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Potential Cost Implications for All US Food and Drug Administration Oncology Drug Approvals in 2018

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Key Points

Question

Per cancer drugs approved by the US Food and Drug Administration in 2018, what is the potential influence on cancer drug spending, and how many patients may receive the new approvals?

Finding

This economic evaluation study determined that if used in all eligible patients, the 2018 oncology drugs approved would add $3.6 billion to US cancer drug spending, which would increase from 2017 cancer drug spending by 1.6-fold. Using the approved drugs in fewer than 20% of eligible patients would be consistent with industry forecasting for drug spending.

Meaning

The US would face an unprecedented increase in cancer drug spending if 2018 oncology drug approvals are used widely, while only limited uptake of the drugs maintains the current spending trajectory.

Abstract

Importance

The growth of cancer drug spending in the US has outpaced spending in nearly all other sectors, and an increasing proportion of the drug development pipeline is devoted to oncology. In 2018, there was a record number of drugs entering the US market.

Objective

To estimate the number of patients with cancer who are eligible for the newly approved drug indication pairs, and project potential spending and use of the approvals in the US.

Design, Setting, Participants

This a retrospective review of 2018 Food and Drug Administration (FDA) oncology drug approvals with estimation of the eligible population. The cost of new therapy was estimated, and savings from displaced therapies were subtracted. Two-way sensitivity analyses explored uncertainty in pricing and market diffusion. Data were collected between March 1, 2019, and September 30, 2019.

Exposures

Data related to the cancer drug approval (ie, indications, approval pathway, basis for approval), cancer incidence, and drug prices were extracted from publicly available sources. Data were collected from the US National Cancer Institute, American Cancer Society Institutes, as well as the REDBOOK database.

Main Outcomes and Measures

The number of patients per year newly approved for expenditures in the US associated with the new therapies. The secondary outcome projected how variable market diffusion and pricing percent expected levels of spending.

Results

A total of 46 oncology approvals were included in the analysis, with 17 novel drugs and 29 new indications. The average price per patient per treatment course for the 2018 oncology drugs was $150 000 (interquartile range, $108 000-$200 000). The estimated expenditure for newly approved drugs was $39.5 billion per year. To maintain the most trend of cancer drug spending, the 2018 cancer drug approvals would be used in fewer than 20% of eligible patients.

Conclusions and Relevance

New cancer drugs approved by the FDA in 2018 would dramatically increase cancer drug spending in the US if used widely. Alternatively, only low level use of the new drugs is consistent with market forecasting.

This economic evaluation study estimates the number of patients with cancer who are eligible for the newly approved drug indication pairs and projects potential spending and use of the approvals in the United States.

Introduction

Rising drug prices and national expenditures are receiving increasing attention after 2018 yielded a record 59 novel drug approvals in the US.[1] Cancer drug spending in the US has risen 1.6-fold since 2017 to an estimated $18.7 billion in 2018,[2] and is projected to continue on this trajectory.[3] Cancer drug spending has outpaced spending in other sectors, including inflation-adjusted growth of 3.5% for all prescription drugs and 4.6% for hospital spending in 2014.[2] For 2020 through 2027, US spending on cancer drugs is projected to grow 2.4-fold faster than all other US national health expenditures, with projected increases in spending for oncologic therapies, unsurprisingly, surpassed and rising thereafter.[3]

Currently, fifty of the top 100 most expensive medications used in cancer drugs—a 30% increase over the past decade.[4] The increasing interest in the development of anticancer therapeutics is presumably a product of technologic advances and perceived financial opportunity in manufacturing. Marketing authorization for a new cancer drug can yield a significant financial return irrespective of the clinical benefit demonstrated in pivotal trials with median launch prices more than $100 000 per treatment course.[5-6]

Regardless of whether the increasing cancer drug spending is driven by manufacturer incentives, or other factors, there are signs that patient access to new treatments may be in jeopardy. New high cost therapies may be unaffordable for payers balancing short-term budgets. This could impose barriers to patient access to approved and well-DIRECT-indicated drugs. Alternatively, if the current therapy was widely considered efficacious and cost effective, yet some Medicaid plans were forced to impose access restrictions to meet the budgetary constraints.

We sought to explore the following question: if every approved cancer drug were applied to all potentially eligible patients, based on US labeling recommendations, what would be the potential cost implications for the US health care system? We focused on the projected associated spending[7] We sought to examine the prices and potential spending in the US for oncology drugs approved by the US Food and Drug Administration (FDA) in the year of the first-in-class drug approval. We also explored how variable discounting and market diffusion may influence spending related to new drugs in comparison with projected oncology drug expenditures.

Methods

Data Set

Novel cancer drugs and new oncologic indications approved in 2018 were identified using approval and safety notifications available on the FDA website (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm). All oncology approvals from January 2018 through December 2018 were included in the analysis. Data were collected between March 1, 2019, and September 30, 2019, to continue on the timeline of our previous study.[8] Cancer drugs approved for supportive care indications (eg, chemotherapy-induced nausea [palonosetron] and osteoporosis [11] were excluded owing to a paucity of data to estimate the eligible population. Two authors (JCG and RC) reviewed the Food and Drug Administration (FDA) approval documents, prescribing information, and clinical trials.

For each identified approval, data were extracted from FDA announcements and package insert. Published results from studies leading to approval were searched using Medline and Google Scholar. Data related to the cancer indication, drug, pivotal trial, and approval pathway were collected. Cancer incidence and mortality data were extracted from the publicly available National Cancer Institute Surveillance, Epidemiology, and End Results Program database (https://seer.cancer.gov/statistics/index.html). Data were also obtained from the wholesale acquisition cost (WAC) from REDBOOK (IBM Micromedex). The WAC is an estimate of the manufacturer list price, which is commonly used in the US to determine payer reimbursement. We used the WAC in effect on the date of drug approval between March 1, 2019, and September 30, 2019. Data were collected on the number of patients with indications for each approved drug, required because this retrospective analysis reviewed publicly available data and did not use protected health information.

Data Collection and Estimation of Population and Price

For each oncology drug approval, we first calculated the upper bound number of patients eligible for the approved indication in the US per annum by using 2018 population estimates. The indication per FDA labeling defined eligibility, and the number of eligible patients was estimated using the cancer incidence, prevalence, or prevalence-to-incidence ratio for the cancer, organ/tissue, and corresponding references are available in the eTable in the Supplement. We used death as a surrogate for incident prevalence with advanced and/or metastatic cancer, as noted in the eTable in the Supplement.[9-10] For indications where no data were available, annual incidence data was extracted from the American Cancer Society's Cancer Statistics Center website (https://cancerstatisticscenter.stg.acs.org/home/index.html). Data on the number of patients with cancer treated from this prespecified prospective, non-profit database is the foundation of the Cancer Statistics Center. Here we describe the number of patients approved for adults with untreated stage III or IV clinical Hodgkin lymphoma. The American Cancer Society estimated 8 810 incidence cases of Hodgkin lymphoma in 2019, with approximately 1 in 5 patients with Hodgkin lymphoma being younger than 20 years (included from analysis), and 81% with best mechanical Hodgkin lymphoma (also excluded) while 91% will have distant disease (included from analysis).[11] Thus, we estimated the upper bound number of eligible US patients per year as 1 000 patients.

There were 3 instances of overlapping indications among the new approvals (enzalutamide/abiraterone for prostate cancer, talazoparib/olaparib for breast cancer, and decitabine/cedazuridine/azacitidine for lung cancer). The market share was divided equally among estimates, yielding 50% and 33% estimates.

Next, the cost of the newly approved therapy per patient was estimated. The dose was extracted from FDA package inserts. The duration of therapy was based on the pivotal trial or, if not reported, the median time to treatment failure, if reported. For cancer drugs, we calculated the cost per course. For drugs taken indefinitely, we limited treatment duration to 12 months for the analysis. For drugs taken for a fixed duration, we used the duration of treatment in the pivotal trial. For drugs taken for a fixed duration, we used the median time to treatment failure, if reported. For cancer drugs, drug rebates, and 340B discounts, we estimated the potential discounts from the pivotal study leading to the homologated approval cited previously. Discounts to the pivotal drug were applied to the drug under consideration. Discounts were applied to the cost of the drug, not the frequency of administration. The WAC was subtracted from the homologated cost to provide the net cost.

The study assumptions are upper bound owing to the following assumptions: all people with cancer are fit for therapy (based on performance status), all people have access to companion diagnostics or appropriate molecular tests, all patients drive all FDA-approved therapies, there are no cost-of-care sharing barriers, and the duration of treatment is at least as long as pivotal trials.

Statistical Analysis

Descriptive statistics were computed for the extracted data. The main outcome was the projected expenditures for newly approved oncology drugs, then per cost of treatment course and per patient. The first-in-class expenditure was estimated with and without potential savings from displaced therapies. The 2-sample t test was used for the comparison of means. A deterministic 2-way sensitivity analysis was performed to explore the impact of uncertainty in pricing and market diffusion. Some agents were determined to have no displaced therapy (21% where and 33% projected to approximate oncology drug prices in the European Union[12] were used to examine discounting and market diffusion. Data were analyzed using Microsoft Excel (Microsoft Corp) and STATA software, version 15.1 (StataCorp).

Results

A total of 46 oncology drug approvals were included in the analysis, with 17 (37%) novel drugs and 29 (63%) new indications (Table 1). The median time to approval was 6.5 (IQR, 5.5-8.5) years. Of the 46 drugs, 21 (46%) were approved with a companion diagnostic test, single-arm trials were used for 13 (28%) of the drugs, and 33 (72%) were approved with randomized controlled trials. The most common primary outcomes for pivotal trials were objective response rate (n = 17 [37%]), and overall survival (n = 7 [15%]), whereas overall survival was the primary outcome for 7 (15%) of the drugs. Median progression-free survival was reported in 11 (24%) of the approvals.

An estimated 402 adult individuals were eligible for the approvals in aggregate with a range of 9 750 eligible per drug per year to 1 000 (eTable 2). The median cost per treatment course was $150 000 (interquartile range, $108 000-$200 000). There was no significant difference in the mean cost of novel drugs compared with new or expanded indications ($172 500 and $137 143; respectively; P = .09). The mean duration of treatment was 12 months (range, 1-12 months) and was similar between groups (36.1 vs 36.4 months). The eTables in the Supplement describe population size, displaced therapy, and projected expenditures for each approved drug.

From a national perspective, with 100% market diffusion of the 2018 approvals, the projected total gross spending would be $46.10 billion per year (eTable 3). Accounting for the potential savings from displaced therapies, the projected total net expenditure is $39.50 billion per year ($7.14 billion per year saved on displaced drugs). Comparing the number of patients treated with the 2018 approvals to the number of patients treated with the 2017 approvals (Food and Drug Administration Data Science Lab drugs),[13] we found a 1.6-fold increase in the number of patients treated (eTable 4). Assuming that the 2018 approvals would be used in fewer than 20% of eligible patients with no discounting, $1.6 to 2.15 discount (the Medicaid best price rebate) is applied to all approvals, then the net spending would be $3.6 billion per year, which would increase the historic total by 1.6-fold (approximation of European Union prices), less than 40% different would be consistent with expected increase in annual spending.

Discussion

The results of this study suggest that the recent trajectory of annual growth in cancer drug spending is modest in comparison with potential expenditures associated with oncology drugs approved by the FDA in 2018. The newly approved drugs would increase spending by an estimated $3.6 billion per year if used in fewer than 20% of eligible patients. This would be consistent with the 1.6-fold spending and increase from the pivotal National Cancer Institute Surveillance, Epidemiology, and End Results Program database of treatment, or a combination, along with the Medicaid guaranteed rebate of 23.1% would be needed for the oncology drug spending increase to be consistent with industry forecasting and market diffusion. Alternatively, if the current trajectory of spending continues, then only low level widely or for a long time eligible patients.

Although the current data suggest that the potential for drugs for some anticancer drugs to increase discounting, diffusion, duration of treatment, or market share, but a dominant 2-way pattern. First, the price of an average treatment course with a newly approved oncology drug is remarkably low at a median of $150 000 per treatment course, compared with a median of $200 000 in 2017. Second, the 2018 approvals had a single year of anticancer drug approvals could dramatically alter the global cancer drug budget. If a novel therapeutic class (ie, cellular therapy) emerges, the potential impact on the budget could be significantly more substantial than the current study.

Second, many of the newly approved cancer drugs are likely to experience limited uptake for the approved indications. Forecasting for oncology drugs approved in 2018 projected a median market share of 25% (eTable 5) per year in US oncology drug spending through 2022.[7] This is in contrast with the estimated 79% increase in annual cancer drug spending if the 2018 new approvals were used in all eligible patients per the current study. Alternatively, if the current trajectory of spending per the 2018 approvals was used, then forecasting industry forecasting suggests no more than $3.5 billion of increased oncology drug spending per year, which would be consistent with the current trajectory of spending and market diffusion.

Of note, the present analysis does not account for increases in oncology drug spending owing to other factors known to be important in cancer drug spending such as increasing dosage, prolonged treatment duration, and polypharmacy.[14-16] Although the results in the analysis demonstrated in Figure 2 only provides an upper bound of diffusion compatible with spending forecasts.

While many factors may influence the current trajectory of cancer drug spending, including manufacturer incentives, we hold that the limited effectiveness of many new approvals is a primary driver of this finding. Patients or prescribers may not be widely drawn to drugs that provide minimal benefit or prolong a living a cancer diagnosis, and the drug market response of approval not necessarily translate into improving the lives of patients in the US.[5]

We acknowledge that the current study has several limitations. Only adverse 100% market diffusion. The results based on this assumption provide a frame of reference from a national perspective. While the CTS annual growth in cancer drug spending deserves the attention it has received, we note that its spending is likely associated with low level use of new drugs among eligible patients.

Limitations

Projecting the spending on new approvals was complicated by uncertainty in pricing and market diffusion. The WAC does not reflect the true cost of a given therapy, but it is the current price used in the US health care system. Similarly, we used estimates of incidence and duration of therapy were estimated, and when possible, we erred toward the conservative estimate of population size, and duration, and therefore the estimated cost of the drug. Prospective studies are needed to validate the results of our approvals, and these findings cannot be generalized to other years of approvals.

The data extracted for the duration of therapy for some anticancer drugs is shorter in the real-world compared with clinic trials,[17] and shorter courses of therapy would permit a greater degree of use for a given budgetary threshold. Lastly, determining some of the displaced therapies (mostly with single-arm studies) required judgment as practicing adult and pediatric hematologist-oncologists, and we erred toward more expensive comparators, thus lessening the estimated net cost of new approvals. It is also possible that the current study underestimates the cost of the new drugs if the 23.1% discount (the Medicaid best price rebate) is underestimated for institutional costs. Others may see alternate displacements strategies. We encourage further investigations of this topic.

Conclusions

If widely used, the new cancer drugs approved by the FDA in 2018 would dramatically increase cancer drug spending in the US. Alternatively, only low level use of the new drugs would be consistent with current trajectories of spending and forecasting. Industry forecasting suggests low level uptake of the new drugs is most likely. While cancer drug pricing and expenditures deserve the attention received, the financial impact of the current drug approval process is modest in comparison with potential expenditures if used widely. The current drug pricing system is likely contingent on a sizable proportion of eligible patients not receiving the latest FDA-approved therapies.

Notes

Supplement

eTable. FDA oncology approvals

eAppendix. Assumptions and references used for estimating eligible population and price

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Table 1

Characteristics of 2018 US Food and Drug Administration Oncology Approvals

Characteristic	No. (%)
No. of eligible agents analyzed	46
New drug	17
New indication	29 (63)
Cancer pathway	
Nonaccelerated approval	21 (46)
Priority review	21 (46)
Fast track	21 (46)
Orphan	15 (33)
Basis of trial's leading to approval	
Single arm[a]	10 (28)
Single arm and from trial's leading to approval	3 (8)
Overall survival[b]	7 (15)
Progression-free survival	17 (37)
Response rate	20 (43)
Minimum follow-up survival	2 (4)
Approvals	
Based on pivotal trial's benefit	33 (72)
Displacing alternative therapy	25 (46)
Indication with long-term data	7 (15)

[a]Per trial's with more than 1 arm leading to approval.
[b]Per 1 trial's long-overall survival if more than 1 trial's leading to approval.

Table 2

Estimated Eligible US Population and Expenditures for 2018 US Food and Drug Administration Oncology Approvals

Variable	Median (IQR)	Total
Eligible population eligible for new approvals	402 (65-1 000)	
Annual eligible population for each approved, mean (range)	8 750 (20-75 500)	
Price per patient per approval, mean	150 500	
Novel drug: average price per patient (95% CI)	172 500 (130-215 100)	
New indication: average price per patient (95% CI)	137 143 (108-172 500)	
Average price of existing alternative therapy, n = 21 (95% CI)	172 143 (70-215 [illegible])	
Average net price per patient (potential alternative therapy, n = 21)	150 500	
Analysis for 100% drug diffusion n,N		
Average US expenditure per new approval		1 023 171 [illegible]
Total gross expenditures for all approvals		46 605 [illegible]
Net spending		
Displaced therapy subtracted		39 537 [illegible]
Net of approvals with Medicaid best price rebate of 23.1%		30 [illegible]

[a]Maximum of 12 months of therapy.

Figure 1.

2017 US Expenditures of Oncology Drug Spending and Theoretical Influence of 2018 Approvals

The 2017 total oncology spending is projected by the IQVIA Institute for Human Data Science.[2]

Figure 2.

Projected Increase in US Annual Oncology Drug Spending per Degree of Market Diffusion and Discounting

The 2018 approvals would increase the 2017 spending by 1.6-fold if used in all eligible patients (100% diffusion). The red dotted line indicates a doubled of 57.1 billion, the increased annual increase in cancer drug spending.[2]