

PBM Drug Exclusion List Changes for 2024

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- The substantial rise in the number of high-cost drugs approved over the past several years has prompted payers to implement stricter utilization management tools and formulary exclusions to curtail rising drug costs.
- The decision-making process behind drug exclusion lists is complex. Rebates from drug manufacturers often drive exclusions in competitive classes, such as autoimmune conditions or type 2 diabetes, for which numerous treatment options exist with similar mechanisms of action. Some exclusions target costly medications that do not exhibit substantial evidence of benefit when compared to competitors in the same class.
- Although exclusion lists often target drugs with little clinical value, exclusions are heavily driven by rebates. As part of the <u>Access Hub</u> suite of products, IPD Analytics has developed a Nonessential Drug List that specifically focuses on drugs that offer little or no clinical differentiation compared to alternative lower-cost therapies to help payers target drugs for exclusion in the absence of rebate-related factors.
- In this report, we review changes in the 2024 drug exclusion lists from the three largest pharmacy benefit managers (PBMs). Noteworthy 2024 exclusions include widespread changes to preferred Humira biosimilars and insulin products and an increasing frequency of drug exclusions in rare disease and oncology.

Background

Drug exclusion lists are tools utilized by pharmacy benefit managers (PBMs) to limit access to certain medications, along with other formulary and utilization management strategies such as preferred drug tiering, prior authorization, and step therapy. The decision-making behind drug exclusion lists is complex. One important consideration is the clinical value of a drug in comparison to alternative treatments; however, rebates from pharmaceutical companies also drive exclusions in competitive classes, such as autoimmune conditions or type 2 diabetes, for which numerous treatment options exist with similar mechanisms of action. In these instances, PBMs will include the drugs with the lowest negotiated net price on their formularies. In recent years, PBMs have begun excluding drugs for diseases with few treatment options, and sometimes drugs for diseases with no other FDA-approved treatments, which makes access to these medications more challenging.

Three large PBMs comprise over 80% of the covered commercial lives in the United States – CVS Caremark, Express Scripts (ESI), and Optum Rx. In this report, we will review the 2024 drug exclusion lists from these companies (CVS: Advanced Control Specialty Formulary and Performance Drug List – Standard Control for Clients with Advanced Control Specialty Formulary; ESI: 2024 National Preferred Formulary Exclusions; Optum Rx: Standard Premium Formulary Exclusions), including key trends and noteworthy exclusions. We note that these exclusion lists are specific to commercial lives and, further, the lists only apply to those lives for which payers and employers choose to implement the exclusions.



In general, the three PBMs have a similar proportion of drug exclusions in each therapeutic area. The therapeutic areas with the most drug exclusions are immunology/rheumatology, endocrinology/metabolic disorders, and dermatology. Initially, biosimilars were only available in oncology; however, recent biosimilar launches for autoimmune diseases, dermatology, rheumatoid arthritis, and diabetes have greatly expanded the PBMs' exclusion lists.

Humira (Adalimumab)

On or around July 1, 2023, seven manufacturers launched biosimilars to AbbVie's Humira (adalimumab) onto the market, joining Amgen's Amjevita, which was launched on January 31, 2023, and was the first biosimilar to Humira to enter the market. Notably, all three PBMs exclude one or more of the biosimilars to Humira. At the start of 2024, all three PBMs preferred brand Humira, along with a few biosimilar options.

In January 2024, CVS announced that, starting on April 1, 2024, it will remove Humira from its major national commercial formularies. CVS will instead cover Humira biosimilars. In the same announcement, CVS also stated that AbbVie has entered into an agreement to supply CVS' wholly owned subsidiary, Cordavis, with co-branded Humira. Launched in August 2023, Cordavis commercializes and/or co-produces private-label biosimilar products. The Cordavis Humira product will be identical to brand Humira and will be available in 2Q 2024. According to CVS, the Cordavis Humira product is intended to provide an additional option for payer customers. CVS did not disclose whether the Cordavis Humira product will be added to any of its formularies; however, CVS currently includes Cordavis-labeled Hyrimoz products as one of its preferred products, along with Sandoz's unbranded Hyrimoz.

Table 1 highlights the Humira biosimilar exclusions and preferred alternatives for each of the PBMs.

Table 1. Humira Biosimilar Exclusions and Preferences Among PBMs as of January 2024*				
Excluded Medications	Preferred Options			
Express Scripts				
Abrilada, Adalimumab-fkjp (unbranded Hulio), Amjevita, Hadlima, Hulio, Hyrimoz (Cordavis), Idacio, Yuflyma, Yusimry	Adalimumab-adaz (unbranded Hyrimoz), Adalimumab- adbm (unbranded Cyltezo), Cyltezo, Humira or Hyrimoz (Sandoz)			
Optum Rx				
Adalimumab-fkip (unbranded Hulio), Hadlima, Hulio, Idacio, Yuflyma, Yusimry	Adalimumab-adaz (unbranded Hyrimoz), Amjevita (preferred NDCs), Cyltezo, Humira, Hyrimoz			
CVS Caremark				
Amjevita	Adalimumab-adaz (unbranded Hyrimoz), Humira*, Hyrimoz			

Abbreviation: PBM, pharmacy benefit manager.

*Humira is not currently excluded by CVS, but it will be excluded from CVS' major national commercial formularies effective April 1, 2024. A co-branded Cordavis Humira product will be available to some payer customers beginning in 2Q 2024.



Insulins

Historically, insulin was a highly rebated drug class and made up a large portion of PBM contracts. However, in March 2023, price cuts to several insulin products were announced by Eli Lilly, Novo Nordisk, and Sanofi. The new prices became effective in 4Q 2023 (for Lilly products) and on January 1, 2024 (for Novo Nordisk and Sanofi products), and may significantly change the role of rebates in management of the class. Because of the price reductions, the rebate amounts for the affected Lilly, Novo Nordisk, and Sanofi insulin products would substantially decrease. Insulin products that have received price reductions may be preferred by payers and patients because of a lower cost for the patient at the point of sale. Alternatively, payers may choose to conserve rebates and prefer the insulin products that did not receive price cuts. To do this, payers may rely on copay cards to lower out-of-pocket (OOP) costs for patients, or they could lower copays on the insulin products without price reductions to match the caps set by Lilly for its insulin products and Sanofi for Lantus (insulin glargine).

From 2023 to 2024, all three PBMs added and removed insulin products to/from their exclusion lists and changed the preference status of existing insulin products. Some changes are the result of the announced price reductions. Table 2 reviews the insulin exclusions and preferred alternatives for ESI, Optum Rx, and CVS in 2024, and the products with price reductions are highlighted in bold.

Table 2. Insulin Exclusions and Preferences Among PBMs						
	Excluded Medications	Preferred Options				
Express Scripts						
Fast- or rapid-acting insulins	Admelog, Afrezza, Apidra , Fiasp, insulin aspart , Lyumjev Tempo, NovoLog , ReliOn NovoLog	Humalog, Humalog Tempo, insulin lispro , Lyumjev, Lyumjev Tempo				
Long-acting insulins	Insulin degludec, insulin glargine (by Winthrop), insulin glargine-yfgn (unbranded Semglee), Lantus, Levemir , Rezvoglar	Semglee (insulin glargine-yfgn), Toujeo, Tresiba				
Insulin mixes	Insulin aspart protamine, NovoLog Mix, ReliOn NovoLog Mix, Novolin Mix, ReliOn Novolin Mix	Humalog mix, Insulin lispro protamine mix, Humulin Mix				
Short-acting insulins	Novolin, ReliOn Novolin	Humulin				
Optum Rx						
Long-acting insulins	Insulin degludec, insulin glargine, insulin glargine-yfgn (unbranded Semglee), Levemir , Semglee, Semglee (insulin glargine-yfgn), Tresiba	Basaglar, Lantus , Rezvoglar, Toujeo				
Fast- or rapid-acting insulins	Insulin aspart, ReliOn NovoLog	Admelog, Apidra , Fiasp, Humalog, insulin lispro, Lyumjev, NovoLog				
Short-acting insulins	ReliOn Novolin	Humulin, Novolin				

Table 2. Insulin Exclusions and Preferences Among PBMs					
	Excluded Medications	Preferred Options			
CVS Caremark					
Long-acting insulins	Basaglar, Levemir	Lantus			
Fast- or rapid-acting insulin	Humalog, Apidra	Fiasp, NovoLog			
Insulin mixes	Humalog Mix 50/50, Humalog Mix 75/25	NovoLog Mix 70/30			
	Humulin 70/30	Novolin 70/30			
Short-acting or regular insulins	Humulin N	Novolin N			
	ReliOn	Novolin			
	Humulin R	Novolin R			

Abbreviation: PBM, pharmacy benefit manager.

Table 3 summarizes the changes in the status of insulin products on PBM exclusion lists and provides IPD's interpretation of the changes and underlying strategies.

	Cummers of Change	to 2024	
PBM	Summary of Change	IPD Insights	
ESI	Lilly's Rezvoglar was excluded, whereas insulin lispro protamine and Lilly's Tempo products (Humalog and Lyumjev) were added as preferred products. Novo Nordisk's Levemir, which had a price decrease, was previously preferred and is now excluded. However, insulin lispro, which had a price decrease, was previously excluded and is now preferred.	The price decrease of Levemir could have affected its status as a preferred option; however, Levemir will be discontinued in 2024. ESI appears to prefer products that did not have a price decrease (i.e. those with higher rebates).	
Optum Rx	In the long-acting insulin space, insulin degludec was excluded, and Rezvoglar was added as a preferred product. Basaglar (previously excluded) became preferred. Novo Nordisk's Novolin, which had a price decrease, was previously excluded and became preferred. Optum previously excluded but now prefers the following insulins: Sanofi's Admelog and Apidra, Novo Nordisk's Fiasp, insulin lispro, and Novo Nordisk's NovoLog; all of these except for Admelog and Fiasp had price decreases.	Optum appeared to change the preference of rapid- or fast-acting insulin based on price decreases, and overall preferred insulins with price decreases.	
CVS	Few changes were made overall to the insulin class. In 2023, Sanofi's Lantus was excluded, and Basaglar and Levemir were preferred. However, in 2024, this switched, with Lantus being preferred and Basaglar and Levemir excluded. This change is likely attributed to the price reduction for Lantus. In addition, Novo Nordisk's ReliOn NovoLog was added to the exclusion list.	A price decrease affected the preference of a long-acting insulin (Lantus). It is likely that, given price decreases for Lilly and Novo Nordisk brand products, CVS made no major changes to its formulary.	

Abbreviations: ESI, Express Scripts; PBM, pharmacy benefit manager.

Also featured in the original report:

- Rare Disease
 - Rare Disease Drug Exclusions and Preferences Among PBMs
- Oncology
 - Oncology Drug Exclusions and Preferences Among PBMs
 - Oncology Biosimilar Exclusions and Preferences Among PBMs

Other Specialty Exclusions

- Multiple Sclerosis (MS)
- o Asthma
- Psoriasis
- Provider-Administered Drugs

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