

Part D Senior Savings Model

Model Reach and Scope

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About This Project Report

The Medicare Prescription Drug Benefit Program (Part D) provides outpatient prescription drug coverage to eligible Medicare beneficiaries. To address the high and increasing costs of prescription drugs, the Center for Medicare & Medicaid Innovation (CMMI) implemented the Part D Senior Savings (PDSS) Model test. The PDSS Model is designed to assess the effects of lower, fixed cost sharing for a specified set of Model drugs on beneficiary out-of-pocket costs, medication adherence, and Medicare spending. Insulins are the Model drugs for the first two years, and participating plans cover a set of insulins for a maximum \$35 copayment per one-month supply as part of the Model test.

This report describes the reach and scope of the Model test during its first two years, 2021 and 2022. Specifically, the report provides background on the basic Part D benefit design and changes made to the design by the PDSS Model; describes characteristics of the Model participants, including Model drug manufacturers and Part D parent organizations (the insurers that provide Part D coverage to beneficiaries); compares characteristics of participating Part D plans with those of eligible nonparticipating plans; and presents information on the specific interventions implemented by Model participants. This report is the first in a planned series of four evaluation reports. Later reports will assess the effects of the Model test on participating manufacturers, plans, and beneficiaries enrolled in these plans over time.

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Summary

The Medicare Prescription Drug Benefit Program (Part D) offers outpatient prescription drug coverage to Medicare beneficiaries. To address the high and increasing costs of prescription drugs, the Center for Medicare & Medicaid Innovation implemented the Part D Senior Savings (PDSS) Model test beginning in 2021. PDSS is designed to assess the effects of lower, fixed cost sharing for a specified set of Model drugs on beneficiary out-of-pocket costs, medication adherence, and Medicare spending. Insulins are the Model drugs for the first two years of the PDSS Model test.

The PDSS Model allows participating parent organizations (POs), which are private insurers offering Part D coverage to beneficiaries, to offer in eligible enhanced Part D plans fixed copayments of no more than \$35 per one-month supply per Model drug through the deductible, initial coverage, and coverage gap phases of the benefit. Enhanced Part D plans offer supplemental benefits in addition to those provided as part of the standard Part D benefit. To enable Part D plans to offer these lower copayments, prescription drug manufacturers agree to participate in the Model test and to provide the same discount that they normally pay in the coverage gap phase for brand name drugs (70 percent) before the application of supplemental benefits. Participating POs enter eligible enhanced Part D plans into the Model and negotiate with manufacturers for inclusion of Model drugs on their formularies.

The Model also includes two optional components: (1) an optional narrower first risk corridor available during the first two years (2021 and 2022), which is designed to protect qualifying participating plans from unforeseen financial losses associated with the Model test; and (2) a Rewards and Incentives (R&I) program, which allows participating plans to offer beneficiaries with diabetes or pre-diabetes incentives to participate in medication therapy management (MTM), comprehensive medication review (CMR), or for maintaining a minimum medication adherence threshold.

Approach

We used PDSS plan participation data in combination with benefit design, enrollment, plan formulary and characteristics information, and prescription drug information from Medi-Span to assess the Model's reach and scope in its first two years (2021 and 2022). This report presents a detailed description of the PDSS Model test, its participating manufacturers and POs, and the plans entered by POs into the Model test. We also describe the characteristics of participating and eligible nonparticipating plans to understand differences in Part D benefit design and enrollee characteristics across participants and nonparticipants.

Model Reach

Participation in the first two years of the Model test has been robust. In 2021, all three of the largest U.S. manufacturers (by insulin revenue in 2020) chose to participate, and by 2022, all five U. S. insulin manufacturers participated in the Model test by entering their insulins as Model drugs. Seventy-five POs in 2021 and 106 in 2022 elected to participate in the Model test; very few POs left the Model test after the first year. Nearly half of eligible Medicare Advantage Prescription Drug plans (MA-PDs) and approximately two-thirds of eligible stand-alone prescription drug plans (PDPs) joined the Model test by the second year.

Characteristics of plans that participated in the Model test in 2021 and 2022 were similar across a number of dimensions, including the geographic area in which the plan is offered and enrollee characteristics. For 2021 participants, a higher percentage of enrollees filled at least one insulin prescription included by plans as part of the Model test (called *plan-selected Model insulins*) in the first six months of 2021 compared with enrollees of eligible nonparticipating plans. Participating PDPs had substantially higher total premiums compared with eligible nonparticipating plans in both 2021 and 2022.

Model Scope

Although participating POs included a variety of insulins as part of the Model test, there was no clear pattern in PO selection of one specific manufacturer over another for coverage of the required insulin types (rapid-, intermediate-, short-, and long-acting). A higher percentage of MA-PD formularies included the Novo Nordisk products for the given insulin type, while PDPs were more likely to include Eli Lilly products. A high percentage of MA-PDs (74.7 percent in 2022) and PDPs (85.7 percent in 2022) included the Sanofi long-acting product on their plan-selected Model insulin lists.

More than half of participating MA-PDs and PDPs elected the narrower first risk corridor option, which offered protection against higher-than-expected plan costs, in both 2021 and 2022, although the percentage of PDSS-participating plans electing this option declined substantially from the first to the second year of the Model test. This decline was largely due to fewer new entrants electing the option.

Few POs (five in 2021, 10 in 2022) offered R&I programs in 76 of the 1,730 participating MA-PDs by 2022. The R&I programs targeted beneficiaries with diabetes or pre-diabetes, using prescription drug fills or eligibility for Star Ratings medication measures as the criteria for eligibility. Beneficiaries were generally rewarded with gift cards for completion of specific tasks, including participation in MTM or CMR and, increasingly in 2022, achievement of a minimum medication adherence threshold (generally at least 80 percent of days covered by a filled medication).

Conclusions

The Model test has generated a robust response from eligible POs, with even greater participation in the second year of implementation. Most participating plans offered plan-selected Model insulins at the maximum \$35 per month copayment, and more than half elected the narrower first risk corridor. In the future, the RAND Corporation will assess its effects on key outcomes, such as costs, medication adherence, and improved health.

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Chapter 1. Introduction

The Medicare Prescription Drug Benefit Program (Part D) provides outpatient prescription drug coverage through private health insurers for over 40 million Medicare beneficiaries. Beneficiaries may choose between stand-alone prescription drug plans (PDPs) that operate alongside fee-for-service (FFS) Medicare or enroll in Medicare Advantage Prescription Drug plans (MA-PDs) that offer combined coverage for health care services and outpatient prescription drugs.

The outpatient prescription drug market has seen substantial change in recent years, with the arrival of important new drugs to the market¹ and the introduction of generic competitors for several major brand name drugs. Although Part D has broadly increased access to outpatient prescription drugs for Medicare beneficiaries, high and increasing prescription drug prices remain a concern for beneficiaries, Part D plans, the Medicare Program, and policymakers.²⁻⁴

In particular, list prices for insulin, a drug used by over 3.3 million Medicare beneficiaries to treat diabetes, nearly tripled from 2002 to 2013 and have continued to increase since then.^{2, 5, 6} List prices, which are the prices set by manufacturers as the cost of a drug, are not the prices paid by beneficiaries nor the final net price paid by Part D plans. Part D plans reimburse pharmacies for the cost of Part D prescription drug fills and negotiate discounts (called *rebates*) with manufacturers, which are paid by manufacturers to the Part D plans and lower the final cost of those drugs paid by plans.

Most Part D plans currently offer insulin under flat-fee copayments during the initial coverage phase of the Part D benefit (see page 3 for a detailed discussion of coverage phases).⁷ However, insulin users who are not eligible for reduced cost sharing under the Part D low-income subsidy (LIS) usually pay 25 percent of the price paid to the pharmacy (the drug's negotiated price) when filling medications in the coverage gap phase of the benefit. Therefore, beneficiaries with diabetes can be exposed to price shocks when moving from the initial coverage to gap phase of the benefit, which could put at risk their reliable and affordable access to insulin. That, in turn, could increase the risk of complications, such as kidney failure, heart attacks, vision loss, and death, if beneficiaries do not adhere to their insulin regimens.⁸⁻¹⁰

To help address these concerns, the Center for Medicare & Medicaid Innovation (CMMI) implemented the Part D Senior Savings Model (hereafter referred to as “the PDSS Model” or “the Model test”) in 2021. The PDSS Model tests the effects of changes to the Medicare Coverage Gap Discount Program on out-of-pocket (OOP) costs for beneficiaries, adherence to insulin regimens, and costs to the Centers for Medicare & Medicaid Services (CMS).¹¹ The remainder of this chapter provides additional background on the Part D benefit and how the benefit changes under the PDSS Model.

Part D–Related Terms

There are many important terms related to Medicare Part D coverage. This text box provides a summary of these terms and their definitions.¹²⁻¹⁴

Part D entities

- **Parent organization (PO):** a legal entity with a controlling interest in one or more PDP sponsors or Medicare Advantage (MA) organization contracts
- **Contract:** a suite of plans offered by the same Part D PO and governed by the same agreement with CMS
- **Plan:** a set of specific Part D benefits offered to potential enrollees; plans are sometimes referred to as plan benefit packages
- **Segment:** an offering within an MA-PD that targets geographic areas within the plan's service area

Coverage-related terms

- **Formulary:** a list of drugs covered by a plan
- **Deductible:** part of the coverage design in which a beneficiary pays 100 percent of drug costs at the beginning of the plan year, up to a certain dollar amount
- **Tier:** an approach to cost sharing in which different drugs appear on different tiers, with cost sharing generally increasing within higher tiers
- **Cost sharing:** the amount a beneficiary pays when filling a prescription at the pharmacy. There are two types of cost sharing:
 - **Coinsurance:** the beneficiary pays a percentage of the price
 - **Copayment:** the beneficiary pays a fixed dollar amount.

Prescription drug prices

- **List price:** the price that the manufacturer sets as the cost of the drug
- **Negotiated price:** reimbursement paid by the plan to the pharmacy for a given prescription drug fill by an enrollee. This price is negotiated between the plan and the pharmacy and includes the drug's ingredient cost plus a dispensing fee. The negotiated price is used to determine the coinsurance that beneficiaries pay when filling a prescription.
- **Rebate:** a discount negotiated between the PO or its pharmacy benefit manager (PBM) and manufacturers, which is paid by manufacturers to the PO or PBM for each prescription drug fill. Rebates are based on inclusion on the formulary, coverage within a lower cost sharing tier, or a specified volume of prescriptions filled.
- **Net price:** the final price paid by the Part D plan for a given drug, which is the negotiated price minus any rebates received

Part D Coverage and Benefit Design

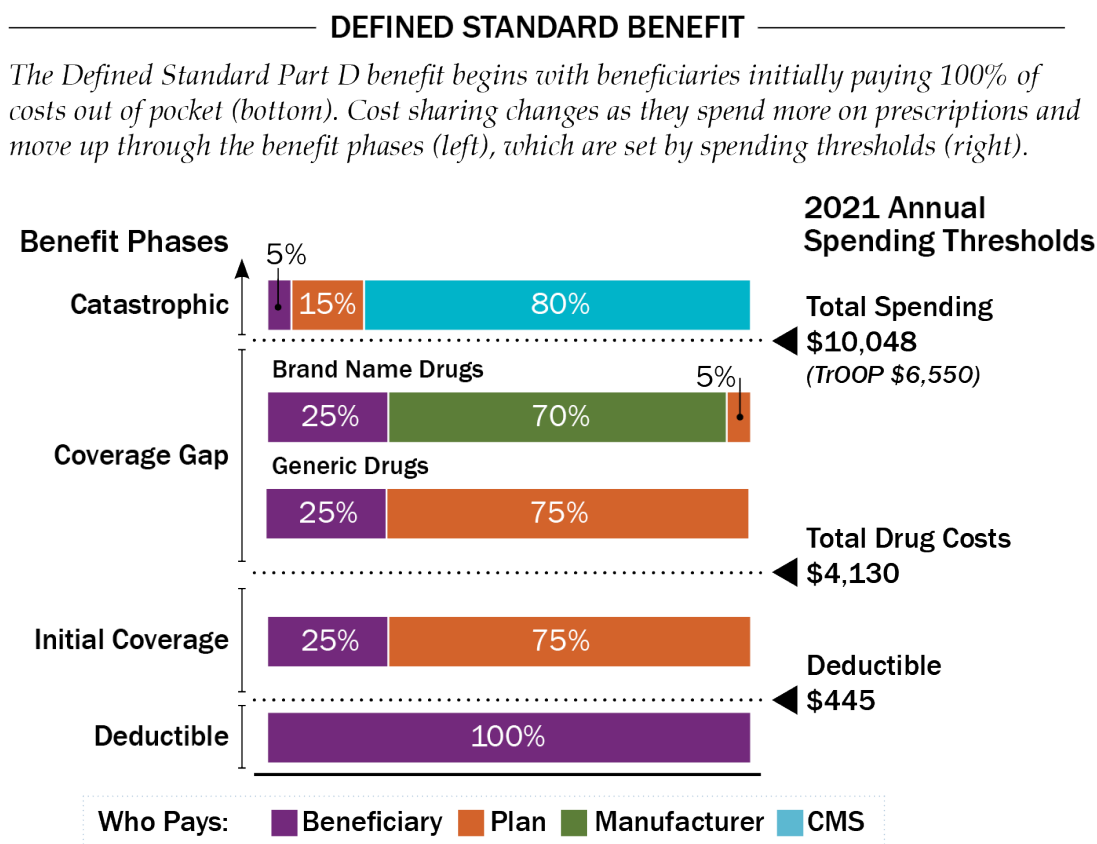
Parent organizations (POs) are entities that offer Part D coverage to Medicare beneficiaries through MA-PDs and/or stand-alone PDPs. POs establish formularies, which are lists of covered drugs. Pharmacy and Therapeutics committees made up of providers and pharmacists consider available evidence for a specific drug, in addition to its cost and substitutes, before including a drug on the formulary.¹⁵ Formularies must meet CMS requirements,¹⁶ which require coverage of at least two drugs in each category or class (for example, antidiabetics).ⁱ

ⁱ CMS also requires plans to cover all or substantially all drugs in six categories or classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

In addition to the formulary, POs have some flexibility in designing benefits to appeal to potential enrollees. The defined standard Part D benefit includes four benefit phases (summarized in Figure 1.1 using 2021 spending thresholds). Beneficiaries who are *not* eligible for the LIS pay different cost sharing amounts for the same drug depending on the phase:

- **deductible**, in which beneficiaries pay the full cost up to \$445
- **initial coverage**, in which beneficiaries pay 25 percent coinsurance (percentage of the price paid to the pharmacy) up to \$4,130 in total drug costs. Plans pay the remaining 75 percent.
- **coverage gap**, in which beneficiaries pay 25 percent coinsurance and manufacturers provide 70 percent discounts on brand name and biosimilar drugs (the Medicare Coverage Gap Discount Program), until beneficiary and manufacturer spending reaches \$6,550 (a total OOP cost measure referred to as true out-of-pocket, or TrOOP). Plans pay the remaining 5 percent. Beneficiaries taking generic drugs pay 25 percent, and plans pay 75 percent.
- **catastrophic**, in which beneficiaries pay the greater of 5 percent coinsurance or \$3.70/\$9.20 for generic and brand name drugs, respectively, for the rest of the year.

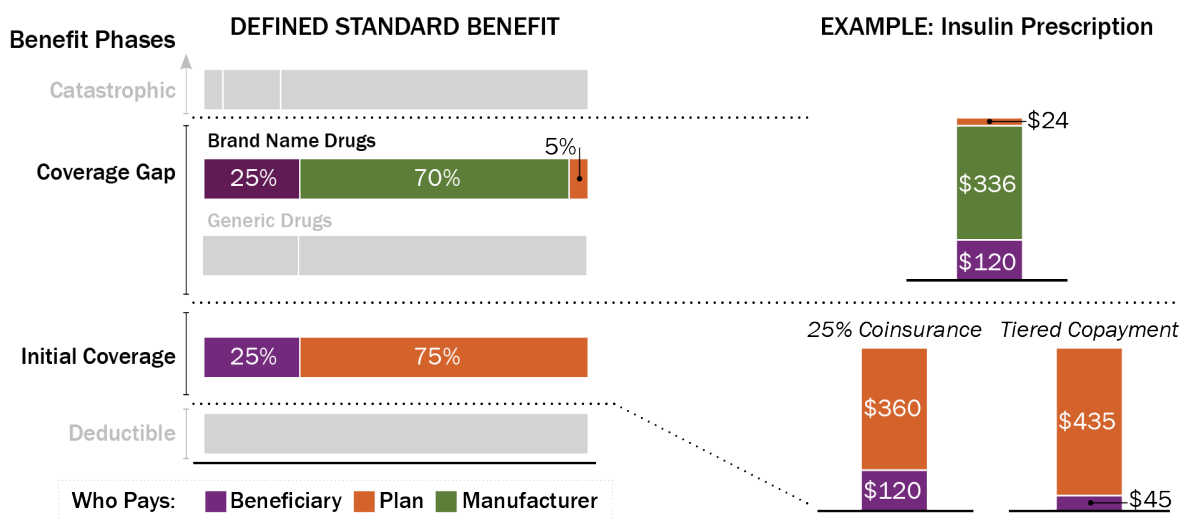
Figure 1.1. Part D Benefit Design and Cost Sharing



POs can—and often do—choose to vary their benefit design from the defined standard benefit shown in Figure 1.1. While still offering coverage that is equivalent in value to the defined standard benefit, POs may reduce or eliminate the deductible or offer tiered cost sharing with flat-fee copayments in the initial coverage phase (shown in the bottom right-hand side of Figure 1.2 as an illustrative \$45 copayment for insulin, to the right of the 25 percent basic benefit payment of \$120). The coverage options that are equivalent in value to the defined standard benefit are collectively referred to as *basic* Part D plans. On average, CMS pays for 74.5 percent of the costs (called the *direct subsidy*) for basic Part D coverage, while beneficiaries pay the remaining 25.5 percent as the basic premium.¹³

When Part D was implemented in 2006, beneficiaries paid 100 percent of their drug costs in the coverage gap. Congress made cost sharing in the coverage gap equal to the cost sharing applied in the initial coverage phase (25 percent) in 2019 with the Bipartisan Budget Act of 2018, which accelerated an in-progress closure of the gap initiated by the Affordable Care Act.¹⁷ However, because of the flexibility in designing Part D benefits that differ from the 25 percent coinsurance in the initial coverage phase, beneficiaries who are enrolled in plans with tiered copayments and enter the coverage gap could still experience a substantial increase in their per-fill OOP insulin costs¹⁸ (from \$45 to 25 percent of the cost of the drug, or \$120, in the illustrative example in Figure 1.2). Beneficiaries who face such OOP cost increases for insulin and other diabetes drugs with high list prices are at greater risk for experiencing disruptions in adherence, relative to those whose OOP costs are consistent⁹ (e.g., beneficiaries eligible for the Part D LIS or those taking drugs with low list prices).

Figure 1.2. Illustrative Example of Copayments for a \$480 Insulin Prescription



In addition to the basic Part D benefit offerings, POs are able to offer supplemental benefits to their enrollees—for example, by covering drugs that Medicare excludes from Part D coverage

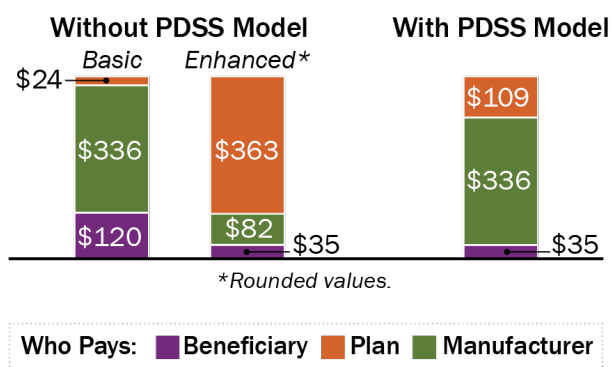
or by lowering cost sharing for beneficiaries in the coverage gap phase. These plans are called *enhanced plans*. Medicare does not pay for the enhanced benefits offered by a plan. Therefore, beneficiaries enrolling in enhanced plans may pay an additional “supplemental premium” to receive them. Nonetheless, beneficiaries enrolling in MA-PDs may pay very low or no enhanced premiums, because these plans are able to use additional funds received based on any difference between their medical services bid and the local area benchmark (“rebate dollars”) to buy down some or all of the Part D basic and supplemental premiums. PDPs do not have this flexibility.

Changes to the Part D Benefit Under the PDSS Model

The PDSS Model examines whether changes to the Part D benefit design can increase the predictability of beneficiaries’ OOP costs by enabling participating plans to offer an enhanced benefit with a maximum \$35 fixed copayment per one-month supply through all but the catastrophic phase of the Part D benefit. This change is a required Model component. The first two years of the Model test (2021 and 2022) focus solely on insulin.¹¹

Figure 1.3 illustrates what beneficiaries, manufacturers, and POs would pay for a hypothetical \$480 insulin prescription filled in the coverage gap,¹⁹ first without the PDSS Model and then as part of the Model test.

Figure 1.3. Coverage Gap Payment Amounts for a \$480 Insulin Prescription Fill, Without and With the PDSS Model



Without the PDSS Model, the application of supplemental benefits before the manufacturer discount means that Part D plans would likely be unwilling to offer the substantial supplemental benefits in the coverage gap, because they would be responsible for a higher per-fill payment (\$363 versus \$24, as shown in Figure 1.3). Specifically, if plans were to offer supplemental benefits with a \$35 beneficiary copay (instead of \$120) in the coverage gap without PDSS, the manufacturer discount (70 percent) would be calculated based on the amount that the beneficiary would have to pay after the application of supplemental benefits.²⁰ Therefore, to achieve a \$35 copayment in the coverage gap for a \$480 insulin prescription fill, the plan would need to

calculate the dollar amount for which a 70 percent discount would result in the \$35 copay. This amount is \$117, which means that the plan would have to pay \$363 (\$480 minus \$117) per one-month supply, while the manufacturer discount would be 70 percent of \$117, or \$82.

With the PDSS Model, however, plans would pay \$109 for a \$480 insulin prescription fill because the discount would be applied *before* the supplemental benefits. That is, the manufacturer discount would be 70 percent of \$480, or \$336, and the beneficiary would pay \$35 of the remaining \$144. By applying the manufacturer discount *before* supplemental benefits, plans would pay less per fill than they would if they offered enhanced coverage without the PDSS Model. Plans would be able to offer beneficiaries lower OOP costs, as well as lower supplemental premium costs, relative to enhanced benefit offerings in the absence of the Model test. This shift in the application of supplemental benefits via the Model test allows participating POs to offer benefit packages that may be more attractive to their beneficiaries.

To be able to apply the manufacturer discount before the supplemental benefits, manufacturers also have to apply to participate in the PDSS Model. The PDSS Model allows manufacturers who join the Model test to provide the 70 percent manufacturer gap discount on Model drugs *before* plans apply the enhanced coverage, instead of *after*, as is currently the case in the existing Medicare Coverage Gap Discount Program. Therefore, the manufacturer discount stays the same as that provided under basic coverage (70 percent of the negotiated pharmacy price of the drug). Manufacturers participating in the Model test contribute the same dollar value discount (\$336), and thus the same proportion of costs, compared with the basic benefit without PDSS. In exchange, manufacturers might see an increased volume of insulin utilization because of the lower copayments to which beneficiaries enrolled in PDSS-participating plans have access. Because of this increased volume, manufacturers may end up paying more in rebates to Part D plans, especially in the coverage gap phase in which both the discount and rebate payments would apply.

Changes in the discount program also make the PDSS Model more financially attractive to POs than the status quo. As a result of this policy change, it is less costly for POs to offer enhanced plans with lower, fixed cost sharing (maximum \$35 per one-month supply) for covered insulins in the deductible, initial coverage, and coverage gap phases. Participating POs may choose which Model insulins (across the participating manufacturers' Model insulin lists) to include in the \$35 enhanced benefit, but they are required to cover at least one pen and one vial form of insulin from each of the four main types of insulins (rapid-, intermediate-, short-, and long-acting). Chapter 2 provides more information on insulins and more detail on which are offered in the Model test. The Model insulins covered by plans are called *plan-selected Model insulins*.

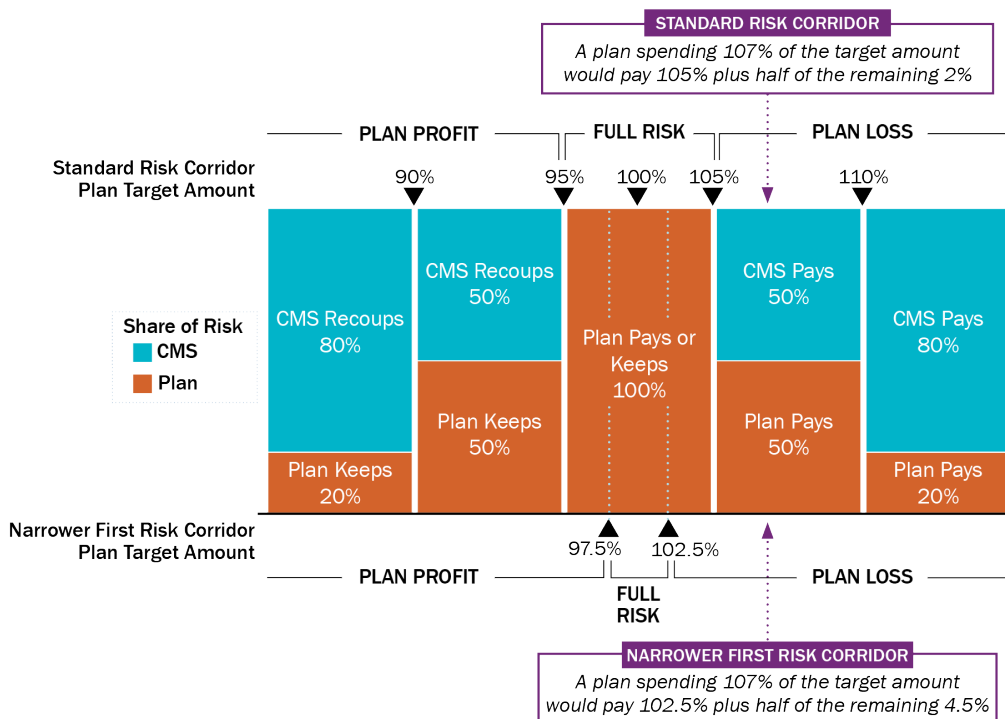
Part D plans that choose to participate in the PDSS Model do not generally pay the higher costs associated with offering supplemental benefits. Although MA-PDs are able to buy down the premium with their rebate dollars, PDPs do not have this option and might pass supplemental benefit costs on to beneficiaries in the form of higher premiums. Plans may want to participate in

order to offer beneficiaries taking insulin a steady, fixed copayment through the first three benefit phases. It is true, however, that they may see a disproportionate increase in enrollment of beneficiaries taking insulins, which is why CMS created the optional component of the narrower first risk corridor (described in the next section), to provide some additional protection against unforeseen losses.

Optional Model Components

The Model test includes two optional components. The first—a narrower first risk corridor—is intended to encourage Model participation among POs by reducing their financial risk. The Part D benefit includes a set of symmetric risk corridors to protect plans from unanticipated higher plan costs for the defined standard benefit, which is associated with enrolling beneficiaries with poorer health who require more expensive prescription drugs, that require plans to share any unanticipated profits that arise from lower spending on prescription drugs for their enrolled beneficiaries. Currently, the Part D risk corridors are set as two 5 percent corridors on either side of the plan target amount (see Figure 1.4). As an example, a plan with actual spending at 107 percent of the plan target amount would pay for the first 5 percent corridor above the target amount and would share in the losses with CMS of the remaining 2 percent.

Figure 1.4. Medicare Part D Risk Corridors



Plans participating in the PDSS Model can choose to participate in a narrower first risk corridor threshold, whereby the first risk corridor is narrowed from 95–105 percent to 97.5–102.5 percent. This may increase plan participation in the Model test by providing additional protection if losses are incurred, but plans would also share a greater amount of any unanticipated profits with CMS. Plans choosing this option will only receive the narrower risk corridor payments if they enroll a statistically significantly larger share of beneficiaries taking plan-selected Model insulins, defined as enrollment that is at least one standard deviation above the mean enrollment for the plan type.²⁰ As shown in Figure 1.4, plans eligible for the narrower first risk corridor and spending 107 percent of the target amount would pay 102.5 percent plus half of the remaining 4.5 percent.

The second optional component is a Part D Rewards and Incentives (R&I) program, which POs may offer to beneficiaries diagnosed with diabetes or pre-diabetes who use insulin or other drugs. The R&I component is intended to encourage beneficiaries to engage in healthier behaviors and improve their medication adherence. R&I offerings could include incentives such as a gift card for the completion of a medication adherence educational consultation, a disease education program, or a care management program.

Purpose of This Report

CMMI has contracted with the RAND Corporation to evaluate the effect of the Model test. The goal of this first report is to describe the scope and reach of the Model test in its first two years, 2021 and 2022. Chapter 2 provides a brief overview of insulin and its history, describes PDSS-participating manufacturers, and characterizes the insulins that they entered into the Model test. Chapter 3 presents the characteristics of participating POs and the plans that they entered into the Model test during the first two years. It also compares Model-participating with eligible but nonparticipating plans. Chapter 4 describes the interventions that were implemented through the Model test, including the Model insulins that participants chose to include, as well as optional Model components that they implemented. Chapter 5 offers concluding observations based on Model participation in the first two years. Tables in the appendix provide additional detail on insulins entered into the Model test by participating manufacturers (Appendix A); dosage-form level of coverage and cost sharing information for both plan-selected Model drugs and additional insulins, by MA-PDs and PDPs (Appendix B); and PO R&I programs offered in 2021 and 2022 (Appendix C).

Future reports will provide a detailed description of our evaluation approach, including an identification of comparison groups, a description of the difference-in-differences methodology, an approach to collecting and analyzing primary data from Model participants and beneficiaries, and a strategy for combining quantitative and qualitative analytical approaches. The evaluation results will focus on the impact of the Model test on key outcomes of interest, such as OOP costs for beneficiaries, adherence to insulin regimens, and CMS costs.

Chapter 2. Model Insulins and Manufacturers

Model Test Insulins



KEY TAKEAWAYS

- By 2022, all five drug manufacturers that market and sell their insulin products in the United States—Eli Lilly, Novo Nordisk, Sanofi, MannKind Corporation, and Mylan Pharmaceuticals, a Viatris company—had joined the Model test.
- The U.S. insulin market is dominated by two manufacturers (Novo Nordisk and Eli Lilly) that produce 70 percent of all available insulins on the market.
- Thirty insulins were entered into the Model test by 2022, representing all insulins sold by participating manufacturers in that year.
- Novo Nordisk and Eli Lilly are also the only manufacturers that produce all four types of insulin (rapid-, short-, intermediate-, and long-acting) that PDSS-participating plans must include for the maximum \$35 copayment.

This chapter describes Model insulins and their manufacturers, focusing on the first two years of the Model test (2021 and 2022). We first provide a brief overview of insulin and its history and define key insulin terminology. We then describe PDSS-participating manufacturers and the insulins that they entered into the Model test.

Insulins

Naturally secreted by the pancreas, insulin is a hormone that controls blood sugar in the body by helping it use and store glucose.²¹ Diabetes mellitus is a chronic condition in which the body either loses its ability to produce insulin or to do so efficiently, which leads to increased levels of blood sugar (hyperglycemia). There are two types of diabetes.²² Type 1 diabetes occurs when the body either cannot or does not produce enough insulin; the first line of treatment for Type 1 diabetes is pharmaceutical insulin administration. Type 2 diabetes, which is the most prevalent type, occurs when the body does not produce enough insulin or does not respond to insulin and requires other medication to control blood sugar levels. For patients with Type 2 diabetes, insulin is generally initiated as a later line of treatment, most commonly after oral medications have been used.²³

Brief History of Insulin

Originally discovered in 1921, insulins are biologic drugs.ⁱⁱ The first insulins were manufactured by Eli Lilly from animals. Initially, there were many problems with the

ⁱⁱ *Biologics* are large-molecule, complex compounds that are manufactured from human, animal, or plant cells. Biologics are different from small-molecule drugs, which can be chemically synthesized (e.g., aspirin), because of their size and complexity, manufacturing processes, special storage and handling needs, and methods of administration.

manufacturing process. Bovine and porcine insulins were not pure enough for people to tolerate well, the potency of manufactured insulins varied widely, and people often experienced toxic reactions.²⁴ Because insulin was in high demand, companies around the world worked to develop purer, more potent, and easier-to-administer insulins.²⁵

Several additional scientific developments in the field of insulin therapy occurred during the 20th century: the purification of animal insulins, the development of insulins with prolonged duration of action, the creation of human insulins, and the introduction of recombinant DNA (rDNA) technology that helped produce human insulins biosynthetically from cultivation in bacteria or yeast.

Moreover, the mode of insulin administration evolved as well. Initially, injection using a syringe was the most common way to administer insulin. Patients required multiple daily injections because the effects of early insulin did not last long. Syringes and needles were reusable and had to be properly sterilized before reuse. Specialized insulin syringes were created in 1924, and technological advances over many years allowed the development of additional insulin administration options, such as pumps (1963), pens (1985), and inhalers (2014).²⁶

In addition, drug manufacturers have developed a wide range of insulins that either start acting more rapidly, such as insulin aspart (NovoLog[®]) created by Novo Nordisk in 2000, or that lower glucose levels more evenly over a longer period of time, such as insulin glargine (Lantus[®]) created by Sanofi-Aventis in 2000. In 2014, MannKind developed Afrezza[®], an ultra-rapid inhaled insulin, which lowers blood sugar quickly and does not require injections. Inhaled via a dedicated device, Afrezza is the only inhaled insulin currently on the U.S. market.²⁷

Because of the complexities of manufacturing biologics, so-called generic and low-cost versions of insulin have historically been largely unavailable.^{iii, 28-31} As a result, the insulin market has long been dominated by brand name drugs, which allows POs to negotiate for rebates off the drugs' list price. These rebates substantially lower what plans and the Medicare Program pay for insulin. Specifically, negotiations that result in some insulins and other drugs being placed in a favorable formulary tier relative to competitors can achieve discounts exceeding 50 percent of the list price.³² Although these rebates lower the net prices paid by plans and allow plans to keep premium increases low, they do not lower the negotiated prices (i.e., pharmacy prices) used to calculate beneficiary deductibles or coinsurance amounts.

More recently, competition has increased largely because of the availability of "biosimilar" competition. Biosimilars are not the same as generic drugs because biologic products cannot be exactly replicated and thus face a different set of licensing requirements. However,

ⁱⁱⁱ *Generic drugs* are medications created to be exact chemical copies of existing brand name drugs. This means that small-molecule generic drugs have been shown to have the same active ingredients as their brand name originator drugs and have the same mechanism of action.²⁸ Because insulin is a biologic made from living organisms, it is virtually impossible to manufacture an exact copy (and therefore be labeled as generic).²⁹ Despite these differences, the insulin market uses the term *authorized generic* to refer to an approved brand name drug that is marketed without the brand name.³⁰ For example, Novo Nordisk offers insulin aspart as an authorized generic version of its brand name Novolog insulin.³¹

manufacturers of biosimilar insulins must still show that their drugs work in the same way as the reference biologics. Biosimilars are now approved through the 351(k) Biologics License Application path that was created by the Biologics Price Competition and Innovation Act of 2010.³³ There are several follow-on or quasi-biosimilar insulins that were approved through an older pathway (Federal Food, Drug, and Cosmetic Act, Section 505(b)(2)),³⁴ which are not technically called *biosimilars*. This older pathway was used for drugs that were neither exact copies nor completely new molecular entities.³⁵ The introduction of authorized generic versions of some insulin products³⁶ (offered with lower list prices and no rebates) and the approval of biosimilar insulins have introduced list price competition into the insulin market.

In 2020, the U.S. Food and Drug Administration (FDA) approved Semglee[®], the first biosimilar insulin for insulin glargine³⁷ (Lantus) and, in 2021, gave it interchangeable status, which indicates that the product can be considered a direct substitute for Lantus and is eligible for pharmacy-level substitution (depending on state law), similar to small-molecule generics. Semglee was launched as both a branded and unbranded product³⁸ (insulin glargine-yfgn), with markedly different list prices (presumably because of larger rebates paid for the branded version of this product). Although the price of the unbranded product is much lower than that of Lantus (the originator drug), the difference in list prices between Semglee and Lantus is only about \$20.³⁹

Patients generally need a prescription for insulin. However, because of variation in health insurance access across the United States and variation in insulin affordability for those who are insured, manufacturers have recently started creating versions that can be sold cheaply over the counter (OTC).⁴⁰ Two types of older insulins (human insulin regular and human insulin NPH, or Neutral Protamine Hagedorn insulin, also known as isophane insulin) are available as OTC products, but they require more time to reach their maximum ability to lower blood sugar levels.⁴¹ Given that insulin requires close monitoring by both patient and physician, OTC insulins have generated controversy for causing negative health effects when patients substitute insulin products that do not work in the same way as prescribed insulins.⁴²

PDSS-Participating Insulin Manufacturers

The global insulin market is dominated by three manufacturers: Eli Lilly, Novo Nordisk, and Sanofi.⁴³ Five drug manufacturers market and sell their insulin products in the United States, with a total U.S. insulin revenue of approximately \$7.5 billion (Table 2.1). Three insulin manufacturers joined the Model test in 2021 (Eli Lilly, Novo Nordisk, and Sanofi) and two others joined in 2022 (MannKind Corporation and Mylan Pharmaceuticals, a Viatris company [henceforth referred to as Viatris]). By 2022, all five insulin manufacturers participated in the PDSS Model. Together, these PDSS-participating insulin manufacturers were responsible for at least \$16.9 billion in U.S. insulin (\$7.5 billion) and noninsulin (\$9.4 billion) diabetes drug sales in 2020 (Viatris data were not available).

Table 2.1. U.S. Net Revenues, by Manufacturer, 2020

Manufacturer	Total	Insulin	Noninsulin Diabetes Drugs	Nondiabetes Products	Share of Insulin Market by Revenue (%)	Share of Part D Insulin Market by Volume (%)
Eli Lilly	\$14.2 billion	\$3.2 billion	\$4.7 billion	\$6.3 billion	42%	28%
Novo Nordisk	\$8.8 billion	\$2.6 billion	\$4.7 billion	\$1.5 billion	35%	41%
Sanofi	\$15.4 billion	\$1.7 billion	\$2.3 million	\$13.7 billion	23%	32%
MannKind ^a	\$32 million	\$32 million	\$0	\$0	< 1%	< 1%
Viatrix ^{a, b}	\$12 billion	N/A	N/A	N/A	N/A	N/A
Total:	\$38.4 billion	\$7.5 billion	\$9.4 billion	\$21.5 billion		

SOURCE: Insulin sales information was obtained from each manufacturer's publicly available annual report.⁴⁴⁻⁴⁸

NOTE: Share of the Part D insulin market by volume was calculated from the publicly available Part D dashboard for 2020. For each manufacturer, we have broken down the total and percentage of revenue (or net sales) after rebates in the United States from insulin products, noninsulin diabetes products, and nondiabetes products. We also added the total amount of revenue (or net sales) for each company's insulin and calculated the percentage of the insulin market for each company by revenue. We converted euros and Danish krone to U.S. dollars using Internal Revenue Service average annual conversion rates for 2020. N/A = not available.

^a Joined the Model test in 2022.

^b Data not available for 2020.

Eli Lilly is a U.S. company founded in 1876 and headquartered in Indiana. It has four core research and development areas (diabetes, oncology, immunology, and neurodegeneration) and an emerging focus on pain management. Eli Lilly was the first manufacturer of insulin products—its scientists won a Nobel Prize for insulin discovery in 1923—and, as noted earlier, the company was among the first to make insulin using rDNA technology. It launched Basaglar, the first biosimilar insulin approved by the FDA in 2015, using the follow-on biologic approval pathway. Eli Lilly's other noninsulin diabetes products include a glucagon-like peptide 1 (GLP-1) agonist, a sodium-glucose co-transporter 2 (SGLT-2) inhibitor, and a dipeptidyl peptidase 4 (DPP-4) inhibitor. Its total U.S. revenue in 2020 was \$14.2 billion,⁴⁴ roughly one-fifth of which came from insulin sales (\$3.2 billion). Eli Lilly had the largest share of the U.S. insulin market by revenue (42 percent), and its highest selling insulin product in 2020 was Humalog[®].

Novo Nordisk is a Danish company founded in 1923 and headquartered in Bagsværd, Denmark. Novo Nordisk has four areas of focus: diabetes, obesity, hemophilia, and growth hormone-related disorders. Novo Nordisk also first started selling insulin products in 1923. In 1985, it introduced the NovoPen[®] device, the first insulin pen that gave patients a simple means of injecting a premeasured dose of insulin.⁴⁹ Novolin[®], a short-acting insulin, received FDA approval in 1991. Novo Nordisk's other noninsulin diabetes products include several GLP-1 agonists. Its total net sales in the United States in 2020 were \$8.8 billion, approximately one-third of which came from insulin sales (\$2.6 billion). Novo Nordisk had the second largest share of the U.S. insulin market by revenue (35 percent) but the highest share of Part D insulin market

by volume (41 percent); its highest selling insulin product in 2020 was NovoRapid[®]/NovoLog, a fast-acting insulin aspart.

Sanofi is a French company founded in 1973⁵⁰ and headquartered in Paris, France. It merged with Aventis to become Sanofi-Aventis in 2004 but changed its name back to Sanofi in 2011. Sanofi's current research areas are immunology and inflammation, oncology, neurology, rare blood disorders, rare diseases, and vaccines. Known for its insulin purification technology, Hoechst (a German life-sciences company that became Aventis in 1999) researchers launched the first semi-synthetic human insulin in 1983. In 2000, the FDA approved Lantus (insulin glargine), the first long-acting insulin developed by Sanofi. Its total net sales in the United States in 2020 were \$15.4 billion,⁴⁷ roughly one-tenth of which came from insulin sales (\$1.7 billion). Insulin constitutes almost all of Sanofi's diabetes products (the company only reported \$2.3 million in revenue from one sulfonylurea diabetes drug in 2020). Sanofi had the third largest share of the U.S. insulin market by revenue (23 percent); Lantus (insulin glargine) was its highest selling insulin product in 2020.⁴⁷

MannKind is a U.S. company founded in 1991 and headquartered in Westlake Village, California. It is a biopharmaceutical company that focuses on the discovery, development, and commercialization of therapeutic products for diabetes and hypertension. It manufactures only one insulin product: an inhaled, rapid-acting human insulin called Afrezza, approved by the FDA in 2014. MannKind's net revenue was \$32 million in 2020, all of which came from Afrezza sales. MannKind's share of the U.S. insulin market by revenue was less than 1 percent.⁴⁵

Viatriis is a U.S. company founded in 2020 and headquartered in Canonsburg, Pennsylvania. It was formed after Upjohn (Pfizer's off-patent medicine division) merged with Mylan. Viatriis manufactures a variety of brand name, generic, biosimilar, and OTC products, such as the well-known brand name drugs Lipitor[®], Viagra[®], and Xanax[®]. Viatriis had a total revenue of \$12 billion in 2020, of which \$4.2 billion net sales were in North America. Viatriis produces both Semglee and its biosimilar. Because the FDA approved Semglee on June 11, 2020, Viatriis did not report any revenue data from this drug in its 2020 annual report;⁴⁸ however, CMS spent less than \$300,000 on Semglee in 2020.⁵¹

Insulin Terminology

Clinicians' choice of an insulin product to be prescribed takes into account such factors as the clinical profile of the medication, patient preference, and convenience factors, such as the frequency of administration, access to care, and personal support.⁵² In describing insulins included in the PDSS Model, it is important to define some key terms, including active ingredients and insulin types.

- The **active ingredient** is the key compound of interest in the given product, which may be referred to as the drug's "generic name" when generic versions exist. There can be multiple manufacturers for a given active ingredient, and some manufacturers will make more than one version of an active ingredient.
- Insulins are classified according to their clinically relevant type, which depends on how quickly they start working, when they peak, and how long their effects last. There are four main **insulin types**: rapid-, short-, intermediate-, and long-acting. The rapid- and short-acting insulins are injected prior to eating to manage glucose after a meal (called *bolus* coverage). The longer-acting formulations are administered once daily to provide consistent insulin levels to manage fasting and nighttime glucose (called *basal* coverage). Ultralong-acting insulins are a subtype of long-acting insulins that offer more sustained insulin coverage than other insulins that provide basal coverage while reducing the potential for hypoglycemia⁵³ (low blood sugar level).
- In addition to single-type products, some **pre-mixed insulin** products combine short- and long-acting insulins (e.g., insulin lispro protamine and insulin lispro–Humalog mix) in various proportions.⁵⁴ These pre-mixed insulins are intended to minimize the number of injections.
- Some insulins are **combination products** that combine insulin with other antidiabetic drugs to help maintain better blood sugar control. There are two main combination products on the market: insulin degludec/liraglutide and insulin glargine/lixisenatide.^{55, 56} Liraglutide and lixisenatide are both incretin mimetics that help the pancreas secrete appropriate levels of insulin.
- Insulins also vary in their dosage. They are available in a concentration of 100 units/mL (U-100), 200 units/mL (U-200), 300 units/mL (U-300), and 500 units/mL (U-500). When larger insulin doses are required, **concentrates**, or products with higher insulin doses, are used to minimize the number of times per day that the insulin needs to be administered.⁵⁷

Insulin Types

Rapid-acting insulins: Taken at mealtime; start working in approximately 15 minutes, peak in an hour, last up to 4 hours.

Short-acting insulins: Taken at mealtime; start working in approximately 30 minutes, peak in 2–3 hours, and last up to a half-day.

Intermediate-acting insulins: Taken once a day; start working 1–1.5 hours later, peak 4–8 hours after being taken, and last up to 18 hours. If taken at bedtime, these insulins are likely to peak at predawn hours.

Long-acting insulins: Taken once a day or less frequently; start working 3–6 hours later and evenly lower glucose levels throughout the day. The effects of some ultralong-lasting insulins can last up to 42 hours.

Syringes specific to the insulin concentration are needed to reduce error in administration. Humulin® R U-500 is the most concentrated FDA-approved insulin on the market. It is five times more concentrated than U-100 insulin,⁵⁸ and it is available in its own syringe⁵⁹ or as a pen; it is therefore considered as a separate insulin type.

Model Drugs

Participating manufacturers entered 30 unique insulins into the Model test, which we defined by the combination of type, manufacturer, drug name, and active ingredient for each insulin. Table 2.2 summarizes the characteristics of the insulins offered in the Model test by each manufacturer. All PDSS-participating manufacturers entered all of their unique insulins into the Model test (see Appendix A for additional details). Novo Nordisk entered the most insulins ($n = 11$), followed closely by Eli Lilly ($n = 10$). Sanofi entered five, Viatris entered three, and MannKind entered one insulin.

Table 2.2. Number of Model Insulins by Type and Manufacturer

Manufacturer	Rapid-Acting	Short-Acting	Intermediate-Acting	Long-Acting	Mixed	Combination	Concentrate	Total
Eli Lilly	3	1	1	1	3		1	10
Novo Nordisk	3	1	1	2	3	1		11
Sanofi	2			2		1		5
MannKind	1							1
Viatris				3				3
Total	9	2	2	8	6	2	1	30

SOURCE: Adapted from the Model formularies posted to the CMMI website and provided to the authors by the PDSS-monitoring contractor. We categorized drugs in collaboration with CMMI using American Diabetes Association (ADA) guidelines⁶⁰ and FDA package labels.⁶¹ We used Medi-Span, a therapeutic classification scheme, to harmonize drug names and active ingredients and to identify the manufacturer.

In 2021, PDSS-participating POs were required to offer at least one vial and one pen dosage of rapid-, short-, intermediate-, and long-acting insulins at a maximum \$35 copayment per one-month supply. Inhaled insulin was not among Model-required products. Table 2.3 shows that Novo Nordisk and Eli Lilly are the two participating manufacturers whose products meet all PDSS requirements, meaning that POs could choose to offer insulins manufactured by only one manufacturer.^{iv} The remaining three participating manufacturers do not make all insulin types: Sanofi manufactures only rapid- and long-acting insulins; MannKind only has one rapid-acting inhaled insulin; and Viatris manufactures insulin glargine (Semglee), which has versions approved under different biosimilar and generic approval pathways resulting in multiple unique

^{iv} Eli Lilly's short-acting Humulin R comes only in a vial. However, Eli Lilly also entered a short-acting concentrate, Humulin R 500, that comes in a vial and a pen form.

insulins for this drug. Eli Lilly and Novo Nordisk both offered pre-mixed insulins, and Eli Lilly and Sanofi entered combination insulins into the Model test.

Table 2.3. Model Insulins, by Type and Manufacturer

Insulin Type and Manufacturer	Brand Name	Active Ingredient	Authorized Generic or Biosimilar (reference product)	Package Type
Rapid-acting				
Eli Lilly	Humalog	Insulin Lispro		cartridge, pen, and vial
	Insulin Lispro	Insulin Lispro	AG (Humalog)	pen and vial
	Lyumjev	Insulin Lispro-aabc ^a	B (Humalog)	pen and vial
Novo Nordisk	Fiasp	Insulin Aspart (with Niacinamide)		cartridge, pen, and vial
	Insulin Aspart	Insulin Aspart	AG (Novolog)	cartridge, pen, and vial
	Novolog	Insulin Aspart		cartridge, pen, and vial
Sanofi	Admelog	Insulin Lispro	B (Humalog)	pen and vial
	Apidra	Insulin Glulisine		pen and vial
Mannkind	Afrezza	Insulin Regular (human)		inhaler
Short-acting				
Eli Lilly	Humulin R	Insulin Regular (human)		vial
Novo Nordisk	Novolin R	Insulin Regular (human)		pen and vial
Intermediate-acting				
Eli Lilly	Humulin N	Insulin NPH (human) (isophane)		pen and vial
Novo Nordisk	Novolin N	Insulin NPH (human) (isophane)		pen and vial
Long-acting				
Eli Lilly	Basaglar	Insulin Glargine	B (Lantus)	pen
Novo Nordisk	Levemir	Insulin Detemir		pen and vial
	Tresiba	Insulin Degludec		pen and vial
Sanofi	Lantus	Insulin Glargine		pen and vial
	Toujeo	Insulin Glargine		pen
Viartis	Insulin Glargine-yfgn	Insulin Glargine-yfgn ^b	AG, B (Lantus)	pen and vial
	Semglee	Insulin Glargine	B (Lantus)	pen and vial
	Semglee (yfgn)	Insulin Glargine-yfgn ^b	B, interchangeable ^b (Lantus)	pen and vial

Insulin Type and Manufacturer	Brand Name	Active Ingredient	Authorized Generic or Biosimilar (reference product)	Package Type
Mixed				
Eli Lilly	Humalog	Insulin Lispro Protamine and Lispro		pen and vial
	Humulin	Insulin NPH Isophane and Regular (human)		pen and vial
	Insulin Lispro	Insulin Lispro Protamine and Lispro	AG	pen
Novo Nordisk	Insulin Aspart	Insulin Aspart Protamine and Aspart (human)	AG (Novolog Mix)	pen and vial
	Novolin	Insulin NPH Isophane and Regular (human)		pen and vial
	Novolog	Insulin Aspart Protamine and Aspart (human)		pen and vial
Combination				
Novo Nordisk	Xultophy	Insulin Degludec/ Liraglutide		pen
Sanofi	Soliqua	Insulin Glargine/ Lixisenatide		pen
Concentrate				
Eli Lilly	Humulin R 500	Insulin Regular (human)		pen and vial






SOURCE: Adapted from the Model formularies posted to the CMMI website¹¹ and provided to the authors by the PDSS monitoring contractor. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹ We used Medi-Span, a therapeutic classification scheme, to harmonize drug names and active ingredients and to identify the manufacturer.

NOTE: MannKind and Viatris participated in the Model test only in 2022 while the other three manufacturers participated in both Model test years (2021 and 2022). AG = authorized generic; B = biosimilar.

^a The four-letter tag indicates biologic or biosimilar approved after 2017.¹¹

^b Semglee (insulin glargine-yfqn) is the first FDA-approved interchangeable biosimilar insulin.

Chapter 3. Characteristics of Parent Organizations and Plans Participating in the Model Test

KEY TAKEAWAYS	
Parent Organizations 	<ul style="list-style-type: none"> • In 2021, 67 POs entered only MA-PDs into the Model test; an additional 33 joined in 2022. • Also in 2021, five POs entered both MA-PDs and PDPs into the Model test; five more joined in 2022. • A small number of POs ($n = 3$) entered only PDPs into the Model test in 2021; one of these POs also entered MA-PDs into the Model test in 2022.
Plan Characteristics 	<ul style="list-style-type: none"> • MA-PD participation increased from 1,195 plans in 2021 to 1,730 plans in 2022. • Compared with eligible nonparticipants, MA-PD participating plans had slightly higher average enrollment in 2022 (5,555 versus 3,118) and a greater proportion of beneficiaries eligible for the Model test in 2021 (4.5 percent versus 3.3 percent). • PDP participation increased by 50 plans from 2021 to 2022, but plan consolidations resulted in a reduction of participating PDPs from 310 to 258 in 2022. • Compared with eligible nonparticipants, participating PDPs had similar average enrollment in 2022 (14,082 versus 14,597) and a greater proportion of beneficiaries eligible for the Model test in 2021 (5.0 percent versus 1.6 percent).
Enrollee Characteristics 	<ul style="list-style-type: none"> • Characteristics of enrollees were largely similar between participating and eligible nonparticipating MA-PDs and PDPs. However, risk scores and the rates of diabetes-related comorbidities were higher on average for PDP participants compared with eligible nonparticipants. • Targeted beneficiary characteristics were largely similar across participating and nonparticipating MA-PDs and PDPs, though targeted beneficiaries in participating MA-PDs were more likely to be White, compared with eligible nonparticipants.
Benefit Design Features 	<ul style="list-style-type: none"> • Average enrollment-weighted premiums were similar across MA-PD participants and eligible nonparticipants and largely stable from 2021 to 2022. • Average enrollment-weighted premiums for PDP participants were substantially higher than for eligible nonparticipants in both 2021 and 2022. • MA-PD participants were slightly more likely than eligible nonparticipants to offer a zero dollar deductible in 2022. • Participating PDPs were more likely than eligible nonparticipants to offer zero dollar deductibles and additional gap coverage in both 2021 and 2022.
Cost Sharing 	<ul style="list-style-type: none"> • Few meaningful differences in cost sharing for all plan-covered drugs emerged between participants and eligible nonparticipants in 2021 and 2022. • Both participating and eligible nonparticipating MA-PDs and PDPs placed a median of 11 to 12 insulins on Tier 3 of the benefit, which generally provided fixed copayments in the initial coverage phase.

POs offering enhanced Part D benefits may enter one or more of their plans into the PDSS Model. Eligible plans include MA-PDs (offering medical and drug benefits) or PDPs (offering drug benefits only). Because the Model test changes how supplemental benefits are applied, basic Part D plans are not eligible to participate in the Model test. There are no geographic

restrictions on participation. POs may enter special needs plans for chronic conditions (C-SNPs) or for institutionalized beneficiaries (I-SNPs) but may not enter dual eligible special needs plans (D-SNPs) because low-income beneficiaries in those plans already pay low or no cost sharing for prescription drugs. In addition, several specific Medicare Advantage (MA) plan types are not eligible to participate, such as private fee-for-service plans, union or employer plans, Section 1876 or 1833 cost plans, Program of All-Inclusive Care for the Elderly (PACE) plans, or Medicare-Medicaid Plans (MMPs).^v

In this chapter, we first describe the characteristics of 2021 and 2022 Model test participants by PO. Then we describe the plans that these POs entered into the Model test and compare their characteristics with PDSS-eligible, nonparticipating plans in both years, separately for 2021 and 2022. This allows us to understand whether there are any underlying differences in the plans that participate in the Model test versus those that do not.

We present results separately for MA-PDs and PDPs because these plans may serve different types of beneficiaries and their POs face very different incentives in designing plan formularies. Specifically, beneficiaries enrolled in MA-PDs receive medical benefits under the PO's managed care program. This provides incentives for MA-PDs to design formularies with increased access to generic or chronic disease maintenance medications that prevent downstream adverse medical utilization, such as emergency department or inpatient stays.⁶²⁻⁶⁵ Beneficiaries enrolled in stand-alone PDPs receive medical benefits under the FFS Medicare Program; therefore, organizations offering PDPs do not necessarily have a financial incentive to design formularies with medical costs in mind.

Parent Organizations

There were 75 PDSS-participating POs in 2021 and 106 in 2022. All of the large Part D POs—UnitedHealth, Humana, CVS, and Centene⁶⁶—participated in the Model test. We sorted PDSS-participating POs into three mutually exclusive groups: (1) those that entered only MA-PDs into the Model test, (2) those that entered MA-PDs and PDPs, and (3) those that entered only PDPs, because each group likely had different rationales for joining the Model test and to help understand the landscape of PO participation across the two types of Part D plans. Table 3.1 presents the characteristics of these three groups separately.

^v 1876 cost plans allow beneficiaries to also receive services paid for by traditional Medicare and 1833 plans are legacy employer plan types; PACE plans provide services to beneficiaries eligible for both Medicare and Medicaid, designed to keep beneficiaries out of nursing homes who are at risk for entering; and MMPs are another CMMI model test available in specific states to evaluate better care coordination for dual-eligible beneficiaries.

Table 3.1. Characteristics of PDSS-Participating Parent Organizations, 2021 and 2022

	Entered MA-PDs Only 2021	Entered MA-PDs Only 2022	Entered MA-PDs and PDPs 2021	Entered MA-PDs and PDPs 2022	Entered PDPs Only 2021	Entered PDPs Only 2022
Number of POs ^a	67	94	5	10	3	2
Exited the Model test in 2022	6	N/A	0	N/A	0	N/A
Joined the Model test in 2022	N/A	33	N/A	4	N/A	0
Changed participation status ^b	0	0	0	1	0	1
Mean PO Part D enrollment ^c	72,674	39,766	2,871,314	2,175,539	272,708	50,874
Percentage of eligible plans in the Model test						
MA-PD	86%	86%	73%	57%	N/A	N/A
PDP	N/A	N/A	80%	80%	92%	100%
Regions offering Part D ^d						
Local	46	69	2	4	1	1
Regional	18	23	0	0	0	0
National	3	2	3	6	2	1
Participation in MA VBID model (MA-PD only)	8	12	1	5	N/A	N/A

SOURCE: Health Plan Management System (HPMS) plan enrollment file (July 2021 and January 2022), MA contract service area by state/county and PDP contract service area by state/county (July 2021 and January 2022),⁶⁷ and PDSS landscape file (2021 and 2022).¹¹

NOTE: N/A = not applicable; VBID = Value-Based Insurance Design.

^a In publicly available CMMI documentation, the total number of POs for 2021 is 76, not 75 as reported here. This is due to one PO offering plans under two different subsidiary organizations, which we combined in this table.

^b One participating PO changed from offering only PDPs in 2021 to offering both MA-PDs and PDPs in 2022.

^c Calculated as the average of enrollment in PDSS-participating plans and PDSS-eligible nonparticipating plans.

^d POs were categorized by the geographic reach of their Part D plan offerings. Local POs were those that offered Part D plans in one or two states. Regional POs offered Part D plans in three to eight states. National POs offered plans in nine or more states.

Parent Organizations Entering Only MA-PDs into the PDSS Model

In 2021, 67 POs entered only MA-PDs into the PDSS Model (Table 3.1, left panel). Most of these POs continued to participate in the Model test in 2022; only six POs ended their participation after the first year (2021). In addition to POs continuing their participation in 2022, 33 new POs entered the Model test: The number of participating POs increased by about 50 percent to 94. At the PO level, mean Part D enrollment among PDSS-eligible MA-PDs was 72,674 in 2021 and 39,766 in 2022, suggesting that POs entering in 2022 were smaller, on average, than POs that entered in 2021. POs entered 86 percent of their eligible MA-PDs in the PDSS Model in both 2021 and 2022. In 2021, 46 POs offered plans locally, 18 offered them

regionally, and three offered them nationally.^{vi} In 2022, more POs offered local plans ($n = 69$), while POs offering plans regionally increased to 23 and POs offering plans nationally decreased to two. In 2021, eight POs also had plans that participated in the MA Value-Based Insurance Design (VBID) model;^{vii} in 2022, the number of POs with plans in both models increased to 12.

Parent Organizations Entering Both MA-PD and PDP Plans into the PDSS Model

In 2021, five POs entered both MA-PDs and PDPs into the PDSS Model (Table 3.1, middle panel). All of these POs continued their Model test participation in 2022. In addition, four new POs entered the Model test, and a PO that had only offered PDPs in 2021 expanded its offerings to MA-PDs in 2022, for a total of ten participating POs in 2022. Among their PDSS-eligible plans, mean PO-level Part D enrollment was 2,871,314 in 2021 and 2,175,539 in 2022. Average enrollment was driven by a small number of large PDSS-participating POs (Centene, Humana, and UnitedHealth). Of eligible MA-PDs within a given PO, 73 percent participated in the PDSS Model in 2021, and 57 percent participated in 2022. Of eligible PDPs within a given PO, 80 percent participated in the PDSS Model in both 2021 and 2022. In 2021, two POs entering both MA-PDs and PDPs offered plans locally, none offered them regionally, and three offered them nationally. In 2022, four offered plans locally and six nationally. In 2021, one PO had MA-PDs that participated in the MA VBID model; in 2022, this number increased to five.

Parent Organizations Entering Only PDPs into the PDSS Model

In 2021, three POs entered only PDPs into the PDSS Model (Table 3.1, right panel). One of these POs also entered MA-PDs in 2022 (moving this PO over to the middle group of those entering both MA-PDs and PDPs). No new POs joined the Model test in 2022, leaving two POs offering only PDPs in the second year. At the PO level, mean Part D enrollment among these eligible PDPs was 272,708 in 2021 and 50,874 in 2022. POs entered 92 percent of eligible plans into the PDSS Model in 2021 and 100 percent in 2022. In 2021, one PO offered PDPs locally, none offered them regionally, and two offered them nationally. In 2022, one PO offered PDPs locally and one nationally.

Plans

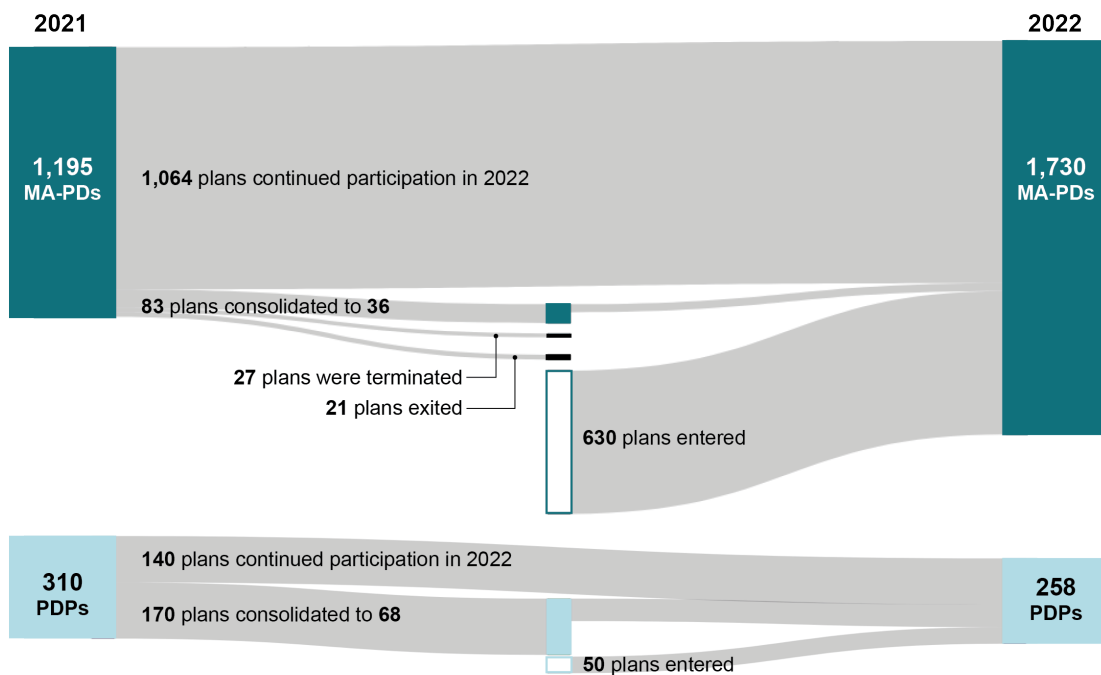
We identified plans that participated in the PDSS Model in 2021 and 2022 and describe their characteristics for either 2021 only or both 2021 and 2022, depending on data availability, in this

^{vi} Local POs were those that offered Part D plans in one or two states. Regional POs offered Part D plans in three to eight states. National POs offered plans in nine or more states.

^{vii} The MA VBID model test allows MA-PDs to experiment with benefit design flexibilities including lowering cost sharing for medical services or prescription drugs, offering targeted supplemental benefits, providing beneficiaries with cash payments, or offering hospice benefits. Because POs could enter MA-PDs in both model tests, we report on the extent to which POs and plans are participating in both models.

section. POs are able to consolidate multiple plans in one year into a single plan in the next year. Beneficiaries enrolled in plans that consolidate are automatically enrolled in the new plan. To track plans across years for tables comparing plan and enrollee characteristics for 2021, we crosswalked 2022 PDSS-participating plans back to their corresponding 2021 PDSS-participating plan to identify and summarize the plans' 2021 characteristics. We could not crosswalk plans that were newly offered in 2022, so their information is not included in tables describing 2021 PDSS-participating plan characteristics. We defined *eligible nonparticipating plans* as those that were Model-eligible in both 2021 and 2022 but did not participate in either year. For ease of comparison at the plan level, we rolled segment-level MA-PD data up to the plan level using enrollment weights. Figure 3.1 shows the number of participating MA-PDs and PDPs in each year and summarizes plans that exited the Model test, as well as new Model entrants and plan consolidations for 2021 to 2022. The number of PDSS-participating MA-PDs increased from 2021 to 2022, with 630 new entrants in 2022. The new MA-PD entrants were mostly from POs that entered only MA-PDs into the Model test. The number of participating PDPs declined from 2021 to 2022 because of consolidations among 170 plans participating in the Model test in 2021.

Figure 3.1. PDSS-Participating Plans, 2021 and 2022



SOURCE: PDSS participation files for 2021 and 2022 and publicly available plan crosswalk files for 2021–2022.

Plan Characteristics

Participation in the PDSS Model among MA-PDs increased from 1,195 plans in 2021 to 1,730 in 2022, compared with 1,710 PDSS-eligible plans that did not participate in either year (Table 3.2).

Table 3.2. PDSS-Participating and Eligible Nonparticipating Plan Characteristics

	MA-PDs 2021 Participants	MA-PDs 2022 Participants	MA-PDs Eligible Non- participants	PDPs 2021 Participants	PDPs 2022 Participants	PDPs Eligible Non- participants
Plan type (MA-PD)						
Local CCP (%)	98.7%	98.7%	99.5%	N/A	N/A	N/A
Regional PPO (%)	1.3%	1.3%	0.5%	N/A	N/A	N/A
SNP (%)	11.3%	9.2%	6.0%	N/A	N/A	N/A
Service area characteristics						
Median income	\$61,221	\$61,518	\$64,150	\$63,095	\$63,368	\$63,218
Mean Part D market share	46.8%	46.6%	45.3%	42.1%	41.9%	42.6%
Mean urbanicity ^a	1.81	1.80	1.82	1.62	1.63	1.62
Mean Part D Star Rating ^b	4.0	3.9	3.8	3.5	3.5	3.5
Getting needed medications	3.5	3.5	3.6	3.1	3.2	3.2
Diabetes adherence	4.0	3.9	3.7	3.7	3.6	3.3
Participation in MA VBID model (%)	137 (11.5%)	194 (12.5%)	47 (2.7%)	N/A	N/A	N/A
Mean enrollment						
Overall	5,868	5,555	3,118	15,514	14,082	14,597
LIS (%)	633 (10.8%)	592 (10.7%)	354 (11.4%)	539 (3.5%)	466 (3.3%)	187 (1.3%)
Targeted beneficiaries ^c (%)	262 (4.5%)	N/A	102 (3.3%)	776 (5.0%)	N/A	231 (1.6%)

SOURCE: Publicly available CMS PBP Benefits Data (2021),⁶⁷ MA and Part D Star Ratings (2021), PBP State/County Penetration (2021),⁶⁷ MA State/County Penetration (2021),⁶⁷ Rural-Urban Continuum Codes,⁶⁸ Area Health Resource File (2015–2019 five-year estimates),⁶⁹ and the CMS Integrated Data Repository (IDR), accessed on February 16–17, 2022, from which we calculated the plan-county enrollment, plan enrollment, LIS enrollment, and targeted beneficiary enrollment.

NOTE: Plan-level characteristics calculated for 2021. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test. For enrollment data, beneficiaries were counted as enrolled if they were continuously enrolled in the same plan from January 1, 2021 through July 1, 2021. CCP = Coordinated Care Plan; N/A = not applicable; PPO = preferred provider organization; SNP = special needs plan.

^a Mean urbanicity was calculated from the U.S. Department of Agriculture's Rural-Urban Continuum Codes;⁶⁸ measures close to 1 indicate counties with populations of at least 1 million people, and measures closer to 9 indicate rural areas.

^b Part D Star Ratings were calculated at the contract level. 2021 Star Ratings were subject to the COVID-19 public health emergency declaration and therefore may not reflect actual quality ratings for the given year.⁷⁰

^c Targeted beneficiaries were those not eligible for the LIS and enrolled in a 2021 PDSS-participating plan with at least one fill of a plan-selected Model insulin in the first six months of 2021. Beneficiaries enrolled in eligible nonparticipating plans were identified as targeted beneficiaries if they had at least one fill of any plan-selected Model insulin in the first six months of 2021. Targeted beneficiaries for 2022 PDSS-participating plans were not identified because utilization data were not yet complete at the time of this evaluation.

The vast majority of MA-PDs were local Coordinated Care Plans (98.7 percent of PDSS-participating plans in 2021 and 2022, 99.5 percent of nonparticipating MA-PDs); the remaining plans were regional preferred provider organizations. Eleven percent of 2021 PDSS-participating MA-PDs, 9.2 percent of 2022 PDSS-participating MA-PDs, and 6.0 percent of eligible nonparticipating MA-PDs were SNPs.

Median income was just over \$61,000 in areas served by MA-PDs participating in the PDSS Model, while income was slightly higher (\$64,000) in areas served by nonparticipating plans. The mean Part D market share was slightly higher among participating plans (46.8 percent for 2021 participants and 46.6 percent for 2022 participants) than among nonparticipating MA-PDs (45.3 percent). Mean urbanicity was similar across years and PDSS participation status.

Both the mean overall Part D Star Rating, as well as the Star Rating for the measure “getting needed medications” (a measure based on survey responses to questions related to how easy it was to fill prescriptions) were similar across PDSS participation year and status. However, the measure “diabetes adherence” (the percentage of plan members who fill their prescriptions frequently enough) had higher scores among PDSS-participating MA-PDs (4.0 for 2021 participants and 3.9 for 2022 participants) compared with nonparticipating MA-PDs (3.7).

Participation in the MA VBID model was much higher in PDSS-participating MA-PDs (11.5 percent for 2021 and 12.5 percent for 2022) compared with nonparticipating plans (2.7 percent). Mean enrollment in PDSS-participating MA-PDs was also substantially higher (5,868 for 2021 participants and 5,555 for 2022 participants) than in nonparticipating plans (3,118). A slightly lower proportion of enrollees in participating plans received the LIS (10.7 percent for 2021 participants and 10.8 percent for 2022 participants) compared with nonparticipating plans (11.4 percent). A higher percentage of beneficiaries in participating plans were considered PDSS targeted beneficiaries (4.5 percent for 2021 participants and 4.8 percent for 2022 participants) compared with nonparticipating plans (3.3 percent).

Among PDPs, participation increased by 50 plans from 2021 to 2022, but consolidations among 170 plans in 2021 resulted in a reduction from 310 to 258 participating PDPs in 2022. Median income was similar in areas served by participating and nonparticipating plans at just over \$63,000. The mean Part D market share was slightly higher (42.6 percent) among nonparticipating PDPs than among participating PDPs (41.9 percent for 2021 participants and 42.1 percent for 2022 participants). Mean urbanicity, which measures the population density of a county, was similar across years and PDSS participation status.

Both the mean overall Part D Star Rating, as well as the Star Rating for the measure “getting needed medications” were similar across years and PDSS participation status. However, the measure “diabetes adherence” had higher scores among PDSS-participating PDPs (3.7 for 2021 participants and 3.6 for 2022 participants) compared with nonparticipating PDPs (3.3).

Mean enrollment in PDPs was similar for participating plans (15,514 for 2021 participants and 14,082 for 2022 participants) and for nonparticipating plans (14,597). A higher proportion of enrollees in participating plans received the LIS (5.0–5.5 percent) compared with nonparticipating plans (1.6 percent). Similar to MA-PDs, a higher percentage of beneficiaries in participating PDPs were considered PDSS targeted beneficiaries (5.0 percent for 2021 participants and 5.5 percent for 2022 participants) compared with nonparticipating PDPs (1.6 percent).

Plan Enrollee Characteristics

Table 3.3 shows 2021 plan enrollee characteristics for both participating and eligible nonparticipating MA-PDs, as well as characteristics of enrollees continuously enrolled in the plan for the first six months of 2021, who filled at least one prescription for a plan-selected Model insulin (or *targeted beneficiaries*) in those six months. Beneficiaries not eligible for the LIS and enrolled in eligible nonparticipating plans were identified as targeted beneficiaries if they had at least one fill of any Model insulin in the first six months of 2021. Targeted beneficiaries for 2022 participating plans were not identified because their utilization data are not yet complete for 2022.

Table 3.3. Characteristics of 2021 Plan Enrollees and Targeted Beneficiaries in PDSS-Participating and Eligible Nonparticipating MA-PDs

	All Enrollees	All Enrollees	All Enrollees	Targeted Beneficiaries	Targeted Beneficiaries
	2021 Participants	2022 Participants	Eligible Non-participants	2021 Participants	Eligible Non-participants
Age	72.95	73.84	71.89	72.33	74.65
Female (%)	54.11%	53.96%	53.45%	47.61%	47.89%
Race/ethnicity					
White	74.24%	74.84%	68.75%	72.44%	66.94%
Black	11.01%	10.22%	13.66%	11.96%	14.62%
Hispanic	9.18%	9.05%	10.42%	10.15%	11.22%
Asian	2.80%	3.08%	4.19%	2.59%	3.64%
AI/AN	0.20%	0.25%	0.25%	0.39%	0.67%
Other	0.86%	0.89%	1.02%	0.99%	1.40%
Part D risk score ^a	0.83	0.81	0.78	1.29	1.29
Comorbid conditions ^b					

	All Enrollees	All Enrollees	All Enrollees	Targeted Beneficiaries	Targeted Beneficiaries
	2021 Participants	2022 Participants	Eligible Non-participants	2021 Participants	Eligible Non-participants
Congestive heart failure	12.80%	12.11%	10.85%	21.29%	19.78%
Kidney failure	0.19%	0.18%	0.16%	0.53%	0.52%
Hypertension	55.37%	55.28%	54.50%	67.71%	67.66%
High cholesterol	63.59%	62.88%	59.24%	83.45%	81.49%

SOURCE: CMS IDR, accessed on February 16 and 17, 2022.

NOTE: All enrollees refers to beneficiaries continuously enrolled from January 1, 2021 through July 1, 2021. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test. AI/AN = American Indian or Alaska Native.

^a Part D risk score (RxHCC) data are from the Part D risk model for 2021, reflecting utilization in 2020.

^b Comorbid condition flags are computed among beneficiaries using 2020 data.

Enrollee characteristics were similar across MA-PDs, regardless of participation status: average age was about 73 years for 2021 participants and 74 for 2022 participants, and about a half of enrollees were female. Model participants had a larger proportion of White enrollees (74–75 percent for 2021 and 2022 participants) than nonparticipating plans (69 percent). Part D risk scores were similar, on average, for participating plans (0.83 for 2021 participants and 0.81 for 2022 participants) compared with nonparticipating plans (0.78). Similarly, the percentage of enrollees with comorbid conditions related to diabetes, such as kidney failure, hypertension, and high cholesterol, was slightly higher among enrollees of participating plans. Compared with all enrollees, targeted beneficiaries in participating plans were of similar age while those in nonparticipating plans were slightly older. Targeted beneficiaries in general were less likely to be female, had higher average risk scores, and higher rates of comorbid conditions.

Table 3.4 presents information on 2021 enrollee and targeted beneficiary characteristics for PDPs. The average age of enrollees (74 for 2021 participants and 76 for 2022 participants) and percent female (55 percent for 2021 participants and 57 percent for 2022 participants) were similar across years and PDSS participation status. PDSS-participating plans had a slightly larger proportion of Black enrollees (3.9 percent), compared with nonparticipating plans (2.8 percent).

Part D risk scores were higher on average for participating plans (0.85 for 2021 participants and 0.87 for 2022 participants), compared with nonparticipating plans (0.74). Similarly, the rates of comorbid conditions related to diabetes were higher among participating plan enrollees. The differences between targeted beneficiaries and all enrollees in both participating and nonparticipating PDPs were similar to those described for MA-PDs.

Table 3.4. Characteristics of 2021 Plan Enrollees and Targeted Beneficiaries in PDSS-Participating and Eligible Nonparticipating PDPs

	All Enrollees	All Enrollees	All Enrollees	Targeted Beneficiaries	Targeted Beneficiaries
	2021 Participants	2022 Participants	Eligible Non-participants	2021 Participants	Eligible Non-participants
Age	74.47	76.04	73.15	73.66	74.39
Female (%)	56.55%	57.26%	56.45%	45.09%	44.88%
Race/ethnicity					
White	87.99%	88.21%	89.41%	85.31%	85.81%
Black	3.86%	3.78%	2.80%	4.78%	4.06%
Hispanic	2.76%	2.71%	1.99%	3.70%	3.05%
Asian	1.93%	1.83%	1.93%	2.48%	2.88%
AI/AN	0.31%	0.50%	0.22%	0.47%	0.87%
Other	0.80%	0.77%	0.71%	1.11%	1.04%
Part D risk score ^a	0.85	0.87	0.74	1.32	1.30
Comorbid conditions ^b					
Congestive heart failure	11.70%	12.64%	8.14%	20.43%	19.67%
Kidney failure	0.16%	0.18%	0.12%	0.55%	0.52%
Hypertension	59.14%	59.72%	54.31%	68.60%	68.03%
High cholesterol	65.92%	66.73%	61.57%	83.00%	82.28%

SOURCE: CMS IDR.

NOTE: All Enrollees refers to beneficiaries continuously enrolled from January 1, 2021 through July 1, 2021. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test. AI/AN = American Indian or Alaska Native.

^a Part D risk score (RxHCC) data are from the Part D risk model for 2021, reflecting utilization in 2020.

^b Comorbid condition flags are computed amongst beneficiaries using 2020 data.

Benefit Design Features

We assessed specific benefit design features for participating and eligible nonparticipating plans. The majority of participating and eligible nonparticipating MA-PDs offered a \$0 premium (approximately 60 percent); this did not change substantially from 2021 to 2022 (see Table 3.5). To explore potential differences across participating and eligible nonparticipating plans in terms of premiums, we calculated enrollment-weighted descriptive statistics. Premiums weighted by the number of enrollees in the plan provide information on the extent to which beneficiaries selected plans that may be less expensive than the average. Average total enrollment-weighted premiums (after application of the MA rebate) for eligible nonparticipating MA-PDs declined slightly from 2021 to 2022 (\$11.88 and \$11.49, respectively), similar to the trends seen for both 2021 participants (\$9.85 to \$9.55) and 2022 participants (\$10.75 to \$10.19). The percentile distributions for the total premium reflect this pattern, with a \$0 premium across all MA-PDs, years, and participation statuses for both the 25th and 50th percentiles.

Table 3.5. MA-PD Part D Benefit Design Features, 2021 and 2022

MA-PD Benefit Design Feature	2021	2021	2022	2022	Eligible Non-	Eligible Non-
	Participants	Participants	Participants	Participants	participants	participants
	2021	2022	2021	2022	2021	2022
Number of plans	1,195	1,121	1,552	1,730	1,710	1,533
Part D premium						
Offered \$0 premium	60.9%	62.4%	59.3%	63.0%	59.7%	62.1%
Basic premium (\$)	9.29	9.12	10.17	9.71	10.71	9.92
Suppl. premium (\$)	0.57	0.43	0.59	0.48	1.17	1.57
Total premium (\$)	9.85	9.55	10.75	10.19	11.88	11.49
25th percentile (\$)	0	0	0	0	0	0
50th percentile (\$)	0	0	0	0	0	0
75th percentile (\$)	19.00	17.20	20.00	18.00	23.00	21.50
Part D deductible						
Offered \$0 deductible	54.6%	64.6%	54.3%	63.3%	53.9%	57.3%
Deductible (\$)	92.22	71.20	98.52	79.17	99.73	92.84
Offered additional gap coverage	34.1%	70.4%	33.1%	63.3%	63.6%	66.5%

SOURCE: Plan and Premium Information for Medicare Plans Offering Part D Coverage (2021 and 2022),⁷¹ HPMS Plan Information data and HPMS Plan Enrollment data (July 2021 and January 2022).

NOTE: Premium and deductible descriptive statistics are calculated using enrollment weighting. Three eligible nonparticipating MA-PDs were missing deductible and coverage in gap coverage data and were therefore excluded from those rows. Eleven PDSS-participating plans and 16 eligible nonparticipating plans did not have enrollment information for 2021. Seventeen PDSS-participating plans and three eligible nonparticipating plans did not have enrollment information for 2022. Plans with no enrollment data were excluded from the enrollment-weighted premiums and deductible calculations. The average deductible was calculated among plans without a \$0 deductible. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test. Suppl. = supplemental.

Because the PDSS Model offers enhanced coverage for insulins, which may increase the supplemental premiums paid by enrollees, we also explored trends in average enrollment-weighted premiums for enhanced coverage from 2021 to 2022. The supplemental premium, which is attributable to enhanced benefits, declined slightly for 2021 and 2022 participating plans (\$0.57 to \$0.43 for 2021 participants, \$0.59 to \$0.48 for 2022 participants), and increased slightly for eligible nonparticipating plans (\$1.17 to \$1.57). As discussed in Chapter 1, the overall stability of supplemental premiums was likely due to plan application of MA rebate dollars to buy down the Part D premium.

More than half of MA-PDs offered a \$0 deductible in 2021, and the proportion of MA-PDs offering a \$0 deductible increased from 2021 to 2022 across all groups, though by a smaller percentage for eligible nonparticipating plans (from 53.9 percent to 57.3 percent). Enrollment-weighted average deductibles were lower for both 2021 and 2022 participating MA-PDs in 2022

compared with 2021 (from \$92.22 and \$98.52 in 2021 to \$71.20 and \$79.17 in 2022, respectively). The percentage of participating plans offering additional gap coverage, excluding the coverage provided via the PDSS Model, increased from 2021 to 2022 (from about 33–34 percent to more than 60 percent), while more than 60 percent of eligible nonparticipating plans offered gap coverage in both 2021 and 2022. It is important to note that the indicator for whether a plan offers additional gap coverage only shows whether or not any gap coverage is provided, and therefore summarizes both more- and less-generous gap coverage offerings into a single summary measure.

Participating PDPs had increases (\$2 to \$5 per month) in total enrollment-weighted average premiums from 2021 to 2022 (Table 3.6). The increases were largely due to increases in the average supplemental premiums, while basic premiums declined. This may reflect an increase in supplemental premiums associated with joining the Model test in 2022. Eligible nonparticipating PDP enrollment-weighted average total premiums remained stable from 2021 to 2022 (from \$27.05 to \$27.11). This group experienced a small increase in supplemental premiums and decrease in the basic premium from 2021 to 2022.

Table 3.6. PDP Part D Benefit Design Features, 2021 and 2022

PDP Benefit Design Feature	2021	2021	2022	2022	Eligible Non-participants	Eligible Non-participants
	Participants	Participants	Participants	Participants	2021	2022
Number of plans	310	208	405	258	212	206
Part D premium						
Offered \$0 premium	0%	0%	0%	0%	0%	0%
Basic premium (\$)	35.13	29.00	33.26	29.25	18.22	16.67
Suppl. premium (\$)	20.58	28.00	19.48	28.79	8.83	10.44
Total premium (\$)	55.71	57.00	52.75	58.04	27.05	27.11
25th percentile (\$)	17.50	12.90	17.80	12.90	14.30	7.50
50th percentile (\$)	65.60	68.90	61.40	68.90	17.20	22.70
75th percentile (\$)	86.00	95.00	81.80	94.30	31.90	29.30
Part D deductible						
Offered \$0 deductible	22.9%	34.1%	29.1%	46.5%	9.9%	7.8%
Deductible	250.89	271.41	254.64	252.77	420.31	428.75
Offered additional gap coverage	22.3%	33.7%	28.6%	40.3%	8.5%	24.3%

SOURCE: Plan and Premium Information for Medicare Plans Offering Part D Coverage (2021 and 2022),⁷¹ HPMS Plan Information data and HPMS Plan Enrollment data (July 2021 and January 2022).

NOTE: Premium and deductible descriptive statistics are calculated using enrollment weighting. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test. Suppl. = supplemental.

Fewer than 50 percent of participating PDPs offered a \$0 deductible in either year, although the percentage of those that did increased from 2021 to 2022 across PDPs that participated in both years. The proportion of eligible nonparticipating plans offering a \$0 deductible declined slightly from 2021 to 2022 but was less than 10 percent in both years. The percentage of PDPs offering gap coverage increased from 2021 to 2022 across all groups but was higher for 2021 and 2022 participants (33.7 percent and 40.3 percent, respectively) compared with eligible nonparticipating plans (24.3 percent) in 2022. The enrollment-weighted average deductible was lower for participating PDPs (\$271.41 for 2021 participants in 2022, and \$252.77 for 2022 participants in 2022) compared with eligible nonparticipating PDPs (\$428.75 in 2022).

Cost Sharing for All Plan Covered Drugs

We also assessed plan cost sharing design for in-network preferred pharmacies to understand the extent to which participating and eligible nonparticipating plans differ in terms of their approach to OOP cost sharing for all covered plan drugs, including insulins. Understanding this aspect of the benefit design will provide insight into potential differences in outcomes for this evaluation, because plans with certain cost sharing designs may have been more likely to participate in the Model test.

In general, POs use tiering to establish cost sharing levels and to encourage utilization of less-expensive drugs placed on lower tiers. In 2021 and 2022, the majority of MA-PDs and all PDPs used a five- or six-tier formulary structure, which generally followed the design shown in the adjacent text box.⁷²⁻⁷³

Eighty-five to 88 percent of Model-participating MA-PDs had a five-tier formulary structure in both years; about 12 percent in 2021 and 14 percent in 2022 had six-tier structures. A higher percentage of eligible nonparticipating MA-PDs had six tiers, increasing from 31.5 percent in 2021 to 39.3 percent in 2022.

Cost Sharing Tiers	
Tier 1:	Preferred generic drugs
Tier 2:	Nonpreferred generic drugs
Tier 3:	Preferred brand name drugs
Tier 4:	Nonpreferred brand name drugs
Tier 5:	Specialty drugs
Tier 6:	Vaccines, other drugs with low or \$0 copayments

Cost sharing for a 30-day supply of a covered prescription drug was set as flat-fee copayments for tiers 1–4 (as indicated by dollar signs [\$] in the first four rows of Table 3.7). The median cost share ranged from \$0 for preferred generics (tier 1) to \$100 for nonpreferred brand name drugs (tier 4). Tier 5 (specialty drugs) were offered under a median coinsurance of 33 percent in the initial coverage phase (as indicated by percentage symbols [%] in the fifth row of Table 3.7). Tier 6 had a median cost share of \$0 across both participating and nonparticipating plans that offered that tier. These values were broadly similar between participating plans and eligible nonparticipating plans.

Table 3.7. MA-PD Part D Median Cost Sharing for All Covered Drugs, 2021 and 2022

Cost Sharing Tier	2021	2021	2022	2022	Eligible	Eligible
	Participants	Participants	Participants	Participants	Non-	Non-
	2021	2022	2021	2022	participants	participants
					2021	2022
1	\$2.00	\$0.00	\$2.00	\$0.00	\$0.00	\$0.00
2	\$10.00	\$10.00	\$10.00	\$10.00	\$9.00	\$7.50
3	\$47.00	\$47.00	\$47.00	\$47.00	\$47.00	\$45.00
4	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$99.00
5	33.00%	33.00%	33.00%	33.00%	33.00%	33.00%
6	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00

SOURCE: Computed from CMS prescription drug plan formulary data⁷⁴; 2021 results were based on Quarter 1 2021 files and 2022 results were based on January 2022 files.

NOTE: Table values represent median plan 30-day supply cost sharing amounts for preferred pharmacies. Cost sharing amounts are shown as dollars when the majority of plans used copayments for the specified tier and as percentages when the majority of plans used coinsurance. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test.

Nearly 78 percent of 2021 PDP participants had a five-tier structure for plan covered drugs in 2021, increasing to 82.7 percent in 2022. A higher proportion of 2022 PDP participants had a five-tier structure in 2021 (83 percent) and 2022 (86 percent). All eligible nonparticipating PDPs had five tiers in both years.

Median plan 30-day supply cost sharing amounts for all plan covered drugs were similar between participating and nonparticipating PDPs, ranging from a median cost share of \$1.00 for tier 1 to \$40–\$45 copayments for tier 3 (Table 3.8).

Table 3.8. PDP Part D Median Cost Sharing for All Covered Drugs, 2021 and 2022

Cost Sharing Tier	2021	2021	2022	2022	Eligible	Eligible
	Participants	Participants	Participants	Participants	Non-	Non-
	2021	2022	2021	2022	participants	participants
					2021	2022
1	\$1.00	\$1.00	\$1.00	\$0.00	\$0.00	\$1.00
2	\$7.00	\$8.00	\$4.00	\$4.00	\$5.00	\$6.00
3	\$43.00	\$45.00	\$43.00	\$45.00	\$40.00	\$42.00
4	48.00%	47.00%	47.00%	50.00%	43.50%	45.00%
5	28.00%	31.00%	28.00%	33.00%	25.00%	25.00%
6	\$0.00	\$0.00	\$0.00	\$0.00	N/A	N/A

SOURCE: Computed from CMS prescription drug plan formulary data⁷⁴; 2021 results were based on Quarter 1 2021 files and 2022 results were based on the January 2022 files.

NOTE: Table values represent median plan 30-day supply cost sharing amounts for preferred pharmacies. Cost sharing amounts are shown as dollars when the majority of plans used copayments for the specified tier and as percentages when the majority of plans used coinsurance. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test. N/A = not applicable.

Cost sharing patterns were similar to those offered by MA-PDs for products placed on tiers 1–3. However, PDPs typically used a high coinsurance (45–50 percent) for tier 4 (nonpreferred drugs) instead of the flat-fee copayment offered by MA-PDs. Tier 5 coinsurance was on average lower (25–33 percent) for PDPs compared with MA-PDs. Tier 6 had a median cost share of \$0 for participating PDPs; none of the eligible nonparticipating PDPs had a tier 6.

Cost Sharing for Insulins

We also examined the tiers to which insulin is most commonly assigned in the absence of the Model test by both PDSS-participating and eligible nonparticipating plans. Participating plans can put Model insulins in a tier with a higher copay. The application of the maximum \$35 cost sharing for plan-selected Model insulins does not change the assigned tier, only the maximum cost sharing. PDSS-participating and eligible nonparticipating MA-PDs and PDPs put the majority of covered insulins on tier 3 (Tables 3.9 and 3.10), reflecting preferred brand/preferred drug cost sharing with flat-fee copayments of \$40 to \$47 per fill in the initial coverage phase. Eligible nonparticipating MA-PDs and both participating and nonparticipating PDPs typically placed one insulin on tier 5 with either a \$97–\$99 copayment (for MA-PDs) or a 28–33 percent coinsurance (for PDPs). In 2021, Humulin R 500, the concentrated insulin, represented approximately two-thirds (68 percent) of the insulins placed on tier 5 across both participating and eligible nonparticipating MA-PDs and PDPs; in 2022 it represented nearly three-quarters (74 percent) of those placed on tier 5.

Table 3.9. Median Number of Insulins on Each Cost Sharing Tier for MA-PDs, 2021 and 2022

Cost Sharing Tier	2021	2021	2022	2022	Eligible	Eligible
	Participants	Participants	Participants	Participants	Non-participants	Non-participants
	2021	2022	2021	2022	2021	2022
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	12	12	12	12	11	11
4	0	0	0	0	0	0
5	0	0	0	0	1	1
6	0	0	0	0	0	0

SOURCE: Computed from CMS prescription drug plan formulary data.⁷⁴ 2021 results were based on the Quarter 1 2021 files and 2022 results were based on the January 2022 files.

NOTE: Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test.

Table 3.10. Median Number of Insulins on Each Cost Sharing Tier for PDPs, 2021 and 2022

Cost Sharing Tier	2021	2021	2022	2022	Eligible	Eligible
	Participants	Participants	Participants	Participants	Non-participants	Non-participants
	2021	2022	2021	2022	2021	2022
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	11	11	11	11	12	12
4	0	0	0	0	0	0
5	1	1	1	1	1	1
6	0	0	0	0	N/A	N/A


SOURCE: Computed from CMS prescription drug plan formulary data.⁷⁴ 2021 results were based on the Quarter 1 2021 files and 2022 results were based on the January 2022 files.

NOTE: None of the eligible nonparticipating PDPs had a tier 6 in either 2021 or 2022. Eligible nonparticipants are those plans that were eligible but did not participate in either year of the Model test.

Chapter 4. PDSS Interventions as Implemented in 2021 and 2022


KEY TAKEAWAYS

Plan-Selected Model Drugs




- MA-PD participants were more likely to include rapid-, short-, and intermediate-acting insulins and pre-mixed insulins manufactured by Novo Nordisk for the maximum \$35 copayment; PDP participants tended to include Eli Lilly insulins in these categories.
- A high proportion of both MA-PD and PDP formularies covered at least one long-acting Novo Nordisk insulin (69.9 percent and 64.3 percent, respectively, in 2022) and more than 74 percent of both MA-PD and PDP participants covered at least one of the two available Sanofi long-acting insulins in 2022.
- Most MA-PD and PDP participants charged enrollees the maximum \$35 copayment for plan-selected Model insulins.

Narrower First Risk Corridor



- There was substantial uptake of the narrower first risk corridor by both MA-PD and PDP participants in 2021 (67 percent and 89 percent, respectively).
- Election of this optional component declined in 2022 to 59 percent of MA-PDs and 55 percent of PDPs.
- About 90 percent of participants that elected this optional component in 2021 continued to elect it in 2022.

Rewards & Incentives



- Very few participating POs ($n = 5$) offered the optional R&I programs in 2021, increasing to 10 POs in 2022.
- POs offered R&I only in participating MA-PDs; no participating PDPs offered R&I.
- POs offering R&I gave beneficiaries gift cards to selected retailers in exchange for completion of activities including comprehensive medication review (CMR), MTM, maintaining minimum adherence criteria, and participation in disease management programs.

As mentioned in Chapter 2, under the PDSS Model in 2021 and 2022, plan formularies had to include at least one pen and one vial form of insulin from each of the clinically relevant insulin types (rapid-, short-, intermediate-, and long-acting) and must have imposed a maximum \$35 per one-month supply cost sharing for plan-selected Model insulins. Plans could participate in two optional components of the Model test: (1) the narrower first risk corridor, designed to protect plans against unforeseen losses during the first two years (2021 and 2022); and/or (2) R&I programs, which reward beneficiaries for participating in medication therapy management (MTM) programs or for achieving certain levels of medication adherence.

This chapter describes insulins that Model participants selected (i.e., plan-selected Model drugs) and optional Model components that plans implemented in 2021 and 2022 using Model test application materials in combination with publicly available Part D formulary data.

Plan-Selected Model Drugs

Inclusion of Insulins by Participating Plans

PDSS-participating plans included an array of insulins as plan-selected Model insulins in both 2021 and 2022. Table 4.1 shows the percentage of formularies that covered at least one insulin, for each manufacturer and type of insulin, separately for MA-PDs and PDPs. We present this information at the formulary level because POs often design a single formulary that applies to most, if not all, of their plans. This means that results shown at the plan level will tend to overweight the larger POs that offer many different plans. For information on the percentage of participating plans covering each insulin, by manufacturer and type, please see Table B.1 in Appendix B.

MA-PDs and PDPs included insulins from different manufacturers on their formularies. For example, more than 63 percent of MA-PD formularies in 2021 and 2022 included at least one Novo Nordisk rapid-acting insulin, but only about 36 percent of PDP formularies did so. PDP formularies were more likely to include the Eli Lilly rapid-acting insulins—more than 63 percent of PDP formularies included at least one. Similar patterns can be observed across the short- and intermediate-acting categories in which a higher percentage of MA-PD formularies (about 38 to 40 percent) covered at least one Eli Lilly insulin and about 64 percent covered Novo Nordisk insulins; the opposite is true for PDP formularies across those categories. Long-acting insulins show different patterns: A higher proportion of formularies covered at least one Novo Nordisk insulin (69.9 percent in 2022 for MA-PDs, 64.3 percent in 2022 for PDPs), and a large proportion of both MA-PDs and PDPs covered at least one of the two available Sanofi long-acting insulins (74.7 percent for MA-PDs and 85.7 percent for PDPs in 2022). More than half of MA-PD formularies covered the single concentrated insulin (Humulin R 500), compared with one-quarter (27.3 percent) to one-third (35.7 percent) of PDP formularies in 2021 and 2022, respectively.

Table 4.1. Percentage of PDSS Formularies Covering Each Type of Plan-Selected Model Insulin, by Manufacturer, 2021 and 2022

	MA-PD	MA-PD	PDP	PDP
	2021	2022	2021	2022
Number of formularies	121	166	11	14
Rapid-acting (9 insulins)				
Eli Lilly (3)	38.0%	40.4%	63.6%	64.3%
Novo Nordisk (3)	63.6%	65.1%	36.4%	35.7%
Sanofi (2)	0%	1.2%	0%	0%
MannKind ^a (1)	N/A	0%	N/A	0%
Short-acting (2 insulins)				
Eli Lilly (1)	38.0%	40.4%	63.6%	64.3%
Novo Nordisk (1)	63.6%	65.1%	36.4%	35.7%
Intermediate-acting (2 insulins)				
Eli Lilly (1)	38.0%	40.4%	63.6%	64.3%
Novo Nordisk (1)	63.6%	65.1%	36.4%	35.7%
Long-acting (8 insulins)				
Eli Lilly (1)	34.7%	34.9%	36.4%	28.6%
Novo Nordisk (2)	69.4%	69.9%	72.7%	64.3%
Sanofi (2)	82.6%	74.7%	81.8%	85.7%
Viatrix ^a (3)	N/A	1.2%	N/A	0%
Mixed (6 insulins)				
Eli Lilly (3)	37.2%	39.8%	63.6%	50.0%
Novo Nordisk (3)	63.6%	64.5%	36.4%	35.7%
Concentrate (1 insulin)				
Eli Lilly (1)	59.5%	55.4%	27.3%	35.7%
Combination (2 insulins)				
Novo Nordisk (1)	47.9%	48.8%	27.3%	42.9%
Sanofi (1)	47.1%	59.0%	45.5%	57.1%

SOURCE: Computed from CMS Part D formulary data:⁷⁴ 2021 results were based on Quarter 1 2021 files and 2022 results were based on January 2022 files. Manufacturer data were at the National Drug Code (NDC) level from Medi-Span. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹

NOTE: This table shows the percentage of formularies that covered at least one insulin produced by a given manufacturer of each insulin type.

^a MannKind and Viatrix joined the Model test in 2022.

Cost Sharing for Plan-Selected Model Insulins

Between 2021 and 2022, average copayments for preferred pharmacies across PDSS-participating plans for a one-month supply of plan-selected Model insulins remained largely unchanged for MA-PDs (Table 4.2) but increased slightly for PDPs (from \$28.57 to \$31.63). Per

the Model participation requirements, insulins included as part of the Model test by specific plans must have fixed copayments of no more than \$35 per one-month supply. Some participating MA-PDs elected to cover insulins for \$0 per month, while the minimum cost sharing for PDPs for plan-selected Model insulins was \$5 per month in both years. Across both plan types and in both 2021 and 2022, the median cost sharing for plan-selected Model insulins was \$35. This means that most plans charged the maximum \$35 copayment, as opposed to offering copayments lower than \$35. For detailed drug-level coverage information for plan-selected Model insulins, please see Tables B.2 and B.3 in Appendix B.

Table 4.2. Cost Sharing for Preferred Pharmacies in Initial Coverage Phase for Plan-Selected Model Insulins, 2021 and 2022

Plan Type	2021	2021	2021	2021	2022	2022	2022	2022
	Mean	Median	Min	Max	Mean	Median	Min	Max
MA-PDs	\$31.34	\$35.00	\$0.00	\$35.00	\$31.43	\$35.00	\$0.00	\$35.00
PDPs	\$28.57	\$35.00	\$5.00	\$35.00	\$31.63	\$35.00	\$5.00	\$35.00

SOURCE: Publicly available CMS prescription drug plan formulary data⁷⁴ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 obtained from the PDSS monitoring contractor. The 2021 results were based on the Quarter 1 2021 formulary files and 2022 results were based on the January 2022 files.

NOTE: Cost sharing was calculated as the average of all copayments indicated by PDSS-participating plans in their Model submissions, for each participating plan type (MA-PD and PDP). Max = maximum; Min = minimum.

Cost Sharing for Additional Insulins

PDSS participants were encouraged, but not required, to include additional insulins on their formularies beyond the plan-selected Model insulins covered by a maximum \$35 copay per month, thereby providing further insulin options for enrollees. Tables B.4 and B.5 in Appendix B provide additional information on the extent to which plans covered additional insulins beyond those included as part of the Model test.

Very few MA-PDs (less than 2 percent) in 2021 and 2022 provided coverage for additional insulins. When they did so, the cost sharing charged was generally greater than \$35 per month (Table B.4). However, Humulin R 500 was a notable exception: About 25 percent of MA-PDs in 2021 and 33 percent in 2022 provided additional coverage for this insulin. MA-PDs applied coinsurance averaging 32 percent for Humulin R 500 in both years. As noted earlier, more than 50 percent of MA-PD formularies included Humulin R 500 as part of their plan-selected Model insulins, with maximum copayments of \$35 per month; the 25 to 33 percent of MA-PDs offering it as an additional insulin chose to include it without lowering the cost sharing to the maximum \$35 per month threshold.

Participating PDPs covered fewer additional insulins compared with MA-PDs (see Tables B.4 and B.5). About 13 percent of plans covered at least one additional insulin. Humulin R 500 was again a notable exception: 88 percent of PDPs in 2021 and 79 percent in 2022 offered

coverage of this insulin. PDPs offering Humulin R 500 coverage all charged coinsurance, which increased from an average of 30 percent in 2021 to 32 percent in 2022.

Narrower First Risk Corridor

There was substantial uptake of the first risk corridor component in the first year of the Model test. In 2021, about three-quarters (71 percent) of all participating plans elected the optional narrower first risk corridor—nearly all (89 percent) PDPs and 67 percent of MA-PDs did so. In 2022, however, 58 percent of participating plans elected the narrower first risk corridor: Fewer PDPs (55 percent) and fewer MA-PDs (59 percent) chose this optional component. The reduction in the overall percentage of plans selecting this optional component was driven by a substantially smaller percentage of plans joining the Model test in 2022 that chose the narrower first risk corridor (4 percent of new PDPs and 47 percent of new MA-PDs). The majority (about 90 percent) of both MA-PDs and PDPs that continued participation from 2021 to 2022 and had elected the narrower first risk corridor option in 2021 continued to elect it in 2022.

Rewards and Incentives Programs

The other optional component is the ability for POs to offer R&I programs that provide financial incentives for healthy behaviors among beneficiaries with pre-diabetes or diabetes. POs can offer eligible beneficiaries gift cards for completing such activities as MTM or CMR. This component was not widely used. Five POs elected to offer the R&I component across 32 MA-PDs in 2021, representing 2.7 percent of participating MA-PDs. One PO stopped offering its R&I program in 2022, and six new POs started offering R&I programs in 2022, for a total of ten POs in 2022 across 76 plans. None of the participating PDPs offered R&I programs in 2021 or 2022.

The five POs that offered R&I programs in 2021 offered five distinct R&I programs (PO 3 offered two types of R&I programs across two sets of subsidiary plans; two other POs [PO 2 and PO 4] offered the exact same R&I program because they have a partnership agreement to provide coverage for MA beneficiaries in different parts of the same state).⁷⁵ Four of the five 2021 R&I programs identified eligible beneficiaries based on prescription fill criteria; the fifth program was offered to beneficiaries with a diabetes diagnosis who met the criteria to receive a CMR. Three R&I programs offered rewards for completing a CMR consultation, and the other two provided \$50 to \$75 gift cards per year for achieving adherence to statins or specified diabetes medications.

The four POs that offered R&I programs in both 2021 and 2022 did not change their targeting criteria or activities. However, they all changed the type of reward available, generally shifting from gift cards for major retailers, such as Target, to gift cards for locations offering specific services, such as gas stations or grocery stores.

The six new POs that offered R&I programs in 2022 identified eligible beneficiaries based on medication fills, diagnosis codes, and/or whether a beneficiary’s medication utilization made them eligible for one or more Star Ratings medication adherence measures. The activity requirements for new POs were similar to those for the 2021 R&I programs, including completion of a CMR, undergoing MTM with a pharmacist, maintaining minimum adherence criteria, and participating in disease management programs offered by the plan. Rewards generally took the form of a gift card to select retailers, such as gas stations or grocery stores, but one PO offered a “credit” to be spent on plan supplemental benefit services, which included OTC items, healthy food, dental services, transportation, or eyewear. For additional details on individual R&I programs offered by POs, please see Table C.1 in Appendix C.

Chapter 5. Conclusion

The PDSS Model provides beneficiaries taking Model drugs with access to lower, fixed cost sharing through all but the catastrophic phase of the benefit. This is accomplished via a change to the Medicare Coverage Gap Discount Program in the coverage gap phase, whereby manufacturers that elect to participate in the Model test provide the 70 percent discount on Model drugs before the application of enhanced benefits. Participating POs enter eligible enhanced Part D plans into the Model test and negotiate with manufacturers for inclusion of Model drugs on their formularies. The first two years of the Model test have used insulin, a drug used to manage diabetes, as the Model drug.

Participation in the first two years of the Model test (2021 and 2022) has been robust. In 2021, all three of the largest manufacturers (based on 2020 insulin revenue) chose to participate, and by 2022, all five U.S. manufacturers of insulin had entered their insulins into the Model test. Seventy-five POs in 2021 and 106 in 2022 elected to participate in the Model test; very few POs left the Model test after the first year. Nearly half of eligible MA-PDs and approximately two-thirds of eligible PDPs joined the Model test by the second year.

Characteristics of plans that participated in the Model test in 2021 and 2022 were similar across a number of dimensions, including area-level characteristics and enrollee characteristics. For 2021 participants, a higher percentage of enrollees filled at least one plan-selected Model insulin in the first six months of 2021 compared with enrollees of eligible nonparticipating plans. Participating PDPs had substantially higher total premiums compared with eligible nonparticipating PDPs in both 2021 and 2022. The formulary tier structures for both participating and nonparticipating MA-PDs and PDPs were broadly similar, with median cost sharing amounts almost identical within each Part D plan type and across the Model test participants and nonparticipants.

Although PDSS participants included a range of insulins on their plan-selected Model insulin lists, there was no clear pattern in selection of one specific manufacturer over another for coverage of the required insulin types (rapid-, intermediate-, short-, and long-acting). Compared with nonparticipants' formularies, a higher percentage of participating MA-PD formularies included the Novo Nordisk insulin option for the given insulin type, while PDPs tended to favor Eli Lilly insulins. MA-PDs and PDPs were more consistent in their inclusion of long-acting insulins on their plan-selected Model insulin lists: A high percentage of MA-PDs (74.7 percent in 2022) and PDPs (85.7 percent in 2022) included at least one Sanofi long-acting insulin. Both MA-PDs and PDPs included some insulins on their formularies in addition to those that they treated as the plan-selected Model insulins. The most commonly included additional insulin was the only FDA-approved highly concentrated insulin, Humulin R 500.

More than half of participating MA-PDs and PDPs elected the narrower first risk corridor option in both 2021 and 2022, although the percentage of PDSS-participating plans electing this option declined substantially from the first to the second year of the Model test. This decline was largely due to fewer new entrants electing the option.

None of the POs that entered PDPs elected to offer R&I programs in either year of the Model test, and a small number (five in 2021, 10 in 2022) of POs offered R&I programs across 76 MA-PD plans by 2022. The R&I programs targeted beneficiaries with diabetes or pre-diabetes, using prescription drug fills or eligibility for Star Ratings medication measures as the criteria for eligibility. Beneficiaries were generally rewarded with gift cards for completion of specific tasks, such as participation in MTM or CMR and (increasingly in 2022) achievement of a minimum medication adherence threshold (generally at least 80 percent of days covered by a filled medication). This latter requirement is consistent with the Star Ratings medication adherence measures and may help plans improve their scores on those measures.

In summary, the Model test has generated a robust response among eligible Part D plans, with even greater participation in the second year of implementation. Participating plans offer a median \$35 per month copayment for plan-selected Model insulins, and more than half have elected the narrower first risk corridor. In the future, RAND will assess the Model test's effects on key outcomes, including costs, medication adherence, and health outcomes.

Appendix A. Insulins Entered into the PDSS Model

Appendix A shows the number of insulins entered into the Model test by each manufacturer, at the NDC level. The FDA assigns each drug product a unique numeric identifier code that includes information on its manufacturer, active ingredient, and route of administration.⁷⁶ A specific active ingredient may have multiple NDCs for each manufacturer. We counted insulins for the results shown in Table 2.2 in Chapter 2 by using observations aggregated across insulin type, manufacturer, brand name, and active ingredient observations. Table A.1 shows the number of insulins when counted at the NDC level.

Table A.1. Number of NDC Model Insulins, by Insulin Type and Manufacturer

Manufacturer	Rapid-Acting	Short-Acting	Intermediate-Acting	Long-Acting	Mixed	Combination	Concentrate	Total
Eli Lilly	23	2	4	2	12		3	46
Novo Nordisk	15	4	4	9	13	1		46
Sanofi	8			14		1		23
Viatris				9				9
MannKind	6							6
Total	52	6	8	34	25	2	3	130

SOURCE: Model drug lists posted to the CMMI website¹¹ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 were obtained from the PDSS monitoring contractor. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹ We used Medi-Span, a therapeutic classification scheme, to harmonize drug names and active ingredients and to identify the manufacturer.

Appendix B. Insulin Coverage by PDSS Model Participants

Appendix B provides additional detail on the formulary design for insulin among PDSS-participating plans, as supplementary content for Chapter 4.

Table B.1. Percentage of PDSS-Participating Plans Covering Each Type of Plan-Selected Model Insulin, by Manufacturer, 2021 and 2022

	MA-PD	MA-PD	PDP	PDP
	2021 (n = 1,191)	2022 (n = 1,711)	2021 (n = 310)	2022 (n = 258)
Rapid-acting (9 insulins)				
Eli Lilly (3)	55.0%	53.0%	55.5%	46.5%
Novo Nordisk (3)	47.8%	50.8%	44.5%	53.5%
Sanofi (2)	0%	0.1%	0%	0%
MannKind ^a (1)	N/A	0%	N/A	0%
Short-acting (2 insulins)				
Eli Lilly (1)	55.0%	53.0%	55.5%	46.5%
Novo Nordisk (1)	47.8%	50.8%	44.5%	53.5%
Intermediate-acting (2 insulins)				
Eli Lilly (1)	55.0%	53.0%	55.5%	46.5%
Novo Nordisk (1)	47.8%	50.8%	44.5%	53.5%
Long-acting (8 insulins)				
Eli Lilly (1)	18.8%	18.8%	33.5%	27.1%
Novo Nordisk (2)	85.7%	84.4%	67.1%	81.0%
Sanofi (2)	88.7%	86.3%	67.1%	73.6%
Viatrix ^a (3)	N/A	0.9%	N/A	0%
Mixed (6 insulins)				
Eli Lilly (3)	54.4%	52.5%	55.5%	41.1%
Novo Nordisk (3)	47.8%	49.8%	44.5%	53.5%
Concentrate (1 insulin)				
Eli Lilly (1)	63.2%	58.7%	11.6%	14.7%
Combination (2 insulins)				
Novo Nordisk (1)	39.0%	43.0%	44.2%	53.9%
Sanofi (1)	78.5%	74.6%	65.8%	79.8%

SOURCE: Publicly available CMS prescription drug plan formulary data⁷⁴ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 obtained from the PDSS monitoring contractor. The 2021 results were based on the Quarter 1 2021 formulary files and 2022 results were based on the January 2022 files.⁷⁴ Manufacturer data were taken at the NDC level from Medi-Span. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹

NOTE: Some plans did not publicly report their formulary data for the year, therefore the number of participating plans shown does not necessarily match the total number of participating plans.

^a MannKind and Viatrix joined the Model test in 2022.

Table B.2. Plan-Selected Model Drug Coverage Among PDSS-Participating MA-PDs, 2021 and 2022

Manufacturer	Brand Name	Active Ingredient	2021	2021	2021	2021	2022	2022	2022	2022
			Number of Plans (n = 1,191)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)	Number of Plans (n = 1,711)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)
Rapid-acting										
Eli Lilly	Humalog	Insulin Lispro	655	33.03	0.00	35.00	906	32.22	0.00	35.00
Eli Lilly	Insulin Lispro	Insulin Lispro	470	34.43	0.00	35.00	625	33.14	0.00	35.00
Eli Lilly	Lyumjev	Insulin Lispro-aabc	476	34.59	0.00	35.00	728	33.41	0.00	35.00
Novo Nordisk	Insulin Aspart	Insulin Aspart	34	19.12	0.00	35.00	90	24.30	0.00	35.00
Novo Nordisk	Novolog	Insulin Aspart	569	28.80	0.00	35.00	852	29.65	0.00	35.00
Novo Nordisk	Fiasp	Insulin Aspart (with Niacinamide)	486	29.93	0.00	35.00	744	31.27	0.00	35.00
Sanofi	Apidra	Insulin Glulisine	0	.	.	.	2	35.00	35.00	35.00
Short-acting										
Eli Lilly	Humulin R	Insulin Regular (Human)	655	31.14	0.00	35.00	906	30.63	0.00	35.00
Novo Nordisk	Novolin R	Insulin Regular (Human)	569	28.68	0.00	35.00	869	30.44	0.00	35.00
Intermediate-acting										
Eli Lilly	Humulin N	Insulin NPH (Human) (Isophane)	655	32.09	0.00	35.00	906	31.16	0.00	35.00
Novo Nordisk	Novolin N	Insulin NPH (Human) (Isophane)	569	28.70	0.00	35.00	869	30.45	0.00	35.00
Long-acting										
Eli Lilly	Basaglar	Insulin Glargine	224	25.59	0.00	35.00	321	28.39	0.00	35.00
Novo Nordisk	Tresiba	Insulin Degludec	981	31.81	0.00	35.00	1,414	32.06	0.00	35.00
Novo Nordisk	Levemir	Insulin Detemir	1,021	31.72	0.00	35.00	1,407	31.93	0.00	35.00
Sanofi	Lantus	Insulin Glargine	1,057	32.47	0.00	35.00	1,476	32.27	0.00	35.00

Manufacturer	Brand Name	Active Ingredient	2021	2021	2021	2021	2022	2022	2022	2022
			Number of Plans (n = 1,191)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)	Number of Plans (n = 1,711)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)
Sanofi	Toujeo	Insulin Glargine	1052	33.05	0.00	35.00	1468	32.56	0.00	35.00
Viartis	Semglee	Insulin Glargine	N/A	N/A	N/A	N/A	16	33.13	5.00	35.00
Mixed										
Eli Lilly	Humalog	Insulin Lispro Protamine & Lispro	648	33.01	0.00	35.00	884	32.15	0.00	35.00
Eli Lilly	Insulin Lispro	Insulin Lispro Protamine & Lispro	470	34.43	0.00	35.00	601	33.15	0.00	35.00
Eli Lilly	Humulin	Insulin NPH Isophane & Regular (Human)	648	32.05	0.00	35.00	898	31.12	0.00	35.00
Novo Nordisk	Insulin Aspart	Insulin Aspart Protamine & Aspart (Human)	34	19.12	0.00	35.00	82	23.26	0.00	35.00
Novo Nordisk	Novolog	Insulin Aspart Protamine & Aspart (Human)	569	28.56	0.00	35.00	852	29.47	0.00	35.00
Novo Nordisk	Novolin	Insulin NPH Isophane & Regular (Human)	569	28.51	0.00	35.00	852	29.83	0.00	35.00
Concentrate										
Eli Lilly	Humulin R 500	Insulin Regular (Human)	753	33.46	0.00	35.00	1005	32.93	0.00	35.00
Combination										
Novo Nordisk	Xultophy	Insulin Degludec-Liraglutide	464	31.00	0.00	35.00	735	32.09	0.00	35.00
Sanofi	Soliqua	Insulin Glargine-Lixisenatide	935	32.86	0.00	35.00	1277	32.50	0.00	35.00

SOURCE: Publicly available CMS prescription drug plan formulary data⁷⁴ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 obtained from the PDSS monitoring contractor. The 2021 results were based on the Quarter 1 2021 formulary files and 2022 results were based on the January 2022 files.⁷⁴ Manufacturer data were taken at the NDC-level from Medi-Span. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹

NOTE: Some insulins are not covered by any plans in a given year; for such insulins, we placed a zero (0) in the “Number of plans” column and a period (.) in the copay columns. An insulin (brand name and active ingredient) is not listed if no plans in either year included it on its plan-selected Model insulin list. Some plans did not publicly report their formulary data for the year; therefore, the number of participating plans shown does not necessarily match the total number of participating plans. Max. = maximum; Min. = minimum.

Table B.3. Plan-Selected Model Drug Coverage Among PDSS-Participating PDPs, 2021 and 2022

Manufacturer	Brand Name	Active Ingredient	2021	2021	2021	2021	2022	2022	2022	2022
			Number of Plans (n = 310)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)	Number of Plans (n = 258)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)
Rapid-acting										
Eli Lilly	Humalog	Insulin Lispro	172	23.59	11.00	35.00	120	28.00	11.00	35.00
Eli Lilly	Insulin Lispro	Insulin Lispro	35	35.00	35.00	35.00	35	35.00	35.00	35.00
Eli Lilly	Lyumjev	Insulin Lispro-aabc	170	23.46	11.00	35.00	106	27.08	11.00	35.00
Novo Nordisk	Insulin Aspart	Insulin Aspart	0	.	.	.	0	.	.	.
Novo Nordisk	Novolog	Insulin Aspart	138	34.78	5.00	35.00	138	34.78	5.00	35.00
Novo Nordisk	Fiasp	Insulin Aspart (with Niacinamide)	138	34.78	5.00	35.00	138	34.78	5.00	35.00
Sanofi	Apidra	Insulin Glulisine	0	.	.	.	0	.	.	.
Short-acting										
Eli Lilly	Humulin R	Insulin Regular (Human)	172	23.59	11.00	35.00	120	28.00	11.00	35.00
Novo Nordisk	Novolin R	Insulin Regular (Human)	138	34.78	5.00	35.00	138	34.78	5.00	35.00
Intermediate-acting										
Eli Lilly	Humulin N	Insulin NPH (Human) (Isophane)	172	23.59	11.00	35.00	120	28.00	11.00	35.00
Novo Nordisk	Novolin N	Insulin NPH (Human) (Isophane)	138	34.78	5.00	35.00	138	34.78	5.00	35.00
Long-acting										
Eli Lilly	Basaglar	Insulin Glargine	104	34.71	5.00	35.00	70	34.57	5.00	35.00
Novo Nordisk	Tresiba	Insulin Degludec	208	30.93	5.00	35.00	209	30.84	5.00	35.00
Novo Nordisk	Levemir	Insulin Detemir	208	30.93	5.00	35.00	209	30.84	5.00	35.00
Sanofi	Lantus	Insulin Glargine	208	25.42	5.00	35.00	190	30.42	5.00	35.00
Sanofi	Toujeo	Insulin Glargine	208	25.42	5.00	35.00	190	30.42	5.00	35.00
Viatrix	Semglee	Insulin Glargine	N/A	N/A	N/A	N/A	0	.	.	.
Mixed										

Manufacturer	Brand Name	Active Ingredient	2021	2021	2021	2021	2022	2022	2022	2022
			Number of Plans (n = 310)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)	Number of Plans (n = 258)	Mean Copay (\$)	Min. Copay (\$)	Max. Copay (\$)
Eli Lilly	Humalog	Insulin Lispro Protamine & Lispro	172	23.59	11.00	35.00	106	27.08	11.00	35.00
Eli Lilly	Insulin Lispro	Insulin Lispro Protamine & Lispro	35	35.00	35.00	35.00	35	35.00	35.00	35.00
Eli Lilly	Humulin	Insulin NPH Isophane & Regular (Human)	172	23.59	11.00	35.00	106	27.08	11.00	35.00
Novo Nordisk	Insulin Aspart	Insulin Aspart Protamine & Aspart (Human)	0	.	.	.	0	.	.	.
Novo Nordisk	Novolog	Insulin Aspart Protamine & Aspart (Human)	138	34.78	5.00	35.00	138	34.78	5.00	35.00
Novo Nordisk	Novolin	Insulin NPH Isophane & Regular (Human)	138	34.78	5.00	35.00	138	34.78	5.00	35.00
Concentrate										
Eli Lilly	Humulin R 500	Insulin Regular (Human)	36	35.00	35.00	35.00	38	35.00	35.00	35.00
Combination										
Novo Nordisk	Xultophy	Insulin Degludec-Liraglutide	137	35.00	35.00	35.00	139	35.00	35.00	35.00
Sanofi	Soliqua	Insulin Glargine-Lixisenatide	204	33.38	25.00	35.00	206	35.00	35.00	35.00

SOURCE: Publicly available CMS prescription drug plan formulary data⁷⁴ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 obtained from the PDSS monitoring contractor. The 2021 results were based on the Quarter 1 2021 formulary files and 2022 results were based on the January 2022 files.⁷⁴ Manufacturer data were taken at the NDC level from Medi-Span. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹

NOTE: Viatrix did not enter the Model test until 2022, so Semglee shows up as N/A for that year. Some insulins are not covered by any plans in a given year; for such insulins, we placed a zero (0) in the “Number of plans” column and a period (.) in the copay columns. An insulin (brand name and active ingredient) is not listed at all if no plans in either year included it on its plan-selected Model insulin list. Max. = maximum; Min. = minimum; N/A = not applicable.

Table B.4. Additional Insulin Coverage Among PDSS-Participating MA-PDs, 2021 and 2022

Manufacturer	Brand Name	Active Ingredient	2021	2021	2021	2021	2022	2022	2022	2022
			Number of Plans (n = 1,191)	Mean Copay (\$)	Number of Plans (n = 1,191)	Mean Coins. (%)	Number of Plans (n = 1,711)	Mean Copay (\$)	Number of Plans (n = 1,711)	Mean Coins. (%)
Rapid-acting										
Eli Lilly	Humalog	Insulin Lispro	6	80.00	4	47.0	60	69.97	5	42.6
Eli Lilly	Insulin Lispro	Insulin Lispro	0	.	4	47.0	7	100.00	4	47.0
Eli Lilly	Lyumjev	Insulin Lispro-aabc	7	70.00	6	33.0	53	70.04	0	.
Novo Nordisk	Insulin Aspart	Insulin Aspart	0	.	1	50.0	7	100.00	2	47.5
Novo Nordisk	Novolog	Insulin Aspart	0	.	4	50.0	17	42.00	0	.
Novo Nordisk	Fiasp	Insulin Aspart (with Niacinamide)	6	0.00	1	50.0	17	42.00	2	47.5
Sanofi	Apidra	Insulin Glulisine	0	.	9	48.67	7	100.00	6	47.2
Short-acting										
Eli Lilly	Humulin R	Insulin Regular (Human)	0	.	4	47.0	11	96.36	5	42.6
Novo Nordisk	Novolin R	Insulin Regular (Human)	0	.	1	50.0	0	.	0	.
Intermediate-acting										
Eli Lilly	Humulin N	Insulin NPH (Human) (Isophane)	0	.	4	47.0	11	96.36	5	42.6
Novo Nordisk	Novolin N	Insulin NPH (Human) (Isophane)	0	.	1	50.0	0	.	0	.
Long-acting										
Eli Lilly	Basaglar	Insulin Glargine	18	42.00	0	.	30	67.13	0	.
Novo Nordisk	Tresiba	Insulin Degludec	0	.	0	.	20	42.00	0	.
Novo Nordisk	Levemir	Insulin Detemir	0	.	0	.	17	42.00	0	.
Sanofi	Lantus	Insulin Glargine	0	.	0	.	17	42.00	0	.
Sanofi	Toujeo	Insulin Glargine	0	.	0	.	20	42.00	0	.
Viartis	Semglee	Insulin Glargine	N/A	N/A	N/A	N/A	22	88.59	0	.
Mixed										
Eli Lilly	Humalog	Insulin Lispro Protamine & Lispro	12	63.50	4	47.0	57	71.44	5	42.6
Eli Lilly	Insulin Lispro	Insulin Lispro Protamine & Lispro	0	.	4	47.0	29	50.69	4	47.0
Eli Lilly	Humulin	Insulin NPH Isophane & Regular (Human)	6	47.00	4	47.0	19	70.53	5	42.6

Manufacturer	Brand Name	Active Ingredient	2021	2021	2021	2021	2022	2022	2022	2022
			Number of Plans (n = 1,191)	Mean Copay (\$)	Number of Plans (n = 1,191)	Mean Coins. (%)	Number of Plans (n = 1,711)	Mean Copay (\$)	Number of Plans (n = 1,711)	Mean Coins. (%)
Novo Nordisk	Insulin Aspart	Insulin Aspart Protamine & Aspart (Human)	0	.	1	50.0	7	100.00	2	47.5
Novo Nordisk	Novolog	Insulin Aspart Protamine & Aspart (Human)	0	.	4	50.0	17	42.00	0	.
Novo Nordisk	Novolin	Insulin NPH Isophane & Regular (Human)	3	35.00	1	50.0	17	42.00	0	.
Concentrate										
Eli Lilly	Humulin R 500	Insulin Regular (Human)	6	47.00	295	31.51	3	42.00	565	31.5
Combination										
Novo Nordisk	Xultophy	Insulin Degludec-Liraglutide	12	40.00	0	.	51	45.27	0	.
Sanofi	Soliqua	Insulin Glargine-Lixisenatide	15	39.00	0	.	51	42.16	0	.

SOURCE: Publicly available CMS prescription drug plan formulary data⁷⁴ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 obtained from the PDSS monitoring contractor. The 2021 results were based on the Quarter 1 2021 formulary files and 2022 results were based on the January 2022 files.⁷⁴ Manufacturer data were taken at the NDC level from Medi-Span. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹

NOTE: Viartis did not enter the Model test until 2022, so Semglee shows up as N/A for that year. Some insulins are not covered by any plans in a given year; for such insulins, we placed a zero (0) in the “Number of plans” column and a period (.) in the copay columns. Additional insulins are those covered by PDSS-participating plans outside of the Model test. These insulins are not included on the list of plan-selected Model insulins and generally have cost sharing greater than \$35 per month. Some plans did not publicly report their formulary data for the year, therefore the number of participating plans shown does not necessarily match the total number of participating plans. An insulin (brand name and active ingredient) is not listed at all if no plans in either year included it as an additional insulin. Coins = coinsurance; N/A = not applicable.

Table B.5. Additional Insulin Coverage among PDSS-Participating PDPs, 2021 and 2022

Manufacturer	Brand Name	Active Ingredient	2021 Number of Plans (n = 310)	2021 Mean Copay (\$)	2021 Number of Plans (n = 310)	2021 Mean Coins. (%)	2022 Number of Plans (n = 258)	2022 Mean Copay (\$)	2022 Number of Plans (n = 258)	2022 Mean Coins. (%)
Rapid-Acting										
Eli Lilly	Humalog	Insulin Lispro	0	.	0	.	14	47.00	0	.
Eli Lilly	Lyumjev	Insulin Lispro-aabc	0	.	0	.	14	47.00	0	.
Novo Nordisk	Novolog	Insulin Aspart	0	.	33	43.88	0	.	33	44.24
Long-Acting										
Novo Nordisk	Levemir	Insulin Detemir	0	.	33	43.88	0	.	33	44.24
Mix										
Eli Lilly	Humalog	Insulin Lispro Protamine & Lispro	0	.	0	.	14	47.00	0	.
Eli Lilly	Humulin	Insulin NPH Isophane & Reg (Human)	0	.	0	.	14	47.00	0	.
Novo Nordisk	Novolog	Insulin Aspart Protamine & Aspart (Human)	0	.	33	43.88	0	.	33	44.24
Concentrate										
Eli Lilly	Humulin R 500	Insulin Regular (Human)	0	.	273	30.17	0	.	205	31.78
Combination										
Novo Nordisk	Xultophy	Insulin Degludec-Liraglutide	34	42.00	0	.	35	42.00	0	.
Sanofi	Soliqua	Insulin Glargine-Lixisenatide	69	38.45	0	.	35	42.00	0	.

SOURCE: Publicly available CMS prescription drug plan formulary data⁷⁴ and NDC-level lists of plan-selected Model insulins for 2021 and 2022 obtained from the PDSS monitoring contractor. The 2021 results were based on the Quarter 1 2021 formulary files and 2022 results were based on the January 2022 files.⁷⁴

Manufacturer data were taken at the NDC level from Medi-Span. We categorized drugs in collaboration with CMMI using ADA guidelines⁶⁰ and FDA package labels.⁶¹

NOTE: Some insulins are not covered by any plans; for such insulins, we placed a zero (0) in the “Number of plans” column and a period (.) in the copay columns. Insulins with no plans covering them for that year are not shown in this table. Additional insulins are those covered by PDSS-participating plans outside of the Model test. These insulins are not included on the list of plan-selected Model insulins and generally have cost sharing greater than \$35 per month. An insulin (brand name and active ingredient) is not listed at all if no plans in either year included it as an additional insulin. Coins. = coinsurance.

Appendix C. PO Rewards and Incentives Programs

Table C.1 summarizes the details of specific R&I programs that participating POs implemented as part of their Model interventions. The R&I component was optional.

Table C.1. PDSS Rewards and Incentives Programs, 2021 and 2022

Parent Organization (N = 11)	Number of Plans, 2021 (N = 32)	Number of Plans, 2022 (N = 76)	Targeting Criteria	Activity	Reward
Offer R&I program in 2021 only					
PO 1	2	N/A	Beneficiaries taking insulin	Participate in MTM and complete a CMR	\$100 gift card
Offer R&I program in 2021 and 2022					
PO 2	2	2	Diabetes diagnosis and meets CMR eligibility criteria	Complete annual CMR	<ul style="list-style-type: none"> \$30 Target gift card (2021) \$30 gas station gift card (2022)
PO 3	7	8	P1: At least two fills of any diabetes medicine on at least two different days	P1: Complete CMR	<ul style="list-style-type: none"> P1: \$25 gift card (Walmart, Amazon, Subway) (2021) P1: \$50 gift card (specific locations/services) (2022)
			P2: At least two fills of any diabetes medicine on at least two different days	P2: Complete consultation and adhere to statin medicines (PDC > 80%)	<ul style="list-style-type: none"> P2: \$50 gift card (Walmart, Amazon, Subway) (2021) P2: \$50 gift card (specific locations/services) (2022)
PO 4	16	14	Diabetes diagnosis and meets CMR eligibility criteria	Complete annual CMR	<ul style="list-style-type: none"> \$30 Target gift card (2021) \$30 gas station gift card (2022)

Parent Organization (N = 11)	Number of Plans, 2021 (N = 32)	Number of Plans, 2022 (N = 76)	Targeting Criteria	Activity	Reward
PO 5	5	5	Diabetes diagnosis and beneficiary takes specific diabetes medications	Receive consultation and adhere to diabetes medicines (at least two fills on separate days of specified medications)	<ul style="list-style-type: none"> \$75 gift card (Mastercard, Visa) (2021) \$75 gift card (specific goods/services) (2022)
Offer R&I program in 2022 only					
PO 6	N/A	3	<ul style="list-style-type: none"> P1: Diabetes based on medication fills P2: Diabetes based on medication fills 	<ul style="list-style-type: none"> P1: Enroll in rewards program, fill at least one statin P2: Enroll in rewards program, achieve 80% PDC 	<ul style="list-style-type: none"> P1: \$15 gift card P2: \$20 gift card
PO 7	N/A	5	Diabetes or pre-diabetes based on fills of diabetes medications	Engage with MTM services provided by partner pharmacists	\$20 Benefit Card to spend on supplemental benefit services
PO 8	N/A	1	Eligible for Star Ratings diabetes medication adherence measure	Adhere to diabetes medication and participate in disease management program	\$10 quarterly gift card (select retailers)
PO 9	N/A	27	Diabetes diagnosis and eligible for CMR	Complete CMR	\$25 gift card (restaurant, gas station, movie theater)
PO 10	N/A	4	<ul style="list-style-type: none"> P1: Diabetes or pre-diabetes diagnosis based on codes and drug utilization P2: Diabetes or pre-diabetes diagnosis based on codes and drug utilization 	<ul style="list-style-type: none"> P1: Diabetes medication adherence of at least 84% PDC and complete CMR P2: Statin adherence of at least 83% and enrolled in Part D disease management program 	<ul style="list-style-type: none"> P1: \$25 quarterly OTC card P2: \$25 quarterly OTC card

Parent Organization (N = 11)	Number of Plans, 2021 (N = 32)	Number of Plans, 2022 (N = 76)	Targeting Criteria	Activity	Reward
PO 11	N/A	7	<ul style="list-style-type: none"> • P1: Beneficiaries eligible for Star Ratings diabetes medication adherence measure; qualify for CMR • P2: Beneficiaries eligible for Star Ratings diabetes medication adherence measure; qualify for CMR 	<ul style="list-style-type: none"> • P1: Complete a CMR and adhere to diabetes medications • P2: Complete a CMR and fill a new statin prescription 	<ul style="list-style-type: none"> • P1: \$100 gift card to select retailers • P2: \$100 gift card to select retailers

SOURCE: PO R&I program participation information provided to the authors by CMMI.

NOTE: P1 and P2 represent program 1 and program 2, respectively. POs offering more than one R&I program offered both programs to the enrollees of the same plans. N/A = not applicable; PDC = proportion of days covered.

Abbreviations

ADA	American Diabetes Association
CCP	Coordinated Care Plan
CMMI	Center for Medicare & Medicaid Innovation
CMR	comprehensive medication review
CMS	Centers for Medicare & Medicaid Services
C-SNP	Chronic Condition Special Needs Plan
DPP-4	dipeptidyl peptidase 4
D-SNP	Dual-Special Needs Plan
FDA	U.S. Food and Drug Administration
FFS	fee-for-service
GLP-1	glucagon-like peptide 1
HPMS	Health Plan Management System
IDR	Integrated Data Repository
I-SNP	Institutional Special Needs Plan
LIS	low-income subsidy
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug plan
MMP	Medicare-Medicaid Plan
MTM	medication therapy management
NDC	National Drug Code
NPH	Neutral Protamine Hagedorn
OOP	out-of-pocket
OTC	over the counter
PACE	Program of All-inclusive Care for the Elderly
Part D	Medicare Prescription Drug Benefit Program
PBM	pharmacy benefit manager
PDP	prescription drug plan
PDSS	Part D Senior Savings Model
PO	parent organization
R&I	Rewards and Incentives
rDNA	recombinant DNA
RxHCC	Prescription Drug Hierarchical Condition Code
SGLT-2	sodium-glucose co-transporter 2
TrOOP	true out-of-pocket
VBID	value-based insurance design

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