The Complex Cancer Care Coverage Environment — What is the Role of Legislation? A Case Study from Massachusetts

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

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

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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]

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, on healthcare utilization, and on affordability by patients. 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.

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 (Table 1). 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) (Annex 1).

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 (a questionnaire is available in Annex 1).

Interviews were conducted by phone between January and March 2018, lasted one hour each, and were

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Table 1
Search criteria and sources for legislative documents

Search Criteria
("off-label" OR "clinical trial*" OR ("chemotherapy" AND "oral*")) AND cancer
("off-label" OR "clinical trial*" OR ("chemotherapy" AND "oral*")) AND (insur*) AND (benefits OR coverage) AND cancer
("off-label" OR "clinical trial*" OR ("chemotherapy" AND "oral*")) AND (insur* OR benefits OR cover*) AND cancer
Sources
Lexis Nexis
Internal memorandum, HPHC, re: Cancer laws in effect in Connecticut, Maine, Massachusetts, and New Hampshire, Nov. 18, 2016
Internal memorandum, HPHC, re: Bills relative to chemotherapy and/or high cost medications generally in MA, CT, NH, and ME, Nov. 18, 2016
State Laws Concerning Clinical Trials and Off-Label Drug Use for Cancer Patients, K.G. Pettibone, R. Wallave, R. Field, and R. Arculi, Presented at APHA Nov. 11, 2002
K. Hanson and E. Bondurant, "Cancer Insurance Mandates and Exceptions," National Conference of State Legislatures, August 2009

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 summarize in Table 2 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 in online Annex 1. 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 (Table 2). 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 (Table 2). In addition to these general insurance coverage requirements, some long-standing 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", Table 2). Also, these plans must cover general patient services furnished to cancer patients enrolled in qualified clinical trials (i.e., the "clinical trial law," Table 2). 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," Table 2). Taken

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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 are included in Table 3 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.

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Table 2

Summary of key legislation on cancer care coverage in Massachusetts

Name of law	Effective date	Summary	Reference to text of law
Off-label drug use law Mass. Ann. Laws ch. 175, § 47K-L: Off-Label drug use: cancer treatment & review panel	Jan. 14, 1993	• Individual and group insurance policies issued in MA that provide prescription drug coverage must cover any drug used for cancer treatment, even for off-label use (i.e. use that has not been FDA-approved), so long as the drug use for that indication is recognized: -- in one of the standard reference compendia; -- in the medical literature; or -- by the MA insurance commissioner under the review of a panel comprised of 6 medical experts. • Coverage is not required when the FDA has determined the drug use to be contraindicated for cancer, or when the drug is experimental and not FDA-approved for any indication.	https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47L
Clinical trial law Mass. Ann. Laws ch. 175, § 110L: Clinical trials: definitions: coverage	Jan. 1, 2003	• Any insurance plan or policy offered in MA, except those providing supplemental Medicare or Medicaid coverage, must cover and reimburse for patient care services furnished to an individual enrolled in a "qualified clinical trial" to the same extent they would be covered and reimbursed if the patient didn't receive the care in a clinical trial. Services excluded from coverage include: -- non-health services, and -- those inconsistent with widely accepted standards of care. • "Qualified clinical trials" must be intended to treat cancer in a patient so diagnosed and be peer-reviewed and approved by the NIH, FDA, DOD, VA, or a qualified IRB for Phase II-IV trials, among other competency and eligibility requirements.	https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section110L
MA health care reform Mass. Gen. Laws ch. 58 of the Acts of 2006: An Act Providing Access to Affordable, Quality, Accountable Health Care	Apr. 12, 2006, and as amended	• Distributes public funds to provide health insurance coverage to uninsured, low-income populations and to provide affordable health insurance coverage options to all Commonwealth residents. • Requires individuals to obtain health insurance, requires employers to offer insurance coverage to employees (if 10 or more) or face financial penalties, authorizes the creation of new health insurance products (including subsidies to purchase insurance for low-income individuals), and reforms the MA Medicaid program (MassHealth) and the free care pool.	https://malegislature.gov/Laws/SessionLaws/Acts/2006/Chapter58

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Name of law	Effective date	Summary	Reference to text of law
Oral chemotherapy parity law Mass. Ann. Laws ch. 175, § 47DD: Coverage for orally administered anticancer medications	Jan. 3, 2013	• Any insurance plan or policy offered in MA that provides medical expense coverage for cancer chemotherapy must cover prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells no less generously than anticancer medications administered or injected that are covered as medical benefits. • Increases in cost-sharing for injectable anticancer medications cannot be used to meet this oral chemotherapy parity requirement.	https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47DD
Patient Protection and Affordable Care Act 42 U.S.C. § 18001 / **Essential Health Benefits** 42 U.S.C. § 18022; 45 C.F.R. §§ 147, 155, 156	Oct. 1, 2013 (for plan-years beginning Jan. 1, 2014); Annually adjusted	• Medicaid expansion and non-grandfathered small or individual group plans offered on the health insurance exchanges must offer essential health benefits, including in the category of prescription drugs, as defined by a state's benchmark plan. • As of 2018, MA's benchmark plan generally offered coverage for chemotherapy, radiation, specialty drugs, generic drugs, preferred brand drugs, and non-preferred brand drugs, all without limitations on quantity.	https://www.gpo.gov/fdsys/granule/USCODE-2010-title42/USCODE-2010-title42-chap157-subchapIII-partA-sec18022 https://www.federalregister.gov/documents/2013/02/25/2013-04084/patient-protection-and-affordable-care-act-standards-related-to-essential-health-benefits-actuarial

Abbreviations: DOD = Department of Defense, FDA = Food and Drug Administration, IRB = Institutional Review Board, MA = Massachusetts, NIH = National Institutes for Health, VA = Veteran Affairs

Table 3

Themes and representative quotes by key subject areas

Subject areas	Main themes	Quote (interviewee stakeholder group)
Coverage of cancer treatments faces unique challenges	A changing landscape	*"The question is, how long do you treat, and in many ways the treatments have become a sort of lifetime treatments."* (private payer) *"Over the next five to ten years, from an era where we talk about lung cancer or kidney cancer or whatever, we talk more about the characteristics of the tumor independent of the target organ, and that's going to make sort of the description and coverage and the idea of off-label more complicated."* (private payer)
	Very expensive, insufficient clinical data, unclear value	*"[Cancer drugs] are all wickedly expensive, and many of them are coming to market with orphan drug designation or breakthrough designation or some other fast-track designation for which the clinical benefit has not been fully elaborated, and the value proposition has definitely not been elaborated."* (public payer) *"One is simply the high cost of the drugs. The second is that … we market to people that we can cure their disease … we also have an incomplete insurance market where patients are allowed to choose high deductible, low cost plans and then when they have catastrophic illnesses they become bankrupt."* (providers)
	Cancer a sensitive topic	*"That kind of kid-glove handling based on special patient needs, perceived or real, exists in the HIV drug therapy management space. They exist for sure in the oncology space, so there's been kind of a hands-off. If the drug comes to market and the doctor and the patient determine that they want access to this drug then the payer pays for it despite issues around whether it's optimal therapy, whether there's value in the therapy, and we get to go down a rabbit hole about "Is it worth paying $100,000 to extend somebody's life by two months?"* (public payer)

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Table 3 (Continued from p. 543)

Themes and representative quotes by key subject areas

Subject areas	Main themes	Quote (interviewee stakeholder group)
MA may be unique in terms of both cancer treatment and legislation of cancer care	Not-for-profit health plans	*"Since many of the health plans that are domiciled in MA are not-for-profit, I think that perhaps our view of the coverage is perhaps more liberal than it might be if the state were dominated by for-profit, you know, large, publicly-traded companies" (private payer)*
	Funding of treatments	*"MA is just a different animal because we send more money in taxes to Washington than we actually get back for these medical programs. And that's been something our legislature has been grappling with for a while."* (policy expert)
	Well-trained oncologists	*"By and large, the oncologists in this state are well-trained, are familiar with the literature and don't do, you know, crazy things" (private payer)* *"MA legislature each year probably has a half-dozen bills introduced that are related to cancer coverage [but] most don't actually pass"* (private payer)
	Small community with well-connected stakeholders	*"The good news in MA is they [legislators] know the contact, the Mass Society of Clinical Oncology...they [legislators] contact the folks from the [Dana] Farber [Cancer Institute] and the [MA] General [Hospital] and they say, "Is this a good idea?" So, it's a pretty tight community when it comes to passing legislation."* (policy expert)
	Special Off-label use law	*"Our [off-label] law is a little bit different than other state laws … So, if a newer drug comes out and if there's a compendia, then even though it wasn't FDA approved for, say, breast cancer, but it works for lung cancer, then it's in the compendia the payers must pay … for the drug. But if it hasn't made it to the compendia, but there's been a meeting and this is the latest drug, you know, this drug has been around for a while, and, look, it works really well for this disease — if you can have two peer-reviewed articles then you can petition the payer and get it paid for. And that's actually worked pretty well in MA."* (provider)
Differential applicability of these laws	Low relevance for public health plans and high relevance for private health plans	*"These laws, when they're written they're explicitly intended to influence the health plans that are regulated by the Division of Insurance, and the Medicaid program is not, so we go through a process of our coverage determinations and the scope and depth of the benefits we provide where the local laws … may or may not apply directly to the Medicaid program … unless it's required under the authority that we have to operate the Medicaid program either in federal or state statute or regulation … [if the] Medicaid program is offered through Medicaid managed care partner plans"* (public payer)
	Coverage processes in public plans are the same for all therapeutic categories while in private plans a faster review process is applied	*"Our processes are agnostic to the therapeutic category for all intents and purposes, so we use the same process for a neurology drug as we use for an oncology drug. When an oncology drug is approved by the FDA, we conduct a review of the literature. That is done internally by MassHealth staff. A monograph evaluating what the reviewer learns is prepared and presented to an internal committee of pharmacists and physicians. We follow a procedure, a set algorithm for making our determinations, and that algorithm in the case of oncology is influenced in part by oncologists either in general or specifically if we feel that there's a need for us to use that level of expertise."* (public payer) *"When we review new medications or coverage decisions for our formulary, since many of them are essentially "me too" drugs, you know, we may wait six months after the FDA approval before we review them in our pharmacy and therapeutics committee. But when it's a cancer drug, we tend to review that drug much sooner, and sometimes with relatively little data other than what's been submitted to the FDA. And the other issue is that we do look — besides a sort of these laws of that are sort of guidelines in terms of what needs to be covered — we also do pay attention to sort of the broader cancer literature in terms of what's ASCO writes about as well as the NCCN guidelines."* (private payer)

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Subject areas	Main themes	Quote (interviewee stakeholder group)
Differential relevance of each law for coverage	The Oral Chemotherapy Parity law may impact insurer financially; not relevant for Medicaid patients	*"This* [the Oral Chemotherapy Parity Law] *is impactful from a cost perspective … as we* [the private payer] *were required to remove all cost sharing for just about all oral chemotherapy drugs, no copays, no deductibles for most oral chemo drugs. So that is a financial impact, you know, a significant financial impact on the company."* (private payer) *"We needed to set the cost sharing for the oral chemotherapy drugs below the lowest cost sharing for any of the infused cancer drugs. So the easiest way to do that in a way that ensures compliance is that the cost sharing be zero for the oral chemotherapy. So this really gets to the constraints that we as a plan have in our internal systems to kind of fine tune a compliant strategy, does that make sense, that sometimes we have to with those limitations revert to a financially disadvantageous solution but it's the only solution that we can be certain is compliant with the statute."* (private payer) *"This bill* [Oral Chemotherapy Parity Law] *was about essentially out-of-pocket expenses, so in the context of a Medicaid program that becomes more or less a moot point, so even if we thought that that was a good idea or a bad idea and wanted to have something to say about it from the Medicaid perspective, copays in the Medicaid world are nominal, and we didn't have a differential there."* (private payer)
	The Clinical Trial Law is difficult to manage for private health plans and not relevant for Medicaid	*"[Clinical trials] have been fairly complicated for us to manage, because it isn't even clear sometimes when a person is on a clinical trial exactly what it is that we would cover that's different other than the cost of the drug … we try to have kind of our utilization management and case management staff try to have a direct communication, usually with the person who is really the manager of that clinical trial so that we can sort out exactly what the expectations are for the insurer versus a what it is that the trial itself is covering."* (private payer) *"The one area that I think is clearly still needed is Part B the clinical trials definitions and coverage, even though it was effective in 2003. In my experience with the industry and on behalf of patients, I think that there are still issues about what has to be covered in the clinical trial versus what is normal medical care or required medical care … private insurance is not equipped to be able to handle clinical trials in my own view. They're just not able to — it's not part of what their mandate should be."* (policy expert) *"In the closed formulary, to the degree that clinical trial law applies here, we are covering drugs that may not necessarily have reached the end of their process through clinical trials and may not have actually made it to the finish line so to speak of FDA approval. So, we have in our member documents, a standard exclusion for drugs that are in clinical trial, so that is our default position on all prescription drugs, if they're in clinical trial, we do not pay for them."* (private payer) *"In the clinical trials law, the first sentence essentially provides an exemption to the Medicaid program: "The law requires any insurance plan offered in MA, except those providing Medicaid coverage, to cover, reimburse …"* (public payer)
	The Off-Label Drug Use Law is less impactful	*"I think the off-label drug use has really become almost passé. We know perfectly well that the drugs are going to be used off-label."* (private payer) *"The Off-Label-Drug Use law … is less impactful [as] … we cover prescription drugs that are medically necessary for the patient but we do not capture diagnosis information as part of our coverage unless we have in place some prior authorization protocol for that drug. So typically, even irrespective of a legislation, we would not even be aware if a drug was being prescribed and that we were covering for a specific diagnosis … we would pay them blind to the diagnosis of the patient."* (private payer) *"Coverage for drugs is influenced by the FDA approval of course and by the labeling because the labeling is part of our evidence-based evaluation process … for which we use clinical literature and we use statutorily mandated compendia to evaluate whether the drug could be determined to be medically necessary.* (public payer)

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Table 3 (Continued from p. 545)

Themes and representative quotes by key subject areas

Subject areas	Main themes	Quote (interviewee stakeholder group)
Stakeholders' concerns with respect to the legal environment	White/ Brown-bagging regulation[1] (29)	*For the Medicaid market, "white-bagging" is a major concern and leads to unnecessary waste. It requires that "medications are filled at a specialty pharmacy [for a specific patient] and delivered to the hospital pharmacy, need to be stored separately, and administered to that specific individual … If the patient doesn't get that drug, then you cannot put it back in your stock and use it for other patients. So, it's wasteful, it's dangerous because you don't have sort of that hand-off and the custody of who's got the drug, you know. You don't know that it's been kept at the right temperature, you don't know that — you don't know anything about the drug once it leaves the pharmacy." (policy expert)* *"There have been some plans that have taken steps to gain better pricing leverage over some of these drugs [that fall under the White-Bagging rules] by handling them differently. But ultimately this law "hinders our [the private insurer's] ability to use different delivery mechanisms to our financial benefit" (private payer)*
Suggested policy options toward sustainable coverage of cancer care	Closed formulary	*"We've actually applied for a waiver to have a closed formulary. Whether we would use it in the oncology space … we haven't envisioned that, but there's a realization we can't keep doing what we're doing. We can't keep going on this way." (public payer)* *"We have a value formulary, which is a closed formulary, which allows us to exclude certain drugs, essentially if a new drug is brought to market, the default position is that it's not on the formulary but we do an assessment of a new drug or device and determine whether it presents a unique clinical benefit that can't be met by existing drugs on the formulary and then also weigh as part of that cost of the drug." (private payer)*
	Comparative-effectiveness analysis	*"Whether we could actually essentially pit two different drug therapies against each other in a head-to-head financial competitive-bid situation — I don't think we're quite there yet … The more we know about oncology and personalized medicine and so forth is that so many cancers are way smarter than we are and for the foreseeable future will be, so until we get to a point where we do have true competition in the oncology space I think we're going to have a problem … If we have a curative therapy for cancer that becomes another story, like we have for Hep-C." (public payer)*
	Value-based pricing	*"This concept of value and what the appropriate price-point should be, will start to take hold … short of having the government set pricing or pricing parameters like we see in the European [countries] and Canada and Australia and things like that, which I don't think will ever happen in this country, I think that the value-pricing concept from an independent third party can influence what the pharmaceutical industry does." (public payer)*
	Pharmaceutical company's patient access schemes	*"We're not crazy about [patient access schemes] for agents that aren't cancer drugs … but I think in the cancer space it's a very reasonable thing for the pharmaceutical companies to do." (private payer)*

Abbreviations: ASCO = American Society of Cancer Oncology, FDA = Food and Drug Administration, MA = Massachusetts, NCCN = National Comprehensive Cancer Network

[1] "*White-bagging*" refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable or infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies. "*Brown-bagging*" refers to the dispensing of a medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to the physician's office for administration.[40]

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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 out-of-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

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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.

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Annex 1— Interview guide professional organization

Semi-structured Interview guide — professional organization

Introduction

Thank you for participating in this interview on cancer therapy coverage laws and mandates. Our interest is to understand the current landscape of cancer therapy coverage legislation and the involvement of different stakeholders in the development and enforcement of coverage mandates. We are particularly interested to learn from you, as a member of a professional organization, about your experiences in advocating for cancer therapy coverage legislation.

My name is Anita Wagner, I am an Associate Professor at the Harvard Medical School Department of Population Medicine (DPM) and I lead this study. With me are Dr. Haffajee, Assistant Professor at University of Michigan and a health policy and health law expert, and Dr. Leopold, Senior Research Fellow at the DPM and a health policy expert.

Your participation in this study is voluntary and you may choose to skip questions or end the interview at any time. We do not expect any risks associated with your participation in our study. What you tell us will be kept confidential.

We have sent you an abbreviated text of cancer coverage legislation and a list of questions we are interested in. It would be helpful if you have those handy but it is not necessary to proceed. There will not be right or wrong answers to these questions. Rather, we wish to get your expert opinion.

Informed Verbal Consent

The interview should take about 30-minutes. Before we go on, please allow me to ask: do you understand the basic picture of this telephone interview study, and the potential risks and benefits to you as a participant?

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Do you have any questions about the study? Is it OK for me to go ahead and start the interview?

Great, thank you.

[If participant declines, thank him/her for his/her time and end the conversation. If participant consents, proceed.]

If you agree, we would like to record the interview so that we capture what you say without errors. The recordings will be destroyed once we have analyzed all interviews. No information will be attributable to you personally. Is that okay with you?

[If participant declines, remind him/her that you will be taking notes about the discussion. If participant agrees, TURN ON RECORDER]

Great. I'm starting the recording now.

Let's get started with the interview. First, we would like to ask a few questions on the current legal landscape of cancer drug coverage.

Regulating cancer drug coverage — mapping the legal basis

We identified the following laws and regulations as relevant for cancer drug coverage by public and private insurers (please see the sheet we sent, if you have it handy):

a. Off-label drug use law (Mass. Ann. Laws ch. 175, § 47K-L: Off-Label drug use: cancer treatment & review panel, date of authorizing legislation: 1992)
b. Clinical trial law (Mass. Ann. Laws ch. 175, § 110L: Clinical trials: definitions: coverage, date of authorization legislation: 2002)
c. Oral chemotherapy parity law (Mass. Ann. Laws ch. 175, § 47DD: Coverage for orally administered anticancer medications, date of authorization of legislation: 2012)
d. ACA/Essential Health Benefits (yearly adjusted and define coverage of chemotherapy drugs)
e. MA comprehensive cancer prevention and control plan 2012-2016[1]

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

1. Which laws / regulations does your organization consider as most relevant for regulating coverage of cancer medicines? Are there new laws/regulations you are proposing or would like to see?
2. What is your organization's role in advocating for and/or drafting these proposed laws?
3. Are you aware of problems the laws and regulations create for regulators, for payers, for patients? Could you give examples of those problems. In particular, has the off-label coverage law provided benefits or posed challenges or both?
4. How is your organization responding to benefits or challenges that may have come up?

Regulating cancer drug coverage — understanding the process of coverage

5. Does your organization play a role when public or private insurers draft coverage policies for cancer medicines? If yes, in which way?
6. In which way can your organization influence public or private insurers' coverage decisions?
7. (For NCCN) We understand that you create national cancer treatment guidelines to inform payer coverage decisions. Which stakeholders are consulted when drafting national guidelines?
8. Does your organization receive funding from pharmaceutical industry? If yes, what mechanisms are in place to safeguard against potential conflict of interest?

Regulating cancer drug coverage — broader considerations

9. How does your organization consider affordability for patients in advocacy for coverage policies?
10. How does your organization consider affordability for payers in advocacy for coverage policies?
11. What does your organization currently consider as the biggest challenge in coverage of cancer care?

Close:

Thank you so much for your time. Your insights will be very helpful to us. I am stopping the recording now.

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