

A Summary of Insulin Coverage in Medicare Part D

Understanding beneficiaries' formulary coverage for insulin products in 2020, 2021, and 2022

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Key Findings: Insulin Formulary Coverage



Insulin products are widely covered on Part D formularies. In 2020, 2021, and 2022 all beneficiaries enrolled in an individual Medicare Part D plan have insulin coverage in the classes we included in our analysis, with a range of coverage options by manufacturer/drug type.



In 2022, approximately 2 out of 3 Part D beneficiaries typically pay \$35 or less for a 30-day supply of insulin.³

In 2022: Percent of Beneficiaries Enrolled in a Part D Plan by Insulin Coverage Strategy and Class

Insulin Class	Exclusively Covers 1 Manufacturer/Drug Type Combination ¹	Covers >1 Manufacturer/Drug Type Combination ²
Long-Acting	13%	87%
Rapid-Acting	71%	29%
Regular / NPH*	21%	79%

*Neutral Protamine Hagedorn

- Formulary coverage for brand insulin products by manufacturer has been relatively consistent from 2020 to 2022 for each of the classes we included in our analysis.
- As biosimilars and authorized generics (AGs) gain FDA approval, these are generally covered less frequently than brand products on Part D formularies.

¹Insulin manufacturers include Eli Lilly, Mylan, Novo Nordisk, and Sanofi; Drug type includes Brand, Biosimilar, and Authorized Generic

²These may be on the same or different formulary tiers

³Through the deductible, initial coverage limit (ICL), and coverage gap phases of the Part D benefit. This includes non-low income (NLI) beneficiaries enrolled in a Senior Savings Model (SSM) participating plan and low income (LI) members whose cost sharing is subsidized for all drugs.

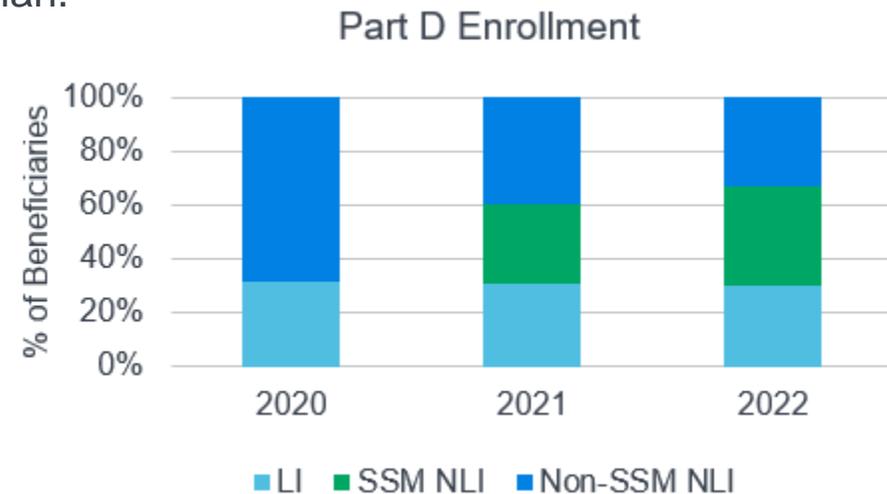
Key Findings: Insulin Tier Placement and Senior Savings Model (SSM) Participation

Tier Placement

- For years 2020-2022, insulins are predominantly covered on the preferred brand tier (often tier 3) of Medicare Part D formularies. CMS requires a 30-day supply cost sharing cap of \$47 for preferred brand tiers in the ICL.¹
- Plan sponsors may cover one or more manufacturers' insulin products on the preferred brand tier and may also cover additional products on non-preferred brand and/or specialty tiers (often tiers 4 and 5).
- A few plan sponsors cover certain insulin products on lower tiers (e.g., tier 2), and a few others have a Select Care tier specific to insulins (e.g., tier 6).
- For formularies that only have a single tier, all insulin products are on tier 1. These one-tier formularies are typically for dual-eligible special needs plans (DSNPs).

SSM Participation

- A larger proportion of NLI beneficiaries are enrolled in an SSM participating plan in 2022 compared to 2021.
- In 2022, of the 70% of beneficiaries that are NLI, about half are enrolled in an SSM participating Part D plan.



¹Plans participating in the SSM cover a set of insulins for a maximum \$35 copay per 30-day supply in the deductible, ICL, and coverage gap phases of the benefit for NLI beneficiaries.

Background: Insulin Types

Insulin types are categorized by how long it takes the insulin to start working / how long the insulin lasts within the body

The FDA defines the following insulin types: rapid-acting, short-acting, intermediate-acting, long-acting, and pre-mixed (a combination of two different types)¹

This analysis summarizes the landscape of insulin coverage in the individual Medicare Part D market in 2020, 2021, and 2022.³ In our summary, we aggregated insulins into three classes:



Currently, more than 3.3 million Medicare beneficiaries use one or more types of insulin²

Long-Acting:	Starts working within 2 to 4 hours and can last in the body for up to 24 hours
Rapid-Acting:	Starts working in 15 minutes, lasts for a few hours
Regular / NPH:	<p>Includes short-acting, intermediate-acting, and pre-mixed combinations of intermediate/rapid-acting, intermediate/short-acting</p> <p>Short-acting starts working within 30 to 60 minutes and lasts for a few hours</p> <p>Intermediate-acting starts working within 2 to 4 hours and reaches highest levels between 6 and 8 hours</p>

¹<https://www.fda.gov/consumers/free-publications-women/insulin#types>

²<https://innovation.cms.gov/innovation-models/part-d-savings-model>

³Includes Medicare Advantage Prescription Drug Plans (MAPDs) and Standalone Prescription Drug Plans (PDPs). Excludes Employer Group Waiver Plans (EGWPs).

Background: Formulary Coverage and Cost Sharing

Preferred Coverage

- Plan sponsors often employ a formulary coverage strategy in which they prefer one manufacturer's insulin products over others to maximize manufacturer rebates.
- They may do so by exclusively covering one manufacturer's insulin products or covering them on a lower formulary tier than other manufacturer's products.

Drug Types

- Plan sponsors may employ formulary strategies in which they prefer an insulin brand product over an AG or biosimilar.
- From a net plan liability perspective, brand products are typically associated with a higher rebate, which may outweigh the lower list price of the AG or biosimilar.

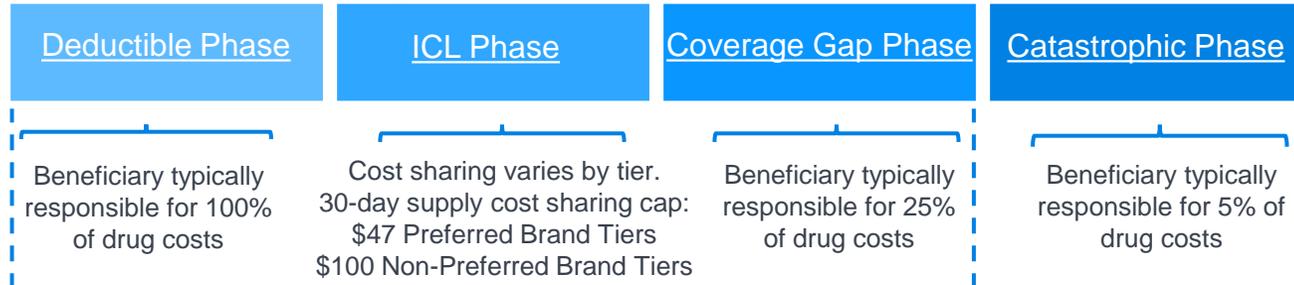


Tiers

- In Part D, formularies are often structured to include a preferred brand tier (often tier 3) and a non-preferred brand tier (often tier 4).
- The Centers for Medicare and Medicaid Services (CMS) requires a 30-day supply cost sharing cap of \$47 for preferred brand tiers and \$100 for non-preferred brand tiers in the ICL phase for NLI beneficiaries.

Background: Formulary Coverage and Cost Sharing

NLI Cost Sharing:



SSM

Beginning in 2021, NLI beneficiaries were given the option to enroll in plans participating in the SSM. Under this voluntary demonstration program introduced by CMS, Part D plan sponsors offer an enhanced alternative plan that covers a select set of insulins for a maximum \$35 copay per 30-day supply in the deductible, ICL, and coverage gap phases of the benefit for NLI beneficiaries. Paying a copay of \$35 or less results in savings for beneficiaries on many insulin products, particularly in the coverage gap.¹



LI Cost Sharing:



LI beneficiaries have the majority of their cost sharing subsidized in all phases through the low income cost sharing subsidy (LICS)

Exceptions:

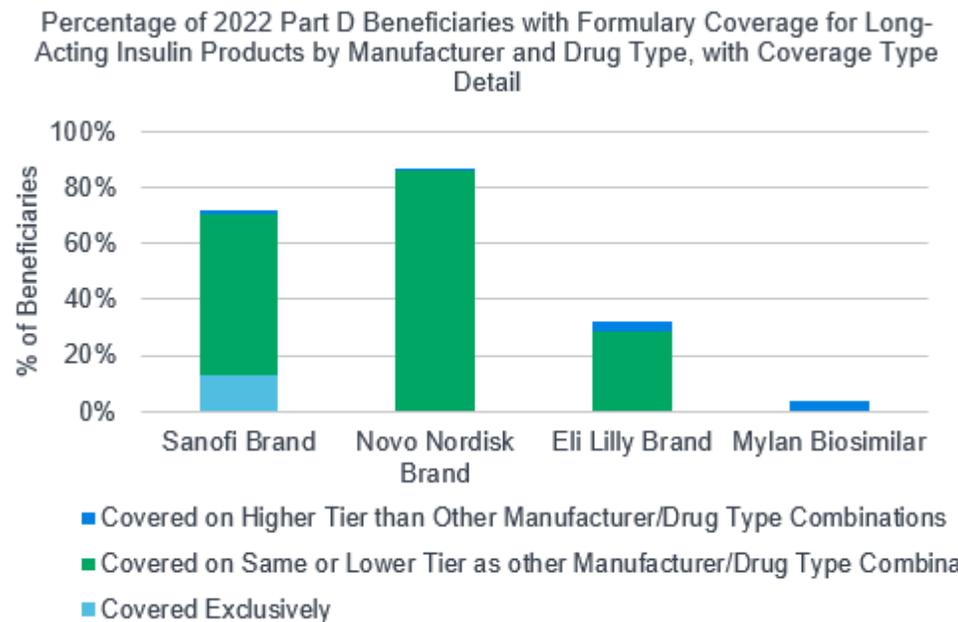
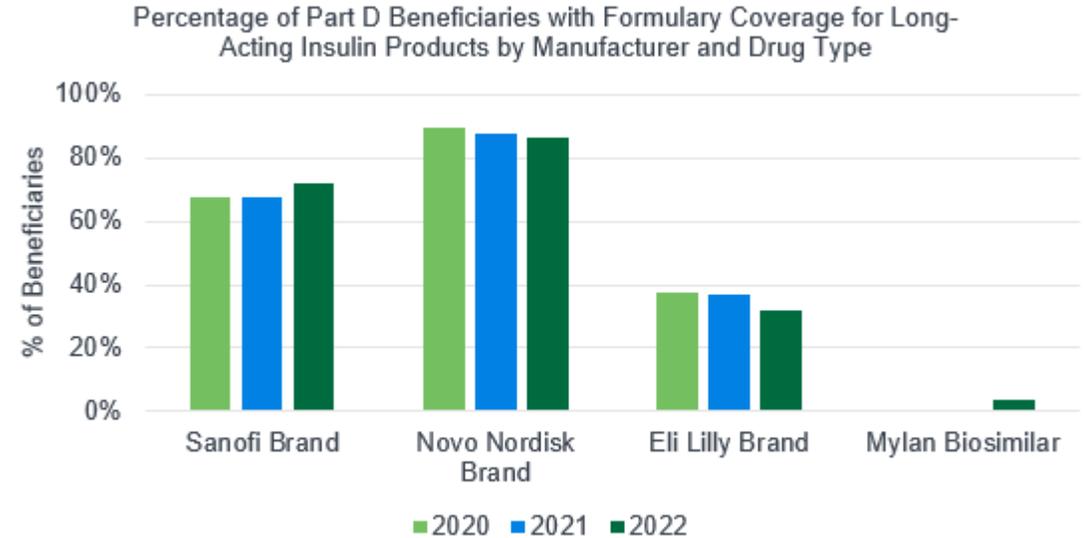
- When non-formulary drug products are deemed medically necessary for a specific beneficiary, they may submit an exception request to gain access to these products. These exceptions, if approved, are typically covered on the non-preferred brand tier (often tier 4).
- Beneficiaries may also submit exception requests to change the tiering of a non-preferred product to a preferred tier, if they have support that the preferred product would not be as effective or would produce worse outcomes.²

Results: Long-Acting Insulin

- In 2020, 2021, and 2022, almost 90% of beneficiaries have formulary coverage for a Novo Nordisk brand, approximately 70% have formulary coverage for a Sanofi brand, and approximately 35% have formulary coverage for an Eli Lilly brand.
- In 2022, most beneficiaries have formulary coverage for more than one manufacturer/drug type combination.
- Mylan's biosimilar Semglee was approved by the FDA in June of 2020. In 2022, 3% of beneficiaries have formulary coverage for Semglee, which is on a higher tier than other covered insulins.

Manufacturer	Drug Type	Products May Include
Sanofi	Brand	Lantus, Lantus Solostar, Toujeo Solostar, Toujeo Max Solostar
Novo Nordisk	Brand	Tresiba Flextouch, Levemir, Levemir Flextouch
Eli Lilly	Brand	Basaglar Kwikpen
Mylan	Biosimilar	Semglee*

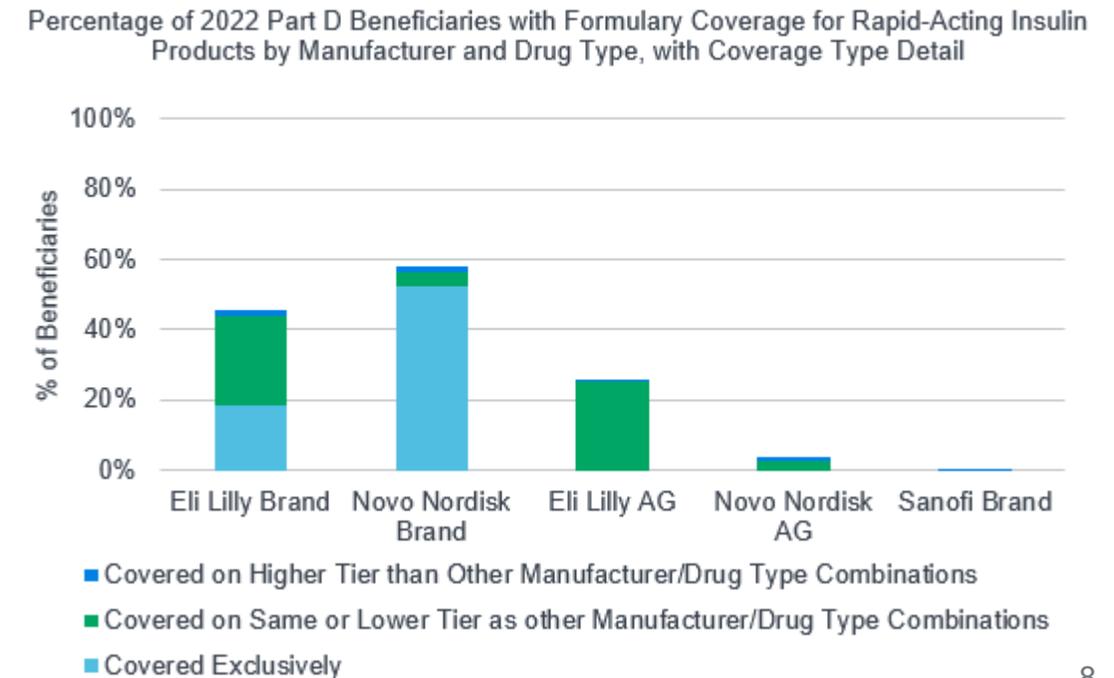
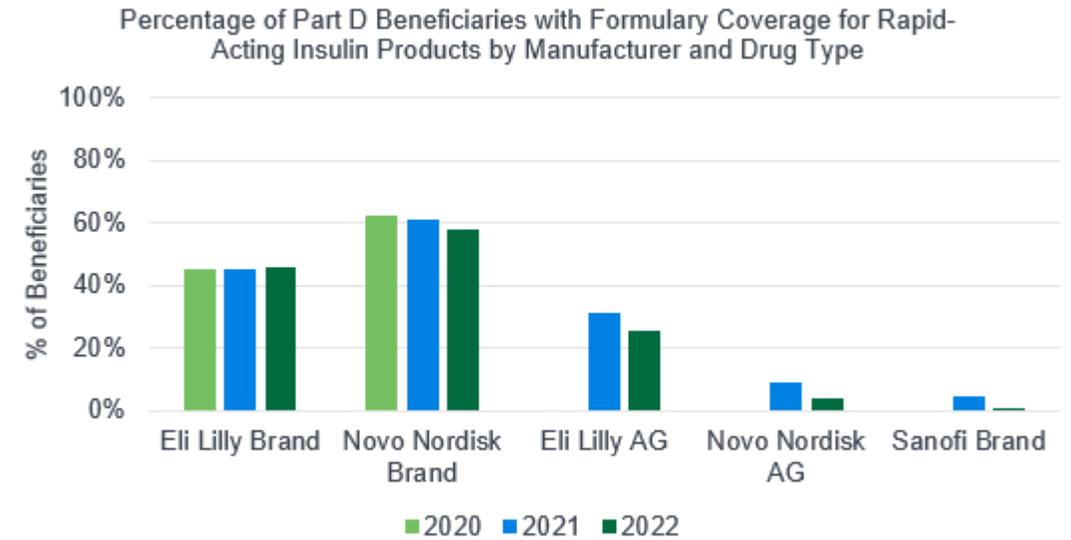
*Semglee approved June 2020



Results: Rapid-Acting Insulin

- In 2020, 2021, and 2022, approximately 60% of beneficiaries have formulary coverage for a Novo Nordisk brand and 45% have formulary coverage for an Eli Lilly brand.
- In 2022, beneficiaries with formulary coverage for a Novo Nordisk brand typically do not have formulary coverage for other insulin products.
- In 2021 and 2022, a lower proportion of beneficiaries have formulary coverage for a Novo Nordisk or Eli Lilly AG compared to a Novo Nordisk or Eli Lilly brand.

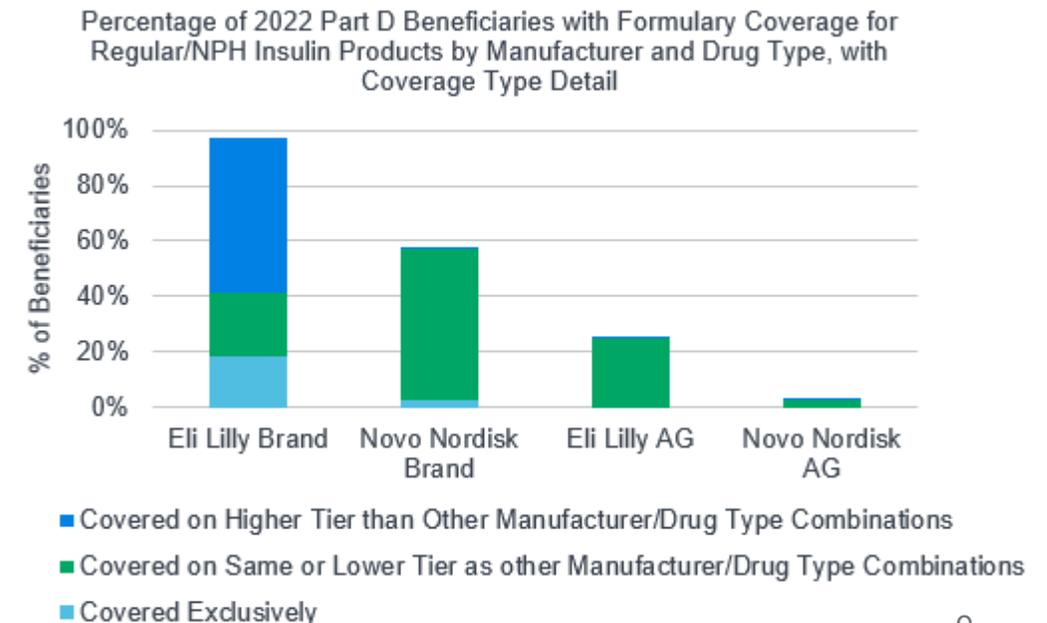
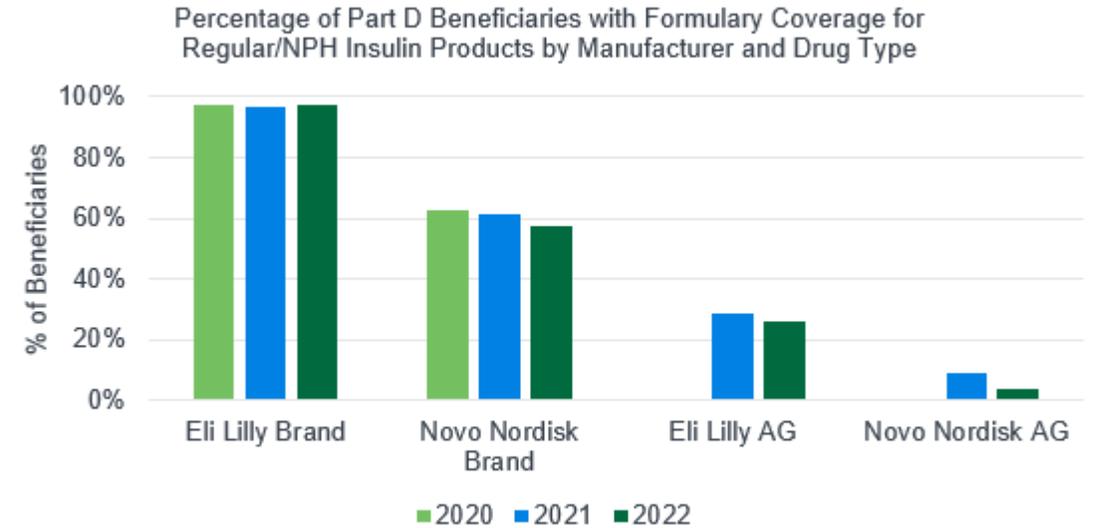
Manufacturer	Drug Type	Products May Include
Eli Lilly	Brand	Humalog, Humalog Kwikpen, Lyumjev
Novo Nordisk	Brand	Novolog, Novolog Flexpen, Fiasp Flextouch
Eli Lilly	AG	Insulin Lispro, Insulin Lispro Kwikpen, Insulin Lispro Junior Kwikpen
Novo Nordisk	AG	Insulin Aspart, Insulin Aspart Flexpen, Insulin Aspart Penfill
Sanofi	Brand	Admelog, Admelog Solostar, Apidra, Apidra Solostar



Results: Regular / NPH Insulin

- In 2020, 2021, and 2022, almost all Part D beneficiaries have formulary coverage for an Eli Lilly brand. In 2022, more than half of the beneficiaries with formulary coverage for an Eli Lilly brand have this covered on a higher tier than other covered insulins. In 2021 and 2022, less than 30% of beneficiaries have formulary coverage for an Eli Lilly AG.
- In 2020, 2021, and 2022, approximately 60% of Part D beneficiaries have formulary coverage for a Novo Nordisk brand. In 2022, most beneficiaries with formulary coverage for a Novo Nordisk brand have this covered on the same or lower tier than other covered insulins. In 2021 and 2022, less than 10% of beneficiaries have formulary coverage for a Novo Nordisk AG.

Manufacturer	Drug Type	Products May Include
Eli Lilly	Brand	Humalog Mix 75/25 Kwikpen, Humulin 70/30, Humulin R U-500 Kwikpen, Humalog Mix 75/25, Humulin 70/30 Kwikpen, Humulin N, Humulin R U-500 (Concentrated), Humulin R, Humulin N Kwikpen, Humalog Mix 50/50 Kwikpen, Humalog Mix 50/50
Novo Nordisk	Brand	Novolog Mix 70/30 Prefilled Flexpen, Novolin 70/30, Novolog Mix 70/30, Novolin N, Novolin R, Novolin 70/30 Flexpen
Eli Lilly	AG	Insulin Lispro Mix 75/25 Kwikpen
Novo Nordisk	AG	Insulin Aspart Protamine/Insulin Aspart Flexpen, Insulin Aspart Protamine/Insulin Aspart



Notes

- Additional insulin products and pre-mixes exist beyond those included in our analysis. For 2022, we reviewed the list of drugs that account for approximately 98% of total 2020 Medicare Part D drug spend. We included all insulin products from this list in our summary. Additionally, we include recently launched brands and generics found on 2022 formularies. We used the same approach for 2021 and 2020, adjusting for the years of available data and formularies accordingly.
- We did not specifically consider insulin devices (e.g., needles/syringes, pens, pumps, inhalers) in this analysis
- CMS typically requires that plans cover at least two products from each drug category or class¹
- Few insulin products meet the CMS cost threshold to be placed on the specialty tier
- Drug types are defined as:
 - Brand: Biologic insulin products that are sold with a brand label
 - AG: Products sold by the original manufacturer that are duplicates of the original brand product, sold without the brand label. These typically have lower point-of-sale costs than the original brand product.
 - Biosimilar: Products that are similar (with similar clinical outcomes) to a referenced brand biologic product but are not the same product. These typically have lower point-of-sale costs than the referenced brand product.

Methodology

We obtained coverage status and drug tier assignments from publicly available 2020, 2021, and 2022 formulary files for the individual Part D market released by CMS as of October 2019, 2020, and 2021, respectively. This analysis does not reflect any changes to formularies after these release dates of the formulary files. This analysis does not include information on any products approved after October 2021. We did not include information from formularies flagged as “suppressed” in the CMS Part D Formulary Public Use File (PUF). We identify formularies used by plans participating in the SSM using CMS’s 2021 and 2022 SSM Landscape Files. All formularies are standardized to reflect the following tiers:

- Tier 1 – Preferred generic (with potentially some brands)
- Tier 2 – Non-preferred generic (with potentially some brands)
- Tier 3 – Preferred brand and Select Care (with potentially some generics)
- Tier 4 – Non-preferred brand (with potentially some generics)
- Tier 5 – Specialty (inclusive of both specialty tiers, where both exist)

The CMS formulary files include the tier assignment for each RxNorm concept unique identifier (RxCUI). This analysis aggregates results by product name. Since many products are associated with multiple RxCUIs, a given product name could be mapped to more than one formulary tier for any given formulary. We assign each product to the formulary tier that appears the most for each product name, separately for each formulary.

A manufacturer/drug type combination was indicated as having formulary coverage if at least one product within the combination has formulary coverage. The average tier of the covered products for each manufacturer/drug type combination was used to determine higher/lower tier placement between manufacturer/drug type combinations.

2022, 2021, and 2020 enrollment is based on the September 2021, September 2020, and September 2019 enrollment files from CMS, crosswalked to a 2022, 2021, and 2020 plan ID basis, respectively. We assume 100% of September enrollment crosswalks from the prior year plan to the corresponding bid year plan, as applicable. Enrollment by income for PDPs is based on CMS’s March 2021, 2020, and 2019 LI enrollment report, respectively. Enrollment by income for MAPDs is based on CMS’s March 2022, 2021, and 2020 LI enrollment report respectively. NLI SSM and non-SSM enrollment is based on the total NLI enrollment in SSM-participating plans and non-SSM participating plans, respectively. EGWP enrollment and formulary coverage was not included in this analysis.

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In performing this analysis, we relied on data and other information from the Centers for Medicare and Medicaid Services (CMS). We have not audited or verified this data and other information but reviewed it for general reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete.

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