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There was a strong significant association between BLA approval and injectable drug administration with the monthly cost of therapy being in the top quartile ($>20,093). No statistically significant associations between other examined variables and monthly cost were observed (p>0.05).

Our study supports the findings of an earlier investigation that demonstrated no association between disease prevalence and treatment costs in the U.S.16

Limitations to this study include:

• The utilization of AWP per unit at approval of evaluated agents to calculate monthly costs, which is higher than the actual cost of acquisition for pharmacies, hospitals, or third-party payers. The challenges associated with estimating disease prevalence at approval due to the limited availability of epidemiologic data, which can also change over time. Classifying drugs according to the degree of innovation is somewhat arbitrary in nature.

• The price of oncology therapeutics may be related to variables that were not investigated in this study, such as clinical evidence, therapeutic goal, and cost of administration.

### Objectives
- This study aimed to examine the following variables for association with monthly cancer drug costs in the U.S.: approval mechanism, review classification, orphan designation, indication at approval, route of administration, company size, disease prevalence, and novelty of the mechanism of action.

### Methods
- In 2017, oncology drugs were among the most expensive therapeutic classes in the U.S. and accounted for over a quarter of all drugs in the late phase R&D pipeline.12
- During the past five years, roughly 80% of oncology drugs were approved with orphan designations.11
- In 2016, approximately 44% of oncology pipeline molecules in late phase R&D were biologics.2

- Legislative efforts have led to the establishment of orphan designation and priority review, which have incentivized the development of drugs for rare diseases and novel drugs, respectively.22
- Escalating prices associated with cancer drugs with marginal clinical benefits have led to concerns over incentivizing the approval of drugs that are similar to predecessors.22
- Pharmaceutical companies often use the costs of R&D to justify the high price of drugs and research has found that, during 1991-2009, the average cost of R&D relative to the lifetime operating costs of bringing a drug to the market has increased.22

### Background

### References

### Results

### Discussion

- There was a strong significant association between BLA approval and injectable drug administration with the monthly cost of therapy being in the top quartile ($>20,093).

- No statistically significant associations between other examined variables and monthly cost were observed (p>0.05).