Lessons from history: Gauging Part D plan access restrictions of protected class drugs as a harbinger for coverage of negotiated drugs

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Background

- The Inflation Reduction Act (IRA) was passed on August 16, 2022, with the goal of reducing inflation and lowering prescription drug prices.
- In 2023, for the first time, the Centers for Medicare & Medicaid Services (CMS) began negotiating a list of high-cost drugs, with the prices effective in 2026.
- Through the negotiation process, CMS determines the new manufacturer's maximum fair price, but it is unclear how Part D plans (PDPs) and Medicare Advantage Part D Plans (MA-PDs) will apply utilization management (UM) criteria to the selected drugs for CMS negotiations.

Objectives

- To explore whether there is a disconnect between the Drug Price Negotiation Program and patient access.
- To show whether patients may have access limitations for drugs negotiated under the IRA, thereby undermining the legislative intent of ensuring the drugs' availability to patients.

Methods

Table 1. CMS Prescription Drug Plans, 2020-2024

Formulary year	CMS plan file/ enrollment file[a]	Number of plans included in analysis	Total enrollment	Antineoplastics on the market without generic equivalents[b]
2020	October 2019/ June 2020	3,686	35,888,623	64
2021	October 2020/ June 2021	4,075	36,467,160	73
2022	October 2021/ June 2022	4,083	37,051,883	78
2023	October 2022/ June 2022	4,328	37,467,970	79
2024	October 2023/ February 2024	4,200	37,746,486	79

[a] CMS Prescription Drug Plan Formulary and Pharmacy Network Information files are released in October of the preceding year.
[b] Count of antineoplastics on the market without generic equivalents in a given year was determined based on whether they were FDA approved in the prior year and had a multi-source code of "M" (ie, single source, no generics available) or "N" (ie, considered single-source, co-licensed).
Key: CMS – Centers for Medicare & Medicaid Services.

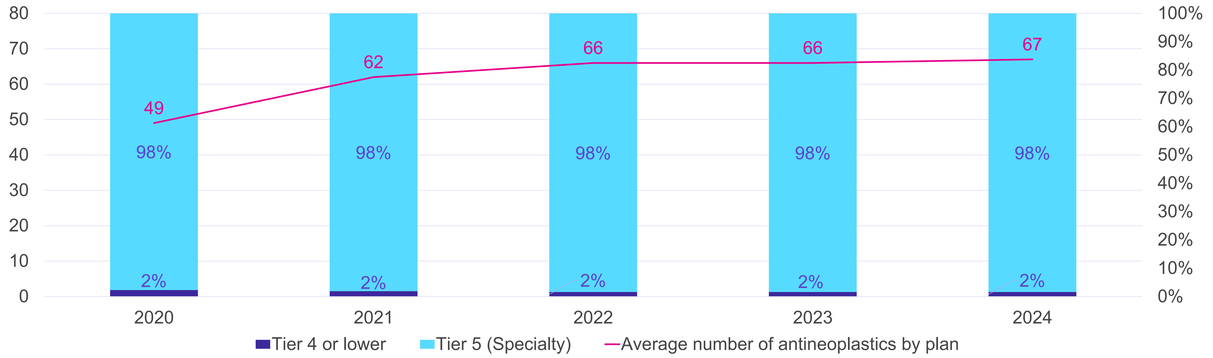
- Cencora assessed coverage and UM of branded antineoplastics (n=79) with the USP classification of molecular target inhibitors from the CMS Prescription Drug Plan Formulary and Pharmacy Network Information October files (2020–2024) (**Table 1**).
- The analysis was restricted to MA-PD plans and PDPs with the most common specialty formulary structure (ie, 5-tier formulary structure).
- UM was categorized as prior authorizations (PAs), quantity limits (QLs), and step edits.
- Findings were weighted by plan enrollment.

Results

- Of the 79 branded antineoplastic regimens, ~85% were covered by MA-PD plans and PDPs in 2024 (**Figure 1**).
- Over time, antineoplastics covered on formularies increased (~49 in 2020 to ~67 in 2024).
- 98% or more of covered antineoplastics were placed in specialty tiers.
- All covered antineoplastics received some form of UM (**Table 2**).
  - The most common forms of UM were PAs.
  - Among antineoplastics on formulary, QL of ≤30 days was the most common limit applied and the use of QLs has steadily increased year over year (~59% of covered antineoplastics in 2020 to ~81% in 2024).

Results (cont.)

Figure 1. Average number of antineoplastics covered by plan and tier,[a] 2020–2024



[a] Part D sponsor formularies must include all or substantially all drugs in all 6 protected class categories (ie, immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics). "Substantially all" means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with the following exceptions: multi-source brands of identical molecular structure; extended-release products when the immediate-release product is included; products with the same active ingredient or moiety; and dosage forms without a unique route of administration (eg, tablets and capsules vs tablets and transdermal).

Table 2. Weighted average rate of utilization management strategies for covered antineoplastics

Year	% requiring prior authorization	% requiring step therapy	Distribution of quantity limits (days)		
			≤30	31+	No limit
2020	97%	0%	59%	1%	40%
2021	97%	0%	64%	1%	36%
2022	97%	0%	72%	1%	26%
2023	97%	0%	73%	2%	25%
2024	97%	0%	81%	2%	17%

Limitations

- Protected-class drugs are being used as surrogates for the drugs being negotiated under IRA, which may not be representative of how UM is applied to negotiated drugs.
- This research assesses the protected class of antineoplastics, which may not be an accurate representation of the initial 10 selected drugs for the IRA negotiations, as most are not antineoplastics.
- Most of the drugs under review for drug price negotiations with CMS may already receive some form of UM, so the IRA may not be the cause of UM with these agents.

Conclusions

- The legislative intent to reduce patient access barriers may not be fully realized with selected drugs under the IRA Drug Price Negotiation Program.
  - Patient access hurdles, like those observed with drugs having protected-class status, may persist.
    - These hurdles create access challenges for patients, leading to adverse health outcomes and financial strain.

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