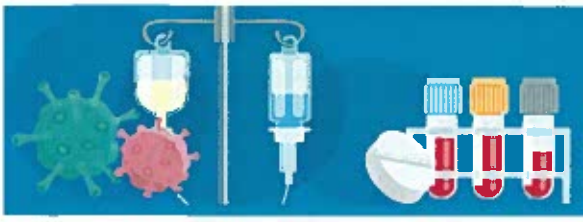
mahp
Michigan Association of Health Plans

The Facts

Your *Source* for Health Care Information



Exploding Cancer Drug Prices

An estimated 56,684 Michiganders were diagnosed with cancer in 2019. As the price of new and existing cancer treatments continue to climb they pose an increasing threat to the affordability of our overall health care system.

With many cancer medications now priced close to $300,000 per year and spending expected to continue growing in the years ahead, it's crucial that we tackle the issue of affordability now to ensure we can keep our health care system healthy for those who need it most.

Source: American Cancer Society

By The Numbers

$75.5 Billion
estimated spend on U.S. cancer drugs in 2021

$283,000
average annual cost of a new cancer drug launched in 2021

Dangerous Trends

Average monthly cancer drug costs more than doubled:

$7,103 in 2006

$25,000 in 2021

U.S. Cancer drug spending doubled over the past 5 years and is expected to double again by 2022.

2022: $100 billion

2021: $75.5 billion

2012: $24.8 billion

$150,000 In 2017

$283,000 In 2021

Average launch price for cancer drugs nearly doubled and is expected to continue rising.

$14,580
Median monthly cost in the US of 65 cancer drugs

$6,867
Median monthly cost in the UK of the same 65 cancer drugs

$6,593
Median monthly cost in Switzerland of the same 65 cancer drugs

Source: JAMA Oncology 2021; 7(9) e212026 Supplement

Only **2%** of cancer drugs in England and **13%** of cancer drugs in Switzerland had a median price increases greater than inflation.

NOTE: **74%** of cancer drugs had price increases in U.S. that were greater than

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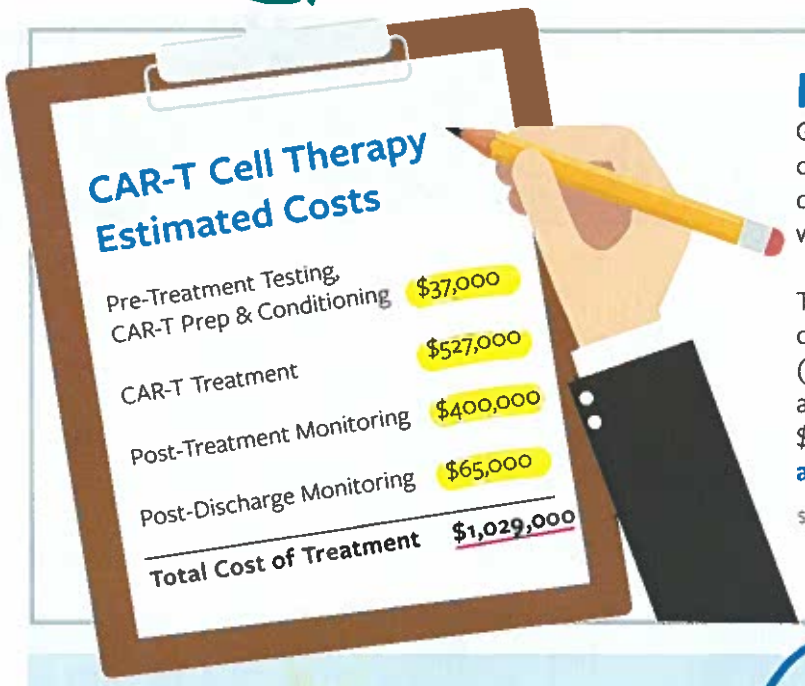


Million Dollar Treatments

Gene therapies, like CAR-T, are closer than ever to curing cancer, but with treatment costs approaching one million dollars the devastating impact a single drug can have on the whole healthcare system is becoming alarmingly clear.

The cost of these treatments is extraordinary. If these CAR-T drugs were used to treat 250,000 cancer patients per year (just 40% of the Americans who die annually from cancer), annual drug spending in the U.S. would increase by approximately $93 billion— **an almost 20% increase in the country's total annual drug spending— for one single medication.**

Source: Wall Street Journal

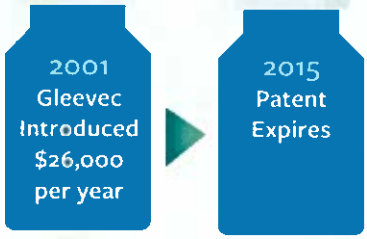
Six Figure Tags. The New Normal.

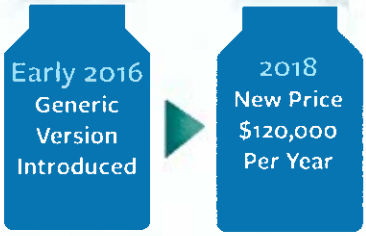
All cancer drugs launched in 2022 carried prices more than $200,000 per year.

[All costs annual]
Source: NIH Source: Reuters Source: The Balance

Then & Now: Concerning Pricing Models

Gleevec first entered the market in 2001 with a $26,000 a year price tag. By the time its patent expired, it had hit $120,000 a year despite the passage of time and introduction of generics— two factors pharma commonly claims should help control drug prices.





"We have tried to live the fantasy that we could afford to give everything to every patient at the same level and not break the bank."
— Leonard Saltz, MD

Breast Cancer Spotlight

Breast cancer is the most commonly diagnosed cancer in women. Along with the diagnosis, rising costs brings a second challenge to women— extreme financial burden for survivors, families and the overall healthcare system.

Over 4.7 million U.S. women have a history of breast cancer - 155,880 in Michigan.

Source: 2019 CDC data

Go-to treatment regimens are pricey and getting pricier:

- Perjeta cost **$5,900 per month** in 2013 to **$10,440 per month** in 2021 - a **57% increase**
- Herceptin cost **$9,170 per month** in 2012 and rose **78%** prior to the launch of its less expensive biosimilar in 2019.
- In 2015, Lynparza was released at **$13,886 per month** and increased to **$17,460 per month** in 2021 - a **192% increase**

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Bill Summary

Your *Source* for Health Care Information

HOUSE BILL 4071: ORAL CHEMOTHERAPY MANDATE

MAHP POSITION: **MONITORING**

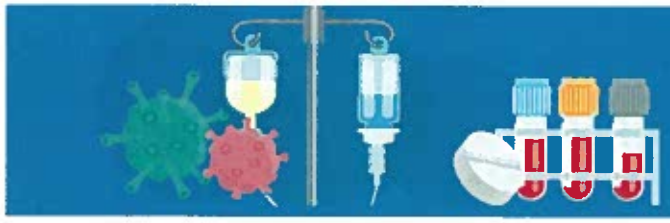
SUMMARY OF HOUSE BILL 4071

House Bill 4071 mandates that customer out-of-pocket expenses shall not exceed $150 per month for oral chemotherapy medication, regardless of the actual cost of the prescription drug. It would also require health insurance providers to apply the same out-of-pocket costs for orally prescribed chemotherapy as intravenously administered chemotherapy, regardless of the cost differential.

BACKGROUND ON ORAL CHEMOTHERAPY

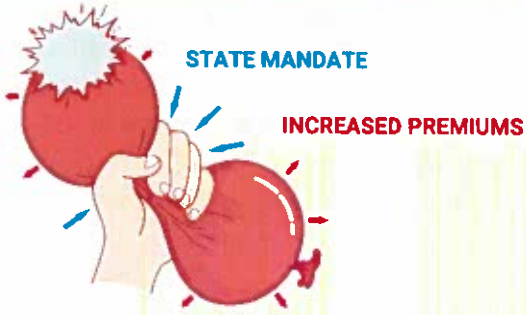
Chemotherapy coverage has been mandated in Michigan since 1989 under Chapter 34 of the Michigan Insurance Code. Today, health plans must provide coverage for all FDA-approved chemotherapy treatments (oral and intravenous chemotherapy drugs).

Cost-sharing requirements for these medicines depend on a customer's chosen policy plan. However, all health plan policies must comply with the Affordable Care Act (ACA), which caps aggregated total out-of-pocket customer costs (co-pays, deductibles, and co-insurance) at $9,000 per individual and $18,200 for families. These caps apply to all prescription and medical out-of-pocket expenses.



The price of oral cancer prescription drugs ranges on average from $10,000 to $25,000 per month.

Efforts by states to mandate lower cost-sharing for enumerated specific drugs like oral chemotherapy or insulin affect the actuarial value of the cost-sharing caps set under the ACA. Health plans must make necessary adjustments when lower cost-sharing mandates are passed on prescription drugs or medical services by increasing cost-sharing on other benefits or raising insurance premiums.



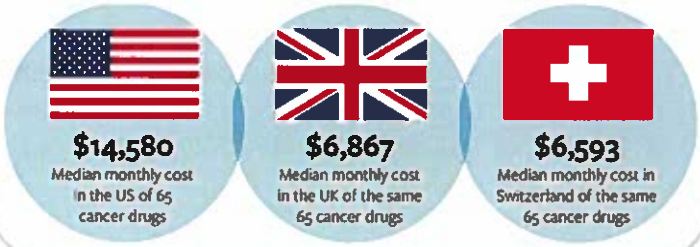
According to a JAMA report, increased spending on oral cancer drugs has risen much faster than inflation. Furthermore, many oral chemotherapy drugs have limited study data that identify favorable response rates (identified as the percentage of patients whose tumors shrink beyond an arbitrary threshold compared to intravenous chemotherapy medications). A 2019 study of 85 oncology oral drugs approved from 2006 to 2018[1] showed that only 21% offered clinically significant benefits. Only one drug, imatinib, offered a transformational impact on cancer treatment with a 98% survival benefit. Most other drugs showed unconfirmed clinical benefit, with only 6 of 85 drugs establishing overall survival advantage in post-marketing studies.

[1] https://pubmed.ncbi.nlm.nih.gov/31135822/

ARGUMENTS AGAINST ORAL CHEMOTHERAPY MANDATE

THIS MANDATE WILL NOT LOWER DRUG COSTS

Reducing out-of-pocket costs does nothing to stop the abusive increases in oral chemotherapy drug pricing. Average monthly cancer drug treatment costs **increased from $7,103 in 2006 to $25,000 in 2021.** The price of oral cancer prescription drugs ranges on average from $10,000 to $25,000 per month. Unlike other counties, the United States does not regulate or negotiate the price of prescription drugs. Drug manufacturers freely set drug pricing without government price control or regulation. Oral chemo drug costs have far outpaced the Consumer Price Index over the last decade.



THIS MANDATE HELPS DRUG MANUFACTURERS

Big Pharma supports and advocates strongly for customer cost-sharing caps because it masks the problem of high-cost prescription drugs. **House Bill 4071 will not lower the costs of oral cancer prescription drugs.** This bill will exacerbate prices by increasing demand for unregulated products with zero price controls.

THIS MANDATE WILL ONLY AFFECT A FEW CUSTOMERS

This legislation will only benefit some patients using oral chemotherapy. Commercially self-insured employers who provide healthcare to their employees (ERISA) represent nearly 60% of the market and are not subject to this state mandate. In Michigan, almost 60% of all cancer diagnoses are to those over 65 years of age and covered by Medicare which is not impacted by this legislation. As such, less than one percent of Michigan's population will benefit from this mandate.

CUSTOMERS WILL PAY THE PRICE FOR THIS UNFUNDED STATE MANDATE

Since the passage of the ACA, states across the country have begun setting up a patchwork of new and additional insurance mandates like House Bill 4071, which exceed federal standards and increase healthcare costs. According to the Journal of Risk and Financial Management, each state has more than forty individual health insurance mandates that exceed federal requirements.

Unfortunately, states force health plans to act like hidden tax collectors. Health plans are forced to charge their customers for state healthcare mandates. Rather than using tax dollars to pay for their mandates, the state is forcing health plans to increase your health insurance costs. To add insult to injury, customers are not even allowed to choose whether they want or need these new state-mandated healthcare coverages. Instead, the mandate is added to your policy, and you're expected to foot the bill.

I WANT YOU
(HEALTH PLANS)
TO TAX CUSTOMERS.

mahp.org (517) 371-3181

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Michigan Association of Health Plans

OTHER ALTERNATIVES TO CONSIDER TO LOWER PRESCRIPTION DRUG COSTS

*The following policy reforms are better alternatives that will **effectively lower oral chemotherapy drug prices**:*

AFFORDABILITY REVIEW BOARD

Establish a prescription drug affordability review board to assess drug affordability and set rates for prescription drugs to bring savings to all patients.[2] Health plans must file and seek approval for their premium rates with state and federal regulatory entities each year; why not drug manufacturers? The creation of a state affordability review board would allow states to review and set rates for certain high-cost prescription drugs.

ACCOUNTABILITY

Enact legislation that fines pharmaceutical manufacturers for price gouging or increases that exceed a state threshold.[3]

IMPORTATION

Allow for importing prescription drugs at a lower cost and highlight why other countries that better regulate drug manufacturers have lower prescription drug costs.

TRANSPARENCY

Force drug manufacturers to provide transparency reports on drug pricing in Michigan.

LIMIT MONOPOLY STATUS OF NEW DRUGS

Call on Congress to change federal prescription drug patent timeframes. New drugs in the U.S. are typically granted monopoly periods that usually last 20 years. During this period, drug companies tend to raise list prices each year, which can lead to higher out-of-pocket patient costs.

EARLY WARNING

Require drug manufacturers to warn early about price increases on prescription drugs. Doing so would provide some accountability and allow health plans, employers, and the state to prepare for those increases.

INTERNATIONAL REFERENCE RATES

Allow state regulators to establish international reference rates for the 250 most costly drugs in the state and prohibit state entities, health plans, or employers from purchasing referenced drugs for a cost higher than the referenced rate.

INFLATIONARY CAPS ON DRUG PRICES

Limit specific drug prices to no greater than inflationary increases.

[2]https://www.billtrack50.com/BillDetail/1061500
[3] https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/07/a-tax-on-drug-price-increases-can-offset-costs

Questions for lawmakers to ask constituents inquiring about Oral Chemo Therapy Parity Legislation

1) May I ask what type of Prescription Insurance Coverage You Currently Have (Medicare, Employer-sponsored, Medicaid, VA or Tricare, Small Group or Individual Market)?

   Reason why this is important: The current legislation will only impact insurance coverage changes for patients who have individual coverage.

   Note: ONLY 0.12% of Michigan's population has insurance coverage that would be impacted by this legislation.

   The Oral Chemo Therapy Parity Legislation will NOT impact persons covered under the following drug benefit plans:

   - Medicare (Part D or Advantage plans)
   - Medicaid
   - Employer sponsored or self-insured (ERISA) health plans that offer benefits to employees and retirees, such as unions (ex: GM, Ford, or any employer with more than 100 people)
   - Federal employees health benefits programs
   - VA or Tricare benefits
   - State sponsored health coverage (state of Michigan employees/retirees, local municipality provided coverage, teachers, firefighters etc.)

2) Insurance coverage for drugs (cancer drugs and other diseases) varies if the drug is an oral medication or an injectable/infused medication due to federal regulation. Oral medication is typically covered under the prescription benefit and injectable/infused medication covered under the medical benefit. Copays or co-insurance varies for prescription coverage compared to the medical benefit. This legislation will not change this coverage variance, have you been made aware of that?

   Note: Medicare only covered drugs under the medical benefit prior to 2006 and the creation of the Medicare Part D benefit. When Part D was implemented, Congress unfortunately did not choose to move all drugs to coverage under the drug benefit, and therefore a disparity exists today on what part of insurance covers drugs. Medical benefit for injectable/infused drugs and drug benefit for most oral drugs. U.S. Congress will need to needs to fix this issue because state statute cannot.

3) Are you aware that this legislation does not address the underlying issue of the high cost of cancer drugs?

   Note: The premise for the legislation is to address cancer drug costs for patients but this will not lower drug pricing. Prices of cancer drugs continue to grow far ahead of the costs of inflation. The mean new cancer drug price is $200,000 compared to $40,000 several years ago. In addition, a one year treatment for a patient with one of the newest infused cancer drugs is almost ONE MILLION dollars. Finally, U.S. drug prices are double that compared to other countries.

4) How did the Michigan Cancer Society or another organization indicate to you that this legislation would help you?

   Note: The majority of insurance plans (Medicare, Medicaid, Employer sponsored) are not impacted by this legislation. In addition, drug coverage (medical verses prescription benefit) cannot be impacted or changed at a state level and needs to be corrected at a federal level.

Proposed Legislative Resolution for Change in Definition of Drug Under Medicare: The Need to Clarify Coverage for Infused and Orally Administered Chemotherapy Drugs.

PROPOSED RESOLUTION

Whereas, there is estimated 1,900,000 new U.S. cancer cases in 2022 with 62,500 of those cases impacting Michiganders. Cancer has a significant impact on society; it is one of the leading causes of death and places significant physical, emotional and financial burden on those individuals impacted.

Whereas, national expenditures for oncology treatment in the U.S. for 2020 reached $157 billion, with much of that cost spent on new cancer drugs. Costs for treatment will continue to rise as the U.S. population continues to age and the incidence of cancer continues to rise.

Whereas, average cancer drug price per treatment year was less than $10,000 before 2000 and has increased to over $400,000; with some oncology treatment costs reaching one million dollars per patient per year.

Whereas oncology drug costs are expected to double again by 2024 posing an increasing threat to the affordability of our overall health care system.

Whereas, more than half of all patients with cancer receive some type of oncology drug treatment, either alone or in combination therapy. These treatments can occur by injection or intravenous therapy or by treatment in the home by taking an orally administered drug.

Whereas, prior to the implementation of the Medicare Part D benefit in 2006, coverage for drugs, including oncology treatments, were only provided under Medicare Part B for drugs administered in a medical facility or administered by a physician. Unfortunately when Part D was implemented, U.S. Congress and the U.S. Health and Human Services Administration did not see fit to reclassify drugs previously covered under Medicare Part B to coverage under Part D creating a bifurcated drug coverage program.

Whereas, insurance coverage for oncology drug varies based upon how the drug is administered; under the medical benefit if the drug is administered by injection or intravenously or under the drug benefit if the drug was orally taken; however some orally administered drugs may still be considered a medical benefit. Navigating coverage creates confusion for patients, providers and insurers and differing cost sharing and coverage requirements.

Whereas, cancer drug parity legislation, introduced at the state level, will not have legislative or regulatory authority over the federally regulated programs such as Medicare. Therefore, efforts to address oral chemotherapy parity and drug coverage under Medicare needs to be directed to the U.S. Congress.

Whereas, the Food and Drug Administration defines a prescription drug (regardless of the route of administration, injection, infusion or oral) as "a substance intended for use in the diagnosis cure, mitigation, treatment, or prevention of a disease"; regardless of their route of administration (i.e. injection, infusion or oral).

Therefore, let it be resolved, that the Legislature, through the adoption of this resolution, convey a firm statement to the U.S. Congress to require all prescriptions drugs, regardless of their route of administration (injection, infusion or oral) to be covered under the Part D benefit including those drugs previously covered under the Part B program.

Honorable (insert full name of lawmaker)

(Choose one of the following – depending on the lawmaker)

United States Senate
Washington, D.C., 20510

United States House of Representatives
Washington, D.C., 20515

Dear (select one: Congressman/Congresswoman) _____(provide name),

I am writing to you today to address my concerns regarding insurance coverage and cost disparities for patients undergoing cancer treatment and the need for your help to correct this problem.

Co-insurance and copay levels vary for coverage of medication for patients if they are orally administered versus provided by infusion or intravenously. Coverage is different, I have been told, because infused agents are covered under the medical benefit, such as Medicare Part B, as compared to oral agents which are covered under the prescription drug benefit, such as Medicare Part D. This coverage variance was established as a necessity prior to Medicare Part D, but today this separation adds to the chemotherapy coverage and cost disparities.

Legislation has been introduced previously in Michigan which attempted to mandate insurance coverage parity for cancer drug treatment so that costs and coverage was no more restrictive for oral medications compared to infused or intravenous drugs. State legislation, however, will not correct coverage problems for federally operated programs such as Medicaid, Medicare, VA, Tricare and ERISA programs; since they would be exempted from state mandates.

(Provide your personal story here including your age, specific type of insurance, impact of your cancer treatment, personally and financially if comfortable)

Congress needs to take action to allow for coverage for all medications in a manner that would result in parity for all patients. State mandated parity in Michigan would only impact a small minority of people that have a small group and individual health insurance coverage, because other programs would be exempted.

However, coverage disparity is only part of the problem. The high costs of medications is also an issue and the continued outrageous drug price increases that negatively impact patients undergoing treatment. Not being able to afford medication creates a barrier to effective health care outcomes.

I am asking for your help to address these concerns for me and my fellow Michiganders. Please let me know if I can provide any additional information that may be helpful to you as you move forward to correct this issue.

Sincerely,

(your name, address, and phone number)

The Detroit News

EDITORIAL | **Editorial** *This editorial reflects the opinion of this publication's Editorial Board.*

Editorial: Bills to cut drug costs would raise insurance premiums

The Detroit News

Published 10:28 p.m. ET Apr. 3, 2021

A well-intentioned pair of bills aimed at reducing the cost of certain essential medicines have passed the state House and are pending in the Senate.

While their goal is laudable, the bills wouldn't actually reduce drug costs — they'd merely shift who pays for them. And they do so in a way that could cause many employees of small businesses to lose their health insurance.

The two bills are part of an ambitious 15-bill package that sponsors say would slash drug prices while increasing access to health care. They passed with bipartisan support.

While there are worrisome issues with several of the bills, the two specifically aimed at insulin and cancer medicines are the most problematic.

One would would cap the out-of-pocket expense of insulin drugs at $50 for a 30-day supply. The other limits outlays for patients taking orally administered anti-cancer medicine at $150 for a monthly prescription.

Prices for both drug categories have risen sharply across the country. Many patients are struggling to pay for them, even with insurance coverage.

So again, the instincts of the Legislature to do something to help patients dependent on these medicines is understandable.

But the arbitrary caps demanded in the bills don't address the cost of the drugs. They just change who pays for them.

Pharmaceutical companies will be able to charge the same for the medicine. But more of the out-of-pocket expense will be billed to insurance companies instead of the patients.

While that may sound like a reasonable solution, the reality is that insurers will pass on the additional cost burden to their clients in the form of higher premiums.

Employer groups are banding together to oppose the legislation, arguing the impact on insurance premiums will force many small businesses to drop coverage for their employees.

The added cost for insurers is expected to be $17.6 million for the cancer drugs and $39.6 million for the insulin medications.

Just 30% of small businesses based in Michigan offer health insurance coverage to employees.

Forcing-up insurance premiums will prompt more employers to suspend coverage and force their workers onto federal insurance exchanges.

State legislatures are not the right places to address the cost of prescription medicine. This is a national problem that demands a national solution.

The better approach would be federal measures to bring more transparency to drug pricing and encourage more competition in the pharmaceutical industry.

The bills pending in Michigan do nothing to address the real cause of rising prices. What patients save at the pharmacy they'll likely give back in their monthly health insurance premium.

The Senate should treat these bills as the right instinct, but wrong approach.

Up, up and not going away: Cancer drug prices

Escalating costs are hitting patients hard. CMS price negotiation and the $2,000 cap on Part D out-of-pocket expenses should benefit many patients with Medicare coverage. by **KEITH LORIA**

Oncology drugs are making up a bigger and bigger part of the money spent on cancer care. The cost of cancer drugs now represents between 50% and 60% of the total cancer spend and continues to climb. Prices for new drugs approved for the treatment of cancer more than doubled between 2009 to 2019, from an average monthly cost of $6,000 to nearly $15,000.

Andrew Hertler, M.D., chief medical officer at New Century Health, a specialty care management company, notes that most of these new, high-priced therapies do not cure cancer — and, on average, have a limited effect on survival. According to Hertler, 71 consecutive FDA approvals of drugs to treat solid tumors increased survival an average of just 2.1 months, and 70% of the drugs approved over the past two decades had no effect on improving overall survival.

Financial toxicity

The high price tags result in "financial toxicity" for patients — prices so high that they affect the well-being of patients, including (but not limited to) treatment itself becoming less effective because patients skip or cut doses or don't take the medication to begin with. Medicare beneficiaries without Medicare supplemental insurance or coverage from a Medicare Advantage plan can easily have out-of-pocket expenses of $50,000 or more per year because of coinsurance in Part B and the lack of a cap on out-of-pocket expenses in Part D. The Inflation Reduction Act of 2022 will, though, put a cap of $2,000 on Part D out-of-pocket expenses starting in 2025.

"Cost-benefit analyses reveal no correlation between price and benefits when measured by objective criteria such as survival or quality of life. One drug may prolong life by days and another by years, and yet they will likely carry very similar price tags."

—ANDREW HERTLER, M.D., NEW CENTURY HEALTH

Pharmaceutical companies have coupon programs that make their drugs more affordable for patients, but Medicare patients are not eligible for them because of anti-kickback statutes and concern that these programs would steer patients toward more expensive drugs.

Private foundation money can help but it often dries up within the first half of a year of treatment, says Hertler. Even when people have ostensibly good private insurance, maximum out-of-pocket costs can reach $10,000 per year, which is significant for many families. "For the first time in my 40-year career, I hear of patients refusing even curative therapies out of fear of jeopardizing their families' savings and retirement. The ethical question arises: Should a family have to conduct a bake sale to cover life-sustaining therapy?" says Hertler.

John Vatkevich, clinical trial site manager at the patient empowerment platform Outcomes4Me, which has developed a cancer care navigation app, notes that financial anxiety is a huge burden on patients who are already under immense stress.

"Patients generally already keep a medical log to keep track

of their care. They shouldn't also have to carry an insurance binder with them to track their medical and treatment expenses. It's overwhelming," he says. During his eight years in the clinical setting, the questions he most often received from cancer patients were related to money and drug costs: "Who will pay for this?" and "What are my co-pays?"

"Patients often don't receive their ideal care options because insurance won't cover the cost of the drug or drugs that could lead to the best health outcomes," Vatkevich says. "Oncology, on the whole, is personalized medicine. Even chemo is personalized to a patient's unique stage and disease pathology. Unfortunately, even though genetic testing has allowed for personalized treatments at scale, insurance companies haven't caught up."

All of these cost and coverage issues are weighing on patients at a time when researchers and oncologists see cancer treatment pivoting away from cytotoxic chemotherapy to immunotherapies that harness the immune system and targeted therapies that home in on cancer cells, Hertler says.

"These two classes of drugs have significantly extended the survival of patients with advanced cancer from months to years and are impacting virtually all tumor types," Hertler says. "Current efforts are aimed at using these types of drugs to treat earlier-stage cancers, which are still potentially curable, to increase the overall cure rate."

Pharmaceutical companies routinely cite the high cost of research and drug development to justify high prices. However, 85% of basic cancer research is funded through taxpayers' money, according to the American Association for Cancer Research.

Roughly half of cancer drug purchases are made for Medicare patients. The Inflation Reduction Act will empower the federal government to negotiate drug prices for the first time, starting with 10 drugs in 2026. But the legislation sets a number of limits on the eligible for negotiation. For example, drugs with generics or biosimilars are ineligible, as are small-molecule drugs that were approved by the FDA less than nine years ago and biologics, less than 13 years.

One important overall factor pushing up oncology drug prices is that many new therapies target relatively small numbers of patients, especially initially, before new indications are added. To recoup the fixed research and development costs associated with bringing a new drug to market — not to mention financing all of the failed attempts — the price per patient has to increase.

"In many cases, given the heterogeneity of cancers with different sets of causes, we are dealing with niche therapies with few competitors," Hertler says. "Unfortunately, free market forces do not function effectively for purchasing health care products and services which involve sickness, suffering and death."

Furthermore, he explains, the situation is often a "double jeopardy" for patients fortunate enough to have health insurance. The patient is not footing most of the bill, and the provider knows this.

"In the setting of life-sustaining treatment, cost is no longer a major concern for many patients," Hertler says.

"Cost-benefit analyses reveal no correlation between price and benefits when measured by objective criteria such as survival or quality of life," he continues. "One drug may prolong life by days and another by years, and yet they will likely carry very similar price tags."

85%

of basic cancer research is funded through taxpayers' money.

Source: American Association for Cancer Research

Coverage concerns

In Medicare, drugs to treat cancer are in one of six "protected classes." Part D plans, including those that are folded into Medicare Advantage plans, must cover every drug available in those protected classes. However, Part D plans can use step therapy and other managed care tactics to control drug costs and utilization.

Medicaid and commercial insurance have a bit more control over their formularies and often have "preferred drugs" with restricted access to those alternatives that may have no proven increase in efficacy or decrease in toxicity, according to Hertler.

Many of the new cancer drugs reaching market today are approved through a process known as accelerated approval, where

drugs are approved when there is an urgent need for them, but typically before definitive evidence is available to demonstrate that they prolong patients' lives or improve their quality of life.

"Accelerated approvals are usually based upon surrogate end points, which suggest there will be an improvement in survival, such as response rate (tumor shrinkage, calculated in various ways) or progression-free survival (the time before a tumor increases in size or patient dies)," Hertler says. "Unfortunately, these surrogate end points translate into an increase in overall survival less than half of the time. Therefore, in exchange for the accelerated approval, the drugmaker is required to complete definitive follow-up studies to prove the drug really works."

Many of these studies are never done. Only 16% of the 93 accelerated approvals between 1992 and 2017 ultimately had confirmed clinical benefit, and 40% did not complete confirmatory trials at all, according to research findings reported in *JAMA Internal Medicine* several years ago by Aaron S. Kesselheim, M.D., J.D., M.P.H., a Harvard drug pricing expert, and his colleagues.

"The prices of drugs that receive accelerated approval are set similar to those drugs that receive regular approvals, meaning that payers are covering some therapies without proven impact on overall survival," says Hertler, who pointed to findings from another *JAMA Internal Medicine* study, this one published in 2021, which calculated that $569 million had been spent by Medicare Parts B and D between 2017 and 2019 on 10 cancer drug indications with confirmed lack of overall survival benefit.

And these days, just because an insurer has a drug on its formulary doesn't mean out-of-pocket costs for patients are affordable, notes Ian Manners, MBA, chief strategy officer and head of life sciences at TailorMed, a drug software company. He cited a study published in the *Journal of the National Cancer Institute* this year that followed 380 patients with advanced colorectal cancer. All but seven had health insurance. After just one year, almost three-quarters of the patients encountered financial hardships even though they had coverage for treatment, and one-quarter indicated that they experienced financial hardships within three months of diagnosis.


MANNERS

Michael Donlin, co-founder of StatsFind, has more than 25 years of experience in oncology care, including administration, financial and patient care. He notes the first challenge of coverage is when the oncology medication is denied. Then the process begins for the provider to navigate the appeals process and provide the necessary documentation. If the appeal is granted, the next challenge is the patient's ability to pay the deductible and coinsurance. "We recently had a Medicare patient who unfortunately had not signed up for a Part D plan need Tarceva (erlotinib)," he says. "He was quoted $1,958 for 30 days of medication. His income exceeded any of the limits for financial assistance programs; therefore, his only option was to use his retirement savings to cover the costs until January 2023, when he would be eligible for Part D coverage."

Finding solutions

In Hertler's opinion, the problem of high cancer drug prices will be helped by the new power that the Inflation Reduction Act gave to CMS to negotiate Medicare prices, which will go into effect in 2026 with 10 Part D drugs and extend in 2028 to Part B drugs. Also on Hertler's list: cancer treatment pathways that incorporate cost-benefit analyses into drug decision-making, allowing the importation of drugs for personal use and eliminating drug rebates.

Donlin believes a rise of local nonprofit pharmacies should be monitored as an interesting option for the underinsured. In addition, new websites, such as Mark Cuban's CostPlusDrugs.com, may make some cancer drugs less expensive for patients. Along with coupon-type arrangements, the number of programs that extend some coverage to the uninsured is expanding out of necessity, he says.

Research has shown that financial navigation services are one of the best ways to address financial toxicity in a hands-on way.

Manners of TailorMed says emerging technologies can help to automate the financial navigation process by uncovering cost savings for patients and streamlining the process of enrolling in resources. "It's unlikely that any single-policy solution will holistically address the affordability problem," he adds. "It's going to take a mix of structural and pragmatic interventions to make meaningful progress."

Keith Loria *is a freelance writer in the Washington, D.C., area.*

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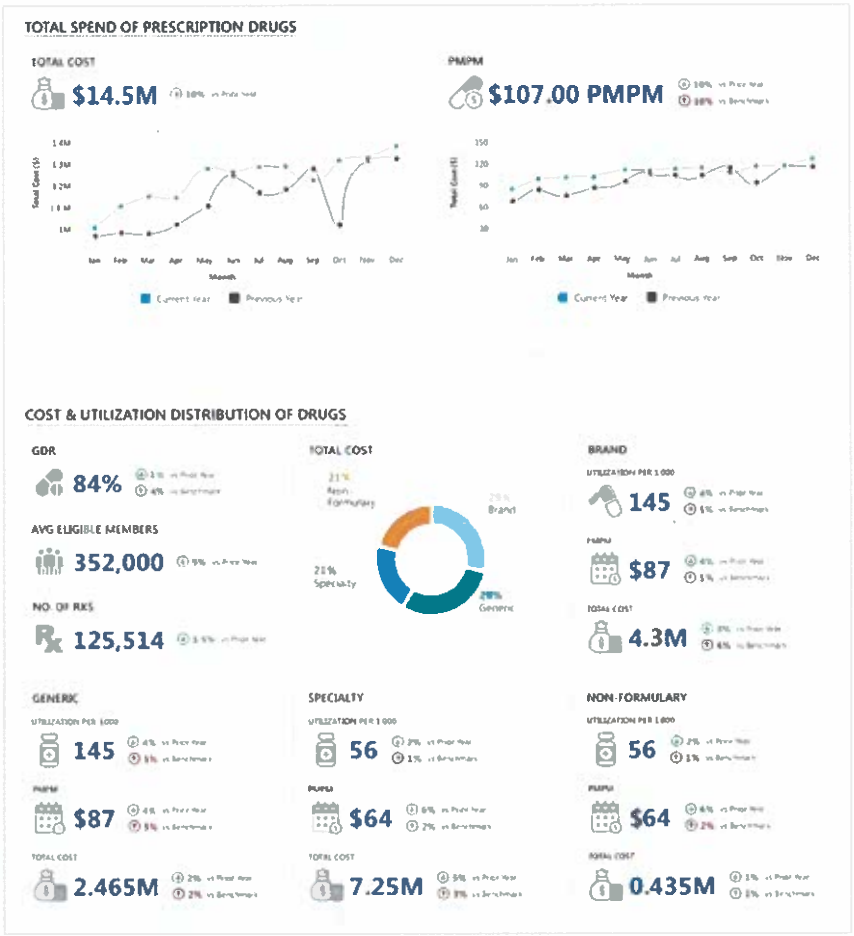

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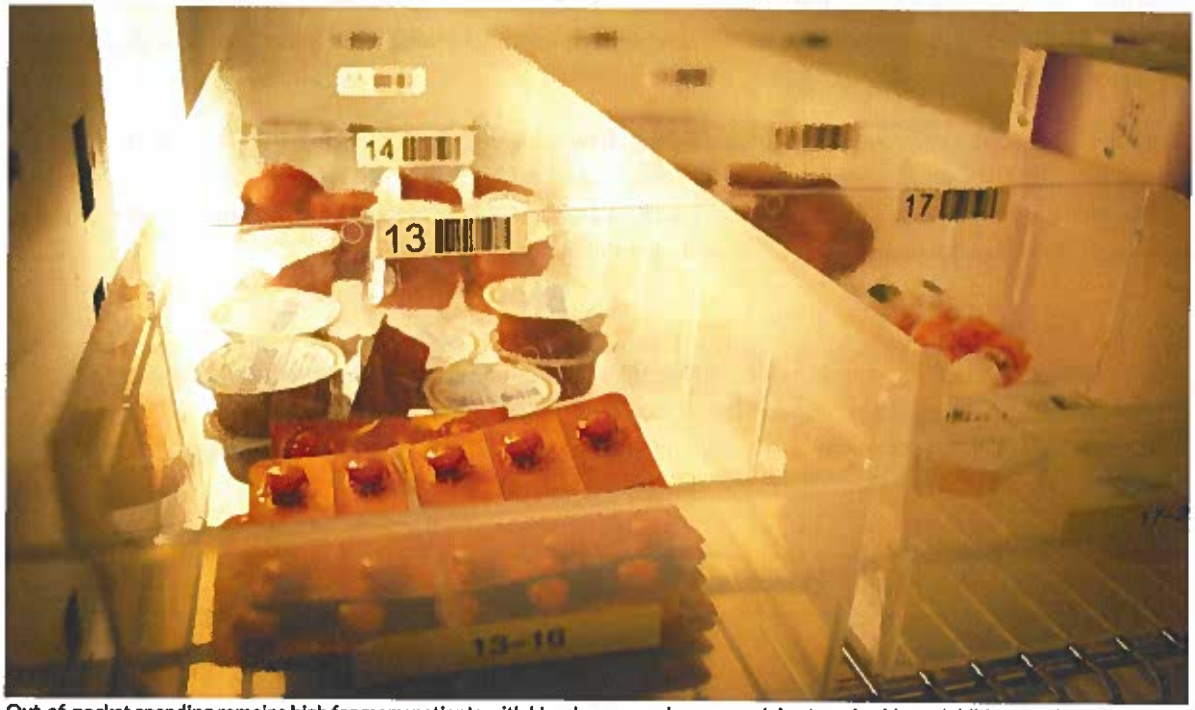
Cancer Therapy Advisor

February 7, 2020

Oral Oncology Parity Laws Don't Make Medications More Affordable

Jessica Wapner



Out-of-pocket spending remains high for many patients with blood cancers who are receiving tyrosine kinase inhibitors and immunomodulatory drugs.

Cancer care is haunted by issues surrounding cost and oral cancer drugs are a stark example. For patients with chronic myeloid leukemia (CML) and multiple myeloma (MM), orally administered drugs have become a mainstay of treatment, but the insurance coverage of these drugs can be different than coverage for infused medications, which can leave patients with higher out-of-pocket (OOP) costs.

Patient advocates have pushed for laws that require insurers to charge patients the same amount for oral medications and intravenous drugs. So far, 43 states and Washington, DC, have passed such legislation, known as oral oncology parity laws.[1]

According to a new, multicenter study led by Stacie Dusetzina, PhD, who researches health policy at Vanderbilt University School of Medicine in Nashville, Tennessee, these laws aren't necessarily helping.[2] The study examined insurance claims from 2008 to 2017 — before and after parity laws were passed — in order to compare OOP spending, adherence, and discontinuation among patients with CML taking tyrosine kinase inhibitors (TKIs; 2082 patients) and patients with MM taking immunomodulatory drugs (IMDs; 3326 patients).

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The researchers found that some patients did benefit. More fully insured patients had initial OOP payments of $0 after parity (5.7% vs 46.1% for TKIs and 10.9% vs 48.8% for IMDs). And people in fully insured plans became more likely to pay nothing for their medications than people in self-funded plans (4.27 times more likely for TKIs and 1.96 times more likely for IMDs).

But decreases in spending were ultimately modest. After parity, the percentage of patients paying more than $100 for TKIs and IMDs did decrease, but not by much: 30.3% compared with 24.7% for TKIs and 30.6% compared with 27.5% for IMDs.

"Requiring medical and pharmacy benefits to be similar to one another does not ensure that either are generous," said Dr Dusetzina, who called the findings, published in the *Journal of the National Cancer Institute* in December 2019, "disappointing." She explained that people with already low payments before parity were the most likely to benefit from the laws, which was not their intention.

Tina Shih, PhD, professor in the department of Health Services Research at the University of Texas MD Anderson Cancer Center in Houston, emphasized that the jump in the number of patients with no OOP costs was more likely the result of changes in the Affordable Care Act rather than the passage of parity laws. "Even among the group of patients who are most likely to benefit from oral oncology parity laws," commented Dr Shih, who was not involved in the research, "they appeared to have provided limited benefits in the private insurance market."

Not everyone agrees that parity is a major issue with oral oncolytics. The only difference, said Yousuf Zafar, MD, MHS, director of the Center for Applied Cancer Health Policy at Duke University in Durham, North Carolina, is the timing of payment: oral drugs are paid for at the pharmacy counter whereas intravenous drugs are billed for months later. Perhaps more concern, according to Dr Zafar, should be placed on how OOP spending decreases adherence among all patients.

Indeed, the impact of parity laws on adherence appeared lackluster in the study. Both fully insured and self-funded patients showed an increase in adherence and discontinuation after the laws were enacted, but the laws weren't responsible for the change, which were slight. For example, among fully insured patients taking TKIs, adherence increased from 71.3% to 74.7%. "Even for people who have health insurance and who live in states that passed parity laws," says Dr Dusetzina, "cancer treatment may still be very expensive."

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Study Gives Mixed Reviews On Laws To Equalize Cancer Patients' Out-Of-Pocket Costs

By **Michelle Andrews** NOVEMBER 10, 2017

Laws designed to equalize out-of-pocket costs faced by cancer patients undergoing chemotherapy — whether treated intravenously, with pills or liquid doses — are having mixed results, according to new research.
The study, published online this week by JAMA Oncology, found these so-called state "parity" laws have not uniformly reduced patients' out-of-pocket spending.

The laws became popular in the past decade as pricey anti-cancer oral medications grew more common. They were intended to address the variation in what insurers expected patients to pay, depending on the form of chemo they received.

In many plans, oral anti-cancer drugs were placed in high cost-sharing tiers in patients' prescription coverage. Drug infusions — which took place at a doctor's office — were handled as an office visit and sometimes required minimal copayments.

The researchers analyzed health plan claims of 63,780 adult cancer patients younger than age 65. All lived in the 43 states and the District of Columbia that passed parity laws from 2008 to 2012.

They compared the use of oral anti-cancer medicines and out-of-pocket spending between patients in two types of health plans: state-regulated plans and "self-funded" employer health plans. The employer plans pay workers' claims directly and therefore are not subject to state parity laws. Just under half of the patients involved in the study had coverage through a self-funded plan.

They came to various conclusions.

First, "these laws have not consistently reduced out-of-pocket spending for orally administered anticancer medications," they wrote. More broadly, they noted, while these parity laws offered many patients "modestly improved financial protection," the laws alone "may be insufficient to ensure that patients are protected from high out-of-pocket medication costs."

And the researchers were surprised and concerned by these findings. "When you think about who would have been the target of the law, parity is intended to help people afford the cost of their treatment," said Stacie Dusetzina, an assistant professor of pharmacy

and public health at the University of North Carolina-Chapel Hill, who was the study's lead author. "The most expensive fills got more expensive after parity. That's concerning."

Among their specific findings:

- The number of prescriptions requiring high out-of-pocket spending grew, despite parity laws. The proportion of prescriptions filled in plans subject to parity that cost more than $100 out-of-pocket per month increased from 8.4 to 11.1 percent, the study found. That figure declined slightly for prescriptions in plans that weren't subject to parity, from 12 to 11.7 percent.
- In plans subject to parity laws, the proportion of prescription fills for orally administered therapy without copayment increased from 15 to 53 percent, more than double the increase in plans not subject to parity. Those plans increased from 12 to 18 percent.
- Parity laws did not increase six-month total spending for users of any anti-cancer therapy or for users of oral anti-cancer therapy alone.

The researchers suggested that continuing growth in high-deductible plans and high coinsurance charges may have contributed to the rise in the number of patients with high out-of-pocket costs for cancer treatment, even in states that have parity laws.

The study also found that out-of-pocket spending on infused drugs, which are typically older and less expensive than oral anti-cancer therapies, remained stable during the study period and was unaffected by parity laws.

A federal law that would extend parity to the seven states that don't have it has been proposed in the past, most recently in March. Such a law could also benefit people in self-funded plans that aren't subject to state laws, as well as Medicare beneficiaries.

"A federal law would potentially provide a lot of benefit, because we do feel parity has a net benefit for patients," Dusetzina said.

KFF

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More Evidence on the Limited Impact of State Oral Oncology Parity Laws

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Precis:

Most states have enacted legislation cancer parity laws in order to ensure that copayments are similar for cancer drugs whether the drug is administered orally or intravenously. However, the parity laws have had a limited impact, often only lower copayment for those that already had low copayments.

Keywords

Policy; Out-of-Pocket Cost; Insurance Design; Adherence; Breast Cancer

By the beginning of 2018, all but 7 states had passed oral oncology parity laws - a dramatic success story for community advocates and grassroots organizing. These laws attempt to address concerns related to very high out-of-pocket costs for patients filling orally-administered anticancer drugs on their private health insurance plans, at least for patients who are enrolled in fully-insured plans that are subject to state insurance mandates. Specifically, they aim to equalize cost-sharing between oral and infused anticancer therapies (i.e., creating "parity" between these two parts of the insurance benefit) or to introduce out-of-pocket spending caps for fills.

In the current issue of *Cancer*, Dr. Chin and colleagues provide an evaluation of how parity has impacted out-of-pocket spending for endocrine therapy for breast cancer recurrence prevention, comparing states with and without oral oncology parity laws between 2007 and 2014[1]. Consistent with prior work, this study finds that oral oncology parity laws did not consistently reduce out-of-pocket spending for endocrine therapy.[2] In fact, parity reduced spending at the 25th percentile of spending for two drugs (anastrazole and exemestane), increased it for a third drug (letrozole), and had no effect on the fourth drug (tamoxifen).

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Conflict of Interest: None

Further, the authors find that there were limited changes in out-of-pocket spending for fills at the 50th percentile or above and no changes in the mean copayment amounts paid for any drug as a result of parity. Despite this, the authors document that adherence improves when copayments decrease, which is consistent with prior research in this area.[3,4]

Prior work by our study team has found similarly disappointing results for the effect of oral oncology parity laws on out-of-pocket spending on anticancer drugs, with most savings accruing to those whose out-of-pocket prices were already low. However, the current study must contend with several other factors that complicate the investigation of the effect of parity. These include generic drug entry over the study period and ambiguity regarding parity's role for adjuvant therapy, where the goals of treatment are recurrence prevention rather than cancer treatment, itself.

Prior studies have documented how generic entry of endocrine therapy reduced copayments and improved adherence,[3–5] therefore the authors try to untangle the impact of generic entry and parity by conducting stratified analyses. The unadjusted analyses show that median copayments are only statistically different when looking at generic drugs, and not branded drugs. The adjusted results show a more consistent impact of parity for generic drugs (a decrease in the 25th percentile of out-of-pocket spending for generic anastrozole, a decrease in median out-of-pocket spending for generic and brand exemestane, and an increase in the median out-of-pocket spending for branded letrozole). This stratified analysis again documents that parity reduced copayments for patients with the lowest out-of-pocket spending, particularly for generics, the most affordable medications.

To the second point, there is ambiguity regarding whether parity laws would extend to adjuvant endocrine therapy. For example, parity laws typically specify that an insurer "shall provide coverage for a prescribed, orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications that are covered as medical benefits." (text from Kansas regulations but is similar or verbatim in other states)[6] Given its role in the adjuvant setting, endocrine therapy may not meet the legal definition for products under the scope of oral oncology parity laws. However, it may be argued that it would fall under this definition since this process should slow the growth of cancer cells.

Beyond the ambiguity regarding whether parity extends to include adjuvant endocrine therapy, the response to parity laws may vary by insurer due to a lack of clarity regarding how these laws should best be implemented. Examples of outstanding questions include: Does cost-sharing for oral therapies have to be actuarily similar to infused therapies over the course of a therapy, the benefit year or for each fill of a prescription? Do copayments have to be reduced for branded products if there is a generic that is below the threshold? Should cost-sharing be similar for medications used for a particular cancer or across all cancers?

In response to these challenges, some insurers such as Blue Cross and Blue Shield of Massachusetts simply decided to reduce copays to zero dollars.[2,7] Some plans may choose this approach since the overall budget impact will be relatively small due to a small patient population and positive publicity. The budget impact would be particularly small if the

insurer is already providing generous coverage with patients having relatively low copays, which has been shown to be true for privately insured patients filling orally-administered anticancer therapies during the timeframe of this study. In the context of endocrine therapy, particularly following approval of generic formulations for these products, reducing cost-sharing for patients from twenty dollars per fill to zero would have a very small budget impact.

Similar to prior work, Chin et al find that oral oncology parity laws modestly reduced out-of-pocket spending for women using endocrine therapy. With median out of pocket prices for the generic products ranging from $11 per month for letrozole and anastrazole to $22 for exemestane, it is unclear whether affordability will remain a challenge for women needing these treatments, with or without parity. However, this issue should be carefully monitored given the long-term use of these drugs. Despite the lack of benefit of parity in this setting, it should be further explored with drug who have higher out-pocket costs, that were likely the original target for parity laws.

Acknowledgments

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The Complex Cancer Care Coverage Environment — What is the Role of Legislation?

A Case Study from Massachusetts

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Christine Leopold, Rebecca L. Haffajee, Christine Y. Lu and Anita K. Wagner

Abstract

Over the past decades, anti-cancer treatments have evolved rapidly from cytotoxic chemotherapies to targeted therapies including oral targeted medications and injectable immunooncology and cell therapies. New anti-cancer medications come to markets at increasingly high prices, and health insurance coverage is crucial for patient access to these therapies. State laws are intended to facilitate insurance coverage of anti-cancer therapies.

Using Massachusetts as a case study, we identified five current cancer coverage state laws and interviewed experts on their perceptions of the relevance of the laws and how well they meet the current needs of cancer care given rapid changes in therapies. Interviewees emphasized that cancer therapies, as compared to many other therapeutic areas, are unique because insurance legislation targets their coverage. They identified the oral chemotherapy parity law as contributing to increasing treatment costs in commercial insurance. For commercial insurers, coverage mandates combined with the realities of new cancer medications — including high prices and often limited evidence of efficacy at approval — compound a difficult situation. Respondents recommended policy approaches to address this challenging coverage environment, including the implementation of closed formularies, the use of cost-effectiveness studies to guide coverage decisions, and the application of value-based pricing concepts. Given the evolution of cancer therapeutics, it may be time to evaluate the benefits and challenges of cancer coverage mandates.

Introduction

Between 2014-2018, 57 cancer medications were launched in the U.S. for 89 indications across 23 different cancer types.[1] In 2018 alone, a record 15 new oncology therapeutics for 17 indications were launched with an increasing trend of oral targeted therapy and immuno-oncology approvals.[2] New cancer treatments generate hope among patients and providers. At the same time, new cancer therapies challenge payers. The rapid increase in anti-cancer medication approvals is due to scientific advances combined with expedited approval processes by the Food and Drug Administration (FDA)[3] to provide patients with early access to promising therapies.[4] Expedited approval pathways require less evidence on efficacy and safety for approval[5] and some mandate post-approval confirmatory studies.[6] However, when evaluated in post-marketing studies, uncertainty about clinical effectiveness often remains;[7] some products approved via expedited pathways have not been found to be effective and safety issues have emerged.[8] Additionally, these innovations come to market at high and increasing prices[9] and pose substantial challenges to societal[10] and individual affordability of cancer medications.[11]

Health insurance coverage of expensive cancer therapies is crucial to make new therapies accessible to patients. State laws to ensure cancer therapy coverage, such as off-label use laws, have origins in various federal laws that facilitate such coverage. Some such laws date back to the 1990s when the environment was different: anti-cancer medications consisted of cytotoxic chemotherapy, their effects had been studied more extensively before approval and they were substantially less expensive than today's new treatments. Moreover, states have enacted additional laws to ensure cancer therapy coverage.[12] For example, oral chemotherapy parity laws have been implemented in the past decade to address higher out-of-pocket costs of increasingly prevalent oral therapies as compared to injectables.[13]

The question arises: to what extent do cancer coverage laws meet the needs of diverse stakeholders given the clinical and regulatory evolution of cancer therapies? Evaluations of coverage policies in cancer care mainly focus on their impacts on the care delivery system,[14] healthcare utilization,[15] and affordability by patients.[16] To our knowledge no previous research examines the dichotomy between cancer coverage mandates and current realities in oncology care that involve novel therapies, many approved based on limited evidence of benefit or evidence of marginal benefit, at ever-increasing prices. At the same time, leading policy fora are highlighting the important role of the interplay between coverage policies and the legal environment with a call for more research in this area.[17]

Materials and Methods

Taking Massachusetts (MA) as a case study, we combine legal and qualitative analyses. We first describe cancer coverage laws and then present and discuss the perspectives of expert stakeholders on these laws today. We focus on MA because of its highly specialized cancer care delivery centers and its generous insurance coverage environment.

First, we performed a content analysis of relevant legislation in MA. We searched Lexis Nexis and other sources for legislation relevant to clinical trials, off-label medication use, and coverage of chemotherapy. Our search for legislative documents included state-level laws enacted and possibly amended since 1990 and still in-effect as of January 2018. We then collected key information on each law, including: 1) type of law/benefit, 2) law provision and title, 3) date of authorizing legislation, 4) effective date, 5) types of insurance policies affected, 6) types of insurance policies exempted, 7) coverage requirements, 8) coverage exemptions, 9) cost-sharing or other insurer managed care approaches allowed, and 10) law citation and Uniform Resource Locator (URL). To put the MA laws into context, we include an overview table of similar laws in Connecticut (CT), Maine (ME), and New Hampshire (NH).

Next, we conducted semi-structured interviews to elicit perspectives of experts about the MA cancer coverage laws to understand how well (or not) existing cancer coverage laws meet the current cancer care needs. The research team leveraged connections with relevant organizations in MA to identify experts for interviews. Different from quantitative studies where the ideal sampling standard is random sampling,[18] we purposefully invited seven experts from regulatory agencies, public and private payers and provider organizations to cover a range of views and experiences of key stakeholder groups in cancer drug coverage. These represent information-rich key informants to illuminate the question of interest, which is the overall purpose of qualitative research. Sample

size is justified on the basis of information power.19 We summarized the identified key laws in MA in a table, which we shared with interview partners prior to the interviews. We developed a semi-structured interview guide that included 11 open-ended questions, categorized into three sections: 1) regulating cancer medication coverage — mapping the legal basis, 2) regulating cancer medication coverage — understanding the process of coverage, and 3) regulating cancer medication coverage — broader considerations. We had separate questionnaires for representatives of provider organizations, state regulators, and insurers. The questionnaires were tested among colleagues at the Department of Population Medicines at Harvard Medical School and Harvard Pilgrim Healthcare Institute.

Interviews were conducted by phone between January and March 2018, lasted one hour each, and were audio-taped. Participation in the interview was voluntary and consent was explicitly given by all participants. CL, RLH, and AKW jointly conducted all interviews; recordings were transcribed. Using qualitative content analysis methods, we systematically extracted themes that emerged across interviews and categorized them into overarching areas.20 After several rounds of review, no further new themes emerged and the investigators created a consensus summary of all themes and selected representative quotes to illustrate the key points made by interviewees. The research protocol and interview guides were approved by the Harvard Pilgrim Health Care Institutional Review Board.

Results

We first describe and summarized the most relevant laws and regulations concerning insurance coverage of cancer treatments in MA. In addition, we include an overview table of similar laws in CT, ME, and NH. National laws were not included in this overview unless they directly influenced state legislation.

MA Cancer Treatment Coverage Mandates

We identified five laws as most relevant for the coverage of cancer treatments. These included the MA off label drug use law, the MA clinical trial law, the MA oral chemotherapy parity law, MA health reform legislation, and the federal Patient Protection and Affordable Care Act (ACA) — including the Essential Health Benefits defined at the state level. During the interviews, "White-Brown Bagging" emerged as another relevant policy to consider.21 The off-label drug use law dates back to the 1990s; the other laws were implemented between 2003 and 2013.

Before the federal ACA, MA provided health insurance coverage to its uninsured and low-income residents and offered affordable health insurance coverage options to all its residents since 2006. MA residents are required to obtain, and most employers must offer, health insurance or face financial penalties. As of 2017, MA plans offered on the ACA exchanges were obligated to cover chemotherapy, radiation, and specialty generic and brand-name drugs, all without limitations on quantity. In addition to these general insurance coverage requirements, some longstanding laws targeting commercial plan coverage of cancer care also exist in MA. Individual and group insurance policies that provide prescription coverage must generally cover anti-cancer medications, including for indications that have not been FDA-approved (i.e., the "off-label drug use law"). Also, these plans must cover general patient services furnished to cancer patients enrolled in qualified clinical trials (i.e., the "clinical trial law,"). Finally, since 2013, any plan offered in MA

that covers cancer chemotherapy must cover orally administered chemotherapy medications as generously as its covers injectables (i.e., the "oral chemotherapy parity law,"). Taken together, these laws are intended to benefit patients by mandating that commercial insurers cover cancer care and treatments along the pathway from clinical research to on- and off-label use of marketed products.

While such laws also exist in similar form in CT, ME, and NH, their effective dates and scopes differ somewhat from those in MA. For example, the requirements for off-label drug coverage vary between the states: CT law mandates coverage of off-label use if the cancer treatment is mentioned in standard reference compendia; ME and NH laws require evidence from standard reference compendia or the medical literature (ME law specifies two publications from high impact journals); the MA law specifies that off-label evidence could also come from a panel of 6 medical experts and then recognized by the MA insurance commissioner. The oral chemotherapy parity laws are similar in substance (except that MA explicitly forbids meeting this coverage requirement by increasing cost sharing for injectable anticancer medications), but effective dates vary across states: CT implemented it's law in 1991, MA in 2003, ME in 2009, and NH in 2017.

Seven experts from regulatory agencies, public and private payers and provider organizations participated in the interviews. To describe the relevance of these laws and how they impact cancer drug coverage in the real world, we present in the following paragraphs the main themes and statements that emerged from key informant interviews. Under each theme, key messages from the interviews are summarized and relevant quotes were included in to exemplify the main points of the interviews.

Coverage of Cancer Treatments Faces Unique Challenges

Interviewees emphasized that oncology is a particularly "difficult" area when it comes to insurance coverage decisions. Reasons for this include: 1) a fast changing treatment environment in which we observe a switch from organ-based to tumor-based treatments independent of a specific organ, 2) a treatment setting with very expensive medications that are often approved based on insufficient data of clinical benefits, and finally 3) the fact that cancer therapy coverage is a sensitive topic given unmet need, hope, and hype in public media.

MA May be Exceptional in Terms of Both Cancer Treatment and Legislation of Cancer care

Interviewees emphasized that MA might be more generous when it comes to covering cancer treatments than other states. Several reasons were offered to support these claims: 1) in contrast to other states, health plans in MA do not seek to maximize profits and may have more generous coverage policies; 2) MA is a hub of highly specialized cancer centers with highly trained, highly-specialized oncologists who conduct trials of cutting-edge therapies; and 3) in MA, oncologists and legislators know each other and can easily communicate about policies.

Differential Applicability of Laws in the Private versus the Public Sector

The state cancer coverage laws are largely only relevant for commercial insurers, meaning that private health plans regulated by the Division of Insurance at the Department of Health must comply with the regulations; public plans, including Medicaid, were not directly affected by the state cancer coverage laws we identified. Medicaid's coverage determination process is agnostic about the therapeutic category and includes a literature review for all FDA-approved medications. Medicaid employs a set process for making all coverage determinations but does engage an oncologist on the Medicaid Drug Use Review Board. Nevertheless, cancer treatments are not assessed or viewed differently from any other therapeutic class. Respondents from private health plans pointed out that they conduct faster coverage assessment and review processes for oncology products.

Differential Relevance of These Laws for Coverage

We learned from the interviewees that each of the highlighted laws has differential relevance in real-world coverage decisions. While the oral chemotherapy parity law is financially impactful for private health plans — as it requires insurers to charge members no more for oral chemotherapies than for medications administered in a clinical setting (i.e., no higher cost sharing for oral chemotherapies) — it is less impactful for patients in Medicaid plans under which out-of-pocket payments are negligible.

With respect to the clinical trial law respondents from private health plans voiced their concerns for the ability to manage patients in clinical trials because for insurers, it is unclear when a patient is part of a clinical trial and which services then must be covered. Again, this seemed to be less of a concern for public payers.

All respondents agreed that the off-label drug use law is less relevant to the reimbursement environment at this time because 1) insurers acknowledge that new drugs are being used off-label; 2) they trust the clinicians in MA in their prescribing, and 3) outside of prior authorization requirements, insurers don't typically check drug use against diagnoses.

Stakeholders' Concerns with Respect to the Legal Environment

When asked about specific concerns regarding MA regulation relevant to cancer treatments, respondents mentioned the "White-Brown Bagging" policy,22 which requires that medications for specific patients are filled in specialty pharmacies and then either delivered directly to administering clinicians in hospitals ("white-bagging") or picked up by patients from pharmacies and brought to clinicians for administration ("brown-bagging"). In both cases, prescriptions are filled for a specific patient and if medications are not picked up, they cannot be returned to the pharmacy stock and used for other patients.23 Respondents were concerned that white-bagging could lead to wasting expensive products if patients do not receive the ordered medication; and that brown-bagging could lead to unsafe handling of medications outside of health care settings.

Policy Options Toward Sustainable Coverage of Cancer Care

Respondents pointed out that the coverage environment is changing, and alternative policies relevant for all therapeutic classes are being tested and implemented. Some of these approaches are already in use or are being developed by public and private insurers. Approaches include the

implementation of a closed formulary, in which not all medications are automatically covered after approval by the FDA; formal comparative- effectiveness assessments as part of coverage decision-making; and value-based reimbursement.

Discussion

This study combined legal and qualitative analyses. We identified relevant legislation in MA and, to add context, provided parallel information on similar laws in CT, ME, and NH. We presented the legal analysis to and elicited perspectives from experts about the MA cancer coverage laws to understand how existing cancer coverage laws meet the current cancer care needs. In the discussion, we reflect on the insights from the interviews and the juxtaposition of the laws with the state of cancer therapies today.

Although our interview partners represented different stakeholders, similar themes emerged from their perspectives on legislation of coverage of cancer care in MA. Interviewees emphasized that cancer therapy coverage is uniquely challenging and has for decades had special insurance coverage legislation. Among the five relevant state laws and policies, the oral chemotherapy parity law was identified as the most impactful in terms of costs in the private insurance sector. Respondents' suggested implementation of closed formularies (e.g., potential exclusion of medications from coverage), comparative cost-effectiveness studies and value-based reimbursement approaches to address the high cost burden of cancer therapies.

Since the earliest cancer coverage mandate in 1993, additional cancer coverage laws have accompanied the scientific evolution that gives rise to new molecules. The off-label laws were meant to ensure covered access to cytotoxic chemotherapies which kill any fast-growing cell, regardless of the cancer type for which the agent was approved as long as patients tolerate the medications. With increasing cancer research producing scientific advances,[24] the clinical trials law in 2003 ensured that cancer patients enrolling in trials have covered access to needed care that is not paid for by the trial. Insurance coverage expansion in 2006 and beyond (including the Federal Medicare Part D drug benefit) also provided incentives for the development of oral cancer treatments. The oral parity law of 2013 ensured that patients' cost sharing for new oral therapies, usually under an insurer's pharmacy benefit, were not higher than the usually limited cost-sharing for injectable therapies administered in provider offices and usually paid under an insurer's medical benefit and with minimal utilization management. While these cancer coverage laws are meant to provide patients with covered access to all available treatments, they limit insurers' ability to manage the use of the products and negotiate prices. That is challenging given that many oncology medications are now approved based on lowered efficacy and safety standards through expedited review programs,[25] based on surrogate outcomes that do not correlate well with overall survival[26] or quality of life,[27] and that almost half of the randomized trials that form the basis of approvals are subject to bias that may exaggerate the outcome findings.[28] Thus, health plans are required to cover new cancer therapies despite increased uncertainty about efficacy, safety, and long term effectiveness.

Steep increases in costs of cancer care over the last decades[29] have raised concerns of affordability for the overall healthcare system as well as for individual patients. Cancer patients' struggles to cover their outof- pocket expenses are widely known;[30] at the same time, private payers are

speaking up about the fact that an increasingly larger share of total health care spending is taken up by higher-priced pharmaceuticals including cancer medications,[31] with limited policy tools to manage those costs.[32] Our interview partners shared these concerns. By definition, cancer treatment coverage mandates do not consider overall affordability of the healthcare system or the payer, nor target medication pricing,[30] which is often cited to be at the root of the tremendous cost burden.[34] In fact, state and federal coverage mandates are thought to contribute to high cancer drug prices.[35]

The experts suggested several policy options such as comparative cost-effectiveness studies, the implementation of value-based reimbursement and pharmaceutical company patient access schemes to address the oncology access-evidence-spending conundrums. While some of these approaches are in use (e.g. cost effectiveness studies and patient access schemes), others such as value-based reimbursement are still mainly theoretical.[36] Most recently, states are considering the establishment of state-governed "prescription drug affordability review boards" charged with reviewing expensive medications and, if deemed too expensive, setting a new, lower maximum price that insurance plans would pay.[37] Maryland was the first state to implement such a review board in July 2019.[38] At the same time, it is not clear whether these approaches offer long-term solutions to the affordability of cancer medications in the US.[39] These suggested approaches — eliminating parity requirements, having closed formularies or the introduction of cost-effectiveness based reimbursement — need to be implemented in ways that balance affordability and access so that patients who can benefit from treatments have access to the therapies.

This study has limitations. We focused on assessing the legal policy environment in MA, which was the first state to mandate insurance enrollment and which offers historically generous health insurance coverage. Our findings might therefore not be generalizable to other states in the US. The results of our qualitative assessment represent subjective experiences of experts, which may reflect a socially desirable response bias. Notwithstanding these limitations, our focus on MA given its unique environment offers in depth insights into contemporary challenges of cancer therapeutics in health systems. Our findings suggest that in combination with FDA regulations for faster approvals based on more limited evidence and the lack of federal price controls, states like MA may be due for a review of current coverage mandates to assess whether they facilitate covered access to important cancer medicines for patients who can benefit from them while also keeping insurance coverage sustainable and affordable for people in the state.

Conclusions

Given the rapid evolution of science and cancer medication approvals, a review and, if needed, updates of the cancer coverage mandates seem worthwhile to ensure sustainable access to both high quality cancer care and health insurance that is affordable to individuals, health plans, and society.

Footnotes

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1 Not specific to coverage but we included it to have a comprehensive overview

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RICE UNIVERSITY'S
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POLICY BRIEF

RECOMMENDATIONS FOR THE NEW ADMINISTRATION

High Cancer Drug Prices: The Harm to Americans and Proposed Solutions

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THE PROBLEM

High cancer drug prices are a significant contributor to health care costs in the United States. The average annual price of new cancer drugs increased from less than $10,000 before 2000 to $145,000 in 2015.

Annual drug industry profits average 20%, the second-highest of any industry. The drug industry needs to make reasonable profits to survive, sustain investment, and fulfill its fiduciary duty toward shareholders. But in its recent laser-focused desire to maximize profits, the drug industry has crossed the line into profiteering—maximizing profits even when it harms patients.

Despite numerous discussions in the media and elsewhere, cancer drug prices are escalating at an alarming rate. The price per year of life gained from such therapies increased from $54,000 in 1995 to $207,000 in 2013 (adjusted for inflation). In contrast, real (inflation adjusted) median U.S. household income decreased by 4% between 1999 and 2015. In Europe and elsewhere, the prices of older drugs remain close to their launch prices, unless new benefits are discovered after the drug is on the market. Not so in the U.S., where prices rise an average 8–12% annually. Newer drugs enter the market at higher prices every year, partly justified by the high prices of older drugs.

The pharmaceutical industry and its lobbying groups (for example, the Pharmaceutical Research and Manufacturers of America [PhRMA]), under criticism, repeat the same mantra: the high cost of research and development; benefit justifies price; market forces settle prices at reasonable levels; and price regulation stifles innovation and hinders important research and discoveries. None of the arguments is convincing. First, independent studies calculate the cost of R&D is only 10% of the $1 billion–$2.6 billion figure claimed in industry-supported studies (all by the same source, the Tufts group). Eighty-five percent of basic research is conducted in academic centers, while the drug industry spends only 1.3% of its budget on basic research, but 20–40% on advertisements and promotion. Over 50% of important research discoveries emerge from independent research, largely funded by taxpayers. The drug industry recently shifted its strategy from in-house R&D to buying most of their pipelines from small biotechnology companies, further increasing prices. Second, studies show no relationship between a drug's benefit and its price. Third, drug companies enjoy monopoly-like conditions that discourage price competition. Fourth, innovation is driven by independent academic scientists who continue their mission of research and discovery regardless of drug prices.

Multiple studies document the harm to Americans of high drug prices. Medical

Generic imatinib, a chronic myeloid leukemia drug, is priced at $5,000–$8,000/year in Canada, $400/year in India, and $140,000/year in the U.S.

This policy brief is part of a series of recommendations from the Baker Institute for the incoming president's administration.

See more policy briefs at:
www.bakerinstitute.org/policy-briefs

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costs and out-of-pocket expenses result in high rates of bankruptcies among cancer patients. About 20–35% of patients delay, abandon, or compromise treatments because of difficulties in meeting costs. Survival rates also drop. The 8- to 10-year survival rate for chronic myeloid leukemia (CML) is 80% in Europe, where treatment is available and affordable to all patients. In the U.S., high drugs prices force many patients to omit or compromise treatment, so that the five-year survival rate for CML is only 60%. The high cost of drugs is the most significant health care concern of Americans.

GENERIC DRUGS

Despite scrutiny of high cancer drug costs, prices continue their relentless ascent. Two issues compound the problem. First is the increasing shift of health care costs and drugs to patients, as insurers seek to reduce spending. But high out-of-pocket expenses deter more than a third of patients from seeking timely care or buying needed drugs. The second is the spillover of high drug prices to generics. Complex regulations and bureaucracies, and drug shortages, have created monopolistic opportunities for drug companies that can increase the price of generics to exorbitant levels. The three latest publicized scandals by Turing, Valiant, and Mylan are the most excessive form of a common pricing strategy by the drug industry. Generic imatinib (a CML drug) is priced at $5,000–$8,000/year in Canada, $400/year in India, and $140,000/year in the U.S. For a generic drug to be priced low, at least 3 to 5 generics must be available in the market. However, the average cost of $5 million to file for Food and Drug Administration approval of a drug in 2016, and average time to approval of 4 years, discourage many companies from filing for generic approvals. Currently, about 3,800 generic drug applications are under FDA consideration. The FDA should review its procedures and timelines, reduce filing costs to less than $1 million, reduce approval times to less than 6–12 months, and ensure continuous availability of multiple generics in the U.S. market.

The drug industry has expressed the desire to be "part of the solution." Some industry CEOs favor lowering prices, arguing that affordable drugs have deeper market penetration, keep more patients alive who continue to use these medications, and thus generate more long-term revenues. However, the industry also launched a $100+ million public relations campaign in 2017 to defend high-price policies.

RECOMMENDATIONS

How can we address high cancer drug prices? Here are several solutions:

1. Allow Medicare to negotiate drug prices (estimated to save $400 billion–$800 billion over a decade).
2. Establish mechanisms to review the benefits of drugs and define fair prices during or following FDA approval.
3. Encourage cancer organizations to incorporate price into the assessment of "treatment value."
4. Prevent strategies that delay the availability of generics (this saved the U.S. health care system $227 billion in 2015 and $1.46 trillion over a decade).
5. Improve the FDA generics approval process and reduce the cost of filing.
6. Request transparent reporting of drug industry R&D costs to justify price.
7. Allow cross-border importation of cancer drugs for personal use if the U.S. price is prohibitive.
8. Disallow direct-to-consumer advertising of cancer drugs (the U.S. and New Zealand are the only nations that allow this). Such advertising creates false impressions and false markets, which increase costs.

These measures have so far been opposed in Congress because of the influence of the drug industry lobby. Our legislators have been representing drug industry interests rather than the interests of the Americans who elected them. We hope that future legislation will show that the U.S. remains a cherished democracy rather than a feared "pharmaceutocracy."