter.
- 9.5. The "Novo Nordisk Product Market Share" for a Contract Quarter and a Plan shall mean Novo Nordisk Product Utilization under the Plan for the Contract Quarter, divided by the sum of Novo Nordisk Product Utilization and Competitive Product Utilization under the Plan during the Contract Quarter. Market Share shall be calculated to the **sixth** decimal place. See **Exhibit C** for complete Details of the market share calculations.
- 9.6. For the purposes of Market Share calculations, the Therapeutic Class for each Product is defined as the Product plus Competitive Products as defined in **Exhibit A**.
- 9.7. Notwithstanding any other provision of this Agreement, in the event that any Rebate amounts and/or Administrative Fee provided to Customer under this Agreement would exceed or establish a new Medicaid "Best Price" for a Novo Nordisk Product, Novo Nordisk reserves the right to adjust the price charged to

Customer for the respective Product to a level that, when taking the Rebate and/or Administrative Fee for that Product into account, no longer set a Medicaid "Best Price" for that Product. As used in this Section 9.7, Medicaid "Best Price" shall have the meaning set forth in 42 U.S.C. 1936r-8(c)(1)(C). In such event, Novo Nordisk shall deduct from any Rebate and/or Administrative Fee amount(s) owed to Customer under this Agreement to reflect this price adjustment.

#### 10. Additional Novo Nordisk Rights and Obligations

- 10.1. Novo Nordisk will not intentionally negotiate with Customer's Plans in regards to pricing and/or distribution of Products included in this Agreement.
- 10.2. Novo Nordisk reserves the right to make adjustments to Product Rebates or terminate the respective Product from this Agreement and amend the appropriate exhibits upon thirty (30) days prior written notice to Customer if market conditions change due to other Competitive Products or alternative treatments at any time during the Term of this Agreement.
- 10.3. Generic or Biosimilar Availability. In the event a generic or Biosimilar version of a Product becomes available on the market in the United States, such Product shall be deemed deleted from this Agreement, on the earlier of the effective date that Customer sets a MAC for such Product or thirty (30) days after such generic or Biosimilar product is available on the market. After such deletion (i) no further Rebates shall be paid by Novo Nordisk to Customer for the dispensing of such Product thereafter, and (ii) neither party shall have any further obligations under this Agreement with respect to such Product (except for obligations arising prior to such deletion), and (iii) reference to such Product on all Rebate Exhibits shall be deemed deleted and such Exhibits shall be amended by Novo Nordisk to reflect such deletion of Products from this Agreement.
- 10.4. Nothing in this Agreement shall be construed to limit or restrict Novo Nordisk's right, in its sole discretion, to discontinue the manufacture, sale, or distribution of any of the Products at any time. In such event, this Agreement, as it relates to any such Product, shall terminate contemporaneously with such discontinuance of manufacture, sale, or distribution and neither party shall have any obligation to the other for any period following such termination.

#### 11. Rebate Eligibility

- 11.1. Rebates will be paid by Novo Nordisk directly to Customer based on the calculation of actual Product Utilization. Rebates will only be paid for submitted Units of Utilization which meet the following requirements:
  - 11.1.1. are submitted under Plans identified as participants in this Agreement in **Exhibit D** or in subsequent communication and agreement between Customer and Novo Nordisk;
  - 11.1.2. are listed on a Formulary for Utilization of such Product(s) for the Plan in question in an equal or advantaged position over Competitive Products unless expressly agreed to elsewhere in this Agreement;
  - 11.1.3. the use or distribution of such Product(s) have not been actively discouraged by Customer;

- 11.1.4. have not had a MAC placed upon such Product by Customer, except as may be required by federal law.
- 11.2. Notwithstanding any provision in this Agreement to the contrary, in no event shall any Rebates be payable by Novo Nordisk, or billed by Customer, for any Products dispensed to any person for which Customer, any Pharmacy, or any other person or entity seeks direct or indirect reimbursement from Medicare (including without limitation Medicare Part D), Medicaid (unless expressly agreed to elsewhere in the Agreement) or any federal, state or local government health care program as defined in Section 1128(h) of the Social Security Act (or any successor thereto).
- 11.3. In the event that any unit of Product purchased is utilized by or for a Member who is a member of or insured by any managed care organization or other insurer which is entitled, whether contractually or otherwise, to discounts, credits, rebates, or other price reductions on the units of Product utilized by such Member or insurers, or if Novo Nordisk is otherwise required to pay rebates, grant credits, discounts or other price reductions with respect to such Product, including without limitation under the 340B Program, Customer shall pay to Novo Nordisk an amount equal to the Rebate granted hereunder with respect to such units of Product within thirty (30) days after being notified of such excess Rebates by Novo Nordisk.
- 11.4. All terms and conditions of the Agreement shall apply to Health Care Exchange Utilization. Notwithstanding any other provision of this Agreement, if after the Effective Date any government authority issues guidance that clarifies that any or all Plans operated under a Health Care Exchange are Government Programs or repeals or substantially amends the law authorizing such Health Care Exchange, the parties shall meet promptly to determine whether such Plans should be removed from the Agreement or treated in some different manner.

### 12. Administrative Fees

- 12.1. Novo Nordisk agrees to pay Customer, on a quarterly basis, an Administrative Fee in the amount of three percent (3%) of Rebate eligible Plan utilization. Utilization of each product by each Plan will be calculated by multiplying the number of Rebate eligible units of the Product dispensed to Members of the Plan during the applicable quarter by the WAC for the Product for the applicable quarter.
- 12.2. Customer shall perform the following activities for Novo Nordisk in consideration of the Administrative Fee: (1) negotiate and contract with Plans regarding Product access; (2) administer this Agreement, including monitoring Plan Rebate eligibility, and maintain records of Rebate payments; (3) maintain and furnish to Novo Nordisk copies of applicable Formularies; (4) distribute Rebates and/or provide cost savings to Plans; and (5) develop and implement internal audit protocols.

### 13. Termination

- 13.1. <u>Termination by either Party</u>. Either party may terminate this Agreement:
  - 13.1.1. <u>Without Cause.</u> At any time with or without cause upon sixty (60) days prior written notice to the other party;
  - 13.1.2. <u>Material Breach.</u> In the event of a Material Breach of the terms of this Agreement by a defaulting party; provided the non-breaching party shall first provide the defaulting party with written notice of such breach, and

- the defaulting party shall thereafter fail to cure such breach within thirty (30) days after such notice is issued;
- 13.1.3. <u>Termination Due to Insolvency</u>. Effective immediately, if the other party files a petition in bankruptcy, is adjudicated bankrupt, makes a general assignment for the benefit of its creditors, is voluntarily or involuntarily dissolved, has a receiver, trustee, or other court officer appointed with respect to its property, or is unable to pay its debts as they mature;
- 13.1.4. Termination Due to Effect of Laws. If after the effective date of this Agreement, there shall be any judicial, legislative, or administrative action, interpretation, enforcement, promulgation, decree, order, judgment, law, ruling or regulation (a) relating to any of (i) the pricing of prescription drugs, or (ii) the terms of this Agreement or the Rebates set forth herein; and (b) which may materially adversely affect the business of Novo Nordisk or Customer, the parties shall negotiate in good faith to amend this Agreement to be consistent with such judicial, legislative, decree, judgment, law, etc. If the parties are unable to reach an agreement within thirty (30) business days, either party may immediately terminate the Agreement upon written notice to the other party.
- 13.2. <u>Termination by Novo Nordisk</u>. Novo Nordisk shall have the right to terminate the Agreement unilaterally on written notice to Customer, effective immediately, if:
  - 13.2.1. Customer undergoes a change of ownership or control or is merged with another entity;
  - 13.2.2. Utilization data has been knowingly submitted by Customer to Novo Nordisk for Rebate payments for ineligible or non-approved Members; or
  - 13.2.3. Customer has provided Incentives for competing products or Disincentives for Products.
- 13.3. Effect of Termination. In the event of termination for reasons other than Customer's breach, Novo Nordisk agrees to pay Rebates and Administrative Fees to Customer on undisputed Utilization through and including the termination date (including prorated Rebates and Administrative Fees, where applicable to a specific Rebate exhibit). Upon any termination of this Agreement for Customer's breach, Customer shall not be eligible for any Rebates for the Contract Quarter in which such breach occurred nor any subsequent period. If Novo Nordisk shall have already paid Rebates to Customer for such Contract Quarter or any subsequent period, Customer shall repay such payments promptly to Novo Nordisk.

### 14. Record Keeping and Audits

14.1. During the Term of this Agreement and for a period of three (3) years from the termination of this Agreement, or longer if required by law, Customer shall keep and maintain accurate records necessary to verify performance and compliance with this Agreement.

### 14.2. Audit Rights

14.2.1. Throughout the Term and for a period of three (3) years after termination, Customer will permit Novo Nordisk, or its designated agents, the right to inspect such records, processes and procedures as Novo Nordisk deems

necessary to ensure that the terms and conditions of this Agreement have been fulfilled. Novo Nordisk shall provide Customer with no less than ten (10) days' written notice prior to conducting any such audit, which shall be conducted during the normal business hours of Customer. The costs of such audits shall be the responsibility of Novo Nordisk, unless such audits discloses that more than three percent (3%) of the Rebate amounts paid by Novo Nordisk were paid or submitted incorrectly, in which case Customer shall be responsible therefore.

- 14.2.2. The parties acknowledge and agree that in the event of an audit conducted pursuant to this Section 14.2 results in the Novo Nordisk discovering an error in the records of Customer relating to any aspect of this Agreement that Novo Nordisk reasonably believes such error may have been consistently made by Customer (and is not just a one-time occurrence), the parties will negotiate in good faith to correct such error including, but not limited to auditing information related to such error created more than one (1) year prior to the audit date; provided, further, that in no event shall Novo Nordisk be permitted to audit information created more than two (2) years prior to the date of the requested audit.
- 14.2.3. The parties agree that Novo Nordisk is neither a "Covered Entity" nor a "Business Associate" of Customer. The parties further agree that the discount or rebate administration process falls within HIPAA's definition of health care payment and operations. The prescription level data disclosed by Customer may contain identifiable health information, but only to the extent necessary for payment purposes related to this Agreement, as contemplated under the HIPAA rules. The parties agree that the prescription level data provided to Novo Nordisk under this Agreement represents the amount minimally necessary to process payments under this Agreement. Novo Nordisk shall use any such information received in connection with this Agreement only for such payment purposes and shall immediately notify Customer in the event that any such information is disclosed to any unauthorized individual or entity.
- 14.2.4. In the event that data required to validate Product Utilization requires access to Protected Health Information (beyond the minimum necessary to confirm Utilization as determined by CMS), such information shall not be transmitted electronically to Novo Nordisk, and shall be reviewed by an independent agent eligible to access such information under HIPAA and any other applicable laws.
- 14.2.5. If Novo Nordisk designates an agent to perform an audit, the designated agent shall be a nationally recognized independent firm that maintains no conflict of interest with Customer and is otherwise reasonably acceptable to Customer. Any information provided by the audited party shall be subject to the confidentiality provisions of Section 15 of this Agreement and applicable state law.
- 14.3. Customer agrees to institute and conduct on a regular basis audits of Pharmacies and Plans to ensure that actual dispensing of Products matches that claimed for Rebates.
- 14.4. In the event that either party determines, based upon its retrospective review, that Rebates and Administrative Fees for claims for Products were inappropriately paid,

such party shall notify the other party, of such determinations and shall refund or debit against any future Rebates and Administrative Fees paid with respect to such Products; except that no refunds or debits shall be paid on Utilization over two hundred seventy (270) days after the relevant claim period, except as otherwise provided for in Section14.2. This Section 14.4 does not supersede the provisions of Section 7 and those listed on **Exhibit E**.

14.5. Adjustments to either Novo Nordisk or Customer shall be refunded by the other party no later than sixty (60) days after completion of such audit or retrospective review.

### 15. Confidentiality

- 15.1. Requirements. Except as otherwise expressly provided in this Agreement or required by law, the existence of, and the terms and conditions of this Agreement are confidential, and each party agrees not to disclose the terms, conditions or existence of this Agreement, or any other confidential information ("Confidential Information"), without the prior written consent of the other. This restriction shall not apply to that information which: (a) was in the possession of the receiving party, as evidenced by its written records, prior to disclosure hereunder; (b) is or becomes generally available to the public, other than through a breach of this Agreement by the receiving party; or (c) is disclosed to the receiving party on a non-confidential basis by a third party having the legal right to disclose same.
- 15.2. Exceptions. Notwithstanding the foregoing, (i) Customer may disclose Confidential Information to one or more Plans to ensure the proper implementation of this Agreement; provided an appropriate non-disclosure agreement is entered into between Customer and such Plan(s) to ensure the confidentiality of the information contained herein; and (ii) Customer shall provide Novo Nordisk with de-identified information sufficient to validate rebate claims, and such information may be submitted to a third party for such validation, provided that the third party is bound by a confidentiality agreement, which requires compliance with all state and federal privacy laws, including but not limited to HIPAA, and restricts the third party from using or disclosing the information for any other purpose.
- 15.3. Patient Confidentiality. Novo Nordisk and Customer agree that nothing in this Agreement shall be construed to require Customer to provide any information, including any Protected Health Information, or any other information that in any way infringes upon patient confidentiality. Customer represents and warrants that (a) it will not infringe upon patient confidentiality in any way relating to any Pharmacy Controls implemented pursuant to this Agreement, and (b) it shall comply fully with all federal, state and local laws and regulations concerning confidentiality of patient information and pharmacy records.
- 15.4. The recipient may disclose the Confidential Information to the extent required by applicable Law, subpoena or court order, provided that the party requested or required to disclose Confidential Information promptly provides to the other party prior notice of such disclosure so that such party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement. If, in the absence of a protective order or other remedy or the receipt of a waiver by the non-disclosing party hereto, the party requested or required to disclose Confidential Information must nonetheless disclose any Confidential Information, such party shall disclose only the minimum information required to be disclosed in order to comply with such Law, subpoena or court order.

#### 16. General Provisions

- 16.1. Governing Law; Jurisdiction and Venue. This Agreement, the rights and obligations of the parties hereto, and any claims or disputes relating thereto, shall be governed by and interpreted in accordance with the laws of the State of Delaware without giving effect to the choice-of-law rules thereof. Any dispute shall be adjudicated in the courts of the State of Delaware, which shall have sole jurisdiction over such dispute. In the event of a dispute under this Agreement, the parties will use good faith efforts to resolve the dispute for a period of sixty (60) days following the date notice of such dispute is provided from one party to the other party. In the event that any such dispute cannot be resolved by the parties within such sixty (60) day period, either party may take any such actions available to it in law or in equity to resolve such dispute; provided, however, that in the event either party determines to litigate such dispute, adjudication of such dispute shall take place in the courts of the State of Delaware, which shall have sole jurisdiction over such dispute.
- 16.2. <u>Compliance with Law</u>. Both parties shall perform all work under this Agreement in compliance with all applicable federal, state and local laws and regulations.
- 16.3. <u>Fraud, Abuse, and Anti-Kickback Compliance</u>. The parties warrant that, in the performance of this Agreement, they will fully comply with 42 USC 1320a-7b(b), and the safe harbor regulations of the Department of Health and Human Services, which prohibit, inter alia, the knowing or willful offer, solicitation or receipt of any remuneration in return for purchasing or recommending the purchase of any products for which payment will be made, in whole or in part, under a federal or state health care program, except for certain exempt practices.
  - 16.3.1. The parties intend that the Rebates and Administrative Fees qualify for protection under the safe harbor and statutory exception for discounts at 42 C.F.R. § 1001.952(h) and 42 U.S.C. § 1320a-7b(b)(3)(A) ("Discount Safe Harbor") and the safe harbor for price reductions offered to eligible managed care organizations at 42 C.F.R. § 1001.952(t) ("Managed Care Safe Harbor"). Consistent with the Managed Care Safe Harbor, Novo Nordisk shall not claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the Agreement.
  - 16.3.2. The Administrative Fees and Rebates offered to Customer qualify for safe harbor protection under the "group purchasing organization" safe harbor set forth in 42 C.F.R. § 1001.952(j) (the "Group Purchasing Organization Safe Harbor"). Customer represents and warrants that it (i) has entered into a written agreement with each Plan that states that vendors from which Plan purchase goods will pay a fee (i.e., the Administrative Fee plus the Rebate) to Customer of three (3) percent or less of the purchase price of the goods provided by such vendor or, if the fee to the Customer is not fixed at three (3) percent or less of the purchase price of the goods, establishes the amount (or if not known, the maximum amount) payable by a vendor (including Novo Nordisk) to Customer (as specified in 42 C.F.R. § 1001.952(j)(i) or (ii)); (ii) shall disclose in writing (at least annually) to each Plan, and to the Department of Health and Human Services upon request, the amount of fees paid to Customer by Novo Nordisk with respect to purchases made by, or on behalf of, such Plan; and (iii) shall comply with all provisions of the Group

Purchasing Organization Safe Harbor. Customer represents and warrants that it shall not submit any Utilization for Administrative Fees or Rebates with respect to any Plan that is wholly-owned by Customer or a subsidiary of a parent corporation that wholly owns Customer (either directly or through another wholly-owned entity).

- 16.3.3. Neither party will take any action that would prevent the other party from complying with the Discount Safe Harbor, the Managed Care Safe Harbor or the Group Purchasing Organization Safe Harbor. The parties further agree that it is not their intent that any payments made under this Agreement be in return for the purchasing or ordering of any goods other than the specific Product(s) described in this Agreement.
- 16.3.4. Customer shall comply with the disclosure provisions set forth in the Discount Safe Harbor and the Group Purchasing Organization Safe Harbor and all disclosure and reporting requirements set forth in any other applicable law. Customer shall (i) accurately disclose and submit all reports to Plans, to third parties who are responsible for the cost of Products, to Government Programs and any other individual or entity regarding the Rebates and Administrative Fees payable under this Agreement to the extent required by applicable law or by contractual commitments undertaken by it; and (ii) remit payments to Plans to the extent required by applicable law and by contractual commitments undertaken by Customer. Disclosures shall be sufficiently detailed and provided in a manner to permit the Plans to meet their reporting and disclosure obligations required under any Government Program or by applicable law. If Customer sponsors an Exchange Plan, Customer shall comply with all applicable disclosure requirements set forth in the Affordable Care Act section 6005 and any applicable implementing regulations.
- 16.3.5. Customer shall comply with all applicable state, local and federal laws and regulations, including without limitation, all federal, state and local laws relating to drug product selection, consumer protection, and disclosure to Plans and Members of the basis of Formulary product selection, including the existence of this Agreement and any other agreement; Customer or Plans are not, and will continue not to be, during all times relevant to this Agreement, excluded from participation in a "Federal Health Care Program" (as defined in 42 U.S.C. § 1320a-7b(f)) or in any other governmental payment program. Customer is solely responsible for all payments by Customer to Plans and/or participating Pharmacies, and Customer represents and warrants that it shall inform any such payment recipient to report the discounts it receives, consistent with the Discount Safe Harbor and applicable law.
- 16.4. Indemnity. Each party (the "Indemnifying Party") shall indemnify, defend and hold harmless the other party (the "Indemnified Party") from any and all claims, demands, actions, causes of action, losses, judgments, damages, costs and expenses (including, but not limited to, reasonable attorneys' fees, court costs and costs of settlement (collectively, "Losses") that the Indemnified Party may suffer as a result of any third party actions, proceedings or claims (collectively "Claims") if and to the extent that such Losses and Claims directly arise out of any breach of applicable laws, any act or omission, negligent or otherwise, or willful misconduct of the Indemnifying Party, or its affiliates, or any of their respective directors, officers, employees or agents. The Indemnified Party shall promptly notify the Indemnifying

Party of any such Claims or Losses, shall fully cooperate with the Indemnifying Party in the investigation and defense thereof, and shall not settle or otherwise compromise such Claims or Losses without the prior written consent of the Indemnifying Party.

- 16.5. Force Majeure. Noncompliance with the obligations hereunder for reasons of any Force Majeure event shall not constitute a breach of this Agreement, but shall relieve the parties of their respective obligations under this Agreement for as long as the Force Majeure event remains in effect; however, such event shall not extend the Term of this Agreement. For purposes of this Agreement, the term "Force Majeure" shall be defined as: (a) any laws or regulations or acts of any government or agency thereof or judicial action which prevent performance hereunder; (b) any inability of a third-party manufacturer to supply Product; (c) acts of God; (d) war or civil commotion; (e) destruction of production facilities and/or materials; (f) fire, flood, explosions, earthquake or storm; (g) labor disturbances; (h) any health reform legislation which materially alters the commercial benefit of this Agreement; (i) any failure of public utilities or common carriers, or (j) any other causes beyond the reasonable control of the parties.
- 16.6. <u>Intellectual Property</u>. Neither party shall use any patented, trade named, trademarked or copyrighted material belonging to the other party, except as expressly permitted by this Agreement or otherwise agreed to in writing by the other party.
- 16.7. <u>Assignment</u>. Customer may not assign this Agreement or any part hereof to a third party without the prior written consent of Novo Nordisk, which consent shall not be unreasonably withheld or delayed. Upon written notice to Customer, Novo Nordisk shall have the right to assign this Agreement to an affiliate or as part of the sale of all or substantially all of the stock or U.S. pharmaceutical business of Novo Nordisk. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations which have accrued prior to such assignment.
- 16.8. <u>No Third Party Benefit</u>. None of the provisions contained herein is intended by the parties, nor shall any provision be deemed, to confer any benefit on any person not a party to this Agreement.
- 16.9. <u>No Waiver</u>. The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future.
- 16.10. <u>Severability</u>. If any provision of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be impaired thereby, and such remaining provisions shall continue to be valid, binding and enforceable, provided the intent of the parties as expressed in this Agreement can be achieved.
- 16.11. <u>Notices</u>. All notices under this Agreement shall be in writing and shall be delivered by (i) certified mail, return receipt requested, postage prepaid, or (ii) by recognized overnight courier service to the following addresses

If to Customer:		
Name:		
Title:		

Address:		
Phone: Facsimile: Email:		
. N P. J.		

If to Novo Nordisk:

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536

Attention: Director, Contract Management & Compliance

Phone: Facsimile:

With a copy to:

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 Attention: General Counsel

Phone: Facsimile:

All notices shall be effective upon receipt.

### 17. Closing

- 17.1. This Agreement, including all Exhibits, constitutes the entire agreement between the parties regarding the subject matter hereof, and all prior agreements, representations and warranties (whether written or oral) are expressly superseded. This Agreement (including the Exhibits) may not be amended or modified except in writings specified to be amendments of modifications signed by duly authorized representative of each party.
- 17.2. This Agreement will supersede any previous agreements between Novo Nordisk and Customer for the Products.
- 17.3. Each person signing this Agreement represents and warrants that they have the requisite authority to obligate the party on whose behalf they have signed.
- 17.4. This Agreement may be executed via e-mail, or other electronic means and in counterparts, each of which shall be deemed to be an original and all of which shall constitute one and the same document.

\*\*\*\*\*

(The next page is the signature page)

**IN WITNESS WHEREOF**, the parties have executed this Agreement on the date set forth below:

NOVO NORDISK INC.	[CUSTOMER]
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:

## **EXHIBIT A**

1.	Products Covered by this Agreement
	[TBD]
2.	Therapeutic Class for Data Submission and Market Share Calculation
	[TBD]
3.	Therapeutic Class for Formulary Positioning
	[TBD]

## **EXHIBIT B: Rebate Structure – by Plan**

[TBD]

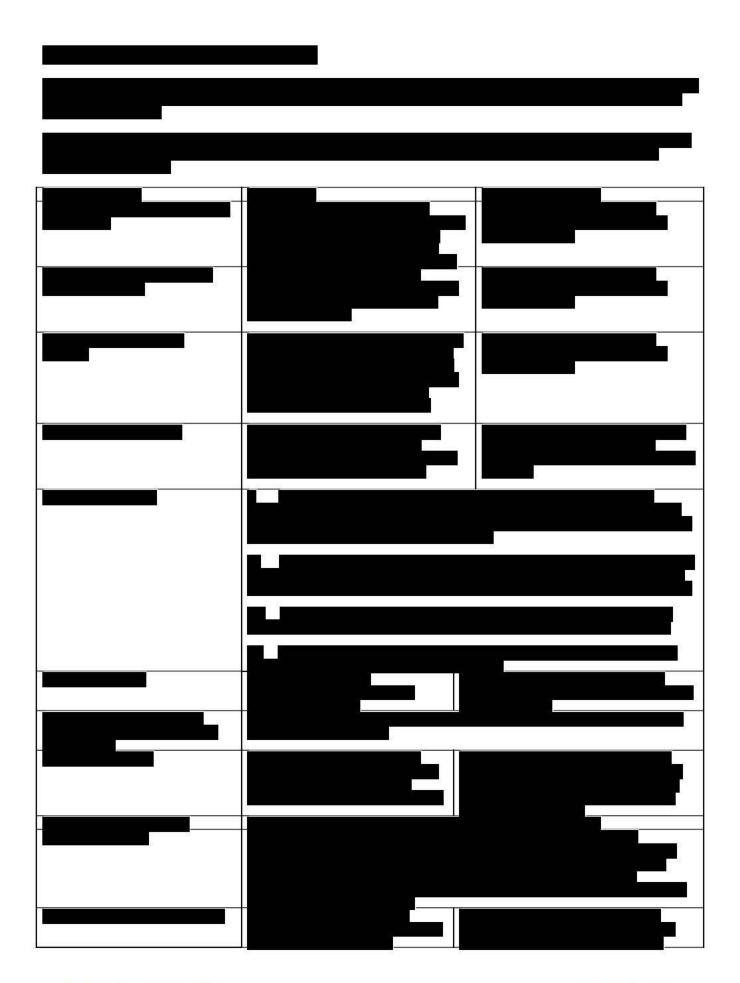
## **EXHIBIT C: Market Share Calculations**

[TBD]

## **EXHIBIT D: Plans**

Plan Name	Address	Туре	Lives	Effective Date	Novo Nordisk Product	NDC Numbers	Formulary Name
			-				
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				5			
			8	6			- 0 - 0 - 0
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CONFIDENTIAL & PROPRIETARY NNI-FINANCE- 000034



**Diabetes PAP** 

## All diabetes medicines

	•	•01=	•04.5	•01=	•010	
	2014	2015	2016	2017	2018	
	92,592	70,884	67,040	56,885	53,431	
Insulin medicines on	ly					
	2014	2015	2016	2017	2018	
	88,550	66,809	62,327	52,589	49,001	
Co-Pay Assistance I	Programs					
	2014	2015	2016	2017	2018	
NovoLog	27,124	45,017	50,375	71,513	86,744	
NovoLog Mix	4,496	5,978	5,335	5,856	7,265	
Levimir	40,682	56,893	48,765	55,860	55,606	
Tresiba		674	34,802	67,024	78,607	
Fiasp					3,914	
Xultophy				1,762	4,526	
Human Insulin Partnerships <sup>1</sup>						
	2014	2015	2016	2017	2018	

344,800

370,300

395,100

297,300

500,000

<sup>&</sup>lt;sup>1</sup> Numbers for 2017 and 2018 include Walmart, CVS, and ESI. Numbers for prior years include only Walmart as partnerships with CVS and ESI and did not begin until 2017. Please note that all numbers are approximate and derived from number of vials and pens sold each year.

## Diabetes PAP<sup>1</sup>

2014	2015	2016	2017	2018
\$341,376,621	\$281,575,961	\$293,636,065	\$266,800,148	\$273,524,422

## Co-Pay Assistance Program

2014	2015	2016	2017	2018
\$13,335,347 <sup>2</sup>	\$22,853,780	\$33,207,119	\$61,218,033	\$79,690,689

## E-Voucher Program<sup>3</sup>

2015	2016	2017	2018
\$86,124	\$17,176,573	\$31,764,227	\$41,160,932

## Pharmacy Donations Through Welvista<sup>4</sup>

2014	2015	2016	2017	2018
\$5,890,254	\$11,666,556	\$7,660,735	\$8,638,003	\$10,789,355

# **Donations To Diabetes Summer Camps<sup>5</sup>**

2014	2015	2016	2017	2018
\$4,256,949	\$5,555,898	\$6,267,905	\$7,163,627	\$6,113,103

<sup>&</sup>lt;sup>1</sup> Does not include costs of administering the program and includes only prices for insulin medicines, not other medicines used to treat diabetes.

<sup>&</sup>lt;sup>2</sup> Does not include costs of administering the program.

<sup>&</sup>lt;sup>3</sup> The E-voucher program was initiated in 2016.

<sup>&</sup>lt;sup>4</sup> Does not include costs of administering the program, which are not paid by Novo Nordisk.

<sup>&</sup>lt;sup>5</sup> Does not include costs of administering the program, which are not paid by Novo Nordisk.



RAPHAEL ADAM PROBER

June 28, 2019

## VIA HAND DELIVERY

The Honorable Charles E. Grassley Chairman

The Honorable Ron Wyden Ranking Member

Committee on Finance United States Senate 219 Dirksen Senate Office Building Washington, DC 20515

Dear Chairman Grassley and Ranking Member Wyden:

On behalf of Novo Nordisk Inc. ("NNI"), we write in further response to your letter dated February 22, 2019 (the "Letter"), in which you requested information and data related to prescription drug prices. As a company dedicated to improving the lives of people with diabetes and other chronic diseases, NNI shares your concerns about affordability and appreciates your commitment to addressing the complicated landscape of laws, regulations, market forces, and supply-chain entities that impact the price of prescription drugs. As discussed with staff, we continue to gather information and data relevant to the requests in your Letter, and will thereafter supplement our responses on a rolling basis.

In Question 2 of your letter, you request information about research and development and innovation. Research and Development ("R&D") at Novo Nordisk covers the entire pharmaceutical drug development process from idea exploration and early research, upscaling, clinical testing, and regulatory submission to ultimately bringing new innovative medicines and devices to patients. Innovation starts early in the drug discovery process, with scientists over periods of several years studying disease mechanisms at the genetic, cellular, tissue and whole-body level to identify novel targets for pharmacological intervention to address unmet medical needs. After a target has been identified, candidate drugs are designed by advanced chemical technologies and screened in specifically designed models of disease. Following an iterative process that typically includes thousands of compounds, a lead candidate drug is selected. That



drug then undergoes upscaling under rigorous control as well as comprehensive and extensive safety, pharmacological and toxicological testing models to comply with international guidelines. The company also has robust "Good Manufacturing Process" guidelines in place during the production of the medicine to ensure the high quality and quantity required for clinical testing.

Prior to initiation of a clinical trial in humans, the company must obtain local / regional regulatory approval to investigate a new medicine, or an existing medicine for a new indication. The company then conducts clinical trials via its global clinical, medical, and regulatory network, while working in close collaboration with external experts and health care professionals. Testing of a new medicine in the diabetes area typically requires evaluation in over 5,000 patients in global clinical trials. Following successful completion of the full clinical program for a new medicine, a registration application must be submitted to local health authorities to obtain marketing authorizations in all countries where the product will be marketed. The process from preclinical research to regulatory approval typically takes 10 to 15 years and costs on average more than \$2.5 billion for each approved medicine. Even after the product is on the market, the R&D organization continues to conduct relevant clinical trials of the marketed medicine, engage in scientific dialogue, maintain regulatory files, and monitor the safety of patients.

It is important to recognize that attrition rates are substantial: Thousands of compounds are tested preclinically and, even for drug candidates that do make it to phase 1 clinical trials, the likelihood of making it to market is less than 10%. Research can be terminated because it is not leading to endpoints, or because it is not demonstrating disease mechanisms worthy of further pursuit. For all of these reasons, investments in R&D must be understood to cover not only those drugs that make it to market, but the countless drug candidates that do not.

Globally, Novo Nordisk employs more than 5,000 people in R&D and invests over 13% of its annual sales revenue back into the innovation and development of new products. In the United States, Novo Nordisk maintains R&D centers in Washington State and Indiana. These centers are focused on protein and stem-cell based therapies for obesity, diabetes, and other chronic diseases, research on the next generation of medical devices and novel methods of transforming the management of cardio-metabolic diseases.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Indeed, in the United States, there were over 12,000 patients enrolled in Novo Nordisk's clinical trials between 2016 and 2018, with an additional 7,400 patients either enrolled or planned to be enrolled in 2019. These trials have been conducted in 48 states.

<sup>&</sup>lt;sup>2</sup> In addition to R&D, Novo Nordisk maintains manufacturing facilities in North Carolina and New Hampshire. In 2016, Novo Nordisk also began a \$2 billion investment in a new production facility in Clayton,



After close to 100 years of developing medicines, Novo Nordisk currently engages in more than seventy partnerships globally and conducts clinical trials in more than fifty countries. Because of this, Novo Nordisk has been ranked in the top 10 of Science Careers Top Employers since 2014.

Novo Nordisk focuses on seven main therapy areas for R&D where it feels it can make the most positive contributions to patients: type 1 diabetes, type 2 diabetes, obesity, atherosclerosis, non-alcoholic steatohepatitis, hemophilia, and growth disorders. Although Novo Nordisk prides itself on its innovative medicines across these disease spaces, its principal mission since day one has been and continues to be improving the lives of people with diabetes, and its R&D efforts reflect that focus.

In the last several years, Novo Nordisk brought several new insulin medications to market. In 2015, Novo Nordisk introduced Tresiba®, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients. This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba® is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Even more recently, in 2017, Novo Nordisk introduced Fiasp®, a new short-acting insulin that offers quicker onset when compared to other current analog insulins. These two recent advances, Tresiba® and Fiasp®, have allowed patients to better control their diabetes, particularly overnight and in between meals. For patients, better nighttime control with Tresiba® could mean the difference between getting a good night's sleep and waking for a productive day ahead, or experiencing the very frightening and dangerous risk for low blood sugar (hypoglycemia) during the night.

Also in 2017, Novo Nordisk introduced Xultophy®, a unique therapy that is a combination of insulin degludec and liraglutide in a single injection. Xultophy® is indicated for adults with type 2 diabetes and, in clinical trials, was shown to significantly reduce A1C and maintain blood sugar levels for 24 hours. Like many of Novo Nordisk's other medicines, Xultophy®, along with diet and exercise, can improve glycemic control in adults with type 2 diabetes.



Novo Nordisk has also formed research collaborations to advance further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop an oral capsule device that contains compressed insulin, which, after being swallowed, is injected into the patient after the capsule reaches the stomach. This capsule could potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. Novo Nordisk is also conducting research using stem cell therapies in collaboration with the University of California, San Francisco to treat diabetes and other serious chronic diseases, such as heart failure, and brain disorders, such as Parkinson's disease. These are just some of the innovative and cuttingedge R&D projects underway at Novo Nordisk.

Novo Nordisk has also introduced numerous innovative devices, such as the "smart" insulin pen, which records the exact time and dose of insulin a patient has injected. For patients on multiple daily injections, this obviates the need to log doses and reduces the likelihood that doses will be missed or accidentally repeated. Novo Nordisk's innovative pen devices also allow for more accurate and convenient delivery of insulin, allowing patients to dose themselves more easily and with less pain. Accordingly, they allow patients who may struggle with fine motor skills to self-dose, thereby obviating the need for medical assistance and permitting patients—particularly elderly patients—to maintain their independence. It is important to recognize that patents on Novo Nordisk's innovative devices do not impede the ability of generic competitors to produce the underlying medication. A generic competitor may produce the unpatented substance and market it in its own delivery device, or for use with a traditional vial and syringe.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving patients' lives through new medications and delivery systems. Novo Nordisk will continue to innovate to address the needs of patients and to meet the goal of defeating diabetes.

In Question 7, you ask about pricing for insulin medicines. As we indicated in an earlier submission, pricing decisions at NNI are made by the Pricing Committee. There are four voting members of the Pricing Committee responsible for pricing—the NNI President, the Senior Vice President for Strategy, Finance and Operations, the Senior Vice President for Market Access, and the Senior Vice President for Commercial. The names of those individuals were provided in an earlier submission.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> Please note that there was a recent change in personnel. Senior Vice President for Commercial David Moore left the company and was replaced by Brian Hilberdink.



The Senior Vice President for Strategy, Finance and Operations is the Chair of the Pricing Committee and is responsible for coordinating and scheduling monthly meetings. For approval of matters brought before the Pricing Committee, there must be agreement among a simple majority of the voting members. In the event of a tie or impasse due to abstentions, if a simple majority cannot be obtained, the matter will go to the NNI President for definitive vote.

NNI follows the following procedures for determining list price. For new products, development of a pricing strategy is expected to begin approximately 24–27 months prior to the anticipated product launch. The Market Access Strategy, Strategic Pricing and Brand teams work to develop a high-level approach to list and net price approximately 12–15 months prior to launch. At that point, the strategy is presented to the Pricing Committee for approval. Subsequently, upon receiving FDA approval and a final product label, the Pricing Committee confirms the final list price strategy prior to launch.

For list prices of existing drugs, initial strategy is developed by Market Access Strategy in coordination with the Strategic Pricing and Brand teams. The list price strategy is then presented (by Market Access Strategy) to the Pricing Committee for approval. All list price strategies for the upcoming year are submitted in the fall of the prior year.

Although a list price strategy may have already been approved by the Pricing Committee months beforehand, Sarbanes-Oxley controls require that, prior to executing any list price change, approvals are obtained from the NNI President and Senior Vice President for Strategy, Finance and Operations. The Pricing Committee is also notified before execution of any list price changes.

NNI is aware that list price plays a role in what patients pay at the pharmacy counter, particularly for patients with high-deductible health plans, those who have co-insurance, and those who are uninsured and not covered by any government drug benefit programs. But it is important to recognize that list price is not set in a vacuum. Rather, list price is set (by way of the procedures just described) against the backdrop of the competitive environment in which the company operates, which includes increasing demands by PBMs and other payers for rebates.

Because of consolidations that have occurred over the past several years, the three largest PBMs now manage access to medications for over 80 percent of the covered U.S. population, or roughly 220 million people. With such a substantial market share, these companies are able to exert considerable leverage in negotiations. If they do not extract the rebate concessions they demand, they can (and do) exclude products from formularies. Exclusion from a major formulary would have significant consequences for patients and for the company. If Novo Nordisk medicines



were not covered on formulary, patients whose diabetes is well-controlled by a Novo Nordisk product would be forced to either switch to another product, which might not work as well for them, or pay much more to stay on their physician-prescribed Novo Nordisk medicine. For the company, exclusion from a major formulary typically results in a significant financial loss, as well as loss of market share.

The pressure to provide higher rebates is constant and escalating, and rebate percentages have increased year over year for the last several years. Today, as a single company, Novo Nordisk pays approximately 10% of all rebates across the entire pharmaceutical industry, much of that within the insulin space. This is a result of the fierce competition between the insulin manufacturers, in the current system, to secure and maintain formulary access.

While increased competition in a marketplace would usually lead to lower prices, our current healthcare system is built on misaligned incentives that have led to rising costs for medicines. Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of list price. That means that a pharmaceutical company like NNI fighting to remain on formulary is constrained from lowering list price because PBMs will then earn less in rebates and potentially choose to exclude Novo Nordisk's products if its rebates are not competitive. In fact, NNI has had discussions with payers about the possibility of eliminating rebates and focusing instead on net price-in other words, lowering list price to the amount the company actually receives from payers. In those discussions, PBMs and other payers have expressed concern about the consequences of such a systemic change and have been unwilling to offer assurances that NNI would maintain its formulary positions if it no longer offered rebates. For that reason, the company continues to invest in rebates. Last year, across all products and channels, Novo Nordisk paid an average of 68 cents for every dollar of sales to PBMs and other payers and supply-side entities in the form of rebates and other discounts and fees—approximately \$18 billion total.<sup>4</sup> These rebates, discounts, and other price concessions are the single largest investment Novo Nordisk makes in ensuring its products are broadly available to patients.

Unfortunately, many patients do not see the full benefit of the discounts NNI and other manufacturers provide to PBMs to secure formulary access, and some see little to no benefit at all. In particular, uninsured patients and patients covered by high-deductible health plans pay close to

<sup>&</sup>lt;sup>4</sup> As discussed in Novo Nordisk's March 8, 2019 submission to this Committee, net prices for Novo Nordisk's insulin medicines have declined year over year for every year from 2015 to 2018 as a result of increasing payer demands for higher rebates.



the full list price for Novo Nordisk's medicines. Others, such as those with co-insurance or Medicare Part D patients in the coverage gap, may also pay a substantial portion of the list price. This is true even where Novo Nordisk has already paid a substantial rebate to the PBM to secure formulary access for the particular medication.

As noted in our prior submission, NNI supports the Administration's efforts to alleviate this problem by implementing the so-called rebate rule. NNI also supports other legislative or regulatory change that would ensure that the rebates pharmaceutical manufacturers pay to secure and maintain formulary access are passed on to the patients who use those medicines.

\* \* \*

Production of this and future information and data is not intended to constitute a waiver of the attorney-client, attorney work product, or any other applicable rights or privileges in this or any other forum. NNI expressly reserves its rights in this regard. In addition, certain information responsive to the Committee's requests, and in particular in future submissions, may contain highly sensitive information – potentially including confidential, proprietary, trade secret, and/or material non-public information. Accordingly, NNI requests that such information be kept confidential by the Committee and its staff. Notwithstanding our request that such information be kept confidential, we would ask that staff provide us with notice and an opportunity to be heard before the Committee discloses any such information or data to third parties.

We appreciate our recent conversations with your staff on these matters and look forward to engaging further with the Committee to continue addressing the questions in your Letter. As discussed with your staff, and as described above, certain of these questions may call for sensitive information, and we will raise such issues with staff as appropriate. NNI is committed to working with the Committee to respond to its inquiry and to addressing the complicated issues surrounding drug pricing more broadly. We look forward to working cooperatively with you and your staff in this regard.

Sincerely,

Raphael A. Prober

Steven R. Ross

Counsel for Novo Nordisk Inc.

A. Pomber MOS

## HISTORIC WAC PRICE FOR INSULIN PRODUCTS

Product Name	NDC/UPC/HRI	History Price Type	History Effective Date	History Package Price	WAC Current Package Price	WAC Current Effective Date	Package Description	Qty 5	Size	Package SUM
Fiasp FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-3204-15	WAC	07/03/2018			07/03/2018		5		3 ML
Fiasp FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-3204-15	WAC	09/29/201			07/03/2018		5		3 ML
Fiasp Subcutaneous Solution 100 UNIT/ML	00169-3201-11	WAC	07/03/201					1		0 ML
Fiasp Subcutaneous Solution 100 UNIT/ML	00169-3201-11	WAC	09/29/201					1		0 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC WAC	01/08/2019		7.00.00	01/08/2019		5		3 ML 3 MI
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10 00169-6438-10	WAC	07/03/2018 01/03/2018		\$462.21 \$462.21			5 5	-	3 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	08/25/201					5		3 MI
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	11/18/2014					5	-	3 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	05/31/2014	\$333.12	\$462.21	01/08/2019	Pen	5	-	3 ML
Levemir FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6438-10	WAC	05/21/2014	\$303.12	\$462.21	01/08/2019	Pen	5		3 ML
Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	01/08/2019	1		. ,		1		0 ML
Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	07/03/2018		7000.2	,,		1		0 ML
Levemir Subcutaneous Solution 100 UNIT/ML Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12 00169-3687-12	WAC WAC	01/03/2018 08/25/2018					1		0 ML 0 ML
Levemir Subcutaneous Solution 100 UNIT/ML Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	11/18/201					1		0 ML
Levenir Subcutaneous Solution 100 UNIT/MI	00169-3687-12	WAC	05/31/2014	,		,,		1		0 MI
Levemir Subcutaneous Solution 100 UNIT/ML	00169-3687-12	WAC	12/19/201		7000.0	,,		1		0 ML
NovoLIN 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3007-15	WAC	10/08/2018					5	-	3 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	07/06/2010	\$137.70	\$137.70	07/06/2016	Vial	1	1/	0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	11/25/201		7-0			1		0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	05/19/201					1		0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11	WAC	11/18/2014	,	\$137.70	. ,		1		0 ML
NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML NovoLIN 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1837-11 00169-1837-11	WAC WAC	05/28/2014 12/03/201			. ,		1		0 ML 0 MI
NovoLIN N Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-1834-11	WAC	07/06/201		7-0	,,		1		0 MI
NovoLiN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	11/25/201					1		0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	05/19/201					1		0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	11/18/2014	\$109.56	\$137.70	07/06/2016	Vial	1	1/	0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	05/28/2014	\$99.65	\$137.70	07/06/2016	Vial	1	1/	0 ML
NovoLIN N Subcutaneous Suspension 100 UNIT/ML	00169-1834-11	WAC	12/03/201		\$137.70			1		0 ML
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC	07/06/2010					1		0 ML
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC	11/25/201	,		. ,		1		0 ML
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC WAC	05/19/201			. ,		1		0 ML 0 ML
NovoLIN R Injection Solution 100 UNIT/ML NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11 00169-1833-11	WAC	11/18/2014 05/28/2014					1		0 MI
NovoLIN R Injection Solution 100 UNIT/ML	00169-1833-11	WAC	12/03/201					1		0 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	07/03/2018					5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	02/23/201		\$558.83	07/03/2018	Pen	5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	07/06/2010	\$493.25	\$558.83	07/03/2018	Pen	5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	11/25/201					5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	05/19/201			. , ,		5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10	WAC	11/18/2014					5		3 ML
NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-6339-10 00169-6339-10	WAC WAC	05/28/2014 12/03/2013			. , ,		5 5	-	3 ML 3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	07/03/201			07/03/2018		5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	02/23/201					5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	07/06/2010			07/03/2018		5	-	3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	11/25/201	\$457.10	\$558.83	07/03/2018	Pen	5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	05/19/201			07/03/2018		5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC	11/18/2014					5		3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML	00169-3696-19	WAC WAC	05/28/2014					5		3 ML 3 ML
NovoLOG Mix 70/30 FlexPen Subcutaneous Suspension Pen-injector (70-30) 100 UNIT/ML NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3696-19 00169-3685-12	WAC	12/03/201 07/03/201					5 1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 ONT/ML  NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	02/23/201					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	07/06/2010					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	11/25/201	\$245.50	\$300.12	07/03/2018	Vial	1	1/	0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	05/19/2019	\$231.75	\$300.12	07/03/2018	Vial	1	10	0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	11/18/2014					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	05/28/2014					1		0 ML
NovoLOG Mix 70/30 Subcutaneous Suspension (70-30) 100 UNIT/ML	00169-3685-12	WAC	12/03/2013		\$300.12			1		0 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12 00169-3303-12	WAC WAC	07/03/2018 02/23/201			07/03/2018 07/03/2018		5 5		3 ML 3 MI
Novol OG PenFill Subcutaneous Solution Cartridge 100 UNIT/MI	00169-3303-12	WAC	07/06/201			07/03/2018		5		3 MI
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	11/25/201		++++++	07/03/2018		5		3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	05/19/201					5		3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	11/18/2014	\$377.56	\$537.47	07/03/2018	Cartridge	5	3	3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	05/28/2014		++++++	07/03/2018		5		3 ML
NovoLOG PenFill Subcutaneous Solution Cartridge 100 UNIT/ML	00169-3303-12	WAC	12/03/201					5		3 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	07/03/2018					1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML NovoLOG Subcutaneous Solution 100 UNIT/MI	00169-7501-11	WAC WAC	02/23/201 07/06/201					1		0 ML 0 MI
NovoLOG Subcutaneous Solution 100 UNIT/ML NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	11/25/201		7-00.00	,,		1		0 MI
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	05/19/201					1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	11/18/2014					1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	05/28/2014	, , , , , , , , , , , , , , , , , , , ,	7-00.00	,,		1		0 ML
NovoLOG Subcutaneous Solution 100 UNIT/ML	00169-7501-11	WAC	12/03/201		7-00.00	,,		1		0 ML
Tresiba FlexTouch Subcutaneous Solution Pen-injector 100 UNIT/ML	00169-2660-15	WAC	01/08/2019	\$508.43	\$508.43	01/08/2019	Pen	5	3	3 ML

#### HISTORIC WAC PRICE FOR INSULIN PRODUCTS

00169-2660-15 WAC	07/03/2018	\$484.68	\$508.43	01/08/2019 Pen	5	3 ML
00169-2660-15 WAC	01/03/2018	\$461.60	\$508.43	01/08/2019 Pen	5	3 ML
00169-2660-15 WAC	10/23/2015	\$443.85	\$508.43	01/08/2019 Pen	5	3 ML
00169-2550-13 WAC	01/08/2019	\$610.11	\$610.11	01/08/2019 Pen	3	3 ML
00169-2550-13 WAC	07/03/2018	\$581.62	\$610.11	01/08/2019 Pen	3	3 ML
00169-2550-13 WAC	01/03/2018	\$553.92	\$610.11	01/08/2019 Pen	3	3 ML
00169-2550-13 WAC	10/23/2015	\$532.62	\$610.11	01/08/2019 Pen	3	3 ML
00169-2662-11 WAC	01/08/2019	\$338.95	\$338.95	01/08/2019 Vial	1	10 ML
00169-2662-11 WAC	12/21/2018	\$323.12	\$338.95	01/08/2019 Vial	1	10 ML
00169-2911-15 WAC	01/08/2019	\$1,039.88	\$1,039.88	01/08/2019 Pen	5	3 ML
00169-2911-15 WAC	01/03/2018	\$991.31	\$1,039.88	01/08/2019 Pen	5	3 ML
00169-2911-15 WAC	03/03/2017	\$953.18	\$1,039.88	01/08/2019 Pen	5	3 ML
	00169-2660-15 WAC 00169-2660-15 WAC 00169-2550-13 WAC 00169-2550-13 WAC 00169-2550-13 WAC 00169-2550-13 WAC 00169-2662-11 WAC 00169-2662-11 WAC 00169-2611-15 WAC 00169-2911-15 WAC	00169-2660-15         WAC         01/03/2018           00169-2560-15         WAC         10/23/2015           00169-2550-13         WAC         01/08/2019           00169-2550-13         WAC         07/03/2018           00169-2550-13         WAC         01/03/2018           00169-2550-13         WAC         10/23/2015           00169-2561-11         WAC         01/08/2019           00169-2662-11         WAC         12/21/2018           00169-2662-11         WAC         01/08/2019           00169-2911-15         WAC         01/03/2018	00169-2660-15         WAC         01/03/2018         \$461.60           00169-2660-15         WAC         10/23/2015         \$443.85           00169-2550-13         WAC         01/08/2019         \$610.11           00169-2550-13         WAC         07/03/2018         \$581.62           00169-2550-13         WAC         01/03/2018         \$553.92           00169-2550-13         WAC         01/03/2015         \$32.62           00169-2662-11         WAC         01/08/2019         \$338.95           00169-2662-11         WAC         01/08/2019         \$323.12           00169-2911-15         WAC         01/08/2019         \$1,039.88           00169-2911-15         WAC         01/03/2018         \$991.31	00169-2660-15         WAC         01/03/2018         \$461.60         \$508.43           00169-2660-15         WAC         10/23/2015         \$443.85         \$508.43           00169-2550-13         WAC         01/08/2019         \$610.11         \$610.11           00169-2550-13         WAC         07/03/2018         \$581.62         \$610.11           00169-2550-13         WAC         01/03/2018         \$553.92         \$610.11           00169-2550-13         WAC         01/03/2015         \$532.62         \$610.11           00169-2550-13         WAC         01/03/2019         \$338.95         \$338.95           00169-2662-11         WAC         01/08/2019         \$323.12         \$338.95           00169-2662-11         WAC         12/21/2018         \$323.12         \$338.95           00169-2911-15         WAC         01/08/2019         \$1,039.88         \$1,039.88           00169-2911-15         WAC         01/03/2018         \$991.31         \$1,039.88	00169-2660-15         WAC         01/03/2018         \$461.60         \$508.43         01/08/2019 Pen           00169-2560-15         WAC         10/23/2015         \$443.85         \$508.43         01/08/2019 Pen           00169-2550-13         WAC         01/08/2019         \$610.11         \$610.11         01/08/2019 Pen           00169-2550-13         WAC         07/03/2018         \$581.62         \$610.11         01/08/2019 Pen           00169-2550-13         WAC         01/03/2018         \$553.92         \$610.11         01/08/2019 Pen           00169-2550-13         WAC         01/03/2015         \$532.62         \$610.11         01/08/2019 Pen           00169-2560-11         WAC         01/08/2019         \$338.95         \$338.95         01/08/2019 Vial           00169-2662-11         WAC         01/08/2019         \$338.95         \$338.95         01/08/2019 Vial           00169-2911-15         WAC         01/08/2019         \$1,039.88         \$1,039.88         01/08/2019 Pen           00169-2911-15         WAC         01/03/2018         \$991.31         \$1,039.88         01/08/2019 Pen	00169-2660-15         WAC         01/03/2018         \$461.60         \$508.43         01/08/2019 Pen         5           00169-2560-15         WAC         10/23/2015         \$443.85         \$508.43         01/08/2019 Pen         5           00169-2550-13         WAC         01/08/2019         \$610.11         \$10.01         01/08/2019 Pen         3           00169-2550-13         WAC         07/03/2018         \$581.62         \$610.11         01/08/2019 Pen         3           00169-2550-13         WAC         01/03/2018         \$553.92         \$610.11         01/08/2019 Pen         3           00169-2550-13         WAC         10/23/2015         \$532.62         \$610.11         01/08/2019 Pen         3           00169-2561-11         WAC         10/23/2015         \$532.62         \$610.11         01/08/2019 Pen         3           00169-2662-11         WAC         01/08/2019         \$338.95         \$338.95         01/08/2019 Vial         1           00169-2911-15         WAC         12/21/2018         \$323.12         \$338.95         01/08/2019 Vial         1           00169-2911-15         WAC         01/08/2019         \$1,039.88         \$1,039.88         01/08/2019 Pen         5           00169-2911-15

CONFIDENTIAL & PROPRIETARY NNI-FINANCE- 000003

## MEDICARE PART D PROGRAM REBATE AGREEMENT



THIS REBATE AGREEMENT (this "Agreement") is made and entered into as of the 1st day of January, 2013 ("Effective Date"), by and between CVS Caremark Part D Services, L.L.C., a Delaware limited liability company ("PBM"), and Novo Nordisk Inc., a Delaware corporation ("Manufacturer").

- 1. <u>Definitions.</u> In addition to terms defined elsewhere herein, the following terms shall have the meanings set forth below:
  - "Administrative Fees" means the administrative fees set forth on Exhibit A attached hereto.
  - "Affiliate" means, with respect to a party, any corporation, partnership or other legal entity directly or indirectly owned or controlled by, or which owns or controls, or which is under common ownership or control with, such party.
  - "Affiliated EGWP Plan" means an Affiliated Plan that is an EGWP Plan.
  - "Baseline Net Price" means Net Price in effect as of the last day of the prior Contract Year,
  - "Baseline WAC" means WAC in effect as of the last day of the prior Contract Year.
  - "CMS" means the Centers for Medicare and Medicaid Services.
  - "Competitive Products" means, with respect to each Product, all single source, branded, prescription products in the same Therapeutic Class as such Product that are manufactured by an entity other than Manufacturer.
  - "Contract Year" means the twelve-month period commencing on January 1, 2013 and each subsequent twelve-month period.
  - "Disadvantage" means intervention activities focused on a Product where such activities are reasonably intended to discourage the utilization of the Product in favor of a Competitive Product, including, without limitation, step edits and prior authorization; provided, however, that "Disadvantage" shall not include Permitted Activities.
  - "EGWP Plan" means a Part D Plan that is operating under a waiver granded pursuant to 42 C.F.R. § 423.458(c).
  - "Exclusion" means that a product is subject to NDC block, step edit or prior authorization requiring demonstrated failure of the Product, or is otherwise not covered by the Part D Plan, subject to medical necessity exceptions and such exceptions as may be required to comply with applicable law, including, without limitation, the MMA.
  - "Medicare Coverage Gap" means the gap phase in prescription drug coverage that occurs between the initial coverage limit (as defined in Section 1860D-2(b)(3) of the Social Security Act) and the out-of-pocket threshold (as defined in Section 1860D-2(b)(4)(B) of the Social Security Act).
  - "Medicare Coverage Gap Discount Program" means the Medicare Coverage Gap Discount Program created pursuant to Section 3301 of the Patient Protection and Affordable Care Act (H.R. 3590), as amended by Section 1101 of the Health Care and Education Reconciliation Act of 2010 (H.R. 4872) and codified in Sections 1860D-43 and 1860D-14A of the Social Security Act.

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"Member" means a person who is enrolled in a Part D Plan.

"MMA" means the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the regulations promulgated thereunder.

"Net Price" means, as determined separately for each applicable Product and each applicable Formulary Status, an amount equal to (i) WAC minus (ii) WAC multiplied by the applicable Rebate percentage. For purposes of clarification, WAC used for "Net Price" equals WAC used for calculation of Rebates (i.e. WAC as of the purpose of the applicable month.)

"Non-Affiliated EGWP Plan" means a Non-Affiliated Plan that is an EGWP Plan.

"Non Affiliated Plan" means any Part D Plan that is not an Affiliated Plan.

"Part D Plan" means each Part D Plan Sponsor prescription drug plan(s) approved by CMS under the Program and for which PBM provides Rebate Contracting Services.

"Part D Plan Sponsor" means a sponsor that has received CMS approval of its prescription drug plan under the Program and for which PBM provides Rebate Contracting Services.

"Participating Pharmacy" means a Network Pharmacy or an Out-of-Network Pharmacy as such terms are defined in the Part D Regulations; provided that Participating Pharmacy shall not include a Network Pharmacy or an Out-of-Network Pharmacy located outside the United States, Puerto Rico, and U.S. Territories, unless approved in writing by Manufacturer, and shall not include non-retail hospital pharmacy that receives purchase discounts on the Products from Manufacturer or any pharmacy owned or operated by a "covered entity" (as defined at 42 U.S.C. §256b(a)(4)), which dispenses drugs under the program established pursuant to Section 340B of the Public Health Service Act or any pharmacy which dispenses drugs pursuant to the Federal Supply Schedule. Manufacturer will provide notice to PBM in accordance with Section 2(d) when Manufacturer identifies such pharmacies that (i) are owned or operated by a "covered entity" (as defined at 42 U.S.C. §256b(a)(4)), which dispenses Product(s) under the program established pursuant to Section 340B of the Public Health Service Act or (ii) dispense Product(s) pursuant to the Federal Supply Schedule.

"Permitted Activities" means actions taken for reasons of clinical appropriateness, or Participant safety, or AB-rated generic substitution/intervention.

"Plan Formulary" means the formulary adopted by the Part D Plan Sponsor pursuant to the MMA, as most recently submitted to CMS.

"Program" means the voluntary Medicare Part D Prescription Drug Benefit Program created by the MMA.

"Products" means the pharmaceutical products listed on Exhibit A attached hereto.

"Rebate Contracting Services" means the negotiation with prescription drug manufacturers and others for discounts and rebates on prescription drugs.

"Rebates" means the rebates set forth on Exhibit A.

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"Second Tier" shall mean the co-pay status under which the Product is at the lowest co-pay level for branded, single source prescription products in the relevant Therapeutic Class. Such co-pay level shall not be greater than the lowest co-pay level for branded, single source prescription products for the majority of all other therapeutic classes.

"Specialty Product" means a pharmaceutical, biotech or biological drug that is used in the treatment of chronic, long-term or genetic disease, including injectable, infused, or oral medications, and that may have mixing and compounding complexities and/or special storage or delivery requirements (e.g. refrigeration).

"Specialty Tier" means the co-pay status under which the Product is adjudicated at the co-pay level for branded, single source prescription Specialty Products.

"Therapeutic Class" means the therapeutic class for each Product as set forth in Exhibit C. In the event the FDA approves additional prescription pharmaceuticals or biologicals within the therapeutic classes of the Products during the Term of this Agreement, such newly approved pharmaceuticals shall be considered to be Competitive Products and added within the appropriate Therapeutic Class listed in Exhibit C upon written notice by Manufacturer to PBM, subject to PBM's written approval, which shall not be unreasonably withheld. If PBM does not respond within of notice to reasonable communication efforts, the Competitive Product will be deemed to be included in the Therapeutic Class.

"Unit" means a single unit (whether a milligram, pill, milliliter, or other measurement), provided that single use items shall be measured per use (i.e. one use equals one unit).

"Wholesale Acquisition Cost" or "WAC" means the wholesale acquisition cost for a Product as determined by Manufacturer and published by First Data Bank and/or Medispan, as selected by PBM. The parties acknowledge that WAC does not reflect wholesaler fees, charges or mark-ups or any chargebacks, rebates or discounts that Manufacturer may provide to wholesalers or any other person or entity.

### 2. Rebates.

(a) <u>Rebates & Administrative Fees.</u> Manufacturer shall pay to PBM the Rebates and Administrative Fees for each Product dispensed to Members by Participating Pharmacies as set forth in and in accordance with Exhibit A.

## (b) PBM Data Reporting.

- (i) Reporting. Within forty-five (45) days after the end of each calendar month for the 2013 contract year and thirty (30) days for the 2014 contract year, PBM shall deliver to Manufacturer an invoice setting forth the calculation of the amounts payable by Manufacturer to PBM for such month and, to the extent not previously submitted, the eight (8) preceding months. The invoice shall be accompanied by a product utilization report (a total across all Plans for each Product identified by brand and by NDC number), which shall be transmitted by electronic data utilizing the National Council for Prescription Drug Programs ("NCPDP") manufacturer rebate utilization flat file standard, PBM's standard reporting format, or as otherwise mutually agreed upon by Manufacturer and PBM, for such month and, to the extent not previously submitted, the eight (8) preceding months ("Data Reports")
- (ii) Utilization by Product. A total across all Plans for each Product (identified by brand and by 11-digit NDC number).

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- (iii) Utilization by Market. Utilization for a given Product and its Therapeutic Class (as set forth in Exhibit C) summarized as follows:
  - i. Listing of pharmaceutical products in the Therapeutic Class.
  - ii. Listing of Manufacturer's Products in the Therapeutic Class
  - iii. For each of Manufacturer's Products individually and for all other pharmaceuticals listed in the Therapeutic Class in the aggregate, the number of prescriptions, the number of Units dispensed and the share of the Therapeutic Class represented.

This information is available in electronic data and can be queried by Manufacturer. The summary level invoice is also available in hard copy. The information provided above, plus claim level detail with Plan names or identification number, shall be provided.

PBM shall use reasonable efforts to notify Manufacturer within of a Product's change in status on its Plan Formulary; provided that failure to give such notice shall not constitute a breach of this Agreement.

- (iv) Notice of Deficiencies & Objections. Manufacturer must notify PBM in writing within following Manufacturer's receipt of the Data Reports if Manufacturer believes the data submitted in the Data Reports is either missing material components of the required data elements for all or any of the Product utilization reported or is not capable of being processed by Manufacturer due to the data files, when delivered, being corrupt, damaged, or otherwise not readable.
- (v) <u>Calculations</u>. Any claims submitted from any of the preceding the current month shall be aggregated with the current month's claims for the purpose of calculating Rebates and Administrative Fees. Calculations for Rebates and Administrative Fees will be performed with six decimal places of precision and summarized to two decimal places of precision for submission. Calculations shall be based upon the bill date of the claim(s), not the fill date.
- (vi) <u>State to Plan Reconciliations</u>. Notwithstanding anything in this Agreement to the contrary, PBM may furnish Data Reports to Manufacturer for state claims within days after the claim period.

## (c) Manufacturer Payment.

- (i) Monthly Payment. For the 2013 contract year, Manufacturer shall pay to PBM the Rebates and Administrative Fees calculated within pf the date of Manufacturer's receipt of the Data Reports submitted in accordance with Section 2(b)(i). For the 2014 contract year, Manufacturer shall pay to PBM the Rebates and Administrative Fees calculated within Notwithstanding the foregoing, sequential payment due dates shall be at least thirty meaning that if PBM submits more than one (1) invoice and Data Report within a period, the payment due date for the additional invoice shall be thirty days from the payment date of the earlier month's invoice.
- (ii) <u>Method of Payment</u>. All payments made by Manufacturer shall be made electronically, via wire transfer, to the bank account designated by PBM.
- (iii) <u>Manufacturer Documentation</u> <u>Manufacturer shall deliver to PBM</u>, electronically and within the same timeframe as the Rebate and Administrative Fee payment, the NCPDP manufacturer rebate reconciliation flat file standard, or alternatively, a reconciliation report in the format set forth in



measured on such data. For the 2014 contract year, the forty-five (45) days will be reduced to thirty (30)

Exhibit E attached hereto or another mutually agreed upon format in the same level that PBM is

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### 3. Confidential Information.

- General. PBM and Manufacturer each shall maintain the confidentiality of any confidential (a) and/or proprietary information of the other party, including, but not limited to, any confidential pricing, marketing or product information; Part D Plan lists and information; information on invoices and reports provided by PBM to Manufacturer ("Claims Data"); the terms of this Agreement; the existence of a dispute and any information generated pursuant to same, such as the information referenced in paragraph 10 in Exhibit B attached hereto; and any other non-public information or documents provided by one party to the other hereunder (collectively, "Confidential Information"). Such Confidential Information shall not be disclosed to the receiving party's employees or representatives or to any third party, or used by or for the benefit of such party or any third party, directly or indirectly, except as may be necessary to carry out or enforce this Agreement. Neither PBM nor Manufacturer shall use the name of the other party, including any tradename or trademark, in any advertising or promotional materials or in any communication without prior written consent of such other party; provided, however, that PBM may reference Manufacturer and the Products in product informational communications. The foregoing notwithstanding, the restrictions of this Section shall not apply to information: (i) which is required to be disclosed by law, including without limitation, MMA, or for purposes of resolving a dispute consistent with the dispute resolution process set forth herein, (ii) which the receiving party can show was known to it prior to the disclosure by the disclosing party, (iii) which is or becomes public knowledge through no fault of the receiving party, (iv) which is lawfully disclosed to the receiving party by a third party; or (v) which a Part D Plan Sponsor, or its agent or representative, reviews in connection with an audit of its agreement with PBM and disclosure of the terms and conditions of this Agreement is reasonably necessary in such context; provided, the receiving party has agreed in writing to hold such documents in confidence prior to receipt of any such Confidential Information. The foregoing notwithstanding, PBM shall have the right to disclose the terms of this Agreement to a Part D Plan Sponsor, or its agent or representative, in connection with the Part D Plan Sponsor's review of a Product's status on a Plan Formulary; provided, the receiving party has agreed in writing to hold such documents in confidence prior to receipt of any such Confidential Information. If a party believes in good faith that it must disclose any Confidential Information to comply with law, then, subject to the next sentence, such party shall notify the other party of such requirement prior to making any disclosure so that the other party may seek a protective order or other appropriate remedy to maintain the confidentiality of such information or limit or condition any disclosure thereof. Notwithstanding the foregoing PBM and a Part D Plan Sponsor may report to CMS Confidential Information with respect to the Rebates claimed, paid or payable bereunder that it is required to disclose pursuant to the MMA Regulations without first notifying Manufacturer provided that the disclosing entity takes all actions available to it to preserve the confidentiality of such Confidential Information to the greatest extent possible in accordance with law, including, without limitation, by expressly designating such information as confidential commercial information which is exempt from disclosure under the Freedom of Information Act
- (b) Return of Information upon Termination. Immediately upon the expiration or termination of this Agreement, PBM and Manufacturer shall cease use of and, upon request, deliver to the other party all Confidential Information of the other party that such party may have in its possession or control; provided that one copy may be kept for archival purposes (subject to the confidentiality requirements of this Agreement).
- (c) <u>Use of Third Party for Rebate Validation Services</u>. In the event Manufacturer desires to engage a third party to provide rebate validation, claim processing or other services relating to this Agreement, such

third party must be mutually acceptable to the parties and enter into a confidentiality agreement with PBM prior to the disclosure by Manufacturer to such third party of any Claims Data or other Confidential Information.



### 5. Term and Termination.

- (a) Term. The initial term of this Agreement shall commence on the Effective Date and continue thereafter until December 31, 2014, subject to earlier termination as provided herein.
- (b) Termination With Cause. Either party may terminate this Agreement upon written notice to the other party: (i) if the other party breaches any term of this Agreement and such breach is not cured within thirty (30) days of written notice thereof; or (ii) if the other party files a petition in bankruptcy, is adjudicated bankrupt, makes a general assignment for the benefit of its creditors, or is voluntarily or involuntarily dissolved.

### (c) Supervening Illegality.

(i) This Agreement shall terminate if both: (A) as a result of the enactment of any new applicable federal or state law or regulation, or any change in any existing applicable federal or state law or regulation or any new interpretation of any applicable federal or state law or regulation by any court or regulatory agency, the performance by a party of any material obligation under this Agreement would be

rendered illegal or any material provision of this Agreement would be rendered invalid or unenforceable, and (B) the parties are unable to negotiate a mutually acceptable amendment to this Agreement pursuant to Section 5(c)(iii) below. If any immaterial provision of this Agreement is held to be illegal, invalid or unenforceable for any reason, this Agreement shall be deemed amended to delete such provision, such amendment to apply only with respect to the operation of this Agreement in the particular jurisdiction in which such provision is held to be illegal, invalid or unenforceable, and the remainder of this Agreement shall remain in full force and effect and enforceable in accordance with their terms.

- (ii) The parties agree that the party affected by the new law or regulation or the change in law or regulation or the interpretation of a law or regulation shall use reasonable efforts to give the other party at least sixty (60) days prior written notice of the effective date of such new law, change, or interpretation.
- The parties agree that, notwithstanding the foregoing provisions of this Section, either party may, within ten (10) business days of giving or receiving notice of the new law, change, or interpretation, notify the other party of its wish to renegotiate the applicable terms of this Agreement ("Renegotiation Notice"), in which event the parties shall negotiate in good faith, for a period of sixty (60) days from delivery of the Renegotiation Notice, an amendment to this Agreement that addresses the portion of this Agreement rendered illegal, invalid or unenforceable by the new law, change, or interpretation while preserving to the greatest extent possible the original intent of this Agreement. If the parties successfully conclude such negotiations prior to the effective date of the new law, change, or interpretation, this Agreement shall not terminate and shall be amended to reflect the negotiated terms. If the parties are unable to successfully conclude such negotiations prior to the effective date of the new law, change, or interpretation and such effective date is within the sixty (60) day negotiation period, negotiations shall continue but this Agreement shall be deemed amended to delete such portion rendered illegal, invalid or unenforceable, such amendment to apply only with respect to the operation of this Agreement in the particular jurisdiction in which such portion is held to be illegal, invalid or unenforceable, and the remainder shall remain in full force and effect and enforceable in accordance with its terms, subject to the subsequent sentence. In the event the parties are unable to successfully conclude such negotiations within the sixty (60) day negotiation period, this Agreement shall terminate at the end of the sixty (60) day negotiation period.
- (d) Manufacturer Change in Control. In the event there is a "Manufacturer Change in Control" (as defined below), Manufacturer shall notify PBM in writing simultaneously with the public announcement of the transaction and PBM, upon written notice to Manufacturer, shall have the right to terminate this Agreement. For purposes of this Section, a "Manufacturer Change in Control" means: (i) an event whereby any person or entity shall become the "beneficial owner" (as defined in Rule 13d-3 under the Securities and Exchange Act of 1934), directly or indirectly, of fifty percent (50%) or more of the securities of Manufacturer; (ii) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of fifty percent (50%) or more of the assets of Manufacturer or any of its Affiliates (other than sales in the ordinary course of business); or (iii) any merger or consolidation to which Manufacturer is a party except for a merger in which Manufacturer is the surviving entity.
- (e) <u>Survival</u>. Termination or expiration of this Agreement for any reason shall not release either party from any liability which at the time of termination or expiration has already accrued to the other party or which thereafter may accrue with respect to any act or omission occurring prior to termination or expiration, including, without limitation, Manufacturer's obligation to pay Rebates and Administrative Fees in accordance with this Agreement for Product(s) dispensed prior to the date of termination or expiration. Without limiting the generality of the foregoing, <u>Sections 2(l)</u>, 3, 4 (for a period of one year), 5(e), 6 and 7 shall survive any termination or expiration of this Agreement and, notwithstanding the removal of a Product from this Agreement, <u>Section 6</u> shall continue to apply with respect to Product dispensed prior to such removal.

#### Warranties; Indemnification.

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- (a) PBM Warranties. PBM represents and warrants that: (i) it has or will disclose to each Part D Plan Sponsor that it receives rebates and administrative fees from pharmaceutical manufacturers; (ii) it has or will make all disclosures and submit all reports to Part D Plan Sponsors and to CMS regarding the Rebates and Administrative Fees claimed, paid or payable pursuant to this Agreement on utilization of the Part D Plans of such Part D Plan Sponsor to the extent such disclosures (A) are required by applicable law or by contractual commitments undertaken by PBM or (B) are necessary to permit Part D Plan Sponsors to comply with their reporting and disclosure obligations to CMS or other government authorities under applicable law (including applicable Program regulations and guidance); (iii) it will remit the Rebates paid hereunder to the applicable Part D Plan Sponsor whose Part D Plan Product utilization gave rise to such Rebates, except to the extent PBM has been authorized to retain such Rebates by such Part D Plan Sponsor; (iv) in the event PBM or any of its Affiliates is a Part D Plan Sponsor, such Part D Plan Sponsor will, to the extent required by applicable law or regulation, including MMA and the Federal anti-kickback statute, treat payments received under this Agreement as discounts (as such term is used at 42 U.S.C. § 1320a-7b(3)(A)) price concessions (as such term is used in the Program regulations), including appropriate reporting in accordance with applicable law, and disclosures to CMS and (v) it has a written agreement with each Part D Plan Sponsor of a Part D Plan which permits it to receive and retain the Administrative Fees provided for in this Agreement.
- (b) Manufacturer Warranties. Manufacturer further represents and warrants that Manufacturer shall properly disclose and report the rebates payable hereunder to government programs and to other third parties to the extent such disclosures are required by applicable law, regulation or contractual commitment. Manufacturer acknowledges and agrees that: (i) Caremark has played no role in the determining or reporting of AWP, ASP, AMP or best price by Manufacturer, and (ii) Caremark has not engaged in any conduct that would impair Manufacturer's ability to accurately report "best price", ASP, or AMP to CMS.
- (c) <u>Product Warranties.</u> Manufacturer represents and warrants that the Products: (i) are free from defect in design, material and workmanship; (ii) are in compliance with applicable law and all regulatory requirements of the Food and Drug Administration ("FDA"), including those related to the adulteration or misbranding of products within the meaning of Sections 501 and 502 of the Food Drug and Cosmetics Act ("FDCA"); (iii) are not articles which may not be introduced into interstate commerce pursuant to the requirements of Sections 505, 514, 515, 516 or 520 of the FDCA; (iv) have been manufactured in accordance with current FDA Good Manufacturing Practices as required by 21 C.F.R. §§ 210 and 820; (v) are not infringing upon the patents or trademarks of any third party; and (vi) have been approved by the FDA pursuant to Section 505 of the FDCA.
- (d) <u>Indemnification.</u> PBM shall indemnify, defend and hold harmless Manufacturer and its Affiliates and their respective officers, directors, employees, agents and subcontractors (collectively, "Manufacturer Indemnitees") from any and all claims, demands, actions, causes of action, losses, liabilities, judgments, damages, costs and expenses (including, but not limited to, reasonable attorneys' fees, court costs and costs of settlement) (collectively, "Losses") that the Manufacturer Indemnitees, or any of them, may suffer as a result of the negligence or willful misconduct of PBM. Manufacturer shall indemnify, defend, and hold harmless PBM and its Affiliates and their respective officers, directors, employees, agents and subcontractors (collectively, "PBM Indemnitees") from any and all Losses that the PBM Indemnitees, or any of them, may suffer that arise from or relate to: (i) the death of, or bodily injury to, any person on account of the use of any Manufacturer product; (ii) any recall, quarantine, warning or withdrawal of any Manufacturer product; (iii) any breach by Manufacturer of any of its representations, warranties, covenants or agreements contained in this Agreement; (iv) any claim that a Manufacturer product infringes on the patent or trademark of any third party; or (v) the negligence or willful misconduct of Manufacturer.
- (e) <u>Product Recall.</u> In the event of a recall, warning, withdrawal or quarantine of a Product, Manufacturer shall give PBM prompt notice thereof and shall reimburse PBM and/or any Part D Plan, within

thirty (30) days of receipt of PBM's invoice, for all actual, reasonable, direct costs incurred as a result of such event.

(f)Insurance. Manufacturer shall maintain in effect during the term of this Agreement a comprehensive general liability policy, including products liability coverage covering all Products, and Manufacturer shall promptly after the execution of this Agreement designate PBM as an additional insured on such policy, and such insurance will be primary insurance with respect to PBM, but only with regard to Manufacturer's Products and performance under this Agreement. The policy shall be underwritten by an insurance company that carries an A- or better rating from A.M. Best. This comprehensive insurance policy shall be in an amount not less than Five Million Dollars (\$5,000,000) per occurrence. Manufacturer shall also maintain in effect Errors and Omissions coverage of at least Two Million Dollars (\$2,000,000), such insurance providing coverage for rebating activity. The Manufacturer shall provide thirty (30) days notice to PBM in the event of any modifications, cancellation, or termination thereof. Manufacturer shall provide PBM with a certificate of insurance naming PBM as additional insured evidencing compliance with this Section within thirty (30) days of execution of this Agreement and thereafter upon request. Manufacturer shall have the right to satisfy the requirements under this Section through any combination of actual insurance and/or self-insurance. The amount of such required insurance coverage under this Section shall not limit Manufacturer's obligations under this Agreement.

### 7. General Provisions.

- Formulary Structure. Except as may otherwise be explicitly provided in this Agreement to the contrary, nothing in this Agreement shall be deemed or construed to in any way limit the ability of PBM to intervene against, or otherwise conduct formulary activities with respect to, any product of Manufacturer; provided, however, that to the extent such actions violate the conditions for Rebates on any Product set forth herein (including conditions in Exhibit A), Rebates and Administrative Fees shall not be payable on Product utilization of the applicable Part D Plan. Nothing in this Agreement shall be construed to require PBM to take any action in contravention of, or refrain from taking any action required by, the plan design or its agreement with a particular Part D Sponsor. To the best of PBM's knowledge, there is nothing in this Agreement which conflicts with the terms of agreement between PBM and Part D Sponsors. Subject to the foregoing, nothing in this Agreement shall be construed to limit the ability of PBM, including PBM's P&T Committee, to remove or add products from or to any drug list or formulary or to limit the ability of any Part D Plan to remove or add products from or to its Plan Formulary, even though such products may compete directly with one or more Products. Within 60 days following FDA approval of insulin degludec, PBM will use commercially reasonable efforts to (i) negotiate in good faith with Manufacturer unrestricted Formulary placement of the product in the lowest brand co-pay tier based on a good faith offer from manufactureri and (ii) PBM will evaluate the product through its Financial Review Committee. In addition, PBM shall use commercially reasonable efforts to ensure that insulin degluded is evaluated at its next regularly scheduled Pharmacy & Therapeutics Committee meeting immediately following FDA approval of the product.
- (b) Entire Agreement; Amendment; Waiver. This Agreement and the Exhibits attached hereto set forth the entire agreement of the parties hereto with respect to the subject matter hereof, and supersede all prior oral and written negotiations, representations, agreements and understandings of the parties with respect thereto. Except as expressly provided herein, this Agreement may not be amended except by a written instrument signed by the parties hereto. No waiver or discharge of any breach of this Agreement shall be effective unless it is in writing signed by both parties hereto. Any waiver of any breach of any provision of this Agreement shall not be a waiver of any subsequent breach of the same or of any other provision of this Agreement. This Agreement shall be construed without regard to the party that drafted it. Any claimed ambiguity shall not be interpreted against either party, but shall, instead, be resolved in accordance with other applicable rules governing the interpretation of contracts.

(c) <u>Notices</u>. Any notice given under this Agreement shall be deemed received if in writing and if sent by hand delivery, facsimile transmission, receipt confirmed, overnight courier which provides confirmation of delivery, or certified mail, return receipt requested, sent to the applicable party at the following addresses:

> If to PBM: CVS Caremark

2211 Sanders Road Northbrook, IL 60062

Attn: Vice President, Trade Relations

If to Manufacturer: Novo Nordisk Inc. 100 College Road West Princeton, NJ 08540

Attn: Director, Contract Management & Compliance

with a copy to: CVS Caremark 9501 E. Shea Blvd. Scottsdale, AZ 85260

Attn: Vice President, Manufacturer Contracting, Law Department with a copy to: Novo Nordisk Inc. 100 College Road West Princeton, NJ 08540

Attention: General Counsel

or to such other address or to the attention of such other person as a party may designate in writing given pursuant to this Section. Notices sent by certified mail shall be deemed received three (3) business days following mailing.

- (d) Governing Law. This Agreement shall be governed by, construed and enforced in accordance with the internal laws of the State of Delaware. No provision of this Agreement shall be applied or construed in a manner inconsistent with applicable state and federal laws and regulations.
- (e) <u>Assignment.</u> None of the parties hereto may assign this Agreement without the prior written consent of the other party, provided, however, that PBM may assign this Agreement, upon notice to Manufacturer, to any of its Affiliates or as part of the sale or transfer of the assets to which this Agreement pertains.
- (f) <u>Headings</u>. The section headings contained herein are solely for the purpose of reference, are not part of the agreement of the parties and shall not in any way affect the meaning or interpretation of this Agreement.
- (g) Independent Contractors. Nothing contained herein shall be deemed or construed by the parties hereto, or by any third party, as creating a relationship of employer and employee, principal and agent, or joint venture of the parties hereto; it being understood and agreed that no provision contained herein nor any acts of the parties hereto shall be deemed to place PBM in any relationship with Manufacturer other than as an independent contractor.
- (h) <u>Dispute Resolution</u>. In the event of a dispute between the parties, PBM or Manufacturer may, by giving written notice to the other party ("Dispute Notice"), request a meeting of authorized representatives of the parties for the purpose of resolving the dispute. The parties agree that, within ten (10) days after issuance of the Dispute Notice, each party shall designate a representative to participate in dispute resolution discussions.

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which will be held at a mutually acceptable time and place (or by telephone) for the purpose of resolving the dispute. Each party agrees to negotiate in good faith to resolve the dispute in a mutually acceptable manner. If despite the good faith efforts of the parties, the authorized representatives of the parties are unable to resolve the dispute within thirty (30) days after the issuance of the Dispute Notice, or if the parties fail to meet within such thirty (30) day period, either party may, by written notice to the other party, submit the dispute to binding arbitration in accordance with the Alternative Dispute Resolution Procedures attached hereto as Exhibit B, the result of which shall be binding upon the parties. The foregoing shall not affect the right of either party to at any time seek appropriate equitable relief to enforce Sections 2(g) or 3. Notwithstanding any provision in this Agreement to the contrary, in no event, as a result of any such arbitration or otherwise, shall: (i) a party be liable under this Agreement for the payment of any consequential, punitive, incidental or special damages or lost profits except to the extent such damages (A) constitute Losses that are covered by such party's indemnification obligations set forth in Section 6(d) and (B) are incurred by or are awarded to a third party (an Affiliate of a party shall not be considered a third party for purposes of this subsection (B)); (ii) PBM be assessed damages under this Agreement in excess of the Rebates and Administrative Fees, if any, received by PBM from Manufacturer under this Agreement.

(i) Counterparts. This Agreement may be executed in counterparts which taken together shall constitute one agreement. This Agreement must be manually signed and may be delivered by facsimile or email (in PDF format) and upon such delivery the facsimile or PDF signature will be deemed to have the same effect as if the original signature had been delivered to the other party.

(j)				hall be construed to limit or restric
				, sale or distribution of any Product a
any time du	iring the term of this Acre	ement Manufacturer n	nay remove ar	ny Product from Exhibit A at any time
by giving f	BM not less than	vritten notic	ce of such ren	noval in the following circumstances
upon such i	removal becoming effective	ve, such Product shall r	no longer cons	titute a Product under this Agreemen
and Rebates	s shall no longer be payat	de on utilization of suc	h Product disp	pensed after such date: (a) the Produc
has been w	ithdrawn from the marke	t in the United States;	or (b) the Pro	oduct will no longer be distributed by
Manufactur	rer in the United Sates, i	neluding, without limit	itation, due to	Manufacturer's sale of its rights to
	uch Product to another en			

IN WITNESS WHEREOF, the parties hereto have caused this Rebate Agreement to be executed by their duly authorized officers or representatives as of the Effective Date.

CVS CAREMARK PART D'SERVICES, L.L.C.

Name: Daniel Best

Title: Vice President, Trade Relations

NOVO NORDISK, INC.

Name: Karsten Munk Knudsen

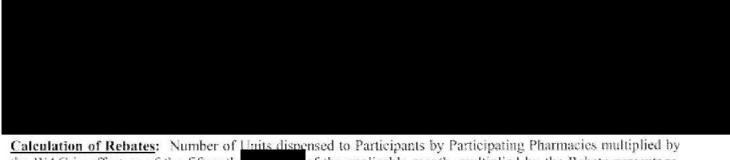
Title: Corporate Vice President, Finance & I.T.

Hilotory

## Exhibit A Products, Rebates & Administrative Fees (Percentage Rebates)

The following Rebates and Administrative Fees shall be payable on Product dispensed to Participants by Participating Pharmacies:

Product Name	NDC#	Strength	Package	R	ebate Basec	l on Formular	y Status	Administrative Fee
			Size	EGWP	Listed	1 of 2	Exclusive	
Novolin®	00169-1833-11; 00169-1834-11; 00169-1837-11	All Strengths	10mL	15%	N/A	18%	57.5%	31/4
NovoLog@	All NDCs	All Strengths	All Package Sizes	15%	N/A	18%	57,5%	3%
NovoLog® Mix 70/30	All NDCs	All Strengths	All Package Sizes	15%	N/A	18%	57.5%	3%
Levemir®	All NDCs	All Strengths	All Package Sizes	15%	N/A	22%	30%	3%
7			D17.03	<u> </u>				



the WAC in effect as of the fifteenth of the applicable month, multiplied by the Rebate percentage. For purposes of clarification a Plan is only eligible to receive an EGWP Rebate, Listed Rebate, Exclusive Rebate, or One of Two Rebate. These Rebates will not be combined.

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Conditions to Rebates: The payment of Rebates is subject to the following conditions, as determined on a Product by Product, Part D Plan by Part D Plan, and month by month basis, provided that if these condition are not met for the entire month, Rebates shall be payable on utilization of that Product for only that portion of the month in which such conditions were met:

- The Product is listed on the Plan Formulary, provided this condition shall not apply to NovoFine®, AutoCover®, and NovoTwist® if the entire Therapeutic Class is not listed;
- 2. The Product adjudicates at Second Tier or, if applicable, the Specialty Tier; and
- 3. The Product is not Disadvantaged.

Additional Conditions for Novolin, Novolog, NovoLog Mix 70/30 Exclusive Rebates: The payment of Exclusive Rebates for Novolin, Novolog, and Novolog Mix 70/30 is subject to the following additional conditions, as determined on a Part D Plan by Part D Plan and month by month basis, provided that if these conditions are not met for the entire month, Rebates shall be payable on utilization of these Products for only that portion of the month in which such conditions were met:

- Novolin®, NovoLog®, NovoLog® Mix 70/30 have Exclusive Formulary Status.
- All Competitive Products are subject to Exclusion, and existing patients using a Competitive Product may not be grandfathered.
- 3. Victoza is listed on the Formulary.
- 4. PBM shall not rebid for products within the Product's Therapeutic Class for placement on the PBM's national Part D formulary prior to January 1, 2015 (the foregoing does not prohibit rebid for product utilization occurring on or after January 1, 2015) unless such rebid is undertaken as a result of clinical or safety issues with the Product (e.g., FDA black box warning or other FDA safety alert, Product withdrawal or recall, etc.).

Additional Conditions for Levemir Exclusive Rebates: The payment of Exclusive Rebates for Levemir is subject to the following additional conditions, as determined on a Part D Plan by Part D Plan and month by month basis, provided that if these conditions are not met for the entire month, Rebates shall be payable on utilization of the Product for only that portion of the quarter in which such conditions were met:

- 1. Levemir has Exclusive Formulary Status; and
- 2. All Competitive Products are subject to Exclusion.



<u>Calculation of Administrative Fee</u>: Number of Rebate eligible Units dispensed to Participants by Participating Pharmacies multiplied by the WAC in effect as of the fifteenth (15<sup>th</sup>) day of the applicable month, multiplied by the Administrative Fee percentage.

Price Protection: This Section applies only to Rebates for NovoLog®, NovoLog® Mix 70/30, Levemir® and Rebates. The Net Price for each Product's Formulary Status shall be reviewed monthly by comparing

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the Net Price of the applicable calendar month to the Baseline Net Price. If the Product's Net Price has increased by more than eight percent (8.00%) over Baseline Net Price ("Net Price Ceiling"), the Rebate percentage(s) for such Product will be increased for such calendar month such that the Net Price will equal the Net Price Ceiling. The increased Rebate percentage(s) shall remain in effect during the remainder of the current Contract Year and shall return to their original percentage at the beginning of the next Contract Year. Calculations will be performed to six decimal places of precision rounded to 2 decimals. If the Rebate percentages are increased pursuant to this section, PBM will notify Manufacturer of the amount of the increase in the Rebate percentages, which notice requirement may be satisfied by PBM submission of an invoice to Manufacturer that reflects the increased Rebate percentages.

An example of the foregoing adjustment is as follows: If the Baseline WAC for a particular Product is \$100, the Rebate Percentage is ten percent (10%), and the Baseline Net Price for the Product is \$90, the Net Price Ceiling would be \$97.20. If the WAC for such Product increases by \$10, the Net Price for the Product would be \$99, which exceeds the Net Price Ceiling. The Rebate Percentage would thus increase to 11.64% (\$110 - \$97.20 = \$12.80; \$12.80/\$110 = 11.64%) in order to maintain a Net Price equal to the Net Price Ceiling.

Introduction of Generic or Biosimilar. In the event a generic or biosimilar version of a Product becomes available on the market in the United States, Manufacturer shall provide written notice thereof to PBM whereupon such Product shall be deemed deleted from this Agreement, on the earlier of the effective date that PBM sets a MAC for such Product or first day of the calendar month following the calendar month in which such notice is received by PBM. After such deletion (i) no further Rebates shall be paid by Manufacturer to PBM for the dispensing of such Product thereafter, and (ii) neither party shall have any further obligations under this Agreement with respect to such Product (except for obligations arising prior to such deletion), and (iii) reference to such Product on all Rebate schedules shall be deemed deleted and such Rebate schedules shall be amended by Manufacturer and PBM to reflect such deletion of Products from this Agreement.

\* \*



#### Exhibit B Alternative Dispute Resolution Procedures

- To begin an Alternative Dispute Resolution ("ADR") proceeding, a party shall provide written notice to 1. the other party of the issues to be resolved by ADR. Within fourteen (14) days after its receipt of such notice, the other party may, by written notice to the party initiating the ADR, add additional issues to be resolved within the same ADR.
- Within twenty-one (21) days following receipt of the original ADR notice, the parties shall select a 2. mutually acceptable neutral to preside in the resolution of any disputes in this ADR proceeding. If the parties are unable to agree on a mutually acceptable neutral within such period, either party may request the American Arbitration Association ("AAA") to select a neutral pursuant to the following procedures:
  - The AAA shall submit to the parties a list of not less than five (5) candidates within fourteen (14) days after receipt of the request, along with a Curriculum Vitae for each candidate. No candidate shall be an employee, director, or shareholder of either party or any of its Affiliates.
  - Such list shall include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.
  - Each party shall number the candidates in order of preference (with the number one (1) signifying the greatest preference) and shall deliver the list to the AAA within seven (7) days following receipt of the list of candidates. If a party believes a conflict of interest exists regarding any of the candidates, that party shall provide a written explanation of the conflict to the AAA along with its list showing its order of preference for the candidates. Any party failing to return a list of preferences on time shall be deemed to have no order of preference.
  - If the parties collectively have identified fewer than three (3) candidates deemed to have conflicts, the AAA immediately shall designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference. If a tie should result between two candidates, the AAA may designate either candidate. If the parties collectively have identified three (3) or more candidates deemed to have conflicts, the AAA shall review the explanations regarding conflicts and, in its sole discretion, may either (i) immediately designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference, or (ii) issue a new list of not less than five (5) candidates, in which case the procedures set forth in subparagraphs 2(a) through 2(d) shall be repeated.
- No earlier than twenty-eight (28) days or later than fifty-six (56) days after selection, the neutral shall hold a hearing to resolve each of the issues identified by the parties. The ADR proceeding shall take place at a location agreed upon by the parties. If the parties cannot agree, the neutral shall designate a location other than the principal place of business of either party or any of its Affiliates.
- At least seven (7) days prior to the hearing, each party shall submit the following to the other party and 4. the neutral:
  - a copy of all exhibits on which such party intends to rely in any oral or written (a) presentation to the neutral;
  - a list of any witnesses such party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;
  - a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed one (1) page per issue.
  - a brief in support of such party's proposed rulings and remedies, provided that the brief shall not exceed twenty (20) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

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Except as expressly set forth in subparagraphs 4(a) through 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

- 5. The hearing shall be conducted on two (2) consecutive days or less and shall be governed by the following rules:
  - (a) Each party shall be entitled to five (5) hours of hearing time to present its case. The neutral shall determine whether each party has had the five (5) hours to which it is entitled.
  - (b) Each party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the party conducting the cross-examination.
  - (c) The party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it raised but also any issues raised by the responding party. The responding party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.
  - (d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments; provided, however, that each party shall be allowed to have a corporate representative stay in the hearing room throughout the entire hearing. All testimony must be provided live at the hearing. Neither party shall be permitted to compel adverse witnesses to appear at the hearing.
  - (e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the neutral shall have sole discretion regarding the admissibility of any evidence.
- 6. Within seven (7) days following completion of the hearing, each party may submit to the other party and the neutral a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.
- 7. The neutral shall rule on each disputed issue within fourteen (14) days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the parties on each disputed issue but may adopt one party's proposed rulings and remedies on some issues and the other party's proposed rulings and remedies on other issues. The neutral shall not issue any written opinion or otherwise explain the basis of the ruling.
- 8. The neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:
  - (a) If the neutral rules in favor of one party on all disputed issues in the ADR, the losing party shall pay 100% of such fees and expenses.
  - (b) If the neutral rules in favor of one party on some issues and the other party on other issues, the neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the parties. The neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.
- 9. The rulings of the neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.

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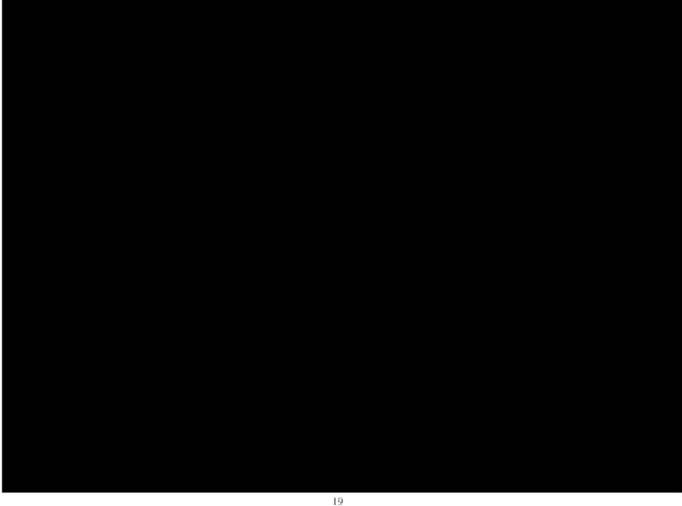
10. Except as provided in paragraph 9 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

\* \* \*

#### Exhibit C THERAPEUTIC CLASSES

1. Therapeutic Class for Formulary Position

Human Insulin	
Novelin®	Humulin (except for Hamulin U-500)
Rapid-Acting Insulin Analog	
NovoLog®	Humalog Apidra
Pre-Mix Insulin Analog	F. Albana
Nevol.og® Mix 70/30	Hunsalog Mix
Basal Insulin Analog	
Levenirs	Lantus



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#### 2. Therapeutic Class for Utilization by Market Report

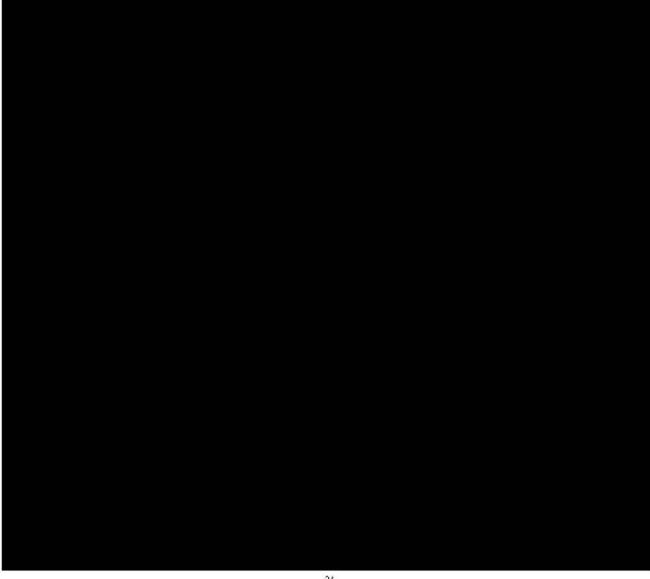
NDC - Novo Nordisk Product	NDC - Competitive Products				
Homan Insulia					
60169-1833-11 Novo(m@ R (Regular)	90002-8215-01 Hamulin R				
00169-1834-11 Novolin® N (NPH)	00002-8215-17 Hamulia R 3mi. Vial				
00169-1837-11 Novolin® 70/30 (70% NPTi 30% Reg.)	00002-8215-91 Hamulio R				
1.741	00002-8501-01 Humulio R 13-500				
	00002-8315-01 Humulio N				
	00002-8315-17 Humulin N 3rd. Vial				
	00002-8315-91 Hamulia N				
	00002-8715-01 Hamulin 70/30 10mL Vial				
	00002-8715-17 Hansuka 20/30 3mt, Vial				
	00002-8715-91 Hamadia 70/30 10mL Vigi				
	00002-9515-01 Hamaika 50/50				
	ö0002-8730-59 Humuka N 3mL Pen				
	00002-8730-01 Humalin N 3ml. Pen - Inner Pack				
	00002-8770-59 Humalia 70/30 3ml. Pen				
	00002-8770-01 Humailin 70/30 3mL Pen - Inner Pack				
Rapid-Acting Insulin Analog					
00169-7501-11 NovoLog@ (0mL	00002-7510-01 Humalog 10mL				
00169-3303-12 NovoLog® PenFill® 3mL	60002-7510-17 Humalog 3ml. Vial				
00169-6339-10 NovoLog® FlexPen® 3mL	90002-7516-59 Humalog 3ml.				
	00002-8725-59 Huntalog Pen				
	00002-8725-01 Humalog Pen (single)				
	00002-8799-59 Humalog KwikPen				
	00002-8799-01 Humalog KwikPen (single)				
	00088-2500-33 Apidra 10mL				
	00088-2500-52 Apidra 2mL				
	00088-2502-05 Apidra SoloSTAR				
	00002-8215-01 Homalin R				
	00002-8215-17 Homelin R 3mL Vial				
	00002-8215-91 Humalin R				
	00002-8501-01 Humalin R U-500				
	(90169-1833-11 Novolin® R (Regular)				
Pre-Mix Insulin Analog					
00169-3685-12 NevoLog® Mix 70/30 10mL	80062-7511-01 Housing 75/25 10mL				
00169-3696-19 NoveLog® Mix 70/30 FlexPen®	00002-7512-01 Humalog Mix 50/50				
	00002-8715-01 Hazadin 70/30 10ml. Vial				
	00002-8715-17 Humulin 70/30 3mt. Vial				
	00002-8715-91 Hustalin 70/30 10mL Vtal				
	00002-8770-01 Humulin 70/30 Pen (single)				
	00062-8370-59 Humalin 70/30 Pen				
	00002-8793-59 Humalog Mtx 56/50 Pcn				

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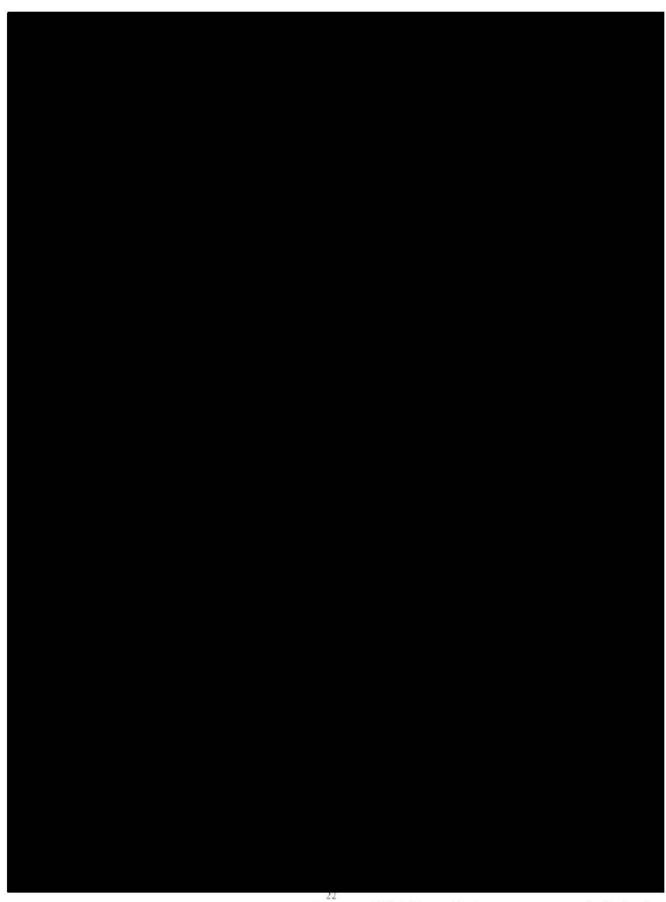
NDC - Novo Nordisk Product	NDC - Competitive Products
	00002-8794-59 Humalog 75/25 Pen
	00002-8797-59 Humalog KwikPen 75/25
	00002-8797-01 Humalog KwikPen 75/25
	00002-8798-59 Humalog KwikPen 50/50
	00002-8798-01 Humalog KwikPen 50/50 (single)
	00002-9515-01 Humulin 50/50
	00169-1837-11 Novalin® 70/30
Basal Insulin Analog	
00169-3687-12 Levermr® 10mL	00088-2220-33 Laptus 10mL
00169-6439-10 Levemer® FlexPen® 5x3mL	00088-2220-52 Lantus 3mL
	00088-2220-60 Lantus (SoloStar) 3ml
	60088-2219-05 Lantus (SoloStar) 3mL
	69002-8315-01 Humakin N
	60002-8315-17 Huntalin N 3ml. Vial
	00002-8315-91 Humalin N 10ml Vial
	00002-8730-59 Humulin N 3ml. Pen
	00002-8730-01 Humakin N 3mL Pen Inner Pack
	60169-1834-11 Novolin N (NPH)



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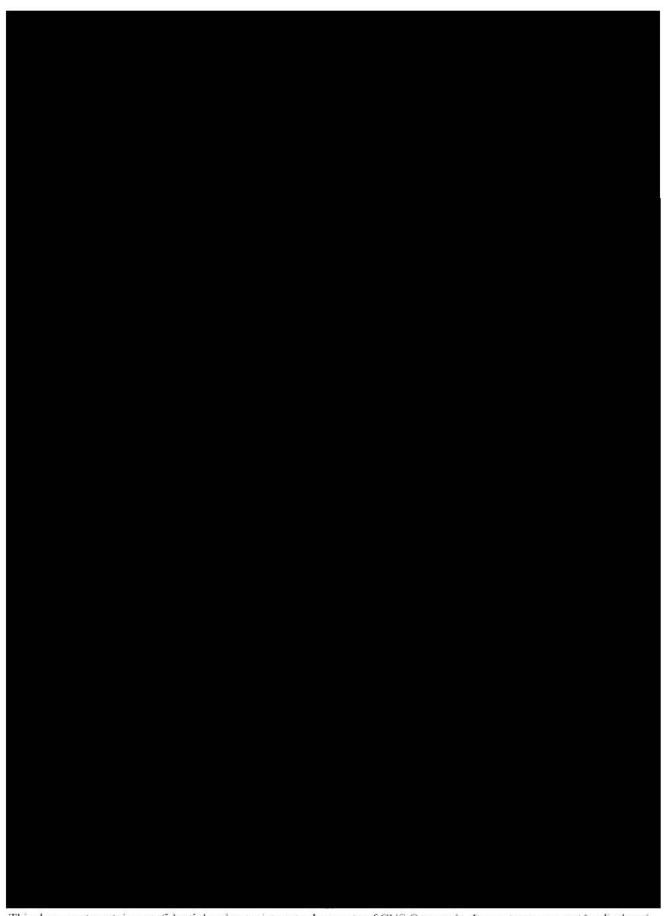
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NDC – Novo Nordisk Product	NDC - Competitive Products
	00781-3004-44 Omnitrope 10x10mg

# Exhibit E Reconciliation Report

[Sample payment report that is currently supplied to Caremark:]

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#### THIRD AMENDMENT TO MEDICARE PART D PROGRAM REBATE AGREEMENT

THIS THIRD AMENDMENT TO THE Medicare Part D Rebate Agreement (the "Third Amendment"), is entered into by and between CVS Caremark Part D Services, L.L.C., a Delaware limited liability company ("PBM"), and Novo Nordisk Inc., a Delaware corporation ("Manufacturer"). Except as otherwise set forth below, this amendment is effective as of May 1, 2014.

#### Background

Manufacturer and PBM entered into a Medicare Part D Program Rebate Agreement, effective January 1, 2013, as amended ("Agreement"). Manufacturer and PBM desire to further amend the Agreement as hereinafter set forth

Manufacturer and PBM agree as follows:

Effective as of January 1, 2015, the definitions of "Baseline Net Price," "Baseline WAC" and
"Exclusive Formulary Status" set forth in Section 1 of the Agreement are hereby deleted in their
entirety and replaced with the following:

"Baseline Net Price" means Net Price in effect as of June 1st of the prior Contract Year.

"Baseline WAC" means WAC in effect as of June 1st of the prior Contract Year-

"Exclusive Formulary Status" means as determined on a Product by Product, Part D Plan by Part D Plan, and month by month basis, that: (i) the Product is listed on the Plan Formulary with a Second Tier designation and no Competitive Products are listed on the Plan Formulary with a Second Tier designation; and (ii) Competitive Products are subject to NDC block and/or prior authorization with no grandfathering of existing Members using Competitive Products.

- 2. Section 5(a) of the Agreement is hereby deleted in its entirety and replaced with the following:
  - (a) <u>Term.</u> The initial term of this Agreement shall commence on the Effective Date and continue thereafter until December 31, 2017, subject to earlier termination as provided herein.
- 3. Section 7(j) of the Agreement is hereby deleted in its entirety.
- Effective as of January 1, 2015, Exhibit A to the Agreement is hereby deleted in its entirety and replaced with the attached Exhibit A.
  - 5. Exhibit C to the Agreement is hereby deleted in its entirety and replaced with the attached Exhibit C.
  - Except as amended herein, all other terms and conditions of the Agreement shall remain in full force
    and effect. In the event of a conflict between the terms of this Third Amendment and the terms of the
    Agreement, the terms of this Third Amendment shall control.



IN WITNESS WHEREOF, the parties hereto have caused this Third Amendment to be executed by their respective duly authorized officers or agents.

NOVO NORDÍKK I

By:

Name: Jesper/HoiJand

TREVIEWED NEW PRINCIPAL NEW MARKETHAN

Title: President/

CVS CAREMARKA ART D SERVICES L.L.C.

Napre: Daniel Best

Title: Vice President, Trade Relations

Contract Ops

#### Exhibit A Products, Rebates & Administrative Fees (Percentage Rebates) (Effective January 1, 2015)

Part D Plans including EGWPs
The following Rebates and Administrative Fees shall be payable on Product dispensed to Members of Part D Plans, including EGWPs, by Participating Pharmacies:

Product				R	ebate Based	on Formulary St	atus	Administrative Fee
Name	NDC#	Strength	Package Size	Listed	1 of 2 Product	1 of 2 Product Enhanced	Exclusive	
Novolin®	00169- 1833-11 00169- 1834-11 00169- 1837-11	All Strengths	All Package Sizes	15%	18%³	N/A	69.5%	3%
NovoLog®	All NDCs	All Strengths	All Package Sizes	15%	18%3	N/A	69.5%	3%
NovoLog® Mix 70/30	All NDCs	All Strengths	All Package Sizes	15%	18%³	N/A	69.5%	3%
Levemir®	All NDCs	All Strengths	All Package Sizes	15%1	22%3	37%	N/A	3%

Available to EGWP Plans only.

Contract Ops.

<u>Calculation of Rebates</u>: Number of Units dispensed to Members by Participating Pharmacies multiplied by the WAC in effect as of the of the applicable month, multiplied by the Rebate percentage. For purposes of clarification a Plan is only eligible to receive a Listed Rebate, Exclusive Rebate, 1 of 2 Product, or 1 of 2 Manufacturer Rebate. These Rebates will not be combined.

<u>Conditions to Rebates</u>: The payment of Rebates is subject to the following conditions, as determined on a Product by Product, Part D Plan by Part D Plan, and month by month basis, provided that if these condition are not met for the entire month, Rebates shall be payable on utilization of that Product for only that portion of the month in which such conditions were met:

- The Product is listed on the Plan Formulary, provided this condition shall not apply to NovoFine®, AutoCover®, and NovoTwist® if the entire Therapeutic Class is not listed;
- 2. The Product adjudicates at Second Tier or, if applicable, the Specialty Tier;
- 3. The Product is not Disadvantaged; and
- 4. Competitive Products not listed on Second Tier of Plan Formulary do not adjudicate at such tier unless a result of Permitted Activities or unless required by the MMA.
- 5. PBM does not solicit a rebid for the Product prior to January 1, 2018 (the foregoing does not prohibit rebid for product utilization occurring on or after January 1, 2018) unless such rebid is undertaken as a result of:
  - a. generic or biosimilar formulation of Product becomes commercially available and such Product is deleted pursuant to this Exhibit A; or
  - b. governmental authority requires the removal of a Product from Formulary(ies); or
  - c. FDA label related safety reasons (e.g., FDA black box warning or other FDA safety alert) or Product withdrawal or recall.

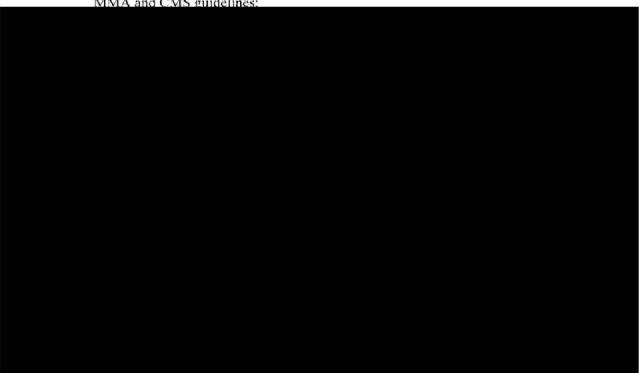
Additional Conditions for Novolin, Novolog, NovoLog Mix 70/30 Exclusive Rebates: The payment of Exclusive Rebates for Novolin, Novolog, and Novolog Mix 70/30 is subject to the following additional conditions, as determined on a Part D Plan by Part D Plan and month by month basis, provided that if these conditions are not met for the entire month, Rebates shall be payable on utilization of these Products for only that portion of the month in which such conditions were met:

- 1. Novolin®, NovoLog®, and NovoLog® Mix 70/30 have Exclusive Formulary Status (which shall be reflected by listing all of the following names of these Products on the Plan Formulary: Novolin® R, Novolin® N, Novolin® 70/30, NovoLog®, NovoLog® PenFill®, NovoLog® FlexPen®, NovoLog® Mix 70/30, and NovoLog® Mix 70/30 Prefill) and all presentations of Novolin®, NovoLog®, and NovoLog® Mix 70/30 are covered by the Part D Plan, to the extent permitted by the MMA and CMS guidelines;
- 2. Victoza and Levemir have 1 of 2 Product Status (which shall be reflected by listing all of the following names of these Products on the Plan Formulary: Levemir®, Levemir® FlexPen, Levemir® FlexTouch and Victoza®) and all presentations of Victoza and Levemir are covered by the Part D Plan, to the extent permitted by the MMA and CMS guidelines:
- All Competitive Products are subject to Exclusion, and existing patients using a Competitive Product may not be grandfathered.

Additional Conditions for Levemir 1 of 2 Product Enhanced Rebates: The payment of 1 of 2 Product Enhanced Rebates for Levemir is subject to the following additional conditions, as determined on a Part D Plan by Part D Plan and month by month basis, provided that if these conditions are not met for the entire month, Rebates shall be payable on utilization of the Product for only that portion of the quarter in which such conditions were met:



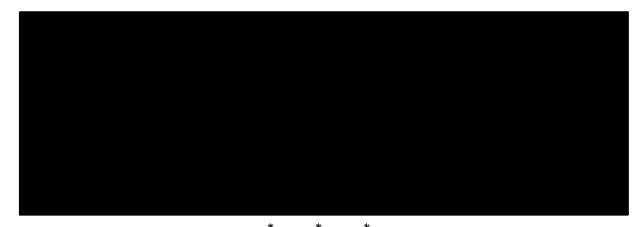
- 1. Novolin®, NovoLog®, and NovoLog® Mix 70/30 have Exclusive Formulary Status (which shall be reflected by listing all of the following names of these Products on the Plan Formulary: Novolin® R, Novolin® N, Novolin® 70/30, NovoLog®, NovoLog® PenFill®, NovoLog® FlexPen®, NovoLog® Mix 70/30, and NovoLog® Mix 70/30 Prefill) and all presentations of Novolin®, NovoLog®, and NovoLog® Mix 70/30 are covered by the Part D Plan, to the extent permitted by the MMA and CMS guidelines;
- 2. Victoza and Levemir have 1 of 2 Product Status (which shall be reflected by listing all of the following names of these Products on the Plan Formulary: Levemir®, Levemir® FlexPen, Levemir® FlexTouch and Victoza®) and all presentations of Victoza and Levemir are covered by the Part D Plan, to the extent permitted by the MMA and CMS guidelines:



<u>Calculation of Administrative Fee:</u> Number of Rebate eligible Units dispensed to Members by Participating Pharmacies multiplied by the WAC in effect as of the applicable month, multiplied by the Administrative Fee percentage.

Price Protection: This Section applies only to Rebates for Novolin®, Novolog®, Novolog® Mix 70/30, Levemir® and Rebates. The Net Price for each Product's Formulary Status shall be reviewed monthly by comparing the Net Price of the applicable calendar month to the Baseline Net Price. If the Product's Net Price has increased by more than eight percent (8.00%) over Baseline Net Price ("Net Price Ceiling"), the Rebate percentage(s) for such Product will be increased for such calendar month such that the Net Price will equal the Net Price Ceiling. The increased Rebate percentage(s) shall remain in effect during the remainder of the current Contract Year and shall return to their original percentage at the beginning of the next Contract Year. Calculations will be performed to six decimal places of precision rounded to 2 decimals. If the Rebate percentages are increased pursuant to this section, PBM will notify Manufacturer of the amount of the increase in the Rebate percentages, which notice requirement may be satisfied by PBM submission of an invoice to Manufacturer that reflects the increased Rebate percentages.

Contract Ops An example of the foregoing adjustment is as follows: If the Baseline WAC for a particular Product is \$100, the Rebate Percentage is ten percent (10%), and the Baseline Net Price for the Product is \$90, the Net Price Ceiling would be \$97.20. If the WAC for such Product increases by \$10, the Net Price for the Product would be \$99, which exceeds the Net Price Ceiling. The Rebate Percentage would thus increase to 11.64% (\$110 - \$97.20 = \$12.80; \$12.80/\$110 = 11.64%) in order to maintain a Net Price equal to the Net Price Ceiling.



#### Exhibit C

#### THERAPEUTIC CLASSES

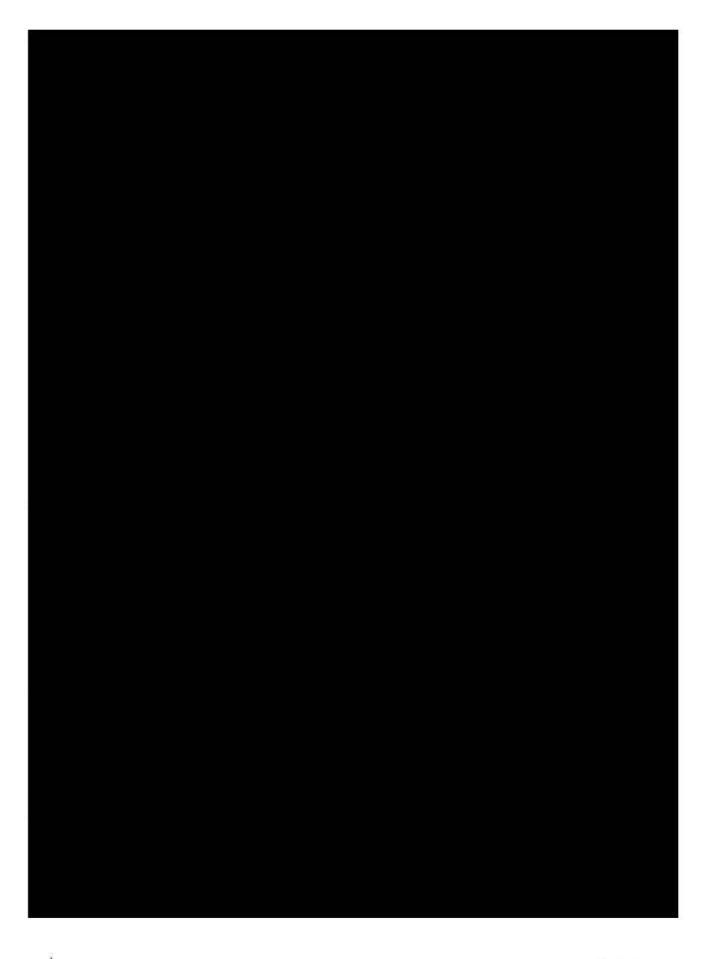
#### 1. Therapeutic Class for Utilization by Market Report

Human Insulin	
00169-1833-11 Novolin® R (Regular)	00002-8215-01 Humulin R 10mL Vial
00169-1834-11 Novolim® N (NPH)	00002-8215-17 Humulin R 3ml. Vial
00169-1837-11 Novolin® 70/30 (70% NPH 30% Reg.)	00002-8315-01 Humulin N 10mi. Vial
	00002-8315-17 Humulin N 3ml. Vial
	00002-8501-01 Humulin R U-500
	90002-8715-01 Humalio 70/30 10ml. Vial
	00002-8715-17 Humulin 70/30 3mL Vial
	00002-8730-01 Humulin N 3ml, Pen - Inner Pack
	00002-8730-59 Flumulin N 3mL Per
	00002-8770-01 Humulin 70/30 3mL Pen = Inner Pack
	00002-8770-59 Flumulin 70/30 3mL Pen
	90002-8803-01 Humulin 70/30 KwikPen – Inner Pack 90002-8803-59 Humulin 70/30 KwikPen
	00002-8805-04 Humufin N KwikPen - Inner Pack
	00002-8805-59 Humulin N KwikPen
Rapid-Acting Insulin Analog	
00169-7501-11 NovoLog® 10ml.	00002-7510-01 Humalog 10mL
00169-3303-12 NovoLog≇ PcaFiH® 3ml.	00002-7510-17 Humalog 3ml. Vial
00169-6339-10 NovoLog# FlexPen# 3mL	00002-7516-01 Humalog 3ml.
	06002-7516-59 Humalog 3ml.
	00002-8215-01 Humalin R
	00002-8215-17 Humalin R 3mL Vial
	00002-8501-01 Humafin R U-500
	00002-8799-01 Humalog KwikPen (single)
	00002-8799-59 Humalog KwikPen
	00088-2500-33 Apidra 10mL
	00088-2502-05 Apidra SoloSTAR
Pre-Mix Insulin Analog	00169-1833-11 Novolinit R (Regular)
00169-3685-12 NovoLog& Mix 70/30 10m2	06002-7511-01 Humalog 78/25 10mL
00169-3696-19 Novol og@ Mix 70/30 FlexPen®	96002-7512-01 Humalog Mix 59/50
CONTRACTOR OF A STATE OF THE ST	00002-8715-01 Famusin 70/30 10mL Vial
	00002-8715-17 Humulin 70/30 3mL Vial
	00002-8770-01 Humulin 70/30 Pen (single)
	00002-8770-59 Humulin 70/30 Pen
	00002-8797-01 Humalog Mix KwikPen 75/25 (single)
	00002-8797-59 Hamalog KwikPen 75/25
	00002-8798-01 Humalog Mix 50/50 KwikPen 1x3mi Pen
	00002-8798-59 Humalog KwikPen 50/50
	00002-8803-01 Humalog 70/30 KwikPen (single)
	00002-8803-59 Humukin 70/30 KwikPen
	00169-1837-11 Nevoting: 70/30



0002-8315-01 Humalin N 0002-8315-17 Humalin N 3ml, Vial
0002-8315-17 Humolin N 3ml Viol
2000 COMO, 2000 P. C.
0002-8730-01 (fumulin N 3mt. Pen - Inner Pack
0002-8730-59 Humulin N 3mL Pen
0002-8805-01 Flumallin N KwikPen – Inner Pack
0002-8805-59 Humalin N KwikPen
0088-2219-05 Lantus (SoloStar) 3mil.00088-2220-33 Lantus 10ml.
0169-1834-11 Nevolin N (NPH)







Contract Ops 2. Therapeutic Class for Formulary Positioning

2. Therapeutic Class for Formulary	y Positioning
Haman Insulin	
Nevolin®	Humulin (except for Humulin U-500)
Rapid-Acting Insulin Analog	Transmit feresters transmit a 2007
NovaLog®	Flumalog
	Apidra
Pre-Mix Insulin Analog	
NovoLog® Mix 70/30	Humalog Mix
Basal Insulin Analog	
Levemir≅	Lantus



**PC Discussion** 

May 19, 2014



### **Agenda**

- Basal Pricing Landscape: Then and Now
- Strategic Decision versus Budget Decision
- 3 Black-out Period





### Aggressive competitor price actions in 2013



#### SANOFI Actions

#### Up to 39.7% increase in 2013

- > 9.9% vial/device April 26
- 14.9% vial / 9.9% device August 2
- 14.9% vial / 9.9% device December 13

#### Possible rationale

- Prep for U300 (early 2015)
- Defense against biosimilar (early 2015)
- Poor financial results





§ Prior to taking any price increase triggered by a market event, Novo Nordisk undertakes a review of all other factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

### Changing and challenging 2014 environment

T	oday's Environment	Considerations	NNI Strategic Recommendation
1	<ul><li>SANOFI</li><li>Lilly biosimilar 18-month stay</li><li>Improving financial performance</li></ul>	Sanofi doesn't need to be as aggressive	FOLLOW
2	<ul> <li>PRESS COVERAGE</li> <li>New York Times 4/5 "Even Small Medical Advances Can Mean Big Jumps in Bills"</li> <li>Bloomberg 4/30 "Drug Prices Defy Gravity, Doubling for Dozens of Products"</li> <li>60 Minutes story late May/June?</li> </ul>	Sanofi feeling reputational pressure?	FOLLOW
3	<ul> <li>PAYER PRESSURES</li> <li>Basal class reviews – big growth in spend</li> <li>Rebate pressure and price protection</li> </ul>	Two key basal negotiations in progress: CVS July, ESI August	FOLLOW/WAIT
4	<ul> <li>PROFITS AND PERFORMANCE</li> <li>Levemir® ARP ahead of AB14 +\$89M</li> <li>But overall company performance behind</li> </ul>	Brand versus Company?	Brand focus → <b>FOLLOW</b> Company focus → <b>LEAD?</b>

### If company profits are primary concern...

#### RE2 assumes 14.9% vial and 8.8% device

#### ...and Sanofi takes less

	<b>July</b> RE2 impact / AB14 impact	
9.9%	+\$11M / +\$100M	
8.0%	-\$8M / +\$81M	
6.0%	-\$28M / +\$61M	



FOLLOW with 2 points higher, but do not exceed 9.9%

 Will revisit PC with specific recommendation once Sanofi takes action.

### ...or Sanofi delays

	August RE2 impact / AB14 impact	September RE2 impact / AB14 impact	
14.9%/ 8.8%	-\$19M / +\$71M	- <b>\$16M</b> / +\$65M	
10.7%	Break-even / +\$89M	-\$6M / +\$83M	
9.9%	-\$6M / +\$83M	-\$12M / +\$77M	



LEAD with 9.9% in August

- Key payer negotiations should be concluded
- Better financial impact than closing gap (v/d mix)
- · Optically less aggressive

§ Prior to taking any price increase triggered by a market event, Novo Nordisk undertakes a review of all other factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

### Timing consideration: Black-out for FlexTouch®

#### **Tactical Launch Team Request**

### 5/20 - 6/16 black-out to ensure smooth launch

- 5/20 Trade preparing to take initial FlexTouch® orders
- 6/16 first shipments

#### **Rationale**

- First shipments are sold at price that was originally communicated
- Maintain good Trade business relationships
- Avoids negative perception by trade and retail partners

		Options	Financial Impact
1	Honor Blackout	No price increase on Levemir® franchise during 5/20-6/16. Earliest timing would be 6/17.	~\$7M-\$14M forgone
2	Vial First	Increase vial only immediately, but delay FlexPen® and FlexTouch® to 6/17	~\$5M-\$9M forgone
3	Entire Brand	Increase Levemir® franchise immediately	No financial impact, but hurts Trade relationships and negative perception

From: EDDW (Eddie Williams) To:

FAJA (Farruq Jafery); CLEE (Camille Lee); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen);

JESH (Jesper Hoiland)

CUOT (Curt Oltmans); SEAP (Sean Phillips); DUGL (Doug Langa); RDZI (Rich DeNunzio); KAYE CC:

(Karen Yee)

Sent: 5/23/2014 1:17:32 PM

Subject: RE: Approval Required: List price increase NovoLog®, NovoLog® Mix, Novolin®, I

Eddie

From: FAJA (Farruq Jafery)

Sent: Friday, May 23, 2014 8:59 AM

To: CLEE (Camille Lee); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); EDDW (Eddie Williams); JESH (Jesper Hoiland)

Cc: CUOT (Curt Oltmans); SEAP (Sean Phillips); DUGL (Doug Langa); RDZI (Rich DeNunzio); KAYE (Karen Yee)

Subject: Approval Required: List price increase NovoLog®, NovoLog® Mix, Novolin®,

Importance: High Sensitivity: Confidential

Dear Pricing Committee:

We are requesting your approval to implement the following list price increases that were built into RE2 forecast recently approved by ET on May 12th:

9.9% NovoLog® and NovoLog® Mix 70/30

9.9% Novolin® (

Effective Date: Wednesday, May 28, 2014 (or as soon as operationally feasible upon final approval). We have secured Brand alignment on the timing and magnitude of the proposed increases above. Your reply is requested by noon on Tuesday (5/27).

Note that RE2 assumes the increases taking effect on 6/1/14, however, we recommend taking the increase sooner to minimize the impact of price protection (e.g. CVS Part D uses a baseline WAC of 6/1/14 to determine PP, CVS Commercial uses baseline WAC as of 6/30 etc.) The 2015 upside from avoiding PP impact for CVS PTD is roughly +\$12M.

Recall that our pricing strategy\*\* for NovoLog® and NovoLog® Mix 70/30 is to be the price leader with a timing of every 6 months:

- The increase supports the brand strategy of maintaining access, achieving volume and profitability goals, and financially offsetting access losses
- Last year's increases were 8% on 7/19 and 9.9% on 12/3 so the proposed timing and magnitude is fairly consistent with recent history
- 2014 RE2 ARP = \$2.191B

With respect to Novolin®, the pricing strategy\*\* is to align with NovoLog® timing and magnitude to keep the portfolio together:

- The increase supports brand objectives of maintaining access, achieving volume and profitability goals, driving value of existing business, and continuing H2A conversion
- Last year's increases were 8.9% on 6/27 (Lilly led) and 9.9% on 12/3
- 2014 RE2 ARP = \$297.5M

<sup>\*\*</sup> Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

List prices resulting from the proposed increases are shown in the table below:

Proposed Effecti	Proposed Pct Change	ct Name	NDC#
.9% \$99.65 5/28/20	9.9%	n® R - 10mL vial	00169-1833-11
.9% \$99.65 5/28/20	9.9%	n® N - 10mL vial	00169-1834-11
.9% \$99.65 5/28/20°	9.9%	n® 70/30 10mL vial	00169-1837-11
.9% \$184.85 5/28/20	9.9%	og® 10mL vial	00169-7501-11
.9% \$343.40 5/28/20	9.9%	og® PenFill cartridge -5x3mL	00169-3303-12
.9% \$357.10 5/28/20	9.9%	og® FlexPen® -5x3mL	00169-6339-10
.9% \$191.75 5/28/20	9.9%	og® Mix 70/30 10mL vial	00169-3685-12
.9% \$357.10 5/28/20	9.9%	og® Mix 70/30 FlexPen® -	00169-3696-19
	9.9	가는 500mm 가장 가장 가장 있다면 그 없어요 하다면 하는 것을 가장 하는 것을 하는 것이다.	00169-3696-19

<sup>\*</sup> or as soon as operationally feasible upon approval.

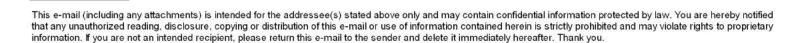
Please reach out if you have any questions.

Kind regards,

Farruq

Farruq Jafery VP, Pricing, Contract Ops & Reimbursement Finance

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA



From: JESH (Jesper Hoiland)

To: FAJA (Farruq Jafery); CLEE (Camille Lee); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); PFO (Phil Fornecker)

CC: CUOT (Curt Oltmans); SEAP (Sean Phillips); BBRT (Bill Breitenbach); DUGL (Doug Langa); KAYE (Karen Yee); RDZI (Rich DeNunzio)

**Sent:** 5/30/2014 10:11:37 PM

Subject: Re: Approval Required: Levemir List price increase

100 agree!! Jesper

From: FAJA (Farrug Jafery)

Sent: Friday, May 30, 2014 06:07 PM

To: CLEE (Camille Lee); JESH (Jesper Hoiland); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); PFO (Phil Fornecker)

Cc: CUOT (Curt Oltmans); SEAP (Sean Phillips); BBRT (Bill Breitenbach); DUGL (Doug Langa); KAYE (Karen Yee); RDZI (Rich DeNunzio)

Subject: RE: Approval Required: Levemir List price increase

#### Camille,

Since we have heard that Sanofi is <u>not passing</u> this through to CVS <u>Commercial</u>, the recommendation is to follow course and not pass on to their commercial book so as not to disadvantage us in the current negotiations.

For their Part D business, we have not heard anything yet to indicate that Sanofi is not passing on. In the event of major pushback on the Part D side, we would need to assess implications and decide whether to pass on or not. By taking this by 6/1, this at least provides us this option.

#### Farrug

From: CLEE (Camille Lee)

**Sent:** Friday, May 30, 2014 5:42 PM

To: FAJA (Farrug Jafery); JESH (Jesper Hoiland); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); PFO (Phil Fornecker)

Cc: CUOT (Curt Oltmans); SEAP (Sean Phillips); BBRT (Bill Breitenbach); DUGL (Doug Langa); KAYE (Karen Yee); RDZI (Rich DeNunzio)

**Subject:** RE: Approval Required: Levemir List price increase

Sensitivity: Confidential

#### Approved.

Can you clarify if we will be passing this through to CVSC?

Camille

**From:** FAJA (Farruq Jafery)

**Sent:** Friday, May 30, 2014 5:30 PM

To: JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); PFO (Phil Fornecker)

Cc: CUOT (Curt Oltmans); SEAP (Sean Phillips); BBRT (Bill Breitenbach); DUGL (Doug Langa); KAYE (Karen Yee); RDZI (Rich DeNunzio)

**Subject:** Approval Required: Levemir List price increase

Importance: High Sensitivity: Confidential Dear Pricing Committee:

Sanofi took a price increase on Lantus effective today: 16.1% vial and 9.9% pen.

Based on our PC discussion on 5/19/2014, we agreed that the best strategy for Levemir® is to observe the market and maintain list price parity to competitors\*\*.

As such, we will be moving forward with a 16.1% increase on Levemir® vial and a 9.9% increase on Levemir® FlexPen® and FlexTouch® effective tomorrow 5/31/2014. This is the approach which minimizes Price Protection impact in 2015 (avoids \$13M in incremental PP rebates vs. taking after 6/1/14).

As we need to move immediately to ensure the increase is operationalized in time, please reply back ASAP. We have discussed the impact with Brand and Trade on FlexTouch launch and with Market Access on impact on ongoing negotiations. Although this will generate some pushback from customers, it is believed that this can be managed to mitigate negative impact.

Note that the RE2 forecast assumed 14.9% vial and 9.9% pen, so the ARP upside from this increase is +\$32.3M vs RE2 and +\$125.9M vs AB14.

List prices resulting from the proposed increase are shown in the table below:

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date*
00169-3687-12	Levemir®	\$191.28	16.1%	\$222.08	5/31/2014
00169-6438-10	Levemir® FlexTouch®	\$303.12	9.9%	\$333.12	5/31/2014
00169-6439-10	Levemir® FlexPen®	\$303.12	9.9%	\$333.12	5/31/2014

<sup>\*</sup> or as soon as operationally feasible upon approval.

Kind regards, Farruq

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<sup>\*\*</sup> Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

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To: FAJA (Farrug Jafery)

CC: JESH (Jesper Hoiland); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); PFO (Phil Fornecker); CUOT (Curt Oltmans); SEAP (Sean

Phillips); BBRT (Bill Breitenbach); DUGL (Doug Langa); KAYE (Karen Yee); RDZI (Rich DeNunzio)

Sent: 5/30/2014 10:15:35 PM

Subject: Re: Approval Required: Levemir List price increase

Great, thanks for clarifying Farruq.

Have a good weekend,

Camille

Sent from my iPhone

On May 30, 2014, at 6:07 PM, "FAJA (Farruq Jafery)"

Camille.

Since we have heard that Sanofi is <u>not passing</u> this through to CVS <u>Commercial</u>, the recommendation is to follow course and not pass on to their commercial book so as not to disadvantage us in the current negotiations.

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Subject: RE: Approval Required: Levemir List price increase

Sensitivity: Confidential

Approved.

Can you clarify if we will be passing this through to CVSC?

Camille

From: FAJA (Farruq Jafery)

Sent: Friday, May 30, 2014 5:30 PM

To: JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); KMKN (Karsten Munk Knudsen); PFO (Phil Fornecker)

Cc: CUOT (Curt Oltmans); SEAP (Sean Phillips); BBRT (Bill Breitenbach); DUGL (Doug Langa); KAYE (Karen Yee); RDZI (Rich DeNunzio)

Subject: Approval Required: Levemir List price increase

Importance: High

Sensitivity: Confidential

Dear Pricing Committee:

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As such, we will be moving forward with a 16.1% increase on Levemir® vial and a 9.9% increase on Levemir® FlexPen® and FlexTouch® effective tomorrow 5/31/2014. This is the approach which minimizes Price Protection impact in 2015 (avoids \$13M in incremental PP rebates vs. taking after 6/1/14).

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00169-6438-10	Levemir® FlexTouch®	\$303.12	9.9%	\$333.12	5/31/2014
00169-6439-10	Levemir® FlexPen®	\$303.12	9.9%	\$333.12	5/31/2014

<sup>\*</sup> or as soon as operationally feasible upon approval.

Kind regards, Farruq

This e-mail (including any attachments) is intended for the addressee(s) stated above only and may contain confidential information protected by law. You are hereby notified that any unauthorized reading, disclosure, copying or distribution of this e-mail or use of information contained herein is strictly prohibited and may violate rights to proprietary information. If you are not an intended recipient, please return this e-mail to the sender and delete it immediately hereafter. Thank you.

<sup>\*\*</sup> Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

From: LAG (Lars Green)
To: ANAJ (Andy Ajello)

CC: FAJA (Farrug Jafery); JESH (Jesper Hoiland); CLEE (Camille Lee); EDDW (Eddie Williams); PFO

(Phil Fornecker); CUOT (Curt Oltmans); SEAP (Sean Phillips); DUGL (Doug Langa); GMCA (George McAvoy); DRPE (Drew Pensyl); JHSR (John Spera); GAGR (Gary Grote); RDZI (Rich DeNunzio);

KAYE (Karen Yee)

Sent: 10/23/2014 4:35:41 PM

Subject: Re: Approval Requested: List price increase - NovoLog®, NovoLog® Mix 70/30, Novolin® &

image001.png

Approved.

Attachments:

Lars

Sent from my iPhone

ok

From: FAJA (Farruq Jafery)

Sent: Thursday, October 23, 2014 10:58 AM

To: JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); LAG (Lars Green); EDDW (Eddie Williams); PFO (Phil

Fornecker)

Cc: CUOT (Curt Oltmans); SEAP (Sean Phillips); DUGL (Doug Langa); GMCA (George McAvoy); DRPE (Drew Pensyl); JHSR

(John Spera); GAGR (Gary Grote); RDZI (Rich DeNunzio); KAYE (Karen Yee)

Subject: Approval Requested: List price increase - NovoLog®, NovoLog® Mix 70/30, Novolin® &

Importance: High Sensitivity: Confidential

Dear Pricing Committee:

We have an opportunity to secure additional upside in 2014 by optimizing timing around some upcoming list price increases. As such, we are requesting your approval to implement the following list price increases earlier than planned, as follows:

9.9% - NovoLog®, NovoLog® Mix 70/30 effective November 18, 2014 [AB15 assumes 9.9% - Dec. 1, 2014]

9.9% - Novolin® effective November 18, 2014

We have secured Brand alignment on the timing and magnitude of the proposed increases. Please note that the NovoLog®, NovoLog® Mix 70/30, Novolin® price increase is timed for mid-quarter to minimize price protection impact.

Total 2014 upside from these increases is +\$9M: and NovoLog®, NovoLog® Mix 70/30, Novolin® will yield +\$6M.

Kindly reply by COB Tuesday, October 28th so that we may operationalize the price increases as proposed.

Regarding NovoLog® and NovoLog® Mix 70/30, the pricing strategy\*\* is to be the price leader with a timing of every 6 months:

- The increase supports the brand strategy of maintaining access, achieving volume and profitability goals, and financially offsetting access losses
- Recent increases were 8% on 7/19/2013, 9.9% on 12/3/2013, and 9.9% on 5/28/2014 so the proposed timing and magnitude is consistent with recent history
- 2014 RE3 ARP = \$2.194B

With respect to Novolin®, the pricing strategy\*\* is to align with NovoLog® timing and magnitude to keep the portfolio together:

- The increase supports brand objectives of maintaining access, achieving volume and profitability goals, driving value of existing business, and continuing H2A conversion
- Recent increases were 8.9% on 6/27/2013 (Lilly led), 9.9% on 12/3/2013, and 9.9% on 5/28/2014
- 2014 RE3 ARP = \$307.1M



\*\* Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

New list prices resulting from the proposed increases are shown in the table below:

<image001.png>

Please reach out if you have any questions. Kind regards,

#### Farruq

Farruq Jafery VP, Pricing, Contract Ops & Reimbursement Finance

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA



This e-mail (including any attachments) is intended for the addressee(s) stated above only and may contain confidential information protected by law. You are hereby notified that any unauthorized reading, disclosure, copying or distribution of this e-mail or use of information contained herein is strictly prohibited and may violate rights to proprietary information. If you are not an intended recipient, please return this e-mail to the sender and delete it immediately hereafter. Thank you.

From: LAG (Lars Green)

To: RDZI (Rich DeNunzio); JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); CUOT (Curt

Oltmans); PFO (Phil Fornecker)

CC: SEAP (Sean Phillips); DUGL (Doug Langa); FAJA (Farrug Jafery); KAYE (Karen Yee); BKNO (Bill

Knott); BBRT (Bill Breitenbach)

**Sent:** 11/7/2014 9:06:10 PM

Subject: RE: Approval Requested: Levemir Price increase

I approve. Best, Lars

From: RDZI (Rich DeNunzio)

Sent: Friday, November 07, 2014 4:03 PM

To: LAG (Lars Green); JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); CUOT (Curt Oltmans); PFO (Phil

Fornecker)

Cc: SEAP (Sean Phillips); DUGL (Doug Langa); FAJA (Farruq Jafery); KAYE (Karen Yee); BKNO (Bill Knott); BBRT (Bill

Breitenbach)

**Subject:** Approval Requested: Levemir Price increase

Dear Pricing Committee,

As stated earlier this morning, we found out, via Trade, that Lantus has taken an 11.9% increase on both their vial and device and we would follow up with a vote post analysis on the optimal time of the increase.

After analyzing the additional cost of rebates and price protection, based on specific contracting terms, it was determined that it makes better financial sense (~+\$10M benefit) to wait until after the 45<sup>th</sup> day of the quarter (11/18 is the first feasible date for the increase) vs increasing price today (effective 11/8). Therefore, we are asking for your approval to follow their 11.9%\*\* on November 18<sup>th</sup> (first feasible increase date post the 15<sup>th</sup>). Approving this request will have a benefit to 2014 of ~\$25M.

Please respond with your approval prior to November 13<sup>th</sup>. Please reach out if you have any questions.

Have a nice weekend, Rich

\*\* Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date
00169-3687-12	Levemir® 10mL vial	\$222.08	11.9%	\$248.56	11/18/2014*
00169-6438-10	Levemir® FlexTouch® - 5x3mL	\$333.12	11.9%	\$372.76	11/18/2014*

<sup>\*</sup> or when operationally feasible upon approval.

From: RDZI (Rich DeNunzio)

Sent: Friday, November 07, 2014 9:15 AM

To: LAG (Lars Green); JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); CUOT (Curt Oltmans); PFO (Phil

Fornecker)

Cc: SEAP (Sean Phillips); DUGL (Doug Langa); FAJA (Farrug Jafery); KAYE (Karen Yee); BKNO (Bill Knott); BBRT (Bill

Breitenbach)

Subject: FW: Lantus PI

Dear Pricing Committee:

We wanted to inform you Lantus communicated a price increase of 11.9% to the wholesalers (provided to us by Trade). Please note that many of our contracts look at the WAC price on the 45<sup>th</sup> day of the quarter (and

monthly paid contracts at the 15<sup>th</sup> day), so before we make a recommendation to follow asap\*\*, we will determine if it makes better financial sense (due to rebate payments and price protection) to align to the increase to same date as NovoLog® (11/18).

We will follow up later this afternoon after we analyze the impact of added rebates and price protection impact on an increase earlier than mid-quarter or month.

Rich

\*\* Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

From: BPL (Brian Perrella)

**Sent:** Friday, November 07, 2014 8:53 AM **To:** KAYE (Karen Yee); RDZI (Rich DeNunzio)

**Subject:** FW: Lantus PI

Trade just informed me that Lantus took a PI (11.9%). It's not posted in WK, so communication must have gone out last night.

Presentation	Old	New	PI%
Vial	\$222.08	\$248.56	11.9%
Pen	\$333.12	\$372.76	11.9%

ВΡ

# Tresiba® Pricing and Market Access Strategy

Pricing Committee Review May 12, 2015





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# OBJECTIVE: Align on Tresiba® US List and Net Price Strategy for Commercial and Medicare Part D

## **Agenda**

**Basal Category Overview** 

Tresiba® Brand Objectives

Recommendation, Options Considered, and Rationale

Implications to Sales, Volume, Market Share

VOTE





# Substantial changes have occurred in the market since original launch plan

### 2013

- Approved Strategy: 10% List Premium;
   10% Net Premium Commercial, Parity in Part D, relative to glargine device
- · Primarily open access to basal insulin
- Limited price protection; mainly in Part D, usually Annual Reset
- Levemir® average rebate ~20%
- Tresiba® was set to be first entrant in basal class since Levemir® launch

### 2015

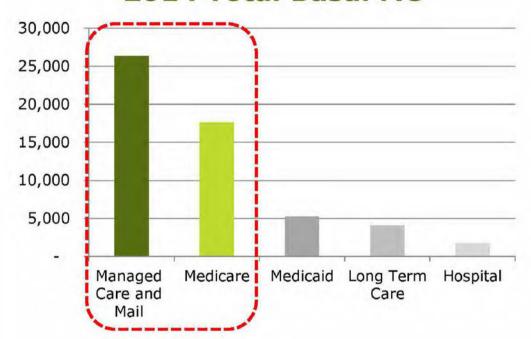
- SPP: 10% List Premium, 20% Net Premium, relative to Levemir®
- High level of price sensitivity and willingness to restrict formularies
- Average Levemir® rebates of 40% with widespread cumulative price protection
- Sanofi making aggressive exclusive offers
- Strong payer interest in biosimilar glargine; expecting 20-30% net price discounts





# Commercial and Medicare Part D are the critical channels for Tresiba®

### 2014 Total Basal MU



Source: SP Projection based on AB2015

### **Growth Opportunities**

- Basal segment to grow ~5% annually through 2017
- Managed Care and Medicare Part D will continue to represent ~70% of total volume

### **NNI Share**

 Levemir® share is currently ~25% of total basal utilization

### **Analog Penetration**

o Analogs represent ~80% of overall basal segment

### **Device Penetration**

- Devices represent >61% of basal analog utilization
  - Levemir®: 70/30 device to vial
     glargine: 58/42 device to vial



insulin degludec [rDNA origin] injection

# It will be important to balance volume and value to achieve Brand objectives

### **Secure Access**

### **PRO**

- Higher volume
- Maintains payer partnership
- · Eases sales force pull-through
- Limits reliance on co-pay support program and market access training
- Build HCP familiarity in preparation for for Xultophy®

### CON

 Rebates at or approaching Levemir® 2016 rates

## **Maximize Profitability**

### **PRO**

- Lower rebate exposure
- Large amount of unrestricted commercial volume

### CON

- Higher patient co-pays requires investment in co-pay support program and sales training
- Challenging for Sales Force execution
- Lower overall breadth of prescribers





## **Summary of List and Net Price Recommendations**

List Price	
Recommendation	+10% of Levemir® list price (~\$410 at May 2015 prices)
Rationale	Captures Tresiba® clinical value* and Produces higher net revenue due to level of unrestricted access in Commercial Channel

## Net Price (versus Levemir®)

### Recommendation

### +20% Commercial

- MaximizesCommercial revenue
- Maintains price potential for pipeline
- ✓ Maintains lower rebate levels

### +10% Part D

- ✓ Maximizes Part D
  revenue
- Maximizes overall access

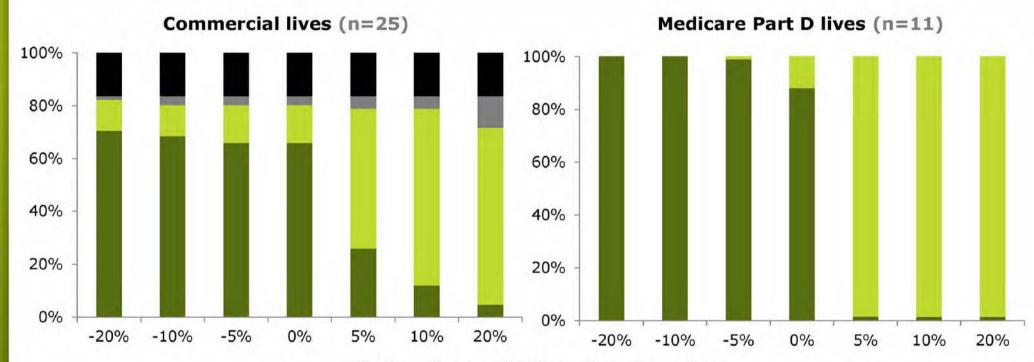
### **Bidding Approach**

- Secure Tier 2<sup>±</sup> status where possible in line with strategy in Commercial and Part D
- 2. Capitalize on unrestricted Tier 3 access in Commercial where Tier 2 isn't possible
- Ensure largest possible unrestricted environment by paying rebates to remove or prevent restrictions

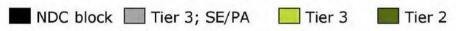
\* Subject to final label \* Tier 2 = preferred brand tier; Tier 3 = non-preferred brand tier



# Research shows a unrestricted access opportunity even at a net price premium







Source: CRA Research, February-March 2015.

novo nordisk



## **Pricing Options Considered**

	24.4	Ne	t vs.
Option	List	glargine	Levemir®*
Base Case	+10%	+10%	+27%
1	+20%	+10%	+27%
2	+20%	+10% Comm +0% Part D	+17%
3	+10%	+10% Comm +0% Part D	+17%

<sup>\*</sup> Tresiba® blended net premium versus Levemir®

# Current Levemir® and glargine device WAC

• \$373

Tresiba® WAC @ +10%

• \$410

Tresiba® WAC @ +20%

• \$448

Therefore Tresiba® average rebate:

- 35% in Commercial\*\*
- · 40% in Part D



insulin degludec [rDNA origin] injection

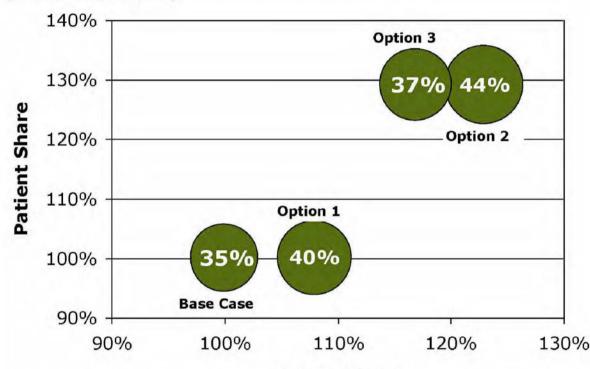
<sup>\*\*</sup> Achieving higher T2 Commercial access will require 40% rebate level.

## Summary of Options: Outlook 1 (baseline access)

Assumes 60/40% Commercial/Part D split\*; excludes Levemir®-preferred accounts

### Net Revenue vs. Patient Share

(indexed to Base Case)



## Key

	14.0	Net vs.		
Option	List	glargine	Levemir®	
Base	+10%	+10%	+27%	
1	+20%	+10%	+27%	
2	+20%	+10% +0%	+17%	
3	+10%	+10% +0%	+17%	

%

% is Tier 2 Rebate Level±
(Size of bubble reflects relative rebate sizes)

#### **Net Revenue**



<sup>\*</sup> Based on AB15's MCO / Part D 2018 split.

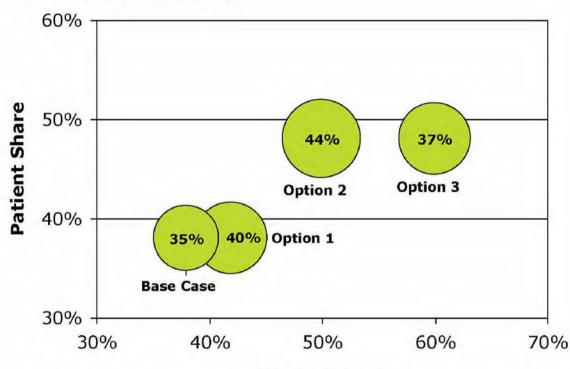
<sup>\*\*</sup> Offer rebates for Tier 2 access. Customer pays list price if not accepted, with a 10% rebate if Tier 3 without SE/PA restrictions.

<sup>±</sup> Tier 2 = preferred brand tier; Tier 3 = non-preferred brand tier

# Summary of Options: Outlook 2 (downside restricted access) Assumes 60/40% Commercial/Part D split\*; excludes Levemir®-preferred accounts

### Net Revenue vs. Patient Share

(indexed to Base Case, baseline)



## Key

	100	Net vs.		
Option	List	glargine	Levemir®	
Base	+10%	+10%	+27%	
1	+20%	+10%	+27%	
2	+20%	+10% +0%	+17%	
3	+10%	+10% +0%	+17%	

% is Tier 2 Rebate Level± (Size of bubble reflects relative rebate sizes)

#### **Net Revenue**

 $\pm$  Tier 2 = preferred brand tier; Tier 3 = non-preferred brand tier



<sup>\*</sup> Based on AB15's MCO / Part D 2018 split.

<sup>\*\*</sup> Offer rebates for Tier 2 access. Customer pays list price if not accepted, with a 10% rebate if Tier 3 without SE/PA restrictions.

# Extract Value from Commercial and Volume from Part D



<sup>±</sup> Tier 2 = preferred brand tier; Tier 3 = non-preferred brand tier. Net price reference is versus Levemir®.

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insulin degludec [rDNA origin] injection

# Strategy will balance volume and value to achieve Brand objectives

# Ensures competitive access at launch to support rapid uptake and patient accessibility

- ✓ Defendable list premium and overall net premium
- ✓ Achieves unrestricted access in Commercial and enables strong access in Part D channel
  - Patient affordability and accessibility
  - While enabling uptake
- ✓ Avoids artificially high rebate levels
- ✓ Preserves value and allows experience with degludec molecule in preparation for Xultophy®
- ✓ Enables NNI to grow footprint in basal category from a volume and value perspective.



insulin degludec [rDNA origin] injection

## **Risks and Contingencies**

Risk	Consequence	Contingency
Levemir® excluded from ESI and CVS for 2016	Not covered position is default for Tresiba®	Focus on Medicare Part D in 2016; close to Levemir® parity
Payers restrict all non-preferred categories	Forced to focus on Tier 2 at high rebates	Higher Tier 3 unrestricted rebates to maintain value
Glargine rebates are deeper than believed to block Tresiba®	Limited Tier 2 access	Focus on Medicare Part D, but will be at higher rebate levels
Payers believe that price premium is not justified	Limited Tier 2 access	Net down to parity or Tier 3 focus
Biosimilar launch in early 2016	Payers do not review until after a biosimilar launch	Higher Tier 3 unrestricted rebates to maintain value





## VOTE

## □ Approve List and Net Price Strategy for Tresiba®

	Versus Levemir® (execution)	Versus Glargine (research reference)
List Premium	+10%	+10%
Net Premium Commercial	+20%	+10%
Net Premium Medicare Part D	+10%	+0%

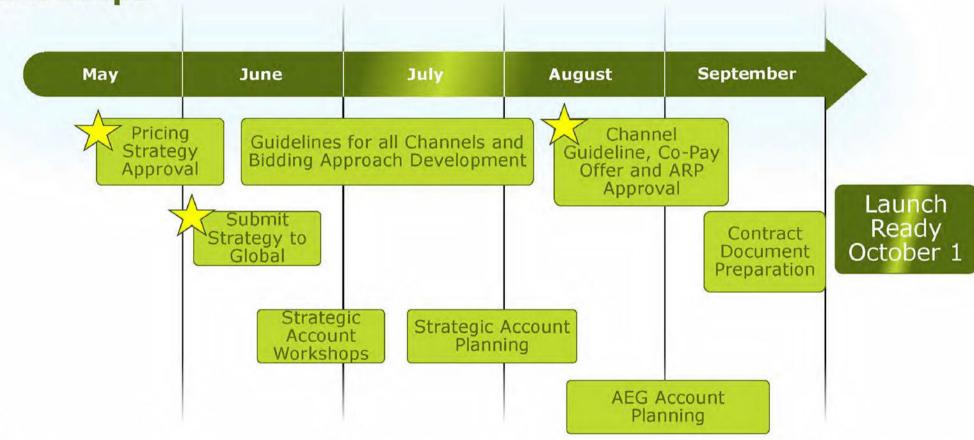
~17% blended net premium versus Levemir® for these key channels

## □ Approve rebates for Tier 3 (non-preferred brand tier) to prevent restrictions



insulin degludec [rDNA origin] injection

**Next Steps** 





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insulin degludec [rDNA origin] injection

From: JESH (Jesper Hoiland)

To: FAJA (Farruq Jafery); ANAJ (Andy Ajello); CLEE (Camille Lee); LAG (Lars Green)

CC: CUOT (Curt Oltmans); DUGL (Doug Langa); SEAP (Sean Phillips); KAYE (Karen Yee); RDZI (Rich

DeNunzio)

Sent: 5/12/2015 9:49:01 AM

Subject: Re: Action Required - List price increase NovoLog®, NovoLog® Mix, Novolin®

Ok! Jesper

From: FAJA (Farruq Jafery)

Sent: Monday, May 11, 2015 11:18 PM

To: JESH (Jesper Hoiland); ANAJ (Andy Ajello); CLEE (Camille Lee); LAG (Lars Green)

Cc: CUOT (Curt Oltmans); DUGL (Doug Langa); SEAP (Sean Phillips); KAYE (Karen Yee); RDZI (Rich DeNunzio)

Subject: Action Required - List price increase NovoLog®, NovoLog® Mix, Novolin®

#### Dear Pricing Committee:

We are requesting your approval to move forward with implementing the following list price increases that are already included in RE1 and in proposed RE2 (no change from RE1 assumption):

9.9% - NovoLog®, NovoLog® Mix 70/30 effective May 19, 2015

9.9% - Novolin® effective May 19, 2015

We have secured Brand alignment on the timing and magnitude of the proposed increases. Please note that the price increase is timed for just after mid-quarter to minimize rebate and price protection impact. (Many contracts base the rebate calculation on the WAC in effect at the 45<sup>th</sup> day of the quarter so taking on May 19 minimizes rebate impact in 2Q).

Your approval is required for Sarbox purposes. Kindly reply by COB on Wednesday (5/13) so that we may operationalize the price increases as proposed.

Regarding NovoLog® and NovoLog® Mix 70/30, the pricing strategy\*\* is to be the price leader with a timing of every 6 months:

- The increase supports the brand strategy of maintaining access, achieving volume and profitability goals, and financially offsetting access losses
- Recent increases were 8% on 7/19/2013, 9.9% on 12/3/2013, 9.9% on 5/28/2014, and 9.9% on 11/18/2014 so the
  proposed timing and magnitude is consistent with recent history
- 2015 AB15 ARP = \$2.3B

With respect to Novolin®, the pricing strategy\*\* is to align with NovoLog® timing and magnitude to keep the portfolio together:

- The increase supports brand objectives of maintaining access, achieving volume and profitability goals, driving value of existing business, and continuing H2A conversion
- Recent increases were 8.9% on 6/27/2013, 9.9% on 12/3/2013, 9.9% on 5/28/2014, and 9.9% on 11/18/2014
- 2015 AB15 ARP = \$280M

New list prices resulting from the proposed increases are shown in the table below:

<sup>\*\*</sup> Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date
V	5,0 Wir	· III	II	In the second se	
00169-1833-11	Novolin® R - 10mL vial	\$109.56	9.9%	\$120.45	5/19/2015*
					accentination in the second se
00169-1834-11	Novolin® N - 10mL vial	\$109.56	9.9%	\$120.45	5/19/2015*
00169-1837-11	Novolin® 70/30 10mL vial	\$109.56	9.9%	\$120.45	5/19/2015*
00169-3303-12	NovoLog® PenFill cartridge -5x3mL	\$377.56	9.9%	\$415.10	5/19/2015*
00169-3685-12	NovoLog® Mix 70/30 10mL vial	\$210.82	9.9%	\$231.75	5/19/2015*
00169-3696-19	NovoLog® Mix 70/30 FlexPen® - 5x3mL	\$392.63	9.9%	\$431.60	5/19/2015*
00169-6339-10	NovoLog® FlexPen® -5x3mL	\$392.63	9.9%	\$431.60	5/19/2015*
00169-7501-11	NovoLog® 10mL vial	\$203.24	9.9%	\$223.45	5/19/2015*

<sup>\*</sup> or when operationally feasible upon approval.

Please reach out if you have any questions.

Kind regards,

Farruq

Farruq Jafery
VP, Pricing, Contract Ops & Reimbursement
Finance & Operations

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA

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From: SEAP (Sean Phillips) To: RDZI (Rich DeNunzio) CC: BBRT (Bill Breitenbach); KAYE (Karen Yee); FAJA (Farrug Jafery); DUGL (Doug Langa) Sent: 6/3/2015 12:31:12 PM Subject: Re: Levemir Price Increase I would stick with our strategy as a follower in the segment. The upside does little to close the AB15 gap we have with Levemir. My two cents Sent from my iPhone On Jun 2, 2015, at 8:20 PM, RDZI (Rich DeNunzio) > wrote: Thanks Bill. I'm sure I'm swimming upstream on this one, as it sounds like JESH okay moving, but I would hold until September. Assuming we gain tresiba approval, I think we'll launch at the same price if we take increase in July vs September, so because of that and this isn't aligned to strategy (follow lantus and no sooner than 9 months), i don't see the upside outside of the few months of added revenue. I feel we could be better positioned allowing lantus to lead, let them be the bad guys again, and as we launch tresiba we do so into what could be good situation - open environment and payers still on our side in basal and not fighting tresiba. So potentially short term upside of a few months could hinder longer term opportunity and I think fast access/uptake with tresiba could outweigh '15 gain. I think if cvs and/or ESI go against us then maybe best to lead to grab what we can now. The only other reason i could see moving now is to a) give a time gap to SNY so they could match tresiba price shortly after we launch or b) we want to take levemir again in early '16 to capture more upside in '16 (need to be okay with levemir tresiba parity price though). Tough call, but I also think Karen has time on the books for this team to review options prior to PC on 6/29 when we'll discuss Levemir. Rich On Jun 2, 2015, at 8:33 AM, BBRT (Bill Breitenbach) wrote: Good morning, I spoke with Doug last night about the CVS and ESI 2016 negotiations and it appears they should be completed by the end of June. With that in mind, I recommend we pull forward the Levemir price increase to July 1st. Taking an increase in July 1st will be 7 months since our last and given the timing we can take a leadership position. The sooner we take the increase the better positioned we'll be in the market place and for the potential launch of Tresiba. I see more downsides by waiting until September vs moving now. Thoughts? BR, Bill

Bill Breitenbach Vice President Diabetes Marketing

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536



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# **Key Principles of Tresiba® Premium Strategy**

Strategic Focus #1	Ensure competitive and profitable access at launch to support rapid uptake
Pricing Strategy	+10% List, +20% Net Commercial, +10% Net Part D
Rationale	<ul> <li>Captures Tresiba® clinical value</li> <li>Produces higher net revenue due to level of unrestricted access in Commercial Channe</li> <li>Lower rebate exposure</li> <li>Maintains price potential for pipeline</li> </ul>

### Payer research and Market Access deep dives corroborated

- Any premium would make Tier 2 access challenging
- But Tier 3 unrestricted coverage potential exists in Commercial channel

### **Tier 2 Commercial positions are expensive**

47% volume increase required to break-even to Tier 3 net revenue



# Commercial co-pay program reduces Tresiba® volume variance between T3 and T2 to 10-20%

~85% of Commercial patients will not pay more than \$25 due to copay offsets

### Commercial patients will not feel T3 vs T2 cost variances

- Patients react to net OOPC (out of pocket cost) after all offsets, e.g. co-pay cards and eVouchers
- Tresiba® co-pay program: \$15 co-pay card and \$25 eVoucher
- eVouchers automatically reduce co-pay to \$25 at pharmacy (no patient involvement)
  - ~80-85% of pharmacies participate in the program

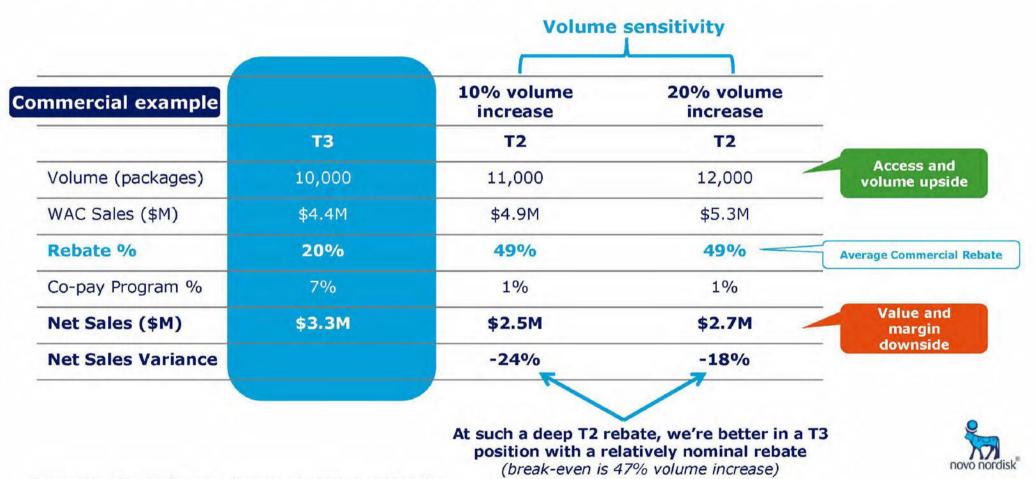
### Part D requires T2/LBC access

Co-pay programs are prohibited by law in government channels

LBC = Lowest Brand Co-pay Source(s): Tresiba® copay offset programs design, prescriber primary research Mar-2015, brand ATU studies, analysis from Commercial Effectiveness



# Capturing the value of Tier 3 in Commercial



Rebate %'s reflect 2016 average Commercial rebates for T3 and T2

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# Tresiba® BRM Follow-up

Can we gain more and faster Tier 2 access?

	Premium Strategy	Hybrid Strategy	Net Parity Strategy
List	10%	10%	10%
Commercial	20%	10%	0%
Part D	10%	0%	0%

**Assumptions** 

Commercial	<ul> <li>3 strategic accounts starting</li> <li>2H16</li> <li>NNI partners already bought into clinical value (deep dive insights)</li> <li>Narrower price gap to glargine</li> </ul>	Majority of strategic accounts 2H16  Payer research  Deep dive insights		
Part D	Limited mid-2016 formulary adds  • Levemir® exclusives  • NNI partners already bought into clinical value (deep dive insights)	Same as Hybrid strategy		

**Evaluation Criteria** 

### Assess the quality of additional access

Volume, ARP Sales, Margin (ARP%)

# Xultophy® and Tresiba® Market Factors



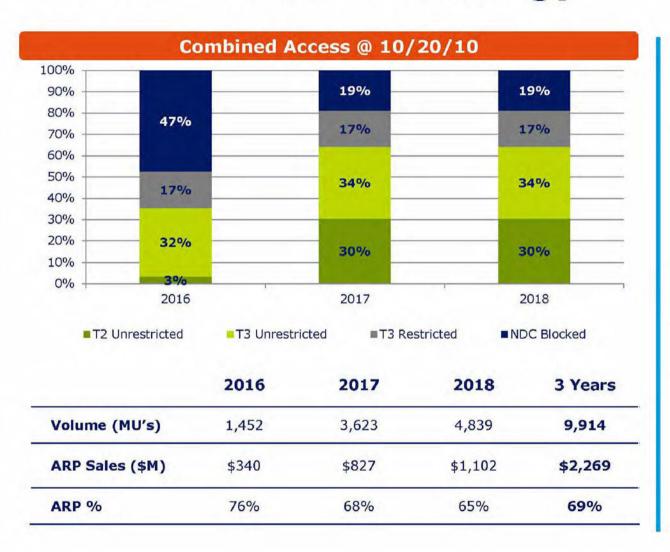
- Payers tending to put Xultophy® in the existing basal class
- Tresiba® may set the stage for Xultophy® access
  - Xultophy<sup>®</sup> likely to have lowest common denominator access of the individual components (e.g. T3 if Tresiba<sup>®</sup> T2, but Victoza<sup>®</sup> T3)
- > Competitor pricing strategies will also have implications for Xultophy® access
- If Tresiba® Tier 3, NNI could leverage Tresiba® Tier 3 volume and enhance rates to gain Tier 2 access for both Tresiba® and Xultophy® if desired



### Market Factors putting Tresiba® access at risk

- Sanofi rebate rates reportedly higher than expected
- 2. Sanofi contracts block Tresiba®
- Customers developing new formulary designs for 2016 that narrow to fewer brands
- Payers expecting 1Q16 launch of competitively priced biosimilar
- 5. Widespread Tier 3 access may be temporary

# **Tresiba® Premium Strategy**



#### **Considerations**

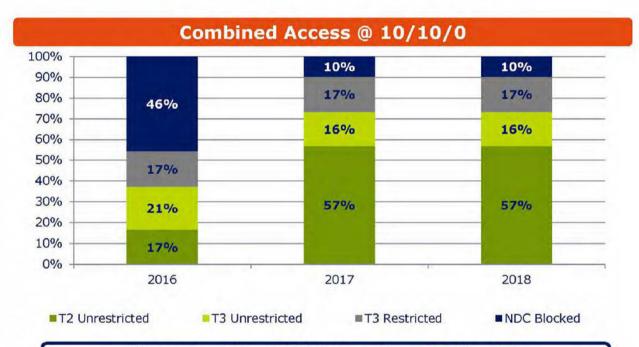
- Difficult to execute premium strategy in today's market
- Tier 2 access expensive; resulting in Tier 3 strategy
- Commercial access largely Tier
   3, but co-pay program
   reduces cost to Tier 2 level
- · Part D access begins in 2017

### **Risks**

- More Tier 3 restrictions than anticipated
- Xultophy® access may be limited to Tier 3 position

Financials based on prelim AB16 9/20/2015.

# Tresiba® Hybrid Strategy



<b>↑Volume +11%, ↓ARP Sales -6%, ↓ARP% -15%</b>					
	2016	2017	2018	3 Years	
Volume (MU's)	1,533	4,036	5,420	10,989	
ARP Sales (\$M)	\$322	\$786	\$1,035	\$2,143	
ARP %	69%	58%	55%	58%	

#### **Considerations**

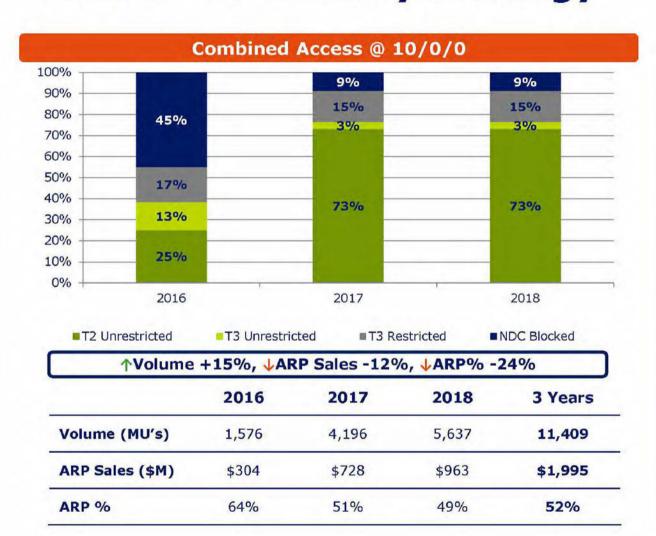
- 11% volume increase
- \$\square\$ 6\% ARP Sales decrease
- 3 strategic Commercial accounts Tier 2 in 2H16
- 3 strategic Part D accounts mid-year 2016 adds
- Little change to 2016 NDCB due to payer new product protocols and Part bidding cycle

#### Risks

- Sanofi rebate rates higher than expected
- Sanofi contracts block Tresiba®
- More Tier 3 restrictions than anticipated

Financials based on prelim AB16 9/20/2015.

## **Tresiba® Net Parity Strategy**



#### **Considerations**

- ↑ 15% volume increase
- 12% ARP Sales decrease
- Majority Commercial strategic accounts Tier 2 in 2H16
- 3 strategic Part D accounts mid-year 2016 adds
- Little change to 2016 NDCB

#### Risks

- Sanofi rebate rates higher than expected
- Sanofi contracts block Tresiba®
- Customers developing new formulary designs for 2016 that narrow to fewer brands
- Payers expecting 1Q16 launch of competitively priced biosimilar

Financials based on prelim AB16 9/20/2015.

# Alternative strategies provide access/volume increases, but sacrifice sales and margin

	3 Year Projection	Variance to Premium Strategy 10/20/10		
	Premium 10/20/10	Hybrid 10/10/0	Net Parity 10/0/0	
Volume (MU's)	9,914	<b>↑+11%</b>	↑ +15%	
ARP Sales (\$M)	\$2,269	<b>↓ -6%</b>	<b>↓ -12%</b>	
ARP %	69%	<b>↓</b> -15%	<b>↓ -24%</b>	

Recommendation to gain additional Tier 2 access

### Current market is complex - one size doesn't fit all

- Attempt Premium via account-by-account negotiations to achieve Tier 2 at a premium, where feasible
- 2. Allow Flexibility to net parity in Part D and smaller premium in Commercial to secure Tier 2
- 3. Accept Tier 3 Commercial position if premium Tier 2 position can't be secured

2016 Target ARP% is 67%, premium vs. Levemir® is 90%

Will not go below Levemir® ARP at individual account level



Balance Tresiba® net premium and access across a range of Commercial and Part D customers to optimize profit while creating a market access beachhead for Xultophy®

<sup>\*</sup> Tier 2 = preferred brand tier; Tier 3 = non-preferred brand tier

From: DUGL (Doug Langa)
To: FAJA (Farruq Jafery)

CC: RDZI (Rich DeNunzio); SEAP (Sean Phillips); BBRT (Bill Breitenbach); KAYE (Karen Yee)

Sent: 8/10/2015 1:05:18 AM
Subject: Re: Levemir Price increase

I'm aligned to the team's feedback and rationale.

In the end as I have stated all along, I don't believe that we should be leading with price increases. Again, I understand the rationale (certainly as it impacts next generation products) but I think that it hurts the message that we have been sending to the market and a bit of our credibility with payers.

On Aug 9, 2015, at 7:49 PM, FAJA (Farruq Jafery)

Aligned. Sets an appropriate launch price for Tresiba and recognizes diminishing returns of double digit increases. If it's under 9%, then less for CVS to complain about since the incremental PP rebates they would have received under a WAC as of dispensing date are now far less than what they would have earned based on historical increases.

#### Farruq

From: RDZI (Rich DeNunzio)

Sent: Friday, August 07, 2015 5:34 PM

To: SEAP (Sean Phillips); FAJA (Farrug Jafery)

Cc: DUGL (Doug Langa); BBRT (Bill Breitenbach); KAYE (Karen Yee)

Subject: RE: Levemir Price increase

Sean, Farruq,

Thank you for your feedback/thoughts. More movement here, so requesting your approval/alignment on 8.x% effective the week of 8/24. Please see below for rationale:

Lars informed me today that him and Jesper were having a conversation on Levemir and that they have to "manage their stakeholders", which I'm interpreting as ExecMan. ExecMan agreed to take a Levemir a price increase to set up Tresiba, however they have concerns this far ahead of launch/approval (and they want us to be confident of approval before moving/leading with Levemir).

With this said, Jesper and Lars suggested we take an increase with an 8 in front of it, to appease our internal stakeholders (justification is us showing the market we're not going to take double digit increases here anymore), but still moving on the 18<sup>th</sup> to hit what's in RE2 and 3. I then informed Lars of CVS issue and PrePC thoughts (minus Doug's).

#### The Update:

We were on a call with Daye to go over the latest amendment language, around WAC as of dispense date, and I asked Daye how upset CVS would be if we increased price in 2015 right after the 45<sup>th</sup> day on one of our products. She said they're going to be upset regardless, unless it's the last week of the quarter, but she said she thought she could manage it as long as the revised contract with us agreeing to WAC as of dispensed date was signed. We should have the CVS contract back to NNI early next week, so if we review and get back to CVS, we should have it locked up mid-August.

So...the thought now is to take price after the CVS contract is signed, which will be the week of the 24<sup>th</sup>. And our price increase rate will be 8.x% (Karen to determine the x based on actual WAC/package price and upside vs offset by pushing back a week), so we appease our management.

Reducing from 9% to 8% has limited impact in 2015, but has about a \$10M impact to Levemir in 2016 and \$3-5M impact on Tresiba (JESH is okay with this and we can alter '16 guidance in AB16).

This was an interesting one - balancing budget, internal management, CVS and PR - but it seems, as long as we have alignment

from PrePC. Karen can move forward with vote to PC.

Please let us know if any concerns.

Thanks, Rich

From: SEAP (Sean Phillips)

Sent: Friday, August 07, 2015 8:02 AM
To: FAJA (Farruq Jafery); RDZI (Rich DeNunzio)

Cc: DUGL (Doug Langa); BBRT (Bill Breitenbach); KAYE (Karen Yee)

Subject: RE: Levemir Price increase

I like Farruq's idea around Labor Day in that in addresses the concerns of CVS.

From: FAJA (Farruq Jafery)

Sent: Friday, August 07, 2015 6:48 AM

To: RDZI (Rich DeNunzio)

Cc: DUGL (Doug Langa); SEAP (Sean Phillips); BBRT (Bill Breitenbach); KAYE (Karen Yee)

Subject: Re: Levemir Price increase

I think we outline for PC that potential upside of 8/18 timing would be substantially negated if CVS forced us to implement the new methodology retroactive to 7/1/15 (which is the date that they claim all other manufs are on for WAC as of dispensing date).

An alternative could be to take just prior to Labor Day weekend. This would basically put us at 9.5 months between increases and not coming immediately after the mid-point of the quarter as with prior increases.

Farruq

Sent from my iPhone

On Aug 6, 2015, at 6:07 PM, "RDZI (Rich DeNunzio)" wrote:

Doug, Sean and Farruq (if checking emails on vacation today),

We have a question, relating to CVS and the timing of Levemir price increase. Should we take 8/18, as agreed to by PC, or do we recommend pushing back due to the recent CVS concerns on how we take price? Farruq raised this as a concern before he left and Sean brought this up during RE3 review, so wanted to gain thoughts/alignment.

#### Background on CVS:

We know CVS has stated their disappointment with our price increase strategy (ie: taking just after the 45<sup>th</sup> day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase. I don't think there's any disputing how we operationalize our price and that we do it this way to create the most value to NNI, but it has been costing CVS a good amount of money.

When CVS was here last week they reiterated their concern and Farruq/Brenda have committed to working on solution (WAC as of dispensed date), to be operationalized in 2016 with a resolution from a financial perspective to be effective 1/1/16 (ie: if implemented in 7/1/16 they will receive adjustment for the 1<sup>st</sup> half of 2016). CVS is requesting this to go back to 7/1/15.

#### Levemir Situation:

We're scheduled to take a Levemir price increase next week (8/18) and Karen is about to finalize the formal email to PC. The 18<sup>th</sup> is the first day after the 45th day we could operationalize the increase. We're doing it to capitalize on all contracts (rebate and PP payments). Specifically with CVS Maria is estimating that it will result in about \$3.8M favorability to NNI (on the flipside cost CVS \$3.8M then if they had WAC as of dispensed).

Our price increase on Levemir roughly garners us \$2.5M per week and it costs CVS about \$634k, so financially it makes sense to take the increase by about \$2M per week.

#### Question:

Is there any appetite to delay the increase by a week or two so it's not so apparent to CVS or are we okay recommending to PC as planned?

#### Other considerations:

- LRS wanted us to hold on taking Levemir price increase, however in a recent communication to LAG and JESH, he said we should make Tresiba our top priority and was okay with taking Levemir prior to Tresiba launch. What he is leaving up to the US though is how tactically we want to take it before launch now or delay before launch (and what we need to ask PC). It sounds from LAG that JESH and him are aligned to take it now, while LRS said he would recommend waiting due to PR risk of leading.
- We're looking to take N-Franchise around the 48<sup>th</sup> too in November, and because of our exclusive status and it's 3 products, this will impact them close to \$10M (\$10M favorable to NNI)

In my opinion, while Farruq is out, being we were asked to send the PC email, is that we should move forward as planned and raise this to PC as another risk on top of PR risk. CVS knows what our strategy is, we didn't deny it, we have stated there's a solution to fix their concern in 2016 and we're better off financially by moving forward by about \$2M per week. If needed we could always come to settlement, financially if needed on their \$600k/week, but would advise against it knowing N-Franchise is coming next.

Please note that although CVS agreed to Levemir remaining on formulary, CVS' will threaten the custom plans and could push Lantus exclusive still

Thanks, Rich From:

CLEE (Camille Lee)

To:

LAG (Lars Green)

CC:

ANAJ (Andy Ajello); JESH (Jesper Hoiland); FAJA (Farruq Jafery); CUOT (Curt Oltmans); RDZI (Rich

DeNunzio); SEAP (Sean Phillips); DUGL (Doug Langa); KAYE (Karen Yee); BBRT (Bill Breitenbach);

EDDW (Eddie Williams)

Sent:

8/14/2015 9:09:13 PM

Subject:

Re: Action Required: List price increase - Levemir®

Approve

Sent from my iPhone

On Aug 14, 2015, at 4:58 PM, LAG (Lars Green)

> wrote:

Approve.

Lars

Sent from my iPhone

On Aug 14, 2015, at 3:13 PM, ANAJ (Andy Ajello)

> wrote:

Approve

Sent from my iPhone

Andy Ajello

Senior Vice President

National Diabetes and Obesity Sales

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, N.J. 08536

**USA** 

On Aug 14, 2015, at 3:07 PM, JESH (Jesper Hoiland)

> wrote:

Agree! Jesper

From: FAJA (Farrug Jafery)

Sent: Friday, August 14, 2015 03:01 PM

To: JESH (Jesper Hoiland): CLEE (Camille Lee): LAG (Lars Green): ANAJ (Andy Ajello)

Cc: CUOT (Curt Oltmans); RDZI (Rich DeNunzio); SEAP (Sean Phillips); DUGL (Doug Langa); KAYE (Karen Yee); BBRT (Bill

Breitenbach); EDDW (Eddie Williams)

Subject: Action Required: List price increase - Levemir®

Dear Pricing Committee:

Although we already have your alignment to move forward with a Levemir® price increase in mid-August, in consideration of ExecMan's concerns around external public relations risk, we're requesting your approval to execute the following price increase:

8.2% Levemir® price increase effective Tuesday, August 25, 2015

Note that the proposed timing and magnitude is slightly later and lower than what we had previously agreed to (9.0% - August 18), but it balances the concerns of ExecMan while also meeting our strategic objectives which are outlined below (as well as in the attached slides).

#### Rationale:

**Timing** is important for executing our Tresiba® premium strategy. With FDA approval anticipated late September (or early October) and "soft launch" in mid-November, we want to ensure a Levemir® price increase sooner rather than later to allow enough time for competition to assess and potentially respond in advance of Tresiba® launch.

- HQ asked us to consider delaying the price increase to as close as possible to Tresiba® launch, however, they ultimately
  agreed that we should use our best judgment to set up Tresiba® for success.
- · From a Levemir® access perspective, we have confirmation that Levemir® will remain on formulary in 2016 at CVS and ESI.
- The price increase is still timed to minimize rebate and price protection impact (many of our contracts have language whereby the rebate and price protection are based on our WAC as of mid-point of the quarter). Note that CVS has pushed back on the timing of our list price increases and demanded changes in contract language which will take effect 1/1/16 to address this. We're finalizing the amendment language which is expected to be signed before 8/25.

Magnitude is within industry norms and is lower than recent history in the basal market.

- It sends a signal to stakeholders that we're cognizant of the public discourse around manufacturer price increases.
- The financial impact to 2015 is negligible given that we have CPP of 8%; downside impact to 2016 is ~\$11M (vs. RE2 assumption).

New list prices resulting from the proposed increase are shown in the table below:

<image003.png>

Please reach out if you have any questions.

Kind regards,

#### Farruq

Farruq Jafery
VP, Pricing, Contract Ops & Reimbursement
Finance & Operations

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536



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From: LAG (Lars Green)
To: ANAJ (Andy Ajello)

CC: JESH (Jesper Hoiland); FAJA (Farruq Jafery); CLEE (Camille Lee); CUOT (Curt Oltmans); RDZI

(Rich DeNunzio); SEAP (Sean Phillips); DUGL (Doug Langa); KAYE (Karen Yee); BBRT (Bill

Breitenbach); EDDW (Eddie Williams)

Sent: 8/14/2015 8:58:49 PM

Subject: Re: Action Required: List price increase - Levemir®

Approve.

Lars

Sent from my iPhone

On Aug 14, 2015, at 3:13 PM, ANAJ (Andy Ajello)

Approve

Sent from my iPhone

Andy Ajello

Senior Vice President National Diabetes and Obesity Sales Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, N.J. 08536

**USA** 

On Aug 14, 2015, at 3:07 PM, JESH (Jesper Hoiland)

Agree! Jesper

From: FAJA (Farruq Jafery)

Sent: Friday, August 14, 2015 03:01 PM

To: JESH (Jesper Hoiland); CLEE (Camille Lee); LAG (Lars Green); ANAJ (Andy Ajello)

Cc: CUOT (Curt Oltmans); RDZI (Rich DeNunzio); SEAP (Sean Phillips); DUGL (Doug Langa); KAYE (Karen Yee); BBRT (Bill

Breitenbach): EDDW (Eddie Williams)

Subject: Action Required: List price increase - Levemir®

Dear Pricing Committee:

Although we already have your alignment to move forward with a Levemir® price increase in mid-August, in consideration of ExecMan's concerns around external public relations risk, we're requesting your approval to execute the following price increase:

8.2% Levemir® price increase effective Tuesday, August 25, 2015

Note that the proposed timing and magnitude is slightly later and lower than what we had previously agreed to (9.0% - August 18), but it balances the concerns of ExecMan while also meeting our strategic objectives which are outlined below (as well as in the attached slides).

Rationale:

**Timing** is important for executing our Tresiba® premium strategy. With FDA approval anticipated late September (or early October) and "soft launch" in mid-November, we want to ensure a Levemir® price increase sooner rather than later to allow enough time for competition to assess and potentially respond in advance of Tresiba® launch.

- HQ asked us to consider delaying the price increase to as close as possible to Tresiba® launch, however, they ultimately
  agreed that we should use our best judgment to set up Tresiba® for success.
- From a Levemir® access perspective, we have confirmation that Levemir® will remain on formulary in 2016 at CVS and ESL
- The price increase is still timed to minimize rebate and price protection impact (many of our contracts have language whereby the rebate and price protection are based on our WAC as of mid-point of the quarter). Note that CVS has pushed back on the timing of our list price increases and demanded changes in contract language which will take effect 1/1/16 to address this. We're finalizing the amendment language which is expected to be signed before 8/25.

Magnitude is within industry norms and is lower than recent history in the basal market.

- It sends a signal to stakeholders that we're cognizant of the public discourse around manufacturer price increases.
- The financial impact to 2015 is negligible given that we have CPP of 8%; downside impact to 2016 is ~\$11M (vs. RE2 assumption).

New list prices resulting from the proposed increase are shown in the table below:

<image003.png>

Please reach out if you have any questions.

Kind regards,

#### Farruq

Farruq Jafery
VP, Pricing, Contract Ops & Reimbursement
Finance & Operations

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA

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# **Action Items from Analog Analysis**

Action Items Irom Andi	og /maryolo	
Key Findings	Levemir® Implications	Tresiba® Implications
HCP/Professional  Ambien CR: Sanofi neglected new starts in effort to switch, competitors captured new start business  Sanofi has likely learned from this and will target new starts, however, may become distracted if they struggle on conversions	<ul> <li>Protect new start business with effective value proposition and tools to counter Toujeo efforts</li> <li>Sanofi will be distracted with questions about Lantus while asking for new starts: utilize simple messaging to protect business, ask for switches</li> <li>Can different FF sleeves be used creatively to deliver concise messages about starts/switches? (i.e. different messages &amp; IC)</li> </ul>	<ul> <li>Should Levemir® conversions (i.e. BID patients) be considered in addition to glargine to facilitate uptake at launch and create momentum for the brand?</li> <li>Can learnings be gathered from Levemir® approach (or Toujeo) to inform Tresiba® tactics?</li> </ul>
All analogs: All manufacturers or their competitors utilized \$0 co-pay offers to incentivize patient switching  In the case of Avonex Pen, the Pen Promise was offered for patients: if not happy with the switch, next 3 Rx free  For VESIcare/Myrbetriq, equal co-pay savings offered to not avoid switches from VESIcare  Avonex Pen/Copaxone: Nurse educator support expanded to successfully facilitate switching  Avonex Pen: Dosing titration tool viewed as successful in transition to Avonex Pen; Sanofi will have Toujeo dose coach  Copaxone: App created to track dosing and injection site reactions, viewed as successful even if patients only used app during initial transition period	<ul> <li>A common finding was \$0 co-pay to drive financial incentive for patients to switch</li> <li>Sanofi showing signs of this with Afrezza \$0 co-pay for first script</li> <li>Sales force response required if \$0 co-pay or aggressive savings offered for Toujeo</li> <li>Explore more creative co-pay offerings: initial trials/discounts or long-term loyalty discounts?</li> <li>Can DEs be more active with FlexTouch® or StartSmart?</li> <li>Leverage C4C + StartSmart platform to blunt new patient support program for Sanofi</li> <li>Ensure adequate titration support for Levemir®</li> </ul>	<ul> <li>Avonex offer is a great example of putting confidence behind brand perception, but rebating process must be executed well</li> <li>Astellas parity co-pay for portfolio vs. \$0 co-pay offerings are strong considerations dependent upon NNI basal portfolio strategy</li> <li>Exploring use of longer-term outcomes data from C4C can be leveraged as competitive advantage over any Sanofi or Lilly basal support program</li> <li>Can mobile platform be explored for C4C or specifically for Tresiba® to facilitate patient start or transition from another basal?</li> </ul>
<ul> <li>Managed Markets</li> <li>Ambien CR: Some of the most successful regions for conversions occurred where Sanofi achieved medicaid coverage (prior to Medicare Part D)</li> <li>Copaxone: Teva was able to secure over 90% access for 40mg at launch due to ~10% discount price to 20mg</li> <li>Even payers who would not cover 40mg brought Teva back to contract after seeing the success in conversion</li> <li>Sanofi claims there is clinical justification for premium pricing for Toujeo, however, pricing won't be a barrier to access</li> <li>VESIcare/Myrbetriq: Astellas sought parity Tier 2 access for portfolio, but payers took hard line due to 10% premium pricing, leading to T3 access at launch</li> <li>Astellas offered higher rebates on VESIcare to get Myrbetriq T2</li> </ul>	<ul> <li>While parity pricing has been assumed for Toujeo, NNI should be prepared for a scenario in which Sanofi prices Toujeo at a discount</li> <li>Any early price increase in February could be an indicator of this approach</li> <li>Sanofi could target managed medicaid for Toujeo to drive switching behavior</li> </ul>	<ul> <li>Achieving Tier 2 access may prove difficult without leaning on current basal market share and NNI portfolio for Tresiba® at launch, as demonstrated by VESIcare/Myrbetriq</li> <li>Sanofi's pricing decision on Toujeo could influence ability to secure premium pricing for next-generation basal insulins</li> <li>If Sanofi fails to drive switches from HCP demand, they may become aggressive in contracting to facilitate the switch ahead of LLY glargine, Peglispro and Tresiba®</li> </ul>

# New Dosing Formulation Analysis

Phase III Analysis

January 30, 2015





CONFIDENTIAL & PROPRIETARY NNI-FINANCE-001825

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- Introduction
- Ambien to Ambien CR
- AVONEX to AVONEX PEN
- Copaxone 20mg to Copaxone 40mg
- VESIcare to Myrbetriq





### Introduction

- Novo Nordisk enlisted the services of IMS Health to evaluate the conversion strategies of four major brands and the level of success each materialized
  - The four analogues analyzed were:
    - Ambien to Ambien CR
    - AVONEX to AVONEX PEN
    - Copaxone 20mg to Copaxone 40mg
    - VESIcare to Myrbetriq
  - IMS analyzed the strategies the companies employed which contributed to a successful or hindered conversion
    - Additionally, IMS provided key learnings for Novo to prepare for the launch of Sanofi' Toujeo and to leverage in their own portfolio expansion





# **Phase II Conversion Methodology**

- a) Calculate the difference between the expected and actual number of NBRx for the originator brand over the first 12 months (when available) post the launch of the follow-on
- b) Calculate the difference between the expected and actual number of Continuing Patients (estimated using CBRx) for the originator brand over the first 12 months (when available) post the launch of the follow-on
  - a) Represents Switch From Losses
- c) Sum (a) + (b) to arrive at the estimated number of patients that the originator brand "lost", with the assumption that they all went to the follow-on brand
- d) Sum the NBRx for the follow-on brand over the analysis period to determine the total patients on the follow-on brand
- e) Conversion Rate = (c) / (d)





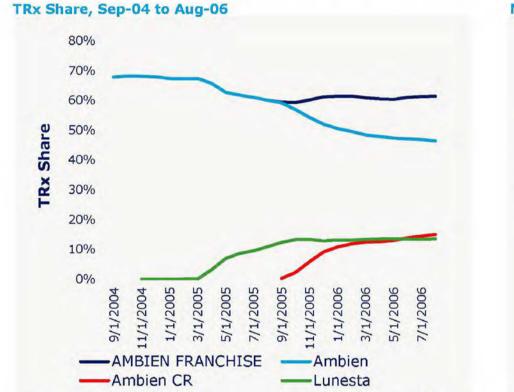
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#### Analysis Brands and Key Competitor TRx & NBRx Share





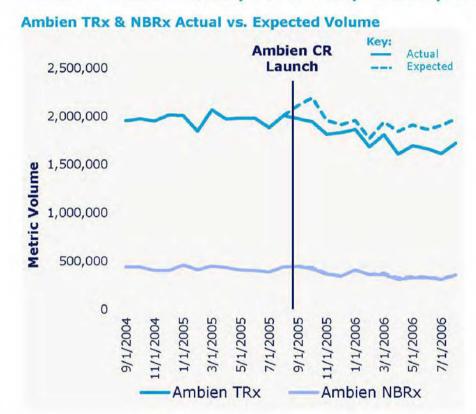
Note: NBRx YOY Market Growth = 23% (1% when Ambien CR volume removed)

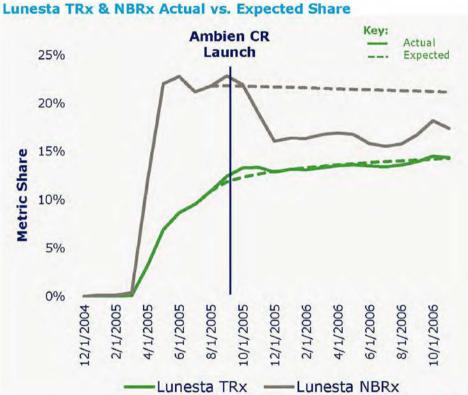


novo nordisk

Source: IMS VONA

#### Conversion Analysis / Key Competitor Effects







Source: IMS VONA

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#### Conversion Results

FIRST 12 MONTHS OF AMBIEN CR LAUNCH			
Expected	Actual	Value	Category
4,423,333	4,336,851	86,482	a. NBRx Loss (Exp - Act)
1,387,016	1,128,255	258,761	b. Continuing Loss (Exp - Act)
		345,243	c. Total Losses (a + b)
		1,770,993	d. Ambien CR NBRx
		19.5%	e. Patient Conversion Rate (c / d)

- Analysis suggests that Sanofi was more successful at getting patients already on Ambien to switch to CR than it was getting prescribers to choose Ambien CR over Ambien when making a new start or change in therapy decision
- Though Lunesta NBRx share declined versus forecast due to NBRx market growth, TRx share hit expectation as the launch of Ambien CR largely just transferred TRx share from Ambien to the CR formulation





#### Conversion Strategy - Sales Force

- Sanofi launched Ambien CR with a sales force of approximately 2,000 reps in late 2005
  - The sales force was made up of a small CNS specialty sales force and a much larger primary sales force who were pulled in from the respiratory division
    - ~1,000 additional reps were added to support the launch 6 months after approval
- Sanofi heavily incentivized reps to focus on switching patients from Ambien and ignored the efforts of competitors
  - Sepracor was not only focused on trying to convert Ambien patients, but grow the market with new start patients, something Sanofi overlooked until their conversion efforts stalled

<b>Sales Force</b>	N	<b>Detail Priority</b>	Targets
CNS	~180	First	Psychiatrists, Long-term Care, Residency programs and sleep clinics
PCP	~1,750	First	GPs
PCP	~1,000	Secondary	Reps from the CV as well as woman's health team were leveraged to further support the launch





Conversion Strategy - Incentives

#### **Physician Initiatives**

- Sanofi greatly benefited from hosting educational programs with physicians, namely residency programs, on the subject of sleep
  - Side effects of commonly prescribed sleeping drugs, such as Seroquel and trazodone, were discussed
  - Benefits of Ambien CR were highlighted, and questions about its use and efficacy were addressed
  - Feedback from residents and attendees was very favorable due to the lack of education provided to medical students on the importance and health benefits of sleep

#### **Patient Initiatives**

- Patients were offered a 7-night trial and discount cards for \$20 off the first five prescriptions
  - Free samples were given to physicians in states where schedule IV narcotics could be distributed legally\*



Based on interviews with Sanofi personnel, many were surprised in the success of the launch of Ambien CR based on how ill-equipped reps were compared to competitors such as Lunesta





#### Conversion Strategy - Competitor Analysis

- Lunesta (eszopiclone) claimed to be the first drug indicated for both sleep onset AND sleep maintenance
  - Lunesta had the second largest share after Ambien in the sleeping medication market
- Sepracor had a large marketing budget to target both patients and prescribers
  - DTC advertising, free samples, 3-day trial vouchers and \$0 copay cards were leveraged from launch to attempt to steal Ambien scripts and blunt the launch of Ambien CR
- Sepracor also aggressively negotiated with payers for exclusive contracts in order to block Ambien CR from access at launch







#### Conversion Strategy - Managed Care

- Coverage from private health insurance companies was in tier 2 and 3 across the nation
  - Due to Ambien CR's 6-month launch delay, Sanofi could not overcome the high rebates that Sepracor offered to regional payers to get one-on-one formulary status for Lunesta
  - Additionally, Sanofi had not consistently offered incentive for payers to cover CR over the immediate release providing no push for patients to be switched at the pharmacy level
- Where Sanofi found their greatest success in the launch of Ambien CR were states who added CR to their Medicaid formulary
  - States like Ohio, Missouri, New York and Texas experienced the greatest conversions rate reaching as high as 80% in the first 6 months of launch; however, because the majority of state programs did not cover Ambien CR – some of them outright restricted access to CR - the rates of conversion seen in these states and nationwide were not what Sanofi had forecast



Conversion Strategy - Key Takeaways

Sanofi Conversion Tactics	Implications for Novo
Sanofi was hyper focused on converting Ambien patients to Ambien CR, and deprioritized new starts, enabling Sepracor (backed with a strong managed care strategy), to take foothold and launch strongly in new start patients. Sanofi recognized their missteps too late, and eventually found strong competition for new starts against both Sepracor and Takeda, who both focused on this key target segment	<ul> <li>If Sanofi follows suit and focuses on converting Lantus patients to Toujeo, opportunities will be created for Levemir and potentially Tresiba in new start patients. Novo can focus on winning the insulin new start segments at the expense of Sanofi's Lantus and Lilly' insulin glargine – as both will potentially look to convert existing glargine patients first</li> <li>However, Sanofi should be expected to have learned from this, as evidenced by communications that Toujeo will compete for existing patients as well as new-to-basal</li> <li>Should protecting new start business be the priority for Levemir®?</li> </ul>
Sanofi's greatest success in converting patients to Ambien CR was leveraging managed care wins	<ul> <li>Novo should seek to pull through key managed care accounts</li> <li>Sanofi will look to gain parity in access once Toujeo is launched, but may face resistance from payers due to the impending Lantus LOE</li> <li>Does Sanofi look at Medicaid as means to drive switch behavior?</li> </ul>
Sanofi leveraged their CNS specialty force to educate residency programs in a disease state that is often overlooked in medical training	Novo could seek to combine both their specialty force/institutional sales force along with their CDEs to supplement disease state and insulin education programs to wider audiences beyond endocrinologists





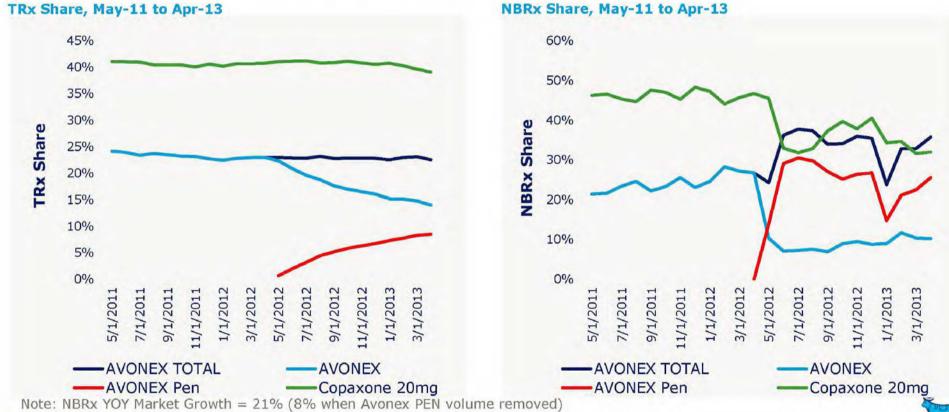
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#### Analysis Brands and Key Competitor TRx & NBRx Share

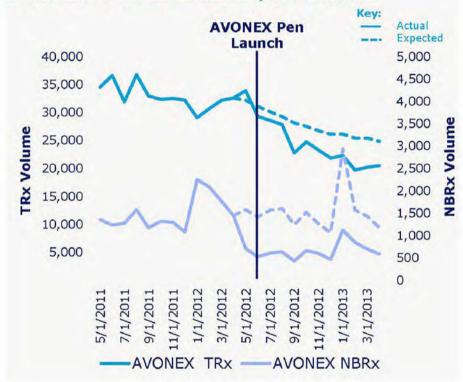


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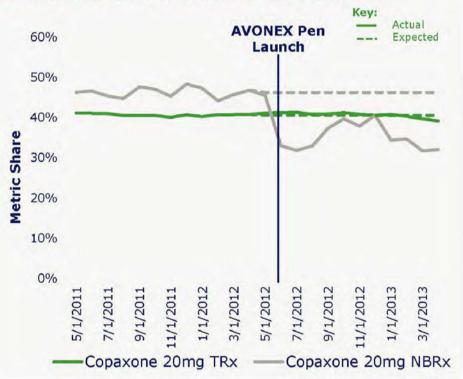
novo nordisk

#### Conversion Analysis / Key Competitor Effects





#### Copaxone 20mg TRx & NBRx Actual vs. Expected Share







Source: IMS NPA Market Dynamics

#### Conversion Results

FIRST 12 MONTHS OF AVONEX PEN LAUNCH			
Expected	Actual	Value	Category
18,433	7,931	10,502	a. NBRx Loss (Exp - Act)
34,290	30,365	3,924	b. Continuing Loss (Exp - Act)
		14,426	c. Total Losses (a + b)
		21,248	d. Avonex Pen NBRx
		67.9%	e. Patient Conversion Rate (c / d)

- Analysis suggests that Biogen Idec had more trouble converting patients already using AVONEX to AVONEX Pen than it did getting prescribers to choose AVONEX Pen over AVONEX when making a dynamic prescribing decision
- •Though Copaxone 20mg NBRx share declined versus forecast due to NBRx market growth from AVONEX Pen, our study suggests AVONEX Pen did not actually bring additional patients into the market or cause significant inter-brand switching, therefore the Copaxone 20mg NBRx share losses were not realized in TRx



#### Conversion Strategy - Sales Force

- Biogen expanded their sales force by over 20% in anticipation of the launch of the AVONEX Pen
  - Reps territories were slightly adjusted, but more to the point their call plan was expanded to reach a greater number of MS prescribers upping their previous weekly goals to over 30/week

Product	Sales Force	<b>Detail Priority</b>	Sales Calls	
AVONEX	~125 Area Business Managers (2012)	First		
Tysabri	~94 Area Business Managers (2011)	Second	25-30 calls per week	





#### Conversion Strategy - Messaging

- Prior to the launch of the AVONEX auto injector, Biogen rep messaging focused on their new dosing titration tool, AVOSTART GRIP used to ease the flu-like adverse event associated with interferon therapy
  - In order to reduce flu adverse events patients would attach a titration dosing cuff to their pre-filled syringe in three consecutive weeks doses prior to switching to the AVONEX PEN
  - Use of the AVOSTARTGRIP reduced flu-like symptoms by over 76%

Identifying the parts of AVOSTARTGRIP titration kit (See Figure G):



Sanofi is likely to have significant messaging surrounding Toujeo and the titration strategy Novo should prepare to counter this messaging as Biogen demonstrated how to effectively blunt competitor counter-messaging with their titration strategy





Conversion Strategy - Patient Support

- In addition to the expansion of the rep head count, Biogen also increased the support provided through the MSActiveNurses support program
  - The MSActiveNurses program provides both in-person support and training as well as 24/7 phone support to patients and caretakers
  - Biogen reps stated the overall MSActiveSource support program was, as much if not more, responsible for the conversion to the AVONEX PEN due to word of mouth of the nurse educators and patient anecdotes



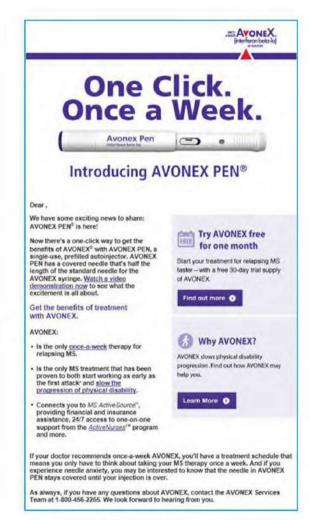






Conversion Strategy - Incentives

- Biogen introduced the AVONEX PEN by offering a comprehensive overview to both prescribers and current AVONEX patients introducing the new auto injector
- The letter included a link for a free month for both new start and patients open to switching from the pre-filled syringe







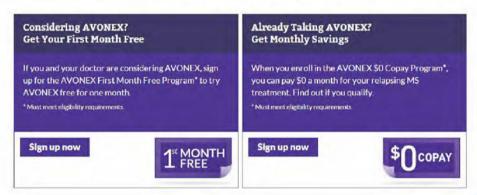
#### Conversion Strategy - Incentives

 In addition to the free first month offer in the announcement letter, Biogen also offered patients, both new and existing, a 0\$ copay for the AVONEX PEN

 Reps stated this applied to both the pre-filled syringe and the auto injector, but at the time of the launch there was some confusion amongst patients who believed it only applied to the AVONEX PEN which attributed to the success of the conversion

strategy

 Biogen backed this offer up by offering to cover the cost of a patients next three scripts of their previous therapy if they were not satisfied with the AVONEX PEN







Conversion Strategy - Competitor Strategy

- Overall, competitors did not put too much consideration into the launch of Biogen's auto injector for a variety of reasons
  - Teva reps interviewed believed the pen was nothing more than a line extension and would not impact the Copaxone business as Avonex was 2<sup>nd</sup> or 3<sup>rd</sup> choice in the ABCR class for MS treatment
  - Additionally, Teva reps were more focused on monitoring the upcoming orals from Biogen, Tecfidera and the impact this drug could not only have on the injectible, but the entire MS treatment paradigm





#### Conversion Strategy - Managed Care

- Payers largely saw the AVONEX PEN as merely a line extension and saw no clinical benefit to the PEN over the pre-filled syringe
- Biogen also chose a very conservative approach to negotiating with payers seeking merely parity in coverage
  - Several payers interviewed believed because AVONEX was not a leader amongst
    the interferon class they did not want to risk the share they had worked to obtain
    by running the risk of a pricing war with competitors
  - This became even more clear when, six months post launch, Biogen was rejected for exclusivity by several payer when they presented adherence and QoL data in attempt to grow within the class and were universally rejected





# Conversion Strategy - Key Takeaways

<b>Biogen Idec Conversion Tactics</b>	Implications
Biogen was attempting to launch the AVONEX PEN and sustain the continued growth of Tysabri in MS. Due to the need for balance, Biogen focused on converting existing AVONEX patients to the pen, while focusing on new starts/adds for Tysabri. Expanding the sales force had a minimal impact on the AVONEX pen conversion strategy, as they were responsible for a portfolio sell, not focused on the single product launch	<ul> <li>Understanding the Sanofi portfolio balance will be key for the Toujeo launch. Since the company is likely to have Toujeo, and Afrezza in the sales bag (while weaning off of Lantus), the full impact of Toujeo messaging may not be realized by prescribers</li> <li>Sanofi will likely dedicate a large sales force headcount to the launch of Toujeo, therefore Novo should be hyper focused at neutralizing both Toujeo messaging and targeted patient segments</li> </ul>
Biogen increased its AVONEX sales force and support/nurse educator program to increase visibility and ease the initial treatment	<ul> <li>Novo should increase its visibility of CornerStones4Care and the proven benefits of the program to patients/caretakers</li> <li>Can DEP be activated in efforts for FlexTouch® and Tresiba®? Or contract with other CDEs?</li> </ul>
Biogen failed to receive exclusive coverage of AVONEX PEN, because the PEN incrementally improves convenience, but is not a novel new treatment	Unless Toujeo provides a substantial value improvement over Lantus, Sanofi may find it difficult to achieve premium pricing or exclusive coverage





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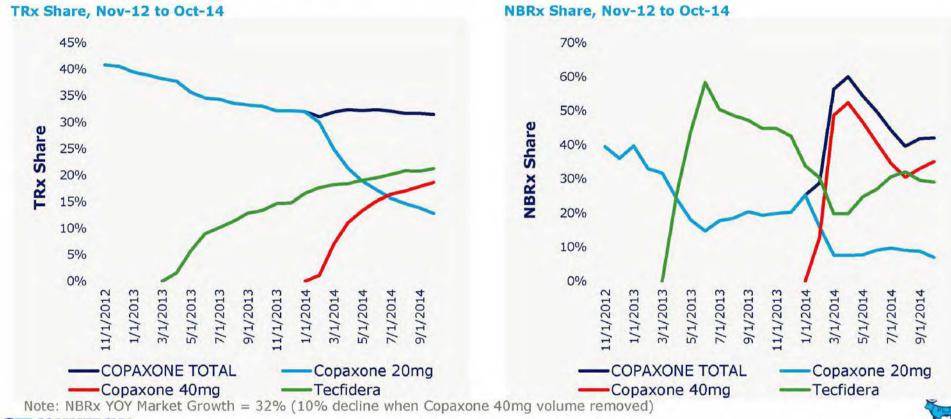
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# Copaxone 20mg to Copaxone 40mg

Analysis Brands and Key Competitor TRx & NBRx Share



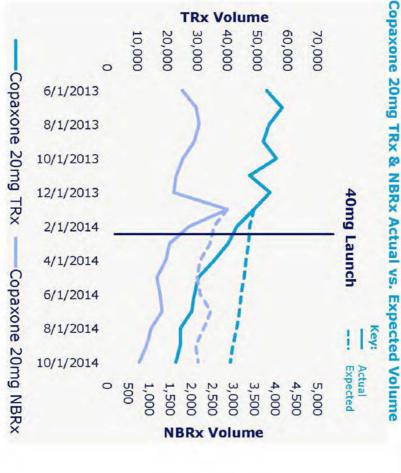


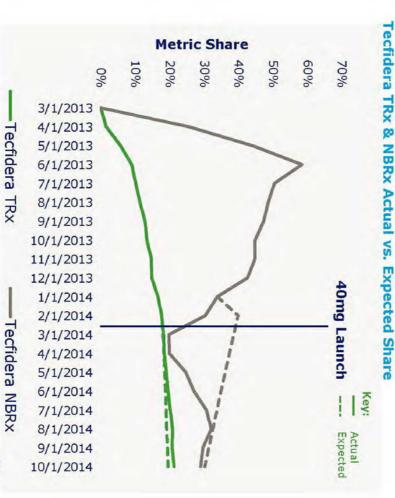
Source: IMS NPA Market Dynamics

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# Copaxone 20mg to Copaxone 40mg

Conversion Analysis / Key Competitor Effects





CE COMMERCIAL EFFECTIVENESS

Source: IMS NPA Market Dynamics

# Copaxone 20mg to Copaxone 40mg

#### Conversion Results

FIRST 9 MONTHS OF COPAXONE 40MG LAUNCH			
Expected	Actual	Value	Category
20,661	11,402	9,259	a. NBRx Loss (Exp - Act)
51,870	36,042	15,828	b. Continuing Loss (Exp - Act)
		25,088	c. Total Losses (a + b)
		49,068	d. Copaxone 40mg NBRx
7		51.1%	e. Patient Conversion Rate (c / d)

- Though only  $\sim 51\%$  of patients were deemed to be converted from 20mg to 40mg, nearly 60% of COPAXONE franchise TRx were 40mg as of October 2014, which is likely the result of superior patient adherence on the 40mg compared to the 20mg
- Similar to what was seen with Lunesta when Ambien CR launched, Tecfidera's TRx share was largely unaffected by 40mg since NBRx share losses were almost exclusively caused by Copaxone intra-brand conversion and were therefore somewhat illusory



Conversion Strategy - Sales Force

- In preparation for the launch of the 40mg Copaxone dose, Teva made no adjustments to their sales force
  - Copaxone 20mg was moved from primary focus to only being discussed when prompted
  - Reps were no longer received bonus payout on the 20mg dose after the 40mg was launched

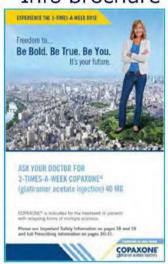
Product	Sales Force	<b>Detail Priority</b>	Weightings		
Copaxone 40mg		First	60%		
Azilect	102	Second	40%		
Copaxone 20mg		When prompted	0%		





Conversion Strategy - Messaging

Info brochure



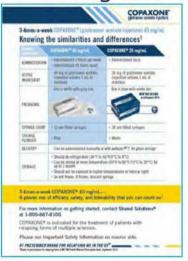
How to start



Events card



Dosing card



Messaging for the 40mg dose was heavily based on the added convenience to the most prescribed treatment for MS





Conversion Strategy - Messaging

 In addition to messaging to physicians Teva launched several DTC and patient support tools

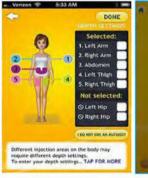
 Shortly before launch, Teva launched a non-branded DTC campaign featuring Ozzy Osbourne's son Jack to discuss his challenges and successes with managing his MS – the campaign was very well received

Additionally, Teva launched an app designed to help 20mg patients

transition to the 40mg dose













Conversion Strategy - Competitor Analysis

- Major competitors, such as Biogen, failed to forecast the potential success of the 20mg to 40mg strategy
  - Biogen senior management saw the 40mg dosing strategy as an act of desperation and admit to not properly managing a proper countermessaging strategy
  - The overwhelming feeling at launch was the 40mg success, if any, would be short lived by an at-risk generic launch of the 20mg dose
  - By the time legal guidance was handed down, Teva had already converted more than half of their target patient population and Biogen felt their was little that could be done





Conversion Strategy - Incentives

- In an effort to push patients towards the 40mg dose Teval launched a \$0 copay
  - Patients wanting to remain on the QD, 20mg dose would still have access to a copay, but the card only lowered the out-of-pocket responsibility for patients to \$35/month







Conversion Strategy - Managed Care

- Within the first three months of launch Teva touted over 90% of commercial patients had access to the 40mg dose
  - That being said, other payers refused to negotiate the 40mg dose until the path to the generic 20mg became more transparent
    - Once Teva's successful conversion strategy became apparent, payers requested
       Teva to return regardless of the status of the generic litigation
    - Some payers interviewed claimed to have seen conversion rates as high as 80% in the first three month at full cost to the payer
- In an additional effort to gain preferred status for the 40mg
   Copaxone, Teva reduced the by \$1000 compared to the 20mg dose





## Copaxone 20mg to Copaxone 40mg Conversion Strategy – Key Takeaways

Teva	Implications
Teva executed a sound launch/conversion strategy that managed to protect its patient base and continue the growth of the Copaxone franchise. Teva focused only on the 40mg dose backed by a sound managed care access strategy and DTC/patient education campaign.  Additionally, the product profile was institutionally strong and didn't warrant replacement by Biogen's Tecifdera. The two brands mutually co-existed in their launch years	Novo should consider a similar strategy when informing patients and physicians and should also consider how they can incentivize patients to utilize their products both current and future
Teva increased their nurse support staff in order to better support physician and patient needs in a time of transition	<ul> <li>Novo should consider increasing their nurse educator staff in order to help patients assimilate to a new treatment</li> <li>Can DEP be activated for Levemir® or Tresiba®?</li> </ul>
Teva differentiated their both copay card value as well as WAC between their two doses appealing both to payers and patients	<ul> <li>Sanofi could look to implement a similar strategy in order to persuade patients and payer</li> <li>One scenario would see Sanofi increase the price of Lantus prior to the launch of Toujeo and offering a perceived discount to the newer insulin</li> <li>Additionally, Sanofi could continue to offer their current patient savings plan to Lantus and provide greater savings to Toujeo patients</li> <li>Farxiga was completely undifferentiated vs. Invokana but yet started on better trajectory due to \$0 co-pay. What impact could this have on new starts?</li> <li>Novo could implement a similar strategy with their insulin portfolio</li> </ul>





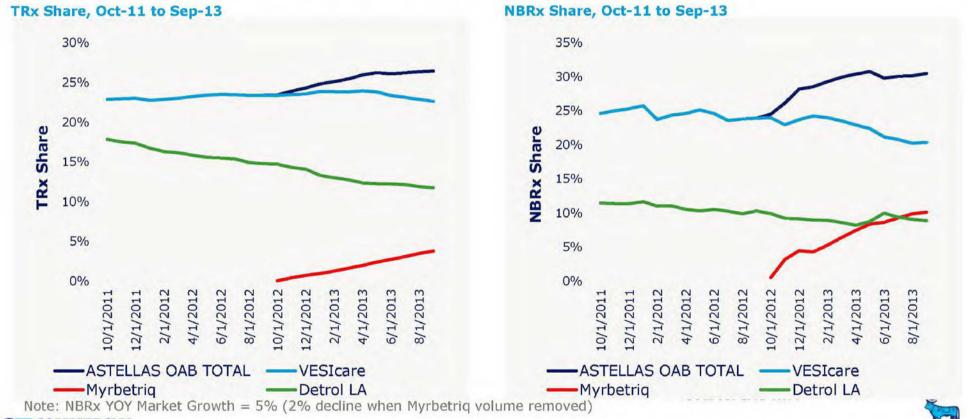
### **Table of Contents**

- Introduction
- Ambien to Ambien CR
- AVONEX to AVONEX PEN
- Copaxone 20mg to Copaxone 40mg
- VESIcare to Myrbetriq





### Analysis Brands and Key Competitor TRx & NBRx Share

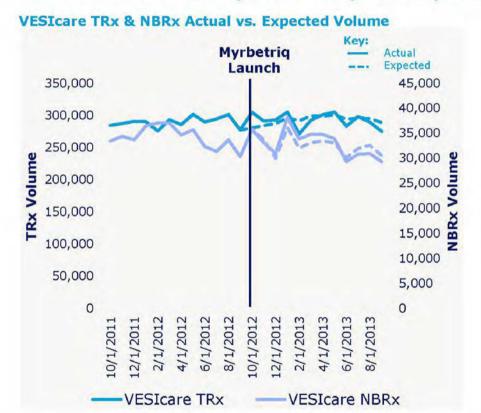


CE COMMERCIAL EFFECTIVENESS

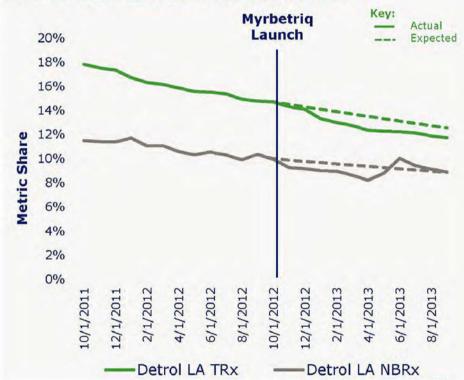
Source: IMS NPA

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### Conversion Analysis / Key Competitor Effects









novo nordisk®

Source: IMS NPA

#### Conversion Results

FIRST 12 MONTHS OF MYRBETRIQ LAUNCH					
Expected	Actual	Value	Category		
392,710	395,949		a. NBRx Loss (Exp - Act)		
352,972	352,636	337	b. Continuing Loss (Exp - Act)		
		337	c. Total Losses (a + b)		
		114,728	d. Myrbetriq NBRx		
		0.3%	e. Patient Conversion Rate (c / d)		

- Myrbetriq was treated as an addition to Astellas' OAB franchise, which is why measured conversion is so low
- Detrol LA appeared to be somewhat affected by the launch of Myrbetriq, losing roughly one TRx share point 12 months after the launch of the new brand





Conversion Strategy - Sales Force

- Astellas did not expand their sales force with the launch of Myrbetriq, but merely moved VESIcare to a distant secondary position
  - Reps stated, initially, during the launch of Myrbetriq that VESIcare was merely sampled and not detailed at all

Product	sct Sales Force Detail Priority		Sales Calls		
Myrbetriq		First	30-50 sales calls per week		
VESIcare	~640	Second	(varies by region)		





Conversion Strategy - Messaging

- Reps spent ~90% of their time detailing physicians on Myrbetriq
- Key messaging focused on the treatment gaps Myrbetriq could fill where VESIcare was not appropriate including:
  - New starts, elderly patients and VESIcare and other OAB failures due to anticholinergic effects
- Reps did not actively promote against VESIcare as Astellas was looking to dominate the OAB market with their portfolio, not replace one with the other





Conversion Strategy - Incentives

- Astellas offered samples and free-trials to physicians to use on patients who were hesitant to start new patients or switch patients from their current therapy
- As to not take away from the VESIcare market, Astellas offered the identical copay savings program for Myrbetriq capping commercial patients out-of-pocket costs to \$20/month

<b>VESIcare Savings Card</b>	Myrbetriq Savings Card
No. May 1940 2 Market Process Control	Rollini, 5105.54 RPCN, Lepthy EXEPT - 97977666 SSUER, SSUER, SSUER SSUER, SSUER, SSUER SSUER, SSUER, SSUER SSUER,





Conversion Strategy - Managed Care

- Where Astellas fell short were their efforts surrounding payer negotiations
  - Astellas petitioned for matched tier 2 access for their portfolio, but due to a 10% premium based on the novel MOA, Myrbetriq launched at almost exclusively a tier 3 copay
  - Payers took a hard line with Astellas demanding additional discounts for VESIcare if Myrbetriq was going to be considered for formulary coverage
    - Astellas initially resisted, but after a weak launch were forced to renegotiate with payers
  - In the end Astellas ended up discounting Myrbetriq 30% and VESIcare 40% in order to obtain tier 2 status for both products





## VESIcare to Myrbetriq Conversion Strategy - Key Takeaways

Astellas	Implications
Astellas considers itself a therapy area leader within the Urology space and continues to invest and generate revenue from it	Novo is a worldwide leader in the diabetes market and should use the experience it has gained to its advantage and continue to be a leader in the space
One of the primary reasons that limited the uptake of Myrbetriq was its tier 3 payer access; while the VESIcare remained on tier 2 access	Clinically superior products will receive a price premium; although, parity pricing will encourage more switches to a new product
Astellas offered similar savings programs across both Myrbetriq and VESIcare to keep patient out- of pocket costs at parity	Offering co-pay cards and savings programs that keep patients' out-of-pocket expenses of new products at parity to older products is key to market uptake
Myrbetriq was promoted by the same reps who carried VESIcare and to the same target physicians	Novo should build on existing relationships that sales reps have with PCPs and specialists in order to maintain its brand image and market position





## **Overall Conversion Strategy Takeaways**

Commercial Strategies	Incentives	Managed Care
Novo should seek to target messaging towards new start patients where Sanofi will likely focus on converting Lantus patients	Novo should consider pricing and copay strategies to blunt the launch of Toujeo by offering lower copay incentives to patients either starting on insulin therapy or switching from Lantus	While Sanofi is touting Toujeo as a premium product, Novo should be prepared for the potential for Sanofi to price their new basal at a discount in order to gain parity or preferred managed care access
	Novo should seek to provide greater education of the advantages to patients and providers surrounding the FlexTouch Pen from DEP	If Sanofi continues on with Toujeo as a premium product, Novo could investigate this strategy for their basal portfolio when Tresiba is approved in the US
	Novo should leverage the success of the CornerStones4Care tools perhaps implementing mobile applications	





# Levemir® Contracting Strategy

Interim Bidding Strategy Update
Pricing Committee
January 27, 2014





CONFIDENTIAL & PROPRIETARY NNI-FINANCE-001939

## Provide interim bidding strategy update on Levemir, ahead of pivotal CVS Part D bid

**Objective** 

Align on a CVS Part D bidding approach and continuing Levemir® exclusive strategy

#### **Contents**

- Recap of November PC Meeting
- Timeline of Current and Potential Levemir® Exclusive Offers
- CVS Part D Influence Scenario Mapping





## We evaluated and approved a Levemir® exclusive strategy at November 2013 PC

## **Exclusive Risks and Rationale Presented**

#### √ Rationale

- Volume: up to 3.0% basal share upside
- Value: net sales-positive opportunities expected to be available

#### × Risks

- Easy for Sanofi to counter with higher co-preferred, or even exclusive Lantus offers
- Threatens Tresiba® environment

#### **Proposed Approach**

#### Stealth

- Start by offering exclusives only at select key accounts
- Observe and evaluate success before rolling out exclusives to a few more accounts
- Widespread success would confirm viability of Levemir® exclusives at more accounts

## Approved Approach That We've Been Following

#### **Target Top 25 Accounts**

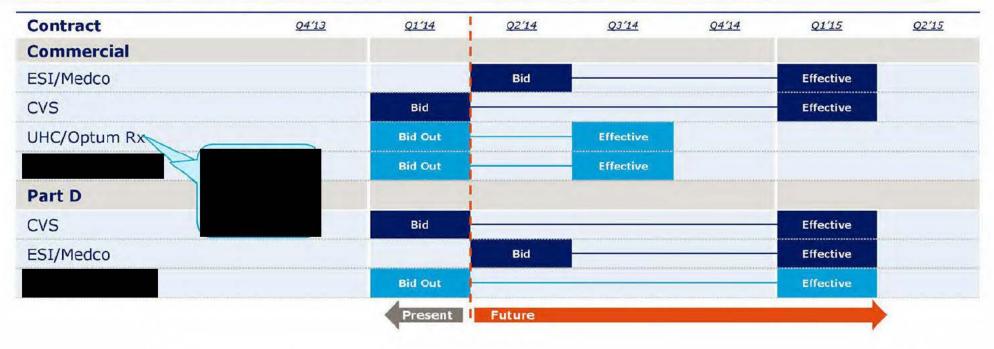
 Instead of waiting, offer attractive exclusive rebates to large, receptive customers

CVS Part D will be the largest Levemir® exclusive bid to date—How should we approach it?



Basal access landscape continues to evolve; however, CVS Part D bid may be a turning point so it is imperative that we get it right

## Discussions with account team narrowed down initial 25 accounts to 11 targeted accounts

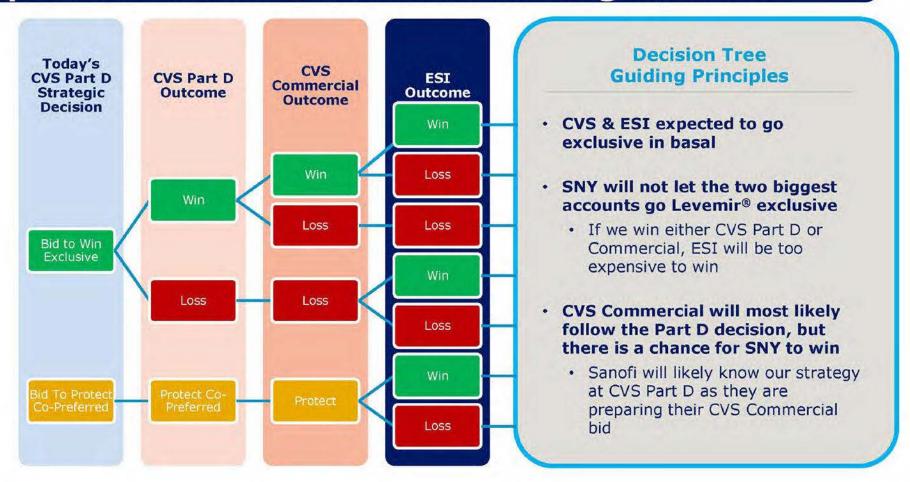




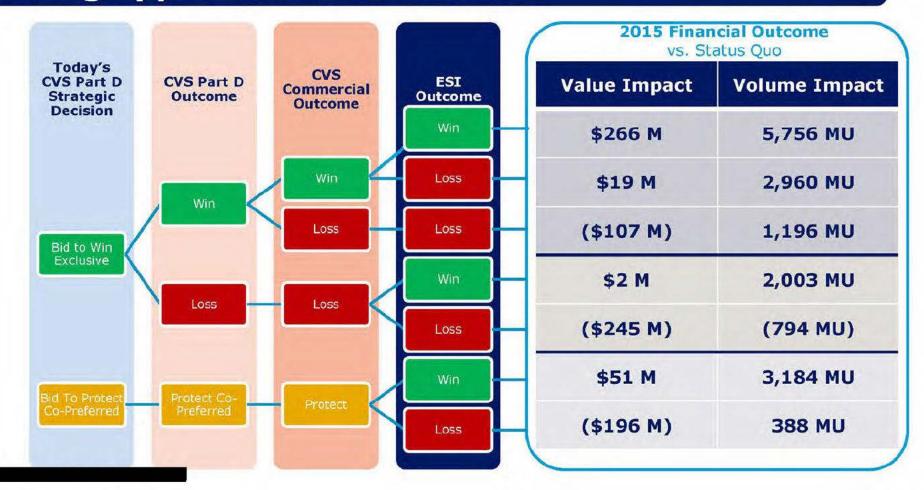
How can our bid approach at CVS Part D set up the best future for Levemir®?



## Our approach at CVS Part D must consider the impact on Levemir® access at the largest PBMs



## Probability of success at ESI can potentially drive bidding approach for CVS Part D



## Risk-based approach suggests that "Bid to Win Exclusive" is the recommended strategy

CVS Part D Approach:	Bid to Win Exclusive	Protect Co-Preferred  ✓ Raises possibility of winning at ESI  ✓ Discourages Sanofi aggression		
Rationale	<ul> <li>✓ Greatest immediate         volume and value impact         at CVS Part D</li> <li>✓ Potentially sets up a CVS         Commercial win</li> </ul>			
Risks	<ul> <li>Encourages stronger</li> <li>response from Sanofi</li> <li>ESI—and other accounts—may become too expensive to win</li> </ul>	× If we cannot win ESI, we leave substantial CVS volume and value on the table		





From: DBEX (Daye Bexley)

To: DUGL (Doug Langa); CYRD (Cheryl Reid)

Sent: 5/28/2014 4:36:04 PM

Subject: FW: Novo Nordisk List Price Increase Notification: Novolin®, ReliOn®, NovoLog®, NovoLog® Mix

70/30,

ughhhh

From: BPL (Brian Perrella)

Sent: Wednesday, May 28, 2014 11:01 AM

To: GM\_MarketAccess\_StrategicPricing; NNI Diabetes Pricing; NNI Forecasting; NNI PCOR; NNI Trade; NNI SLS\_Market

Access All; NNI MM Team; NNI HEOR; NNI BioPharm Market Access Team

Cc: RDZI (Rich DeNunzio); KAYE (Karen Yee)

Subject: Novo Nordisk List Price Increase Notification: Novolin®, ReliOn®, NovoLog®, NovoLog® Mix 70/30,



Hello All-

Effective Wednesday, May 28, 2014 – 12:01 am EDT Novo Nordisk increased the prices of the following products:

NDC#	Product Name	Pct Change	New WAC/pkg
00169-1833-11	Novolin <sup>®</sup> R - 10mL vial	9.9%	\$99.65
00169-1834-11	Novolin® N - 10mL vial	9.9%	\$99.65
00169-1837-11	Novolin® 70/30 10mL vial	9.9%	\$99.65
00169-7501-11	NovoLog® 10mL vial	9.9%	\$184.85
	1101008 201101	2.2.0	
	NovoLog® PenFill cartridge -5x3mL	9.9%	5343.40
00169-3303-12	NovoLog® PenFill cartridge -5x3mL NovoLog® FlexPen® -5x3mL	9.9% 9.9%	\$343.40 \$357.10
00169-3303-12 00169-6339-10 00169-3685-12			

Please reach out if you have any questions.

Regards, Brian

Brian Perrella

Sr. Associate, Strategic Pricing Finance

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA

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May 29th, 2018





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## Reducing list price addresses Insulin market issues, without alleviating industry wide challenges

### Why would we do this?



#### Why wouldn't we?

- Relieves pressure from media and Congressional hearings
- Closes list to net price gap while supporting patient affordability
- Aligns to HHS's call for affordable pricing options
- Mitigates increased Coverage Gap exposure and upcoming 2020 "cliff"
- Mitigates potential uncapping of Medicaid rates

- Financial risk without eliminating industry wide legislation changes
- Does not alleviate overall US drug spend as net price would remain
- Upset payers may pressure GLP1 portfolio
- Many in the supply chain will be negatively affected (\$) and may retaliate
- Competitors may not follow putting NNI at a disadvantage





## If aligned to decrease list price, recommendation is to reduce Insulin\* list prices by 50%



#### **Rationale for 50%**

- √ Significantly closes the list to net gap
- ✓ Believe 50% is a meaningful reduction to patients
- √ Minimizes net price exposure on lower rebated accounts
- ✓ Minimal reduction needed to offset proposed Medicaid rate cap provision (\$850M) = 36%
- x Results in list prices lower than DPP-4s

#### **Why Insulin only**

- √ Focus of Media scrutiny
- ✓ Contains largest list to net gap
- Could execute GLP-1 portfolio and Xultophy® if gap widens (i.e. 50%+)



\*Insulins include N-franchise, Tresiba $^{\otimes}$ , Levemir $^{\otimes}$ , and Fiasp $^{\otimes}$  Note: Prior to taking any price actions, Novo Nordisk undertakes a review of all factors relevant to the price action

## Financial impact ranges from (\$100M) to +\$200M

Most likely scenario yields (\$85M)

Category	Downside	Flow Thru	Upside	Comment
Cov Gap*	\$200M	<u>\$200M</u>	\$200M	TBD unknown add'l time in gap risk offsets delay to gap risk
Payer AF	<u>\$60M</u>	\$150M	\$150M	Downside: CVS, ESI, & Optum push to be kept whole
PPD	\$150M	<u>\$150M</u>	\$150M	
DSA	<u>\$0M</u>	\$100M	\$100M	Downside: wholesalers push to renegotiate due to cost structure
Medicaid	\$35M	<u>\$50M</u>	\$50M	Downside: Negative formulary change
Pharma Fee	\$20M	<u>\$20M</u>	\$20M	
Cash/Non- Contracted*	(\$300M)	(\$300M)	(\$280)	Upside: 20% volume growth
LTC*	(\$100M)	<u>(\$100M)</u>	(\$60)	Upside: 40% volume growth
FSS*	(\$100M)	(\$100M)	(\$80M)	Upside: 20% volume growth
Net Price Erosion	<u>(\$65M</u> )	(\$50M)	(\$50M)	Downside: Add'l net price erosion
TOTAL	(\$100M)	\$120M	\$200M	

Pending PCOR/Finance sign-off

#### **Indirect Impacts**

- + IDN/HS
- + EHR
- + Comm leverage
- Formulary removal
- Same Rebate %

Most likely

\*Assumes other manufacturers list price stays as is

NOTE: 1x Inventory Adjustment offset by pipeline inventory adjustment

### What do we need to succeed?

#### Must Haves

- ✓ Alignment with all National payers that they wont remove us from formulary
- ✓ Agreement with payers to hold net price (i.e. lessen rebate %)
- √ Willingness to forgo list increase in year of execution (~\$200M)

#### VS.

#### **Nice to Have**

- ✓ Backing from HHS
- √ 1 or 2 National payers to publicly support initiative
- √ Bipartisan support
- ✓ Wholesalers allow renegotiation of contracts
- ✓ Support from ADA and other patient advocacy groups





## Alignment needed on timing and list increase approach



#### "First Mover"?

- √ NNI spotlighted as pioneer in the industry
- ✓ Opportunity to be in control
- Positive company media and perception
- ✓ Potential volume upside
- x Competitors don't follow and NNI is outlier

#### 2019?

- √ Part D has limited ability to move against us
- √ Shows willingness to take immediate action
- x Less ability to offset downside through OpEx
- × Large operational lift
- x Inability for payers & other key stakeholders to plan

#### **List Increase?**

- x Forgo list?
  - '18 increase est. at (\$370M)
  - '19 increase est. at add'l (\$140M-\$200M)
- √ Take list and simultaneously announce willingness to reduce
  - Staying in system until we can execute decrease
  - Attempt to negotiate the '19 price increase into the payer net price





### **Guidance for LJF discussion**

Prior to execution official PC vote to be captured



If aligned to make up to a \$300M investment to reduce list...

Products: N-Franchise, FIASP®, Tresiba®, & Levemir®

Yes

No

Reduction: 50%

Yes

No

Timing: Implement for 2019 or 2020?

2019

2020

**Execution:** Inform market we're implementing or announce our willingness if 'must haves' are attained?

Implement

Announce

List Price: Take list price prior?

Yes

No

Other: Should we evaluate Norditropin®?

Yes

No



### **2019 List Price Schedule**

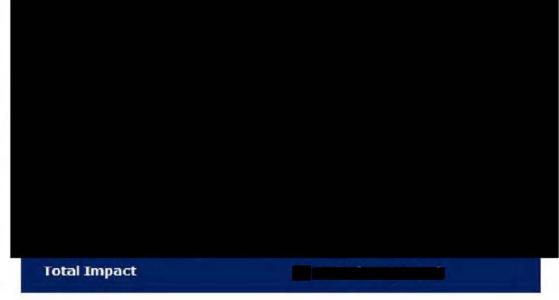
AB19 PROPOSED





## Financial impact of proposal

Brand	Assum AB19	ptions Upside	Impact (mUSD)	Impact (mDKK)	
Levemir Xultophy	June @ 4%	Jan @ 4.9%	33	208	
NovoLog @x70/30	No Increase	No Increase	0	0	
Fiasp* list-ecting insulin aspert	No Increase	No Increase	0	0	





## **Updated financials**

2019 vs. 2018	\$M	sM	sM	\$M	\$M	sM	\$M	%	%	%	%
	2019	2018		1000-							
	AB	RE4	change	Price	Vol	Product Mix	Total	Price	Vol	Product Mix	Total
- Tresiba®	955	836	120	(40)	160	0	120	-4.8%	19.1%	0.0%	14.3%
- Xultophy®	123	87	36	(20)	56	1(*)	36	-22.7%	64.2%	0.0%	41.5%
- Levemir®	891	1,123	(232)	(150)	(82)	(0)	(232)	-13.4%	-7.3%	0.0%	-20.7%
Long-acting Insulin	1,969	2,046	(2)	(211)	34	101	(76)	-10.3%	1.6%	4.9%	-3.7%
- Faster Acting Insulin Aspart	100	42	58	(15)	72	D=2	58	-34.4%	170.6%	0.0%	136.2%
- NovoLog®	1,320	1,489	(169)	(163)	(6)	(0)	(169)	-11.0%	-0.4%	0.0%	-11.3%
Fast acting Insulin	1,421	1,532	(11	(178)	24	42	(111)	-11.5%	1.6%	2.8%	-7.2%
- Ryzodeg®				-	9	*	- 4	0.0%	0.0%	0.0%	0.0%
- NovoLog@ Mix	145	214	(69)	(57)	(12)	-	(69)	-26.7%	-5.4%	0.0%	-32.2%
Pre-mix Insulin	145	214	(6	(57)	(12)	(#6	(69)	-26.7%	-5.4%	0.0%	-32.2%
- Human insulin	269	293	(24)	(37)	13	D	(24)	-12.6%	4.4%	0.0%	-8.1%
Total Insulin	3,805	4.084	(28	(482)	75	127	(280)	-11.8%	1.8%	3.1%	-6.9%



## **AB19** for reference

2019 vs. 2018	\$M	\$M	\$M	sM	\$M	\$M	sM	%	%	%	%
	2019	2018									
	AB	RE4	change	Price	Vol	Product Mix	Total	Price	Vol	Product Mix	Total
- Tresiba®	936	836	101	(59)	160	0	101	-7.1%	19.1%	0.0%	12.0%
- Xultophy®	121	87	34	(22)	56	725	34	-25.0%	64.2%	0.0%	39.2%
- Levemir®	879	1,123	(244)	(162)	(82)	(0)	(244)	-14.5%	-7.3%	0.0%	-21.7%
Long-acting Insulin	1,936	2,046	(109	(244)	34	101	(109)	-11.9%	1.6%	4.9%	-5.3%
- Faster Acting Insulin Aspart	100	42	58	(15)	72		58	-34.4%	170.6%	0.0%	136.2%
- NovoLog®	1,320	1,489	(169)	(163)	(6)	(0)	(169)	-11.0%	-0.4%	0.0%	-11.3%
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- Ryzodeg®					-			0.0%	0.0%	0.0%	0.0%
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- Human insulin	269	293	(24)	(37)	13	0	(24)	-12.6%	4.4%	0.0%	-8.1%
Total Insulin	3,772	4,084	(313	(515)	75	127	(313)	-12.6%	1.8%	3.1%	-7.7%



From: FAJA (Farruq Jafery)
To: DUGL (Doug Langa)

CC: UCO (Ulrich Christian Otte); SALR (Steve Albers); RDZI (Rich DeNunzio)

Sent: 11/3/2017 3:00:42 AM

Subject: Recap of 11/2 Pricing Committee Decisions
Attachments: 1\_National Part D Bids\_2017.11.02 PC.pptx

Hi Doug,

At Pricing Committee today, we discussed the following:

- 2019 Part D Bidding Approach
- Basal List Price Increase

All of the proposals were **approved as recommended**. The details and rationale of each are spelled out below.

#### 2019 Part D Bidding Approach: (initial offers by account are listed in the attached slides)



- Asking for enhancements for UHC PTD and being at high risk
- Asking for enhancements for Cigna-HS PTD as it could be a "1 and done" bid
- Other remaining Part D bids will offer at 2018 rates or slight enhancements
- Expectation is a number of the Part D bids will come back to PC with some additional feedback

#### Basal List Price Increase:



- \$61M upside vs. AB
- Not anticipated to impact access or HCP prescribing behavior

- Potentially last opportunity to take price due to future biosimlar entrants
- Will move up Xultophy, Needles, HypoKit from 2% in March to 4% in January to align with timing of basal (4% is still within the approved strategy of 2-4%)


Please let me know if you have any questions/comments.

Farruq

**Farruq Jafery** 

VP, Pricing, Contract Ops & Reimbursement Finance & Operations

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536

From:	FAJA (Farruq Jafery)
То:	DUGL (Doug Langa); UCO (Ulrich Christian Otte); SALR (Steve Albers); DDME (David Moore); MPDU (Pia D'Urbano)
CC:	CBLE (Craig Bleifer); BKNO (Bill Knott); RDZI (Rich DeNunzio); FCC (Franco Cognata); EDCI (Ed Cinca); ELIV (Elena Livshina); BLMI (Blandine Lacroix); JTCX (Jack Cox)
Sent:	11/21/2018 5:56:47 PM
Subject:	PC Vote - & Execution of 2019 Planned Price Increases
Attachments:	2019 List Price Alignment.pptx
Dear Pricing Commit	ttee,
Please recall that on	Aug 30 PC discussion around 2019 list price, PC concluded on the following:
list price. If to portfolio (with Continue to Healthcare Es	
Limit any pri	ice increases to once per year <u>per brand</u>
portfolio) effective <b>J</b> brands have not bee	anounced that it intends to take a price increase on 41 of its products (or 10% of its anuary 15, 2019. The average price increase for the 41 products is 5% (the specific en disclosed). The Wall Street Journal article noted that BMS and Allergan have also issued by CA law to take an increase in January.
	d with executing all other 2019 planned increases <b>effective February 1</b> instead of June umption (please see attached for scheduled increases by product)
Please provide you	ur vote on both #1 and #2 above. Kindly reply by EOD on Tuesday (11/27).
Kind regards,	
_	
Farruq	
Farruq Jafery VP, Pricing, Contract Ops	& Reimbursement

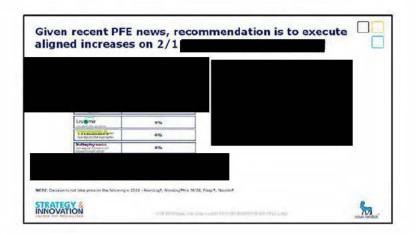
Finance & Operations

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536





PC alignment to take agreed upon '19 price increases as early as possible upon other manufacturer taking only product that requires CA notification, decision to not proactively inform



Reco- take all aligned price increases on 2/1, notify CA now
All planned increase currently planned for June (AB19)
Comp news:

- -Pfizer 41 drugs, 10% of portfolio, 5% with 3 at 3% and 1 at 9%
- -Bristol-Myers Squibb Co. BMY 1.50% and Allergan also made notifications to CA. BMS' not to exceed 6%

From: SALR (Steve Albers)

To: DUGL (Doug Langa); RISP (Richard Sperry)

Sent: 4/19/2018 9:05:26 PM

Subject: Basal List Price Change - Background for Execmgmt
Attachments: Basal List Price Preliminary Recommendation (2).docx

#### Doug,

I know we agreed on this at PC today but wanted you to have this backgrounder just in case it comes up during execmgmt tomorrow.

Let me know if any questions.

Steve

#### Steve Albers

Corporate Vice President Market Access & Public Affairs

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA

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#### **Basal List Price Preliminary Recommendation**

Doug, post SNY's basal price increase, we took a quick look at our options and wanted to share initial thoughts in case you're asked at ExecMgmt tomorrow.

Ultimately we are aligned to take a 4% price increase on both Levemir® and Tresiba®. The increase allows us to capitalize on the financial upside, focusing on Devote results, while not increasing our historic list premium vs Lantus. The recommended timing would be in July in and NovoLog® price increases.

So this proposed basal price increase would help offset the \$8M delay. The NovoLog<sup>®</sup> price increase had already been previously loss realized on a planned for the July timeframe. This aligned increase would put all price increases through and NovoLog®, the basal increases do not cross the CA state at one time. Unlike law threshold.

We put some thoughts and facts below for you to have.

#### Rationale for:

- Financial upside assists in closing basal AB gap ~\$40M
- Cost of access is increasing (20% YoY reduction in net realization)
- The Devote Label update justifies keeping the previous status quo price spread vs
- The increase stays within our 9.9% price commitment
- With multiple glargine biosimilars on the horizon we have limited opportunities to take price

#### Basal List Price Increase Consideration







#### Pros

- Financial Upside
  - 4% approximate \$40M upside
- Continues status quo spread vs Lantus
- Offsets ARP Decline
- Capitalizes on limited future opportunity to continue to take price post 2019
- Justified due to Devote label update
- LLY likely to follow SNY increase

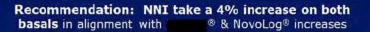
#### Cons

- Likely to give back in future bids
- Increase cost to cash, HDHP, and coinsurance patients
- Negative impact on LTC Part A business
- Optics in current political climate after taking 4% in January
- Spread vs Basaglar & future Biosimilars if not followed by LLY
- List Price is increasingly more transparent to Health Systems, HCPs & Patients (IDN WAC Risk Contracts)
- Counter to List Price Reduction Strategy



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#### **Current State**

- SNY implemented a 5.3% price increase on 4/13/18
  - SNY previous increase was taken 09/2017, LLY followed 12/17
- NNI last basal increase was 4% in January
  - Prior increase was 2 years earlier on Levemir. Tresiba price had been flat since launch.
- > Current Price spread vs Tresiba:
  - Lantus: -12.4%Basaglar: -29.3%



#### **Rationale for Increase**

- Financial upside assists in closing basal AB gap + \$40M
- Cost of access increasing (competitive pressure for higher payer/PBM rebates continues)
- Devote Label update justifies keeping status quo price spread vs Lantus
- Stays within NNI Price commitment of 9.9%
- With multiple glargine biosimilars on the horizon we have limited opportunities to take price



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#### Novo Nordisk Inc.

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#### Insulin Price Comparison

Novo Nordisk Products

#### Competitor Products

Insulin Sub-Class	Product	WAC Price	Insulin Units/ Pkg	WAC/ Insuin Unit	Latest % Increase	Effective Date	Product	WAC Price	Insulin Units/ Pkg	WAC/ Iosulin Unit	Increase	Effective Date	Competitor Unit Price vs. NNI
	Levenir® 10 m L	\$279.76	1,000	\$0.280	4.0%	1/3/18	Lantus 10 mL (SANOFI)	\$269.54	1,000	\$0.270	5,3%	4/13/18	-3.7% Levernin® -12.4% Tresba®
Basal Insulin	Levenir® FlexTouch® 15mL	\$419.64	1,500	\$0.280	4.0%	1/3/18	Lantus Solostar 15mL (SANCE)	\$404.29	1,500	\$0.270	5,3%	4/13/18	-3.7% Leverning -12.4% Tresbas
							Basagiar KwikPen 15mL (LILLY)	\$325.36	1,500	50.218	3,0%	12/15/17	-22.2% Levenir® -29.3% Tresba®
1	Tresiba® FlexTouch®U-100 15m	\$46160	1,500	\$0.308	4,0%	1/3/18	Toujeo SoloStar 4.5mL (SANOFI)	\$372,34	1,390	\$0.276	5,3%	4/13/18	-1.4% Levening -10.4% Tresba®
	Tresiba® FlexTouch®U-200 9mL	\$55392	1,800	\$0.308	4.0%	1/3/18	Tomica May CalaCtra Coul	\$495.46	1,800	\$0.276	Launch	4/23/18	-1.4% Leveror® -10.4% Tresba®

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From: RDZI (Rich DeNunzio) To: SALR (Steve Albers) Sent: 10/27/2017 3:03:59 AM Subject: Fwd: The Pre Read for the 10/26 Special Pre PC is attached Agenda\_PrePC\_2017.10.26.pdf; ATT00001.htm; 2017.10.26 Basal and Pre-PC.pdf; Attachments: ATT00002.htm FYI on PrePC outcome on basal and list price. PrePC aligned to 4% on basal in January and recommended taking 4% on non-strategic, Xultophy and all at the same time. Martin was concerned about perception and affordability, but agreed to take. Will be coming to PC on 11/2. Rich Begin forwarded message: From: "MYME (Mary Merrifield)"

Date: October 25, 2017 at 5:35:24 PM EDT To: "FAJA (Farrug Jafery)" >, "RDZI (Rich DeNunzio)" < "BKNO (Bill Knott)" >, "MJGN (Martin Jernigan)" >, "EDCI (Ed Cinca)" "EZB (Erik Zbranak)" , "JRGG (Jen Madrid)" "JKMS (James Kalmes)" "QARS (Andy Schultz)" "FCC (Franco Cognata)" "BKKY (Boris Kaushansky)" "DAPR (Dan Park)" "DIAO (David Amoroso)" "BPL (Brian Perrella)" "DJAH (David Jahnke)" "DUCV (Dustin Carver)" , "KRHL (Kate Taylor)" "DMY (Dmitriy Yelskiy)"

Subject: The Pre Read for the 10/26 Special Pre PC is attached

Please see attached.

# Basal and Increases

Pre-PC

October 26th, 2017





# PC alignment to AB reco; re-evaluation requested for '18



# Nearly 3 years later, SNY finally takes price increase on Basals (3% Lantus, 5.4% Toujeo)



### Rationale/Why now?

- Previous analyses suggest optimal timing for increase was Jan'18
- Price 'predictability' did not prevent major account losses
- Substantial value lost over past year
  - CVS & UHC Comm losses
  - Enhanced rates to protect current positions
  - Denial Conversion Program aids in retaining volume but at significant cost
- · Non-contracted business increasing
- Toujeo increase likely higher due to PP terms (and thus price realization)
- Both products still at discount vs. NNI
- In line with **price commitment** of 'at or below the rate of medical inflation' (NHE benchmark, '17 est = 5.6%)

#### Current

Current					
Product	Competitor Unit				
Lantus 10 mL	-4.8% Levemir@				
(SANOFI)	-13.5% Tresiba@				
Lantus Solostar 15mL	-4.8% Levemir@				
(SANOFI)	-13.5% Tresiba@				
Basaglar KwikPen 15mL	-21.5% Levemir@				
(LILLY)	-28.6% Tresiba@				
Toujeo Solostar 4.5mL	-2.6% Levemir@				

# Consistent with list price approach endorsed by PC, variety of factors considered for potential Basal increase

#### **Recommendation:**

4% increase in January\* on both Levemir® & Tresiba®

#### Pros

- ✓ Financial Upside vs. AB: +\$55M
- Maintains ~same prior spread vs. Lantus (vs. Toujeo lessened)
- ✓ Mkt research list \$ has limited influence on retail HCPs
- Offsets some ARP decline
- Likely last oppty take price due to future entrants
- Simple message by taking same increase on both products
- Taking at same time others minimizes perception of collusion (will be seen as NNI portfolio decision) and limits media activity
- LLY likely to take increase coming weeks

#### Cons

- x Likely to give back value in '19 bids, however...
  - '19 rates already increasing
- x Increased cost to cash, HDHP, & co-insur patients
- x Impact on Part A LTC prescribers (manage per diem cost)
- X Optics given intensifying political environment and pressure on cost of insulin
- V Until they take, spread vs. Basaglar widens
- Widens gap vs. future entrants

\*reco to take Xultophy®

as well. Planned for March in AB.

# Basal price increase messaging- reactive only



- Haven't take increase in over 2 years
- Cost of access increasing (competitive pressure for higher payer/PBM rebates continues)
- Percent increase is in line with our pricing commitment (net realized percent is less due to above)



- Haven't taken increase since launch (Oct 2015)
- Cost of access increasing (competitive pressure for higher payer/PBM rebates continues)
- SWITCH and DEVOTE value evidence
- Percent increase is in line with our pricing commitment (net realized percent is less due to above)





## **Vote**



**CONFIDENTIAL & PROPRIETARY** 







CONFIDENTIAL & PROPRIETARY NNI-FINANCE-003630







CONFIDENTIAL & PROPRIETARY NNI-FINANCE-003633





 From:
 RDZI (Rich DeNunzio)

 To:
 SALR (Steve Albers)

 Sent:
 5/26/2018 5:09:33 AM

Subject: Fwd: List Price Decrease\_PC-052918.pdf

Attachments: List Price Decrease\_PC-052918.pdf; ATT00001.htm

FYI - sent to Anne Mette.

Note they asked for downside risk to coverage gap, but there's also upside. Dan's model takes all that into consideration until we think other companies could follow, than we don't have data to truly know as there's upside, slower to get into gap, and downside, longer in gap and not hitting catastrophic, but we're not sure

FYI - Michael and Erik connecting with Milliman to discuss RFI and other thoughts on affordability options. In that conversation they'll discuss list reduction to camouflage it.

One thing I realized we forgot to put in slides is what we would do if we say no to reduction, but LLY goes as Dan is pushing. To me it comes down to will we or won't we take list price irrespective, so if we think others will go, based on pressure, and start to guide market, I rather be the ones guiding with reduction, list, setting tone with payers, wholesalers, public, etc..

So I would go and lead, but only on the premise we continue to take list and try for net price increase to try to limit full downside of not taking price in that year. I would also do 2020 to allow lead time, to also allow internal assessment of OpEx alterations to support, and if say no, then we don't go.

Also note the 2019 downside on list is only 200M because of what's in budget (6 on NL and 3 on basal), so it could potentially be higher vs budgeted assumptions.

Jen is all set to present, in discussion format set up and knows outside of financials, you'll likely take the questions.

Begin forwarded message:

From: "RDZI (Rich DeNunzio)"

Date: May 26, 2018 at 12:44:03 AM EDT

To: "AMWV (Anne Mette Vogelsang)"

Subject: List Price Decrease PC-052918.pdf

Hi Anne Mette,

Please find the slides for PC attached which include the ranges and likely scenario (down \$85M primarily driven by holding wholesalers whole, full \$100M).

We are going to have to really think and likely get support thinking about coverage gap because although we can be in the gap longer, that means they'll take longer to get there, so we have to understand time to get in, time in and time to get out. For now, in those numbers for CG it does assume we're the only pharma co altering and it does take into account timing in and out, but once other pharma might do it, we're not sure exactly what the avg diabetic person is on and how it would alter in, out, etc. What we do know is we'll have both upside and downside at a given patient level based on concomitant drugs.

From: JRGG (Jen Madrid)

To: SALR (Steve Albers); RDZI (Rich DeNunzio)

CC: FCC (Franco Cognata) Sent: 10/26/2018 3:52:54 PM

List Price Actions - updated document Subject:

Attachments: NNI Thoughts on Recent Manufacturer List Price Actions and Recommendation-v3.docx

#### Steve/Rich,

Attached please find the updated List Price Actions document that provides our recommendation and thoughts around launching a new lower list NDC.

Please let me know if you have any questions.

Thanks, Jen

#### Jennifer Madrid

Assoc. Director, Pricing & Contract Strategy Market Access, Strategy & Innovation

### Novo Nordisk Inc.

800 Scudders Mill Road Plainsboro, NJ 08536









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# NNI Thoughts on Recent Manufacturer List Price Actions and Recommendation

#### **NNI Recommendation on Launching New Lower List NDC:**

- Continue 'Wait and See' approach recommended in June
- Rationale:
  - \$33M of downside identified (NovoLog<sup>®</sup> only)
  - Will cause confusion/complexity in the market
  - Risk of payer backlash or demand for current rebate on new NDC\*
     \*impact not included in above \$33M
  - High likelihood of immediate pressure to take similar action on other products and/or reduce list price/remove from market entirely the higher NDC option
  - Likely won't stop anticipated proposed HHS rule and/or additional Gov't intervention



#### Other Previously Explored Options, Decision, and Rationale:

- List Price Reduction on Insulin Portfolio NNI was aligned to lead and state
  willingness to lower list price within 1 year, but only execute if 'must-haves' were met.
  Viewed as better option vs. lower NDC as reduces complexity, increases transparency,
  and provides more affordable option to HDHP, donut hole, and cash pay patients
  - Decision by BoD to not be first mover nor fast follower
  - As a result, NNI identified strategic reactive response sequence



 Tresiba® Vial List \$ - NNI evaluated a unit discount launch price option but recommended unit parity as discounted price not deemed an affordability solution and expects it will put pressure on Tresiba® device/other inline products



#### Critical Path Considerations to Launch Lower Priced NDC

- Regulatory/FDA
  - FCC connected with AMWV who will help determine if we could do same pack size and what the FDA approval timeframe would be

Product Supply

- Novolog® FlexPen® 4 pack No FDA approval req'd, 4-6mos lead time; I10 vial FDA submission/approval req'd, 12mos lead time
- AMWV to determine lead time of same pack size if possible (could potentially just over-label NDC on current packages for time being)

#### **Other Considerations**

#### Trade

- Need to determine how to mitigate confusion at the pharmacy (i.e. one NDC isn't covered by payer but other is, how does pharmacist know to check vs offer competitive product?)
- Pharmacies (and thus wholesalers) would need to stock both NDCs

#### • PCOR

- Payer contracts need to prepare for contract language updates and negotiations with customers (i.e. do we allow both NDCs on contract? Some may demand current rebate on lower priced NDC, do we allow? (impact not yet cal'd)
- Gov't Pricing/Medicaid NDCs likely connected, latest assessment from PCOR shows lower URA (and potential upside)

#### Portfolio Implications

- If launch lower list price NovoLog® NDC need to be prepared to take similar action of other products in portfolio
- Previous evaluation only included NovoLog® due to lack of sales force/marketing efforts

#### Sales/Marketing Messaging

 Updates to sales pieces, digital resources, DTC adv, EMR prescribing, and copay assistance programs required. Complete PRB review of all resources is required in which new NDC information is added. Limited if just legacy brands

#### Market Access Strategy

 Updates to messaging/resources required. Complete PRB review of any slide decks is required in which new NDC information is added. Limited impact if just legacy brands

#### External Communications

KIAU to develop external communications with input from MLHC

#### Channel Considerations

- PTD payers may lobby CMS to block lower priced NDC because of actuarial impact, but agree to find a way to deliver cost savings to patient. CMS may perceive this negatively because it runs counter to lowering list prices and may create a disincentive for other manufacturers to follow suit
- Comm & Managed Medicaid likely to be a benefit if they can pick and choose which NDCs to place on formulary and/or choose what to reimburse for especially in a non-formulary, non-rebated situation

#### Anticipated HHS proposed ruling

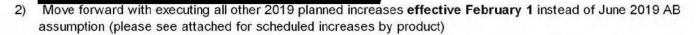
 Announcement seems imminent, perhaps the strongest argument for a 'wait and see approach' due to the uncertainty of what will be included  Announcement could include elimination of safe harbor in government programs (Medicare Part D) and eliminates the benefit provided by multiple NDCs



From:	
To:	SALR (Steve Albers)
CC:	FAJA (Farruq Jafery); UCO (Ulrich Christian Otte); DDME (David Moore); MPDU (Pia D'Urbano); CBLE (Craig Bleifer); BKNO (Bill Knott); RDZI (Rich DeNunzio); FCC (Franco Cognata); EDCI (Ed Cinca); ELIV (Elena Livshina); BLMI (Blandine Lacroix); JTCX (Jack Cox)
Sent:	11/21/2018 8:15:23 PM
Subject:	Re: PC Vote - & Execution of 2019 Planned Price Increases
We can notify bu	at we certainly need PC alignment and above to proceed.
On Nov 21, 2018	8, at 2:43 PM, SALR (Steve Albers) wrote:
Farruq,	
clear that withou	ation and moving forward with one caveat: This week the administration met PhRMA and made at 20-30% price decreases Trump will push for drastic measures like reference pricing (more broadly AID uncapping and looking at pricing for duals. We should see how January goes for Pfizer.
Best,	
Steve	
Sent from my iPl	hone
On Nov 21, 2018	8, at 12:56 PM, FAJA (Farruq Jafery) wrote:
Dear Pricing Comr	mittee,
Please recall that	on Aug 30 PC discussion around 2019 list price, PC concluded on the following:
market su NovoLog,	the market in 4Q18 and Jan. 2019 to determine if other major pharma companies are taking list price. If the pports it, we would continue to take a list price increase in 2019 across our portfolio (with the exception of NovoLog Mix and Novolin)
Estimate)	e to stick to our pricing pledge and do not anchor to another benchmark such as NHE (Nat'l Healthcare y price increases to once per year <u>per brand</u>
Little dity	y price mercases to office per year per brand
January 15, 2019	announced that it intends to take a price increase on 41 of its products (or 10% of its portfolio) effective. The average price increase for the 41 products is 5% (the specific brands have not been disclosed). The all article noted that BMS and Allergan have also issued a notification required by CA law to take an increase in
The latest AB10 fr	om HQ assumes a June 2019 increase across the portfolio.
The latest ADT9 II	chi i ig assumos a dune 2019 morease across the portrollo.
	®

competitors end up taking an increase in January.

To recap, there are 2 votes:



Please provide your vote on both #1 and #2 above. Kindly reply by EOD on Tuesday (11/27).

Kind regards,

Farruq

Farruq Jafery
VP, Pricing, Contract Ops & Reimbursement
Finance & Operations

Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 USA

<2019 List Price Alignment.pptx>