

Trends In Prices Of New Oral Drugs For Chronic Use Approved By The FDA (1980-2021)

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Background

The high cost of new drugs is a major concern in the US healthcare system, and the trend in drug treatment cost of new drugs at market entry has received relatively little attention.

Objectives

To evaluate trends and factors associated with the drug treatment cost at market entry for new oral chronic use drugs first marketed in the US between 1980 and 2021.

Methods

Data on regulatory information, defined daily dosages, and wholesale acquisition cost (WAC) at market entry were extracted from the FDA, World Health Organization, and IBM Micromedex, respectively. These drugs were considered as intended for chronic use when the treatment was expected to last at least one year based on the FDA-approved labeling. Prices were converted to average 2021 US dollars using the consumer price index. Descriptive statistics were conducted. We used multiple linear regression to identify the potential explanatory factors associated with the estimated drug treatment cost per year at market entry for new oral chronic use drugs and the Variance Inflation Factor (VIF) to measure the correlation and strength of correlation between the predictor variables.

Results

	1980-1989	1990-1999	2000-2009	2010-2019	2020-2021	Total
Orphan designation*						
Yes	\$1,908.47 (\$895.77) (n=6, 1.4%)	\$3,706.06 (\$11,758.77) (n=16, 3.7%)	\$102,058.32 (\$40,489.65) (n=9, 2.1%)	\$137,557.46 (\$111,297.34) (n=65, 14.9%)	\$264,881.60 (\$255,060.93) (n=25, 5.7%)	\$120,285.14 (IQR=\$172,463.40) (n=121, 27.8%)
No	\$870.82 (\$749.76) (n=43, 9.9%)	\$1,167.39 (\$2,812.24) (n=114,26.1%)	\$2,069.10 (\$5,162.45) (n=66, 15.1%)	\$12,665.72 (\$62,449.15) (n=63, 14.4%)	\$13,219.79 (\$85,388.71) (n=12, 2.8%)	\$1,978.98 (IQR=\$6,521.85) (n=298, 68.3%)
FDA review type*						
Priority	\$1,172.42 (\$974.54) (n=33, 7.6%)	\$3,767.10 (\$6,229.85) (n=51, 11.7%)	\$12,510.82 (\$64,572.53) (n=25, 5.7%)	\$131,725.26 (\$126,910.48) (n=75, 17.2%)	\$254,625.34 (\$259,271.02) (n=26, 6.0%)	\$17,637.64 (IQR=\$139,564.40) (n=210, 48.2%)
Standard	\$694.42 (\$729.17) (n=33, 7.6%)	\$973.61 (\$1,106.47) (n=79, 18.1%)	\$1,899.56 (\$2,557.19) (n=50, 11.5%)	\$8,865.47 (\$59,816.46) (n=53, 12.2%)	\$88,009.05 (\$99,169.61) (n=10, 2.3%)	\$1,579.48 (IQR=\$4,672.37) (n=225, 51.6%)
Market Status*						
Marketed	\$1,083.89 (\$1,657.62) (n=10, 2.3%)	\$2,028.59 (\$3,387.09) (n=18, 4.1%)	\$73,659.66 (\$54,976.83) (n=10, 2.3%)	\$95,442.62 (\$144,786.40) (n=108, 24.8%)	\$219,219.14 (\$319,039.49) (n=37, 8.5%)	\$78,234.45 (IQR=\$161,211.51) (n=183, 42.0%)
Discontinued	\$887.98 (\$866.91) (n=56, 12.8%)	\$1,210.37 (\$3,033.18) (n=112,25.7%)	\$2,097.48 (\$5,427.13) (n=65, 14.9%)	\$8,455.60 (\$56,769.01) (n=20, 4.6%)	Not Available (n=0)	\$1,492.71 (IQR=\$3,289.02) (n=253, 58.0%)
Boxed Warning**						
Yes	\$1,000.12 (\$863.58) (n=34, 7.8%)	\$1,391.99 (\$3,202.05) (n=63, 14.4%)	\$4,532.39 (\$28,686.47) (n=31, 7.1%)	\$45,920.27 (\$128,124.68) (n=44, 10.1%)	\$149,349.20 (\$283,757.11) (n=5, 1.1%)	\$2,678.76 (IQR=\$13,143.76) (n=177, 40.6%)
No	\$770.55 (\$813.80) (n=30, 6.9%)	\$1,548.56 (\$2,904.22) (n=65, 14.9%)	\$2,211.17 (\$8,862.41) (n=44, 10.1%)	\$94,160.35 (\$148,857.85) (n=84, 19.3%)	\$225,800.54 (\$329,147.73) (n=32, 7.3%)	\$5,496.45 (IQR=\$106,942.13) (n=255, 58.5%)
Country of incorporation (US)***						
Yes	\$922.74 (\$856.68) (n=48,11.0%)	\$1,335.84 (\$2,748.40) (n=66, 15.1%)	\$3,543.89 (\$10,576.88) (n=41, 9.4%)	\$69,949.25 (\$136,540.52) (n=70, 16.1%)	\$232,381.95 (\$345,601.15) (n=23, 5.3%)	\$3,699.02 (IQR=\$62,221.09) (n=248,56.9%)
No	\$893.25 (\$1,032.52) (n=18, 4.1%)	\$1,477.20 (\$3,860.38) (n=64, 14.7%)	\$2,138.91 (\$5,160.31) (n=34, 7.8%)	\$94,160.35 (\$139,282.36) (n=58, 13.3%)	\$185,788.90 (\$240,835.33) (n=14, 3.2%)	\$4,115.08 (IQR=\$71,695.07) (n=188, 43.1%)
Total	\$922.74 (\$871.71) (n=66,15.1%)	\$1,466.56 (\$3,134.39) (n=130,29.8%)	\$2,434.34 (\$9,923.70) (n=75, 17.2%)	\$76,390.10 (\$138,847.03) (n=128, 29.4%)	\$219,219.14 (\$319,039.49) (n=37, 8.5%)	\$3,846.64 (IQR=\$64456.34) (n=436,100%)

*p<0.001, **p=0.016, ***p=0.470

Table 1. Inflation-Adjusted Median Drug Treatment Cost per Year at Market Entry for New Oral Chronic Use Drugs (1980-2021)

During the study period, antineoplastic and immunomodulating agents had the highest median treatment cost per year (\$127,731.99, IQR=\$139,911.72), followed by anti-infectives for systemic use (\$9,733.85, IQR=\$11,778.33), and blood and blood forming organs (\$3,111.7, IQR=\$3,637.08).

The FDA approved 436 new drugs with oral formulations for chronic use from 1980 to 2021. Among these, 121 (27.1%) had orphan designation, 210 (47.1%) were approved using the FDA priority review designation, and 210 (47.1%) had generic competition as of December 2021. This study observed a significant upward trend in the prices at market entry of new molecular entities approved by the FDA between 1980 and 2021.

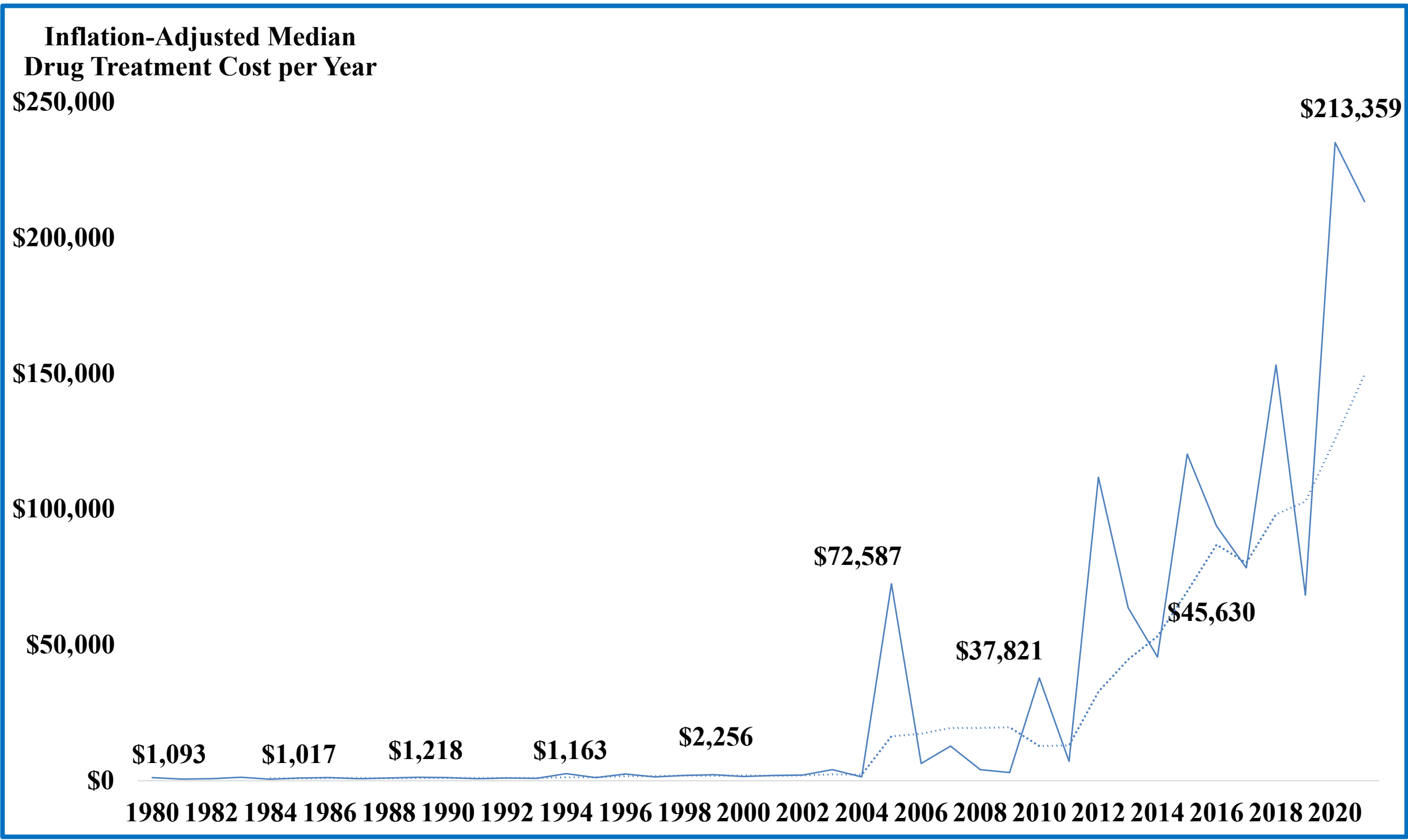


Figure 1. Drug Treatment Cost per Year at Market Entry for New Oral Chronic Use Drugs (1980-2021)

The median inflation-adjusted price per year at market entry was \$923 (IQR=\$872) in the 1980s (n=66, 15.1%), \$1,467 (IQR=\$3,134) in the 1990s (n=130, 29.8%), \$2,434 (IQR=\$9,924) in the 2000s (n=75, 17.2%), \$76,390 (IQR=\$138,847) in the 2010s (n=128, 29.4%), and \$219,219 (IQR=\$319,039) in 2020-2021 (n=37, 8.5%).

	Coefficients	ratio of means*	Std. Error	p-value	95% Confidence Interval	variance inflation factor (VIF)
Intercept	5.47	236.92	0.14	<0.000		
FDA Approval Date (1/1/1980=0)	0.09	1.095	0.005	<0.000	0.08, 0.10	1.24
Orphan designation	1.29	3.64	0.250	<0.000	1.04, 1.54	1.28
FDA Priority Review	0.49	1.63	0.209	<0.000	0.27, 0.70	1.21
FDA Boxed Warning	-0.06	0.94	0.199	0.637	-0.26, 0.13	1.08
ATC: Cardiovascular System (Reference)						1.04
Antineoplastic & Immunomodulating Agents	1.74	5.71	0.17	<0.000	1.41, 2.07	
Anti-infectives For Systemic Use	1.26	3.54	0.2	<0.000	0.87, 1.66	
Nervous System	0.29	1.35	0.15	0.04	0.01, 0.58	
Alimentary Tract and Metabolism	0.46	1.58	0.18	0.01	0.10, 0.81	
Genito Urinary System and Sex Hormones	-0.17	0.84	0.24	0.47	-0.65, 0.30	
Respiratory System	-0.02	0.98	0.30	0.95	-0.61, 0.57	
Blood and Blood Forming Organs	0.08	1.09	0.28	0.77	-0.47, 0.63	
Musculo-Skeletal System	0.30	1.35	0.25	0.23	-0.19, 0.79	

*exponentiated coefficient, exp(β)

Table 2. Factors Associated with Drug Treatment Cost at Market Entry of New Oral Chronic Use Drugs (1980-2021)

The price at market entry per year was positively associated with orphan drug designation, priority review designation, approval date, antineoplastic and immunomodulating agents, anti-infectives for systemic use, nervous system, and alimentary tract and metabolism.

Conclusions

The study findings suggest that the substantial increase in drug treatment cost per year at the market entry could be attributed to the approval of new drugs, especially those with orphan and priority review designations and certain therapeutic classes such as antineoplastic agents. These findings highlight the necessity to analyze the rising cost of drug treatment and to develop strategies to address the affordability and accessibility of these treatments for patients.