The Most Heavily Managed Drug Categories on Part D Formularies

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BACKGROUND AND OBJECTIVE

The Centers for Medicare and Medicaid Services (CMS) requires all Part D plan sponsors to report formulary information on exclusions, prior authorizations (PAs), and step edits (STs) for all drugs listed in the CMS formulary reference file (FRF).[1,2]

The objective of this research was to identify the most heavily managed United States Pharmacopeia (USP) categories on Part D formularies and explore how management varies for branded-only, generic-only, and mixed (branded and generic) groupings of the same drug active substance.

METHODS

- The CMS Part D formulary file for the third quarter of 2022 was used to determine management across 458 unique formularies.[3]
- 1397 active substance groupings (ASGs) were manually created for 6377 RxNORM Concept Unique Identifiers (RXCUIs) included on the CY2022-CMS-FRF.[2]
  - ASGs are groups of RXCUIs with the same drug active substance. Each ASG represents a single drug across various dosages, package sizes, and salt forms.
  - This process yielded 591 branded-only ASGs, 254 generic-only ASGs, and 552 mixed ASGs.
- Supergroupings of ASGs by type were also created; for example, the branded-only supergroup contained all 591 branded-only ASGs.
- Each ASG also was assigned a USP category and class using the USP Medicare Model Guidelines v8.0 Alignment File.[4] ASGs can be assigned to more than 1 USP category.
- Spending within each USP category on a per drug (ASG) basis was determined using the Medicare Part D Spending file for 2022.[5]

RESULTS

- Across all Part D formularies, 38% of branded-only drugs were excluded, on average (Table 1).
  - Among branded-only drugs not excluded, 54% and 2% had PAs and STs, respectively.
- In the mixed supergroup, 75% of branded drugs were excluded and 25% and 3% of those not excluded had PAs and STs, respectively.

Table 1. Formulary Management by Supergroupings of Branded-Only, Generic-Only, and Mixed ASGs

ASG (drug) supergroup	No. of drugs (ASGs) by type (%)	Drugs with exclusions	Drugs without exclusions		
		Avg % of drugs	Avg tier for each drug	Avg % of drugs with PA	Avg % of drugs with ST
Branded only	591 (42)	38	3.6	54	2
Mixed	552 (40)	15	2.4	20	1
Branded only with generic[a]	552 (40)	75	3.5	25	3
Generic only	254 (18)	18	2.2	9	0
All drugs	1397 (100)	25	2.8	29	1

ASG = active substance grouping; avg = average.

Notes: ASGs are groups of RXCUIs with the same drug active substance. Each ASG represents a single drug across various dosages, package sizes, and salt forms. In the table, ASGs also are referred to simply as drugs. The mixed category contains ASGs with both branded and generic drugs of the same active substance. All Part D formularies have 5 tier levels.

[a] The "branded only with generic" category reports exclusions, tiering, PAs, and STs only for the brands within the ASG.

- To visualize the relationship between formulary management and Part D spending, the top 10 USP drug categories by average Part D spending per drug (ASG) are reported in Table 2. This analysis was done by matching the 3276 drugs that appear in the Part D spending file with the 1397 ASGs created for this study. Total Part D spending in 2022 was $239 billion, and 90% of spending was assigned to ASGs.
  - Categories with the most exclusions were blood glucose regulators (36%), blood products and modifiers (33%), and central nervous system agents (32%)
  - Categories with the most PAs were antineoplastics (81%), respiratory/pulmonary agents (50%), and immunological agents (50%)

Table 2. Formulary Management of Top 10 USP Drug Categories by Average Part D Spending per Drug in 2022

USP drug category	No. of ASGs (drugs)	Avg % of drugs with exclusions	Avg % of drugs with PA (not excluded)	Total Part D spending	Avg Part D spending per ASG (drug)
Blood products and modifiers	32	33	31	$23,414,629,383	$731,707,168
Blood glucose regulators	57	36	5	$39,264,595,515	$688,852,552
Hormonal agents SRM, thyroid	2	0	0	$1,103,809,762	$551,904,881
Antineoplastics	91	1	81	$29,756,318,685	$326,992,513
Respiratory tract/pulmonary agents	68	24	50	$19,549,676,484	$287,495,242
Immunological agents	72	15	50	$20,659,903,236	$286,943,100
Antipsychotics	27	0	24	$6,223,767,071	$230,509,891
Central nervous system agents	34	32	49	$6,969,763,255	$204,993,036
Bipolar agents	11	0	18	$1,816,485,982	$165,135,089
Genitourinary agents	22	22	7	$3,621,718,808	$164,623,582

SRM = stimulant/replacement/modifying.

Note: Exclusions and PAs for USP drug categories include a mix of branded-only, generic-only, and mixed drugs.

- Part D formularies must include all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.[1] USP categories that align to these formulary classes can be observed in the universe of Part D management in Figure 1.
  - Drugs (ASGs) assigned to the USP categories of antineoplastics, anticonvulsants, and antipsychotics have approximately no exclusions in this study. Exceptions include antineoplastic-supporting therapies that are assigned to the USP category but are not antineoplastic treatments.
  - The USP categories for immunological agents and antivirals include drugs that are not organ transplant rejection treatments or antiretrovirals, respectively.
  - The USP antidepressant category contains drug substances with multiple salt forms that are difficult to compress into the same ASG (drug), which complicates determining whether a drug active substance is excluded.

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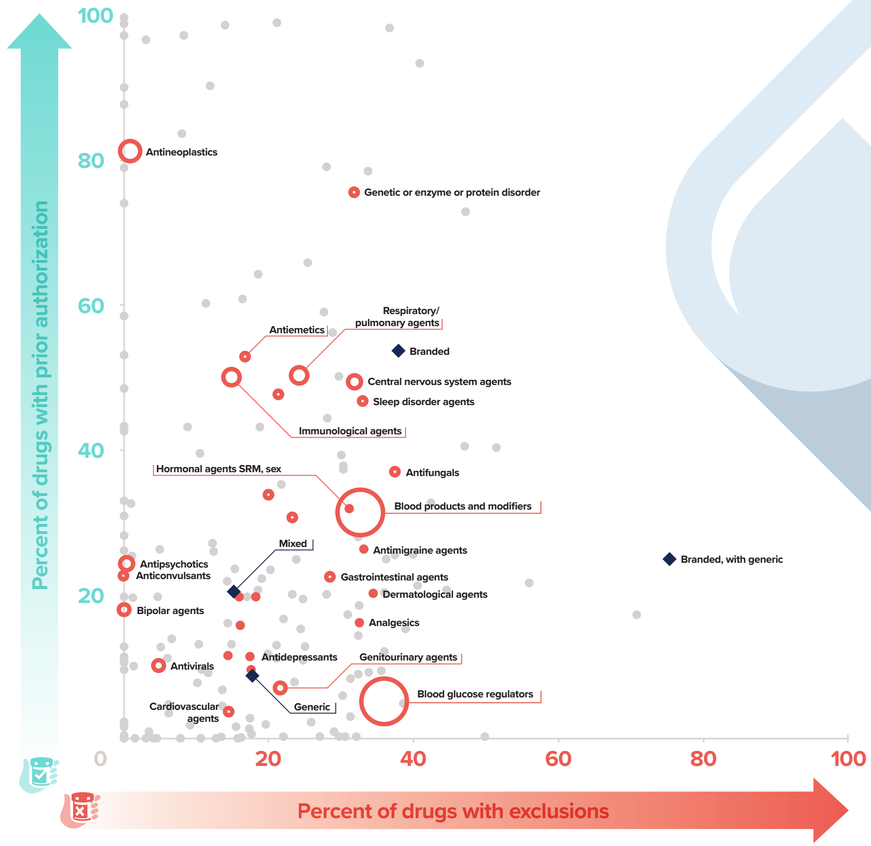
Figure 1. The Universe of Part D Formulary Management



SRM Notes: Across all Part D formularies, drugs are plotted by percentage of exclusions or PAs within USP categories (red) and classes (gray). Only USP categories with greater than 10 drugs are shown. Point size for USP categories (red) is relative to 2022 average Part D spending per drug in category. Exclusions and PAs are also plotted for supergroups (blue) of branded-only, generic-only, mixed (branded and generic), and "branded, with generic" (exclusions or PAs only apply to the branded drugs in mixed groups) drugs.

DISCUSSION AND CONCLUSIONS

Among top selling drug categories, there were large differences in the preferred Part D formulary management approach, driven in part by average spending per drug and/or the protected status of the category.

- Categories with high rates of PA often include drugs with potential for nonmedically accepted use (e.g., antiemetics, sleep disorder agents), drugs requiring safety monitoring (e.g., antineoplastics, immunological agents), or drugs in high-spending categories where the cost of the PA program is offset by reduced utilization.
- Drugs with higher rates of formulary exclusion that have lower average spending per drug include more drugs with similar mechanisms of action and overlapping indications (e.g., gastrointestinal agents, antifungals, analgesics, dermatological agents).
- Categories with low rates of formulary exclusion are more likely to be protected but also more likely to have STs (not shown, e.g., antipsychotic, antidepressant).

Moving forward, formulary management decisions will likely also be based on comparative effectiveness data collected through real-world efficacy and safety studies that are sponsored by pharmacy benefit managers and conducted with observational research partners.[6,7] Innovators should consider how heavily managed a drug candidate will be at launch and build evidence to address any potential access issues early in the development process and throughout the product life cycle.

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