

The Association Between Average Sales Price Decline and Shortages in Small Molecule Injectable Oncology Therapies with Generic Competition

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Objective

This study explored the association between Medicare Average Sales Price (ASP) decline and incidence of drug shortages for small molecule injectable oncology therapies with generic competition in the United States



Conclusions

In the United States from 2018-2023, small molecule injectable oncology drugs with ASP decline had several-fold increased risk of shortage vs. drugs without decline



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Background

- Generic oncology drug shortages are a persistent issue that can have significant clinical and economic consequences for patients and the healthcare system. These include:¹⁻⁵
 - Disruptions in patient treatment, leading to medication errors and/or reliance on less effective alternatives
 - Diminished patient health outcomes, including side effects, disease progression, and mortality
 - Increased cost of care, increased patient out-of-pocket costs, and additional labor and resource burdens for health systems.
- Understanding the relationship between predictors of generic oncology drug shortages, such as price erosion, is critical to anticipating and mitigating shortage risks, but remains understudied.

Study Objectives

- To identify and describe shortages among small molecule, sterile injectables with an indication in oncology and generic competition.
- To evaluate the association between Medicare Average Sales Price (ASP) change and U.S. Food & Drug Administration (FDA)-reported drug shortages.

Materials and Methods

This retrospective study examined publicly reported ASP and drug shortage data from January 1, 2018 through December 31, 2024. The study sample included FDA-approved, injectable oncology therapies with generic competition.

DATA SOURCES AND DRUG IDENTIFICATION

- The National Institutes of Health (NIH) Surveillance, Epidemiology, and End Results (SEER) Program Cancer Medications Enquiry Database (CanMED) was used to select injectables with both a National Drug Code (NDC) and Healthcare Common Procedure Coding System (HCPCS) code
- The FDA NDC Directory was used to select FDA-approved oncology therapies between Q1 of 2018 and Q4 of 2023, as well as to identify product manufacturers
- The Anticancer Fund Database of Cancer Drugs was used to identify drugs with generic competition and categorize drug indication (e.g., solid, hematologic, or both)
- The Medicare Part B ASP Pricing Files were used to identify inflation-adjusted ASP and percent change since Q4 of 2017
- FDA Drug Shortage Directory – used to identify FDA-reported drug shortages between Q1 of 2018 and Q4 of 2023

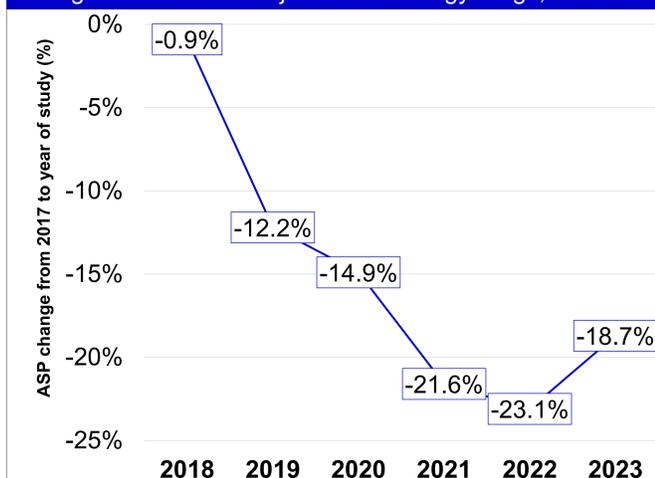
STATISTICAL ANALYSIS

- A time-varying proportional hazards model was used to assess the association between ASP change and 2-quarter lagged drug shortage.
- Due to small sample size, the model was run using unrestricted random sampling with replacement sample size=20 and resamples=1,000.
- In adjusted analysis, observations were censored after the first quarter in shortage to account for compensatory ASP increases.

Results

- 50 small molecule, injectable oncology drugs with generic competition met inclusion criteria (**Table 1**). In 2018, there were 634 unique NDCs across these included drugs with mean 8.4 manufacturers per drug.
- More than 60% of drugs experienced an inflation-adjusted ASP decrease since Q4 of 2017 (**Figure 1**).
- The included drugs with FDA-reported shortages increased from 0 in 2018 to 12 (25.0%) in 2023 (**Figure 2**). Drugs with documented shortages are highlighted in blue in **Table 1**.
- Long-term, mean inflation-adjusted ASP decreased across drugs with and without shortages, but when drugs first entered shortage, they had a mean ASP decrease of -32.7% from Q4 of 2017 vs. -13.6% among drugs that never entered shortage.

Figure 1. Mean inflation-adjusted ASP change from Q4 of 2017 among small molecule injectable oncology drugs, 2018 - 2023



ASP=Average Sales Price

-32.7%
Mean ASP change among drugs entering shortage

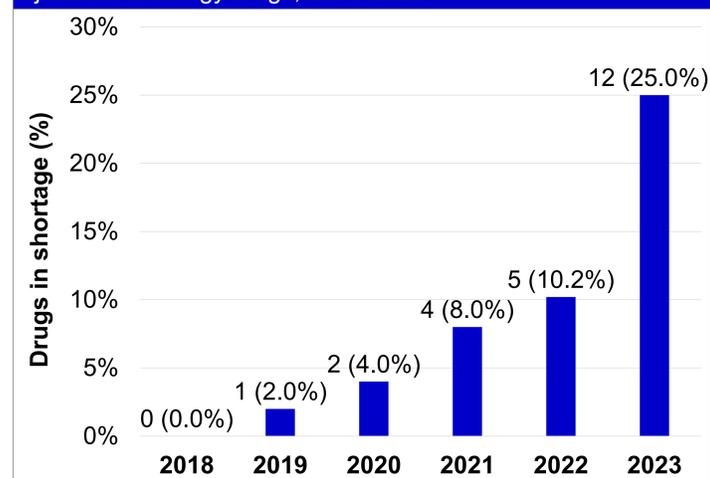
- Shortages of ≥ 1 quarter coincided with short-term mean ASP increases of +16.6%, likely due to compensatory market pressures.
- In the base case adjusted model without replacement, inflation-adjusted ASP decreases of $\geq 5\%$ demonstrated a *non-significant* trend toward association with risk of shortage vs. drugs without ASP change (HR=4.23, 95% CI=0.54-33.04).
- In the adjusted model with replacement, drugs with inflation-adjusted ASP decreases of $\geq 5\%$ were associated with >6-fold increased risk of shortage vs. drugs without ASP change (**Figure 3**).

Table 1. Small molecule injectable oncology drugs evaluated

1. Arsenic Trioxide	14. Dacarbazine	27. Gemcitabine	39. Oxaliplatin
2. Azacitidine	15. Dactinomycin	28. Idarubicin	40. Paclitaxel
3. Bendamustine	16. Daunorubicin	29. Ifosfamide	41. Pemetrexed
4. Bleomycin	17. Decitabine	30. Irinotecan	42. Pentostatin
5. Bortezomib	18. Dexamethasone	31. Lanreotide	43. Pralatrexate
6. Busulfan	19. Docetaxel	32. Leuprolide	44. Romidepsin
7. Carboplatin	20. Doxorubicin	33. Medroxy-progesterone	45. Temozolomide
8. Carmustine	21. Epirubicin	34. Melfalphan	46. Temsirolimus
9. Cisplatin	22. Eribulin	35. Methotrexate	47. Topotecan
10. Cladribine	23. Etoposide	36. Mitomycin	48. Vinblastine
11. Clofarabine	24. Fludarabine	37. Mitoxantrone	49. Vincristine
12. Cyclophosphamide	25. Fluorouracil	38. Nelarabine	50. Vinorelbine
13. Cytarabine	26. Fulvestrant		

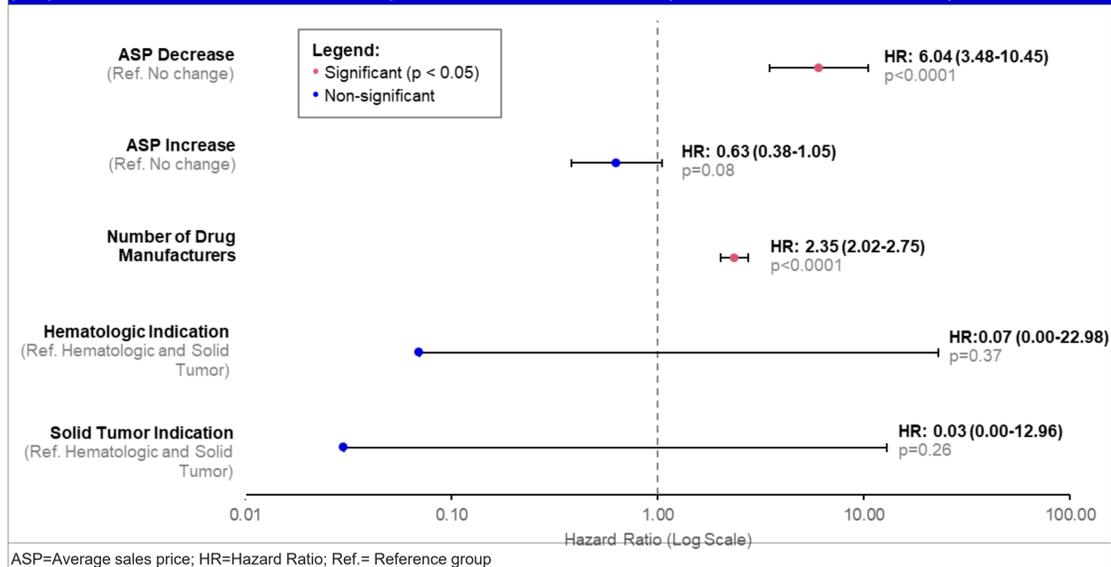
Highlighted drugs experienced ≥ 1 FDA-reported drug shortage from Q1, 2018 to Q4, 2023

Figure 2. FDA-reported shortages among small molecule injectable oncology drugs, 2018-2023



FDA=Food & Drug Administration

Figure 3. Factors associated with oncology small molecule drug shortages in the adjusted proportional hazards model with replacement, hazard ratios (95% confidence intervals)



ASP=Average sales price; HR=Hazard Ratio; Ref.= Reference group

Limitations

- The regression model without replacement had limited statistical power due to a relatively small number of first-time drug shortages over the study horizon, so we focused statistical reporting on the alternative model with replacement to more precisely estimate the strength of association between ASP decrease and shortages.
- The study relies on publicly available data sources. Any errors or inconsistencies in the data sources could result in study errors or inconsistencies. Drugs that were unable to be matched across all data sources were not included in analysis.
- Drug shortage severity is not reported by the FDA.
- The COVID-19 pandemic resulted in supply chain issues and substantial health system impact. The impact of COVID-19 on drug shortages has been established and was not specifically evaluated in this study.

Discussion

- Our findings suggest that policies that support more stable and predictable oncology generics reimbursement could be critical to preventing drug shortages.
- Future research should generate additional evidence about price decline as a cause of drug shortages and should extend to oncology biosimilars given similar ASP trends.



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