



Increasing Access to Oral Anticancer Medicines in Middle-Income Countries: A Case Study of Private Health Insurance Coverage in Brazil

abstract

The World Health Organization estimates that approximately 60% of the world's new annual cancer cases occur in Asia, Africa, and Central and South America, and that 70% of cancer deaths occur in these regions. Although oral chemotherapy is a promising intervention for cancer treatment, given its high cost, it is usually unavailable in middle-income countries. In 2013, after strong lobbying from civil society, Brazil's Congress passed legislation mandating that all private health insurance companies provide access to oral antineoplastic treatment. The decision to scale up the provision of oral chemotherapy was a watershed event in the regulation of private health insurance in Brazil. Until then, private insurers, which cover 25% of the population, were exempted from the provision of pharmaceutical drugs for home care treatments. This article explores the political process involved in regulating the provision of oral chemotherapy medicines by private health insurers. Elements of this successful advocacy case included investment in strategic communication, specialized knowledge of regulatory policy, and the ability to act via democratic channels of political representation. In turn, the receptiveness of government branches such as the Congress and regulating bodies, as well as the Cancer Awareness Month campaign, opened a window of opportunity. However, prospects for expanded access to such medicines in the public health system are bleak in the short term because of the ongoing political and economic crisis.

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INTRODUCTION

Cancer is a leading cause of morbidity and mortality worldwide, with approximately 14 million new cases and 8.2 million cancer-related deaths in 2012.¹ More than 60% of the world's total new annual cases occur in Asia, Africa, and Central and South America, and these areas account for 70% of the world's cancer deaths. Since the 1990s, oncology treatment has advanced from intravenous chemotherapy to include only orally administered antineoplastic agents, which are more convenient to administer and often have fewer adverse effects than do their older parenteral counterparts.² Oral drugs may also lead to lower costs through savings related to decreased hospitalization times, for instance, and better quality of life.^{3,4} Usually, newer technologies such as oral antineoplastics put pressure on health care budgets and are incorporated infrequently by health systems in middle-income countries because of their added direct cost.⁵

Brazil is well known for offering free and universal access to antiretroviral drugs, which are delivered exclusively through its public dispensing units.⁶ However, far less is known and has been published about the country's experience with other, noncommunicable diseases that require high-cost treatments, such as cancer. Unlike drugs for AIDS, cancer medicines have been provided within the public health care system, purchased out of pocket at pharmacies by individuals and families, or purchased/reimbursed by private insurance companies. This article focuses on the recent developments in oral anticancer drug coverage through the supplemental (private) health insurance system.

After a new parenterally administered anticancer drug is approved by ANVISA, the Brazilian regulatory agency, it gains coverage automatically in the private health care system after a price is set by an interministerial commission. Historically, however, oral drugs were not covered. In 2013, after

strong lobbying from civil society, Congress approved legislation mandating that all private health insurance companies provide access to oral antineoplastic treatment (Brazilian Federation Law 12880/2013). At the same time, the National Regulatory Agency for Private Health Insurance (ANS) issued a resolution mandating private health insurance companies to cover 37 orally administered oncology drugs for home cancer treatment (ANS Resolution 388/2013). Between January 2013 and December 2014, the number of requests for oral antineoplastic treatment increased by almost 90% in the private health insurance sector.⁷

The decision to scale up the provision of oral chemotherapy was a watershed event in the regulation of private health insurance in Brazil, which was until then exempted from the provision of pharmaceuticals drugs for home care treatment. In addition, it is particularly important to highlight that this case builds evidence for the role of civil society in advocating access to cancer treatment within a middle-income country. Although much has been said regarding the relevance of civil groups to cancer policy advocacy,⁸ we know little about the processes by which they affected change in regulatory policies. This article aims to explore the political process involved in regulating the provision of oral chemotherapy medicines by private health insurance companies for cancer home care treatment in Brazil.

BACKGROUND

The Brazilian National Cancer Institute estimates that there will be 576,000 new cases of cancer, including nonmelanoma skin cancer, in the country in 2015. Among men, prostate cancer represents 22.8% of incident cases, whereas among women, breast cancer represents 20.8% of all cases.⁹ Breast cancer has been one of the leading causes of death from cancer among Brazilian women, whereas lung and prostate cancer have been among the leading causes of death in men.¹⁰

Oncology treatment in public health care in Brazil is provided by 278 accredited establishments.¹¹ It is the responsibility of the reference service to purchase and provide chemotherapy, which is reimbursed by the state government with resources transferred from the Ministry of Health and funded through general taxation.¹² Between 2006 and 2011, a commission was established in the Ministry of Health to assess the inclusion of new technologies into the National Health Service (SUS); before that, health technology assessment was not commonly performed in Brazil. During this

period, only two oral antineoplastic medicines (nilotinib and dasatinib) were incorporated into the SUS (public) list.

Parallel to the SUS, which covers all Brazilian citizens and foreigners who are physically present in the country (including illegal aliens), private health insurance companies are also responsible for providing oncology treatment to their clients. Although Brazil has one of the largest public health systems in the world, approximately 25% of the population is also enrolled in private health insurance.¹³ The majority of private health insurance plans are collective plans (approximately 80%) obtained through work or cooperatives, and a small and declining percentage are individual plans (approximately 20%). The *Private Health Insurance Act* (Law 9656/1998) regulates private insurance in Brazil. According to this act, insurance companies are required to cover only medicines used during periods of hospitalization and during ambulatory visits (article 12) and not during home care treatment (article 10). Therefore, oral antineoplastic medicines for home care were excluded from the list of procedures covered by private insurance. These two scenarios led to an increase in the number of lawsuits over access to cancer medicines.¹⁴

The 2013 National Health Survey, a household-based nationwide study, suggested that 49 million people are covered by private health insurance in Brazil. Among these, approximately 17% do not pay for their medicines because they have free access to medicines through their governmental programs or employer's insurance program; 60.9% had to pay for medications out of pocket, 16.1% paid for a percentage of the medicines needed, and 6% were not able to afford the medicines prescribed. As such, it is clear that among those people who hold private health insurance, a large proportion pay for 100% of their medicines themselves.

In 2011, three parallel events paved the way for the inclusion of oral cancer treatments in private health insurance coverage; they are divided here for clarity. [Table 1](#) provides a chronologic list of these events.

Revision of the Minimal List of Procedures Covered by Private Health Insurance

Every 2 years, the ANS revises the minimal list of procedures with mandated coverage by private health insurance companies, and this process is open to different segments of society through public consultation. In May 2011, the regulatory

Table 1 – List of Events Preceding Approval of Law 12.880/2013

Date	Event	Action
2011	Publishing of the ANS Regulatory Agenda for 2011-2012	Inclusion of the question of pharmaceutical assistance as a core issue for discussion in the ANS
Apr 15, 2011 to May 21, 2011	ANS Public Consultation No. 40	Different segments of society given the opportunity to comment on the revision of the list of procedures covered by private health insurance
May 2, 2011 to May 20, 2011	Instituto Oncoguia mobilizes other civil society organizations and begins a mass media campaign for the inclusion of oral chemotherapy in private health insurance plans	Signatures supporting the campaign submitted to the ANS, distribution of folders informing the population about oral chemotherapy
May 11, 2011	Seminar in Congress to discuss the rights of people living with cancer	The Instituto Oncoguia and the ANS invited to give speeches
Jun 22, 2011	Presentation of Bill 352/2011	Senator Ana Amélia presents Bill 325/2011 to Senate
Aug 1, 2011	ANS Resolution 262	Updated list of procedures mandatory for inclusion in health insurance plans; oral chemotherapy is not among them
Aug 18, 2011	Oncoguia meets with the minister of health	The minister endorses the campaign on oral chemotherapy, which receives inclusion in the ANS list of procedures
Sep 29, 2011	First meeting of the WGPA at the ANS	Presentation of successful cases of pharmaceutical care packages offered by nonprofit, private insurance companies
Dec 15, 2011	Congress Hearing on Bill 352/2011	Different stakeholders express their positions
Mar 27, 2012	Second meeting of the WGPA at the ANS	One of the directors of the ANS, Maurício Ceschin, opens the meeting stating the relevance of this issue; different stakeholders express their positions
Apr 28, 2012	Senate approval of Bill 352/2011	Bill 352/2011 is submitted to the Chamber of Deputies
Apr 30, 2012	Third meeting of the WGPA at the ANS	Discussions to provide input regarding a resolution to regulate a voluntary pharmaceutical care package that would include oral chemotherapy in private health insurance plans
Sep 4, 2012 to Oct 6, 2012	ANS Public Consultation No. 49	Different segments of society invited to comment on the regulation of the pharmaceutical care package
Oct 30, 2012	Resolution 310	Regulation of voluntary pharmaceutical care packages offered by private health insurance companies
Nov 30, 2012	Fourth meeting of the WGPA at the ANS	Presentation of ANS Resolution 310
Aug 27, 2013	Bill 3.998/2012* is approved by the CCJC of the Chamber of Deputies	The CCJC acknowledges the importance of the mobilization of civil society in the approval of this proposal
Oct 21, 2013	The ANS issues Resolution 338	Update to list of procedures covered by private insurance plans; this time, the list includes oral chemotherapy
Oct 22, 2013	Senate approves the amendment proposed by the Chamber of Deputies	Legislation submitted to President Dilma Rousseff for ratification
Nov 12, 2013	President Dilma Rousseff enacts Law 12.880/2013	

Abbreviations: ANS, National Regulatory Agency for Private Health Insurance; CCJC, Commission on Constitution, Justice and Citizenship; WGPA, Working Group on Pharmaceutical Assistance.

*Bill 352/2011 and 3.998/2012 are the same. The bill number was modified once submitted to Congress.

agency promoted Public Consultation No. 40, inviting comments and suggestions from the public on the list of procedures covered by insurance companies.

A group called Instituto Oncoguia, which represents people living with cancer, saw this as an opportunity to submit a much-sought-after claim for these patients, that is, that insurance companies should cover the cost of oral antineoplastic medicines. A number of patients reported to Oncoguia that their insurance plans did not cover oral antineoplastic drugs and that they were also denied access to these medicines in the public sector, forcing them to file lawsuits to obtain treatment. The institute, a nonprofit organization, was formed in 2009 by health professionals working with people living with cancer in the state of São Paulo. This civil society organization is sponsored by pharmaceutical industries and other private sector companies such as Google Grants, Asics, and others. In addition, the American Cancer Society has provided training on strategic political advocacy and technical assistance to cancer nongovernmental organizations (NGOs), including Oncoguia and the Brazilian Federation of Philanthropic Breast Health Institutions.^{15,16}

Between May 2 and May 20, 2011, the Instituto Oncoguia launched a large mass media campaign called the “Campaign for Inclusion of Oral Chemo” to put pressure on the government to include oral antineoplastic medicines on the mandated list of ANS procedures. For the duration of this campaign, Oncoguia coordinated a group of more than 17 associations including medical and professional societies and AIDS and hepatitis NGOs that were sympathetic to this demand, as well as specific groups of patients with cancer, such as those representing individuals with lymphoma and others. According to their records, the social media campaign received more than 900 citations, 2,500 informative folders were distributed to inform the population about their demands, and a petition was submitted to the ANS after collecting 18,000 signatures. Despite these efforts, the ANS initially denied their claim for the inclusion of oral chemotherapy drugs in the new list of procedures covered by insurance (Resolution 262/2011). The ANS argued that this inclusion was not allowed under the *Private Health Insurance Act*.^{16a} However, after this decision, the agency created a Working Group of Pharmaceutical Assistance (WGPA) to discuss avenues for pharmaceutical care within private health insurance in Brazil. Instituto Oncoguia not only participated in this working group, but also coordinated, in tandem

with a group of other NGOs, a campaign in Congress to amend the *Private Health Insurance Act*, which we discuss in the next section.

Working Group of Pharmaceutical Assistance

The ANS noted that the theme of pharmaceutical care was a main concern of the “Regulatory Agenda for 2011/2012,” which is the planning instrument that set the priority goals for the agency in the biennium. As a consequence, in September 2011, the WGPA was created that included representation from private insurance companies, consumers, health professionals, and regulators. The motivation for the creation of the WGPA was twofold. First, the agency was aware that a large proportion of consumers were paying out of pocket for medicines not covered by insurance plans. Second, the ANS was concerned that the regulatory framework for private health insurance in Brazil was encouraging a health care model strongly focused on hospital and ambulatory care, with little focus on home care coverage.¹⁷

During the first WGPA meeting, the ANS invited some private health insurance companies that provided a pharmaceutical care package, in addition to their regular coverage, to share their experiences. However, these were nonprofit health care plans (ie, self-managed by the company or a third party responsible for the social benefit),¹⁸ and therefore, other insurance companies questioned the viability of applying their experience to for-profit insurance plan models.

One of the opponents to the idea of including pharmaceutical care coverage in insurance plans was the Institute of Studies of Supplementary Health Care, a think tank that produces analyses for the sector, which prepared a technical note discussing cases of pharmaceutical coverage by private health insurance in several countries.¹⁹ They argued, mostly on the basis of the United States Medicare model, that there was no evidence to suggest that pharmaceutical coverage reduces health care expenditure, but that in contrast, there was evidence to indicate that new medicines increase cost and that there is an increased use of medicines among healthy people after enrolling in such insurance coverage (ie, it would increase moral hazard). Although their study did not provide a comprehensive discussion of the methodologic procedures necessary to draw such conclusions, it was widely used by private insurance representatives as evidence against the idea of regulating the inclusion of pharmaceuticals in insurance plans (personal communication,

October 24, 2014). However, civil society groups such as the Otimismo Group, which represents patients living with viral hepatitis B and C, and Oncoguia also participated in the WGPA discussions. These civil society groups demanded that the ANS request a more effective response from private health insurance companies regarding the provision pharmaceutical care.

Given the strong conflicting positions, the coordinator of the WGPA consulted the attorney general for the ANS and requested a legal opinion on this matter. The interpretation was that because article 10 of the *Private Health Insurance Regulatory Act* exempted private health insurances from covering medicines for home care treatment, the ANS would be entitled to regulate only complementary, voluntary packages of pharmaceutical care.²⁰

The WGPA was therefore able to discuss a draft resolution for pharmaceutical care packages that could be offered as additional, voluntary products to willing private health insurance plans. A draft resolution was then submitted for public consultation (Public Consultation No. 49/2012). The final document, approved in 2012 (Resolution 310/2012), established that pharmaceutical care is a voluntary and supplementary product to health insurance plans, similar to products such as air ambulance services. Therefore, civil society groups were once more left with just one avenue for action: the *Private Health Insurance Act* would have to be amended to allow access to home pharmaceutical care in private insurance plans. This would require a political debate in Congress.

Legislative Actions to Amend the *Private Health Insurance Act*

Parallel to the discussions at the ANS, Oncoguia, together with other civil society organizations, coordinated a campaign to amend the *Private Health Insurance Act* in Congress. The first step was taken in May 2011 after a meeting with Senator Ana Amélia Lemos (Progressive Party, Rio Grande do Sul State), who organized a seminar to discuss the rights of people living with cancer. During this event, a main discussion point was the denied coverage of oral antineoplastics by private health insurance providers.^{20a} As a consequence, Senator Ana Amélia, sensitive to issues related to cancer control, tabled a bill in Congress (Bill 352/2011) that would mandate that all private health insurance plans include oral cancer treatment as a mandatory procedure. Oncoguia also appealed to the minister of health for support of Bill 352/2011.²¹

In December 2011, a public hearing was held in Congress to discuss the different positions around this bill.²² Several stakeholders took part, including representatives from the ANS; representatives of a reference cancer hospital; a representative from the Brazilian Association of Group Medicine (Abramge); a representative from the Brazilian Medical Association; and Oncoguia, representing the interests of civil society. During this event, Abramge, with Arlindo de Almeida representing private health insurance companies, argued that there is a lack of governmental funds to support cancer care treatment and that oral antineoplastic medicines should be the responsibility of the federal government. Abramge also mentioned that there was a reorganization of private health insurance companies, with more than 1,100 companies exiting the market since the creation of the ANS in 1998. Finally, he stated that annual margins for the private health insurance sector were less than 1%. The arguments used by private insurance companies to emphasize the cost of providing oral antineoplastics, and the effects of the bill on the private insurance sector, were not well received in Congress.²² On the other hand, the argument for supporting the needs of people living with cancer resonated more widely in the Senate and Chamber of Deputies (the two houses that form the Brazilian Congress). Access to cancer treatment is an argument that is hard to counter when elections are around the corner.

Records of Oncoguia's and its partners' activities are publicly available online^{22a} and suggest that these groups constantly lobbied members of the commissions responsible for the bill. They also identified other civil society organizations that could help them in the advocacy process. For instance, in August 2013, the bill was approved by the Commission of the Constitution, Justice and Citizenship, which received more than 250 messages of support for this proposal.^{22b} The final step in approving the legislation was the endorsement of the Senate. The Brazilian Congress joined the international Breast Cancer Awareness Month campaign in October and, as a consequence, the president of the Senate agreed to make all bills related to cancer care a voting priority. In this context, the bill was finally approved. In November 2013, President Dilma Rousseff enacted Law 12.880/2013.

Interestingly, a day before the Senate approved the bill, the ANS, foreseeing the decision, also decided to include 37 oral antineoplastic drugs in the new revision of the list of procedures covered by

insurance plans (Resolution 338/2013). Together, the ANS resolution and Law 12.880/2013 ensure that all consumers of private health insurance in Brazil are eligible to receive the 37 oral antineoplastic medicines, if needed.

Using as an example the experience of Brazil in covering oral antineoplastic medicines through private health insurance plans, it is possible to draw some conclusions regarding regulatory policy.

Civil Society Advocacy on Pharmaceutical Care

We know a great deal about the role of civil society in advocating for antiretroviral medicines in Brazil and other developing countries^{6,23} and about the necessity of empowering cancer advocacy groups in developing countries.⁸ Findings from this study suggest that civil society, coordinated by the Instituto Oncoguia, played a crucial role in Brazil's regulation of oral antineoplastic coverage under private health insurance. On the other hand, there were several institutional channels, including public consultations, congressional hearings, and a meeting with the minister of health, through which these advocacy groups could voice their concerns. The process described here suggests a democratic, pluralist process of policy making.

Persuading Decision Makers

Studies of HIV/AIDS advocacy have long called attention to the policy frame and strategic use of ideas,^{24,25} that is, the use of normative values and information to influence policy debates. In the process discussed here, medicines can save lives or extend the lives of people living with cancer, arguments that are persuasive and hard to deconstruct. Therefore, the second explanatory element for the successful campaign on oral chemotherapy was the ability of civil society to frame their demands and publicize their position in different political arenas.

Policy Context

The third important element in the case of oral antineoplastic medicines refers to the context in which this proposal was formulated. Scholars of policy argue that it is crucial to understand the historical circumstances through which public policies are designed and implemented.²⁶ The ANS was sensitive to the discussion of

pharmaceutical care presented by private health insurance companies. Although the initial outcome was unsatisfactory because it proposed voluntary coverage only, the ANS ended up including oral antineoplastic treatment in the minimum coverage list of procedures. In addition, given the strong support of civil society, Congress was mobilized to endorse an amendment in the *Private Health Insurance Act*. Finally, the recognition and marking of Breast Cancer Awareness Month created a window of opportunity to finally approve the bill in Congress.

Few studies have detailed the consequences of this change in regulatory policy on the private health insurance sector and on the treatment of people living with cancer; however, the available data suggest an important increase in the percentage of requests for oral chemotherapy in private health insurance between 2013 and 2014 (approximately 90%),⁷ and the authors are currently working with data from Intercontinental Marketing Services Health to quantify the increase to access that has occurred since January 2014 when the coverage became official. In the current context of political and economic crisis, it is unlikely that such innovations could be incorporated into Brazil's public health system, already affected by dramatic cuts of 70 billion reais (nearly 20 billion dollars) in 2015.²⁷ In any case, the successful reform of private health insurance plans may pave the way for future changes in the public sphere.

In summary, this Brazil case study suggests that civil society played a crucial role in the regulatory process. The main elements leading to this successful intervention were (1) the investment in strategic communication, (2) the possession of specialized knowledge of regulatory policy, and (3) the ability to act via democratic channels of political representation, such as public consultations. In turn, the receptiveness of government branches such as Congress and the ANS, and the Cancer Awareness Month campaign, opened a window of opportunity for the change desired by these groups. The impact of civil society was less a result of their material resources and more a result of their capacity to persuade decision makers, despite the strong and resourceful lobbying of the private health insurance sector.

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