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Access to the population, financing and availability times of antineoplastic drugs incorporated into the SUS between 2012 and 2024

Acesso a população, financiamento e tempos de disponibilização de medicamentos antineoplásicos incorporados ao SUS entre 2012 e 2024

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ABSTRACT

Objective: The study aimed to evaluate the effectiveness of the process of incorporating antineoplastic drugs into the Sistema Único de Saúde (SUS) from 2012 to October 2024. Whether these treatments are being made available in a timely manner and what limitations exist was investigated. **Methods:** A retrospective analysis of CONITEC reports was used, where data on 24 drugs was collected, including dates of incorporation and publication in the Diário Oficial da União, as well as information on published oncology therapeutic guidelines, antineoplasic drug costs and transfer values for Autorizações de Procedimentos Ambulatoriais (APAC). **Results:** The results showed that, from a total of 24 antineoplasic drugs incorporated during the analyzed period, a significant amount experience limitations on access, including 7 drugs not included on therapeutic guidelines and 15 with insufficient federal transfer values. In total, treatment costs for 15 technologies are over 100% above values determined for APAC. **Conclusions:** The study revealed that important barriers compromise availability of incorporated antineoplasic drugs in SUS, with treatment costs currently significantly outweighting APAC values. There exists a visible need for efficient alternatives for finance and management in oncology, as demonstrated by the examples of blinatumomab and drugs centrally acquired by the Ministry of Health, to improve access to oncology in the SUS.

Keywords: Brazilian Unified Health System; Oncology; Access to Health; APAC; Centrally Acquired; Incorporating

RESUMO

Objetivo: O estudo teve como objetivo avaliar a eficácia do processo de incorporação de medicamentos antineoplásicos no Sistema Único de Saúde (SUS) de 2012 a outubro de 2024. Foram investigados se esses tratamentos estão sendo disponibilizados em tempo hábil e quais limitações existem. **Métodos:** Utilizou-se uma análise retrospectiva dos relatórios da CONITEC, onde foram coletados dados sobre medicamentos antineoplásicos, suas datas de incorporação e de publicação no Diário Oficial da União, assim como informações sobre diretrizes terapêuticas publicadas em oncologia, custos de aquisição de medicamentos antineoplásicos e valores de repasse de Autorizações de Procedimentos Ambulatoriais (APACs). **Resultados:** Os resultados mostraram que, de um total de 24 antineoplásicos incorporados no período, significativa quantidade possui limitações em seu acesso, incluindo 7 ausentes em diretrizes terapêuticas e insuficiente financiamento por repasse federal para 15 destes. Ao todo, 15 tecnologias possuem custo de tratamento superior ao dobro do repasse determinado em APAC. **Conclusões:** O estudo revelou que existem importantes barreiras que comprometem a disponibilidade de tratamentos antineoplásicos incorporados ao SUS, pois os custos de tratamento, em muito superam os valores repassados pelas APACs. Existe uma evidente necessidade de alternativas eficientes de financiamento e gestão em oncologia, como demonstrado possíveis a exemplo do blinatumomabe e dos medicamentos adquiridos por compra centralizada, para melhorar o acesso em oncologia no SUS.

Palavras-chave: Sistema Único de Saúde; Oncologia; Acesso a Saúde; APAC; Compra Centralizada; Incorporação

Introduction

Oncological care within the Brazilian Unified Health System (Sistema Único de Saúde – SUS) was initially instituted independently from pharmaceutical services. It was first regulated in 2005 under the National Policy for Oncological Care (Política Nacional de Atenção Oncológica do SUS) through Ordinance No. 2,439,[1] and later renamed in 2013 as the National Policy for Cancer Prevention and Control (PNPCC) by Ordinance No. 874.[2] Oncological care is provided in a decentralized manner through specific accredited centers: the High-Complexity Oncology Care Units (Unacons) and the High-Complexity Oncology Care Centers (Cacons).

These centers are responsible for offering oncological surgery, radiotherapy, and chemotherapy to the population they serve, while retaining autonomy to establish their own clinical protocols and define standard chemotherapy regimens.[3]

The decentralization of oncological services is mirrored in the financing of antineoplastic drugs, which is largely supported by federal transfers to Cacons and Unacons. These transfers are based on the value of procedures registered in the Ambulatory Information System of SUS (SIA/SUS), through Ambulatory Procedure Authorizations (APACs). Each APAC record is categorized according to tumor location and staging, and its reimbursement amount includes the costs of professional care, medical supplies, and medications.

Each accredited institution is responsible for defining which treatments and materials will be standardized for each procedure, leading to considerable variability in oncological care among centers. A nationwide study identified substantial differences in treatment protocols for lung, breast, colorectal, and prostate cancers across SUS oncology centers — with some offering substandard protocols compared to Ministry of Health guidelines, while others provided care equivalent to that in the private health sector.[4]

With ongoing technological innovation in oncology and the advent of precision medicine, new cancer therapies have become increasingly expensive, threatening the ability of institutions to afford drug acquisition solely through APAC-related funding.[5] A study conducted in the state of Pernambuco showed that, while reimbursement values for major APACs related to breast cancer treatment remained stagnant for years, the therapeutic costs for this condition increased by more than 200% between 2011 and 2020.[6]

Some antineoplastic drugs, however, are centrally procured by the Ministry of Health and distributed to State Health Departments for subsequent delivery to Cacons and Unacons. According to the National Cancer Institute (INCA), centralized procurement aims to reduce treatment costs and expand population access to selected therapies.[7]

In 2023, Law No. 14,758 was enacted, establishing priority review for the inclusion of new drugs, procedures, and technologies for cancer care within SUS by the Ministry of Health. However, the legislation does not define the source of funding required to ensure their effective incorporation.[8,9] As a result, the number of new antineoplastic agents incorporated into SUS may substantially increase in the coming years.

The objective of this study was to evaluate whether the process of incorporating antineoplastic drugs into SUS is effectively followed by their timely availability to the population and, if not, to identify the financial and/or administrative barriers hindering access to these treatments.

Methodology

This study was conducted through a retrospective analysis of recommendation reports issued by the National Committee for Health Technology Incorporation into the Brazilian Unified Health System (CONITEC) between January 2012 and October 2024. A qualitative and quantitative assessment was performed for all drugs with oncological indications that received a decision for incorporation into the SUS.

Medications used solely as adjuvant therapy for cancer treatment – such as those intended to control chemotherapy – related adverse events – were excluded from the analysis. Information collected included the submission date of the incorporation request, the technology assessed, the proposed indication, and the publication date of the incorporation decision in the **Federal Official Gazette (Diário Oficial da União – DOU).**[10]

Data on incorporated antineoplastic drugs were retrieved from the Brazilian Health Regulatory Agency (Anvisa) and the Drug Market Regulation Chamber (CMED), including the recommended dosage for the approved indication and the available pharmaceutical presentations.[11,12] In addition, the Clinical Protocols and Therapeutic Guidelines (PCDTs) published by CONITEC were reviewed to identify the medications listed for use according to their approved indications.[13-18]

Information on Ambulatory Procedure Authorizations (APACs) related to the use of each antineoplastic drug (Table 1) was collected from SIGTAP (the SUS Management System for Procedures, Medications, and Medical Devices), including the creation or modification date, reimbursement amount, classification (as a single or continuous procedure), and included therapeutic regimens.[19]

Additionally, potential procurement contracts for each antineoplastic drug were reviewed. Decentralized purchases were obtained from the Ministry of Health's Health Price Panel (Painel de Preços da Saúde), while centralized purchase contracts were accessed via the Department of Logistics of the Ministry of Health (DLOG/MS) website.[20,21]

From the data collected on the dates of submission, incorporation, and first DLOG contract, time intervals in days were calculated for: incorporation to the creation or modification of a procedure, incorporation to the first centralized purchase, and incorporation to the moment of this analysis, defined as October 1, 2024. These time intervals were compared to the regulated period of 180 days for the effective availability of technologies incorporated into the SUS.[22]

Monthly treatment costs were estimated by calculating the required drug dosage, as determined in the dosage regimen specified in the package insert, multiplied by the cost per dose of the drug, considering the median government purchase price between January 1, 2020, and October 1, 2024, as reported in the Health Price Panel.[11,21] Only drug acquisition costs were considered within the scope of this study. The level of federal funding was then calculated as the ratio between the monthly treatment cost and the value of the procedure. Costs related to professional care and medical supplies were not included in the calculation of the level of federal funding. Technologies with prior centralized purchase contracts through DLOG were considered fully funded at the federal level.

Table 1. Data collected for the analysis of antineoplastic drugs incorporated into the SUS

Data Category	Data	Source
Technology	Registration	Consulta Anvisa
	Submission date	Relatório CONITEC
	Incorporation date	
	Indication	
	Marketed presentations	DMRC
Therapeutic Guidelines	Indicated drugs	CONITEC PCDTs
Treatment Cost	Dosage	ANVISA Package Insert
	Median government purchase price	Health Price Panel
Financing	Date of first DHL contract	DHL
	Procedure	MSSTP
	Date of procedure creation or modification	
	Type of procedure	
	Procedure value	

DMRC: Drug Market Regulation Chamber; DHL: Department of Health Logistics, Ministry of Health; MSSTP: Management System of the SUS Table of Procedures, Medications, and OPM.

Within the scope of this study, antineoplastic drugs with full patient access were defined as those with centralized purchase or APAC procedures with full reimbursement of the drug acquisition cost. Similarly, antineoplastic drugs with partial access were defined as those with APAC procedures with federal funding equal to or greater than 75% of the available drug acquisition cost. Finally, all antineoplastic drugs without centralized purchase and without an available APAC providing a minimum of 75% federal funding of the drug acquisition cost were classified as having no patient access.

Results

A total of 24 antineoplastic drugs incorporated by CONITEC between January 2012 and July 2024 were analyzed, comprising 23 new technologies and one expansion of use (thalidomide for low-risk myelodysplastic syndrome). Of these, eight drugs were classified as having full access, one as having partial access, and fifteen as having no patient access (Figure 1). Among the eight drugs with full access, six are funded through centralized purchase (alpha-interferon, imatinib mesylate, pertuzumab, rituximab, thalidomide, and trastuzumab), one has a drug-specific APAC (blinatumomab) with a value of R$ 8,904.20 per vial of the medication – an amount sufficient to cover the median government purchase cost of R$ 8,780.67 per vial – and one has a standard APAC that fully covers the treatment cost (bortezomib). The only drug with partial access was abiraterone acetate, for which the treatment cost is 77% covered by APAC 03.04.02.008-7 (CHEMOTHERAPY FOR HORMONE-THERAPY-RESISTANT PROSTATE ADENOCARCINOMA).

Although currently with full access, the drugs acquired through centralized purchasing by the Ministry of Health took an average of 66 months from incorporation to the publication of the first purchase contract by DLOG. Pertuzumab was the drug most rapidly standardized for acquisition through centralized purchasing, 31 months after the publication of its incorporation in the Official Gazette (Table 2).

The drugs without patient access have been incorporated for an average of 47 months. Thus, with the exception of durvalumab, all have remained unavailable for a period exceeding 180 days, the timeframe established for availability within the SUS following incorporation (Table 3).

It was found that the estimated level of federal funding for drugs without patient access averaged 20.7% of the monthly treatment cost. The reimbursements through APAC ranged from 3.6% to 49.1% of the treatment cost, thereby leaving a significant portion of the medication cost, as well as professional and material costs, to be entirely covered by the institution. The APAC funding per drug without access is presented in Table 4.

Discussion

This study demonstrated that most antineoplastic drugs incorporated into the SUS remain inaccessible to patients due to delays in updating the Clinical Protocols and Therapeutic Guidelines (PCDTs) and the Therapeutic Directives (DDTs) by the Ministry of Health, as well as discrepancies between the monthly treatment costs and the standardized reimbursement values of procedures. This situation results in long periods without access to medications even after formal evaluation and incorporation processes, thereby depriving many patients of indicated treatments and violating the current SUS regulation.[22]

The delay in the effective availability of incorporated medicines and the limitations of their funding have led to a significant number of lawsuits seeking access to treatments, a phenomenon known as the judicialization of health, which is a subject of ongoing debate in public health.[25] One study found that up to 50% of medicines obtained by patients through the SUS between 2003 and 2015 resulted from legal action, with this percentage being even higher in the case of chronic diseases, indicating the system's failure to ensure universal access for its population.[26]

In addition to lawsuits filed to guarantee access to antineoplastic treatments for specific patients, there are also legal actions aimed at ensuring the implementation of incorporated technologies. An example is Public Civil Action No. 5044034-65.2020.4.04.7100, filed by the Federal Public Prosecutor's Office, which requests that the Federal Government examine the funding sources for antineoplastic drugs incorporated into the SUS to ensure adequate financial coverage.[27]

Figura 1. Classificação de acesso aos pacientes de medicamentos antineoplásicos incorporados ao SUS entre janeiro de 2012 e julho de 2024, com destaque ao método de financiamento dos antineoplásicos com pleno acesso

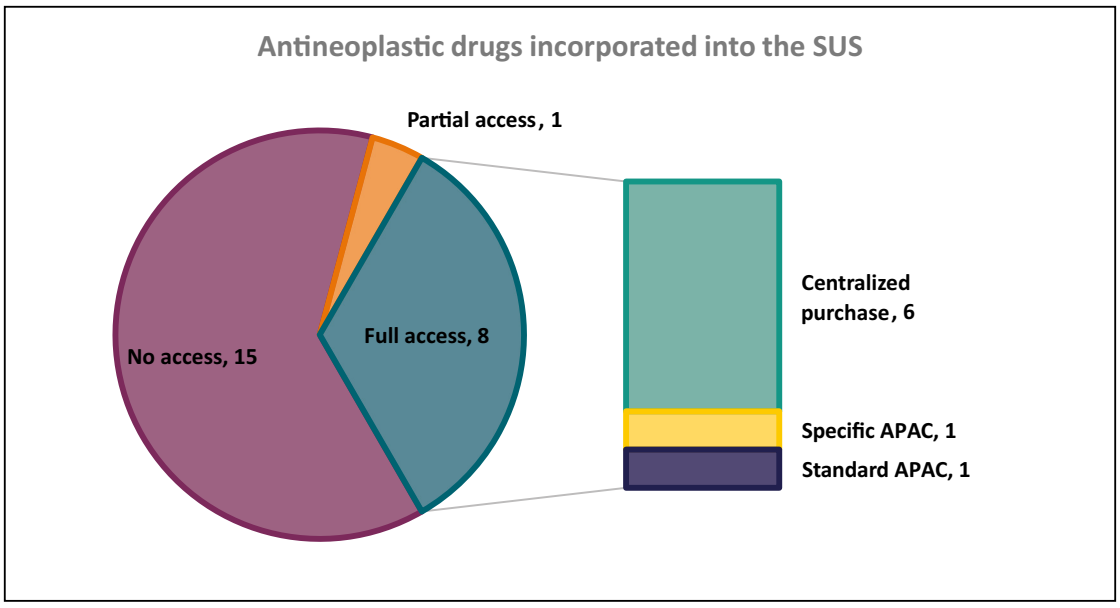

Table 2. Time from incorporation to first contract for antineoplastic drugs acquired through centralized purchasing

Drug	Indication	Time to centralized purchase* (months)
Alpha-interferon	Cutaneous melanoma	132
Trastuzumab	HER2+ breast cancer	69
Rituximab	Follicular lymphoma	52
Thalidomide	Myelodysplastic syndrome	49
Imatinib	Gastrointestinal stromal tumor	45
Pertuzumab	HER2+ breast cancer	31

*Time from publication of incorporation in the Diário Oficial da União (Official Gazette) to publication of the first purchase contract by DHL.

Table 3. Time since incorporation of antineoplastic drugs without access as of October 1, 2024

Drug	Indication	Time since incorporation* (months)
Erlotinib e Gefitinib	Metastatic lung cancer	133
Pazopanib e Sunitinib	Metastatic renal cancer	70
Brentuximab vedotin	Hodgkin's lymphoma	68
Pembrolizumab e Nivolumab	Advanced or metastatic melanoma	51
Palbociclib, Ribociclib e Abemaciclib	Advanced or metastatic breast cancer	34
Trastuzumab emtansine	Stage III breast cancer	25
Crizotinib	Advanced lung cancer	22
Carfilzomib	Relapsed or refractory multiple myeloma	11
Lanreotide	Gastroenteropancreatic neuroendocrine tumor	7
Durvalumab	Advanced lung cancer	5

*Time from publication of incorporation in the Diário Oficial da União (Official Gazette) to October 1, 2024.

Table 4. Level of federal funding for antineoplastic treatments without full access as of October 1, 2024, through primary APAC, in relation to drug acquisition costs

Drug (indication)	Monthly treatment cost	APAC value (procedure)	Level of federal funding
Abiraterone (CRPC)	R$ 1,380.00	R$ 1,062.65 (03.04.02.008-7)	77.0%
Gefitinib (advanced NSCLC)	R$ 2,239.20	R$ 1,100.00 (03.04.02.021-4)	49.1%
Lanreotide (advanced NET)	R$ 2,401.35	R$ 1,062.65 (02.04.02.011-7)	44.3%
Pazopanib (advanced RCC)	R$ 8,127.60	R$ 3,311.50 (03.04.02.016-8)	40.7%
Pembrolizumab (advanced melanoma)	R$ 28,634.08	R$ 7,500.00 (03.04.02.023-0)	26.2%
Carfilzomib (MM, 2nd line)	R$ 22,935.58	R$ 5,224.65 (03.04.03.026-0)	22.8%
Nivolumab (advanced melanoma)	R$ 33,293.76	R$ 7,500.00 (03.04.02.023-0)	22.5%
Sunitinib (advanced RCC)	R$ 16,277.80	R$ 3,311.50 (03.04.02.016-8)	20.3%
Palbociclib (MBC, 2nd line)	R$ 11,759.74	R$ 2,378.90 (03.04.02.014-1)	20.2%
Erlotinib (advanced NSCLC)	R$ 5,506.20	R$ 1,100.00 (03.04.02.021-4)	20.0%
Brentuximab vedotin (Hodgkin, 3rd line)	R$ 32,989.31	R$ 5,767.33 (03.04.06.004-6)	17.5%
Ribociclib (MBC, 2nd line)	R$ 14,430.15	R$ 2,378.90 (03.04.02.014-1)	16.5%
Trastuzumab emtansine (HER2+ MBC, 2nd line)	R$ 14,715.22	R$ 2,378.90 (03.04.02.014-1)	16.2%
Palbociclib (MBC, 1st line)	R$ 11,759.74	R$ 1,700.00 (03.04.02.013-3)	14.5%
Abemaciclib (MBC, 2nd line)	R$ 18,704.40	R$ 2,378.90 (03.04.02.014-1)	12.7%
Ribociclib (MBC, 1st line)	R$ 14,430.15	R$ 1,700.00 (03.04.02.013-3)	11.8%
Abemaciclib (MBC, 1st line)	R$ 18,704.40	R$ 1,700.00 (03.04.02.013-3)	9.1%
Crizotinib (advanced NSCLC)	R$ 25,167.00	R$ 1,100.00 (03.04.02.021-4)	4.4%
Durvalumab (advanced NSCLC)	R$ 30,387.61	R$ 1,100.00 (03.04.02.021-4)	3.6%

MBC: mammary carcinoma; RCC: renal cell carcinoma; NSCLC: non-small cell lung carcinoma; CRPC: castration-resistant prostate cancer; MM: multiple myeloma; NET: neuroendocrine tumor.

Finally, seven of the currently incorporated antineoplastic drugs without access are not even included in the therapeutic protocols and guidelines of the Ministry of Health (Table 5). The update of protocols following the incorporation of new treatments is established in CONITEC's workflow[23,2].

Table 5. Update status of PCDTs and DDTs related to antineoplastic drugs incorporated without access as of October 1, 2024

Drug (incorporation date)	Therapeutic guideline (last update)	Status in guideline
Erlotinib and Gefitinib (Nov 8, 2013)	DDT Lung Carcinoma (Sep 26, 2014)	Mentioned in DDT
Pazopanib and Sunitinib (Dec 28, 2018)	DDT Renal Cell Carcinoma (Nov 8, 2022)	Mentioned in DDT
Brentuximab vedotin (Mar 13, 2019)	PCDT Hodgkin's Lymphoma in Adults (Dec 29, 2020)	Mentioned in DDT
Pembrolizumab and Nivolumab (Aug 5, 2020)	DDT Cutaneous Melanoma (Oct 25, 2022)	Mentioned in DDT
Palbociclib, Ribociclib, and Abemaciclib (Dec 6, 2021)	DDT Breast Carcinoma (Apr 18, 2019)	Not mentioned in DDT
Trastuzumab emtansine (Sep 12, 2022)	DDT Breast Carcinoma (Apr 18, 2019)	Mentioned in DDT
Crizotinib (Dec 8, 2022)	DDT Lung Carcinoma (Sep 26, 2014)	Not mentioned in DDT
Carfilzomib (Nov 13, 2023)	DDT Multiple Myeloma (Dec 5, 2023)	Not mentioned in DDT
Lanreotide (Mar 6, 2024)	No published guideline	
Durvalumab (Apr 22, 2024)	DDT Lung Carcinoma (Sep 26, 2014)	Not mentioned in DDT

DTG: Diagnostic and Therapeutic Guidelines; PCDT: Clinical Protocols and Therapeutic Guidelines.

The issues of inequity and delays in patient access to antineoplastic treatments have been widely discussed in the health sector. Proposals have been made for the implementation of hybrid financing mechanisms that seek not to disrupt established treatments and procedures while ensuring effective funding for new and costly technologies.[28]

According to the results of this study, most antineoplastic drugs currently providing full patient access are acquired through centralized purchasing by the Ministry of Health. This highlights the success of this mechanism in ensuring access to treatments for the population. However, in these cases, a long period elapsed before the decision to centralize the acquisition, resulting in limited access for a significant time after incorporation. In addition to the experience with centralized purchasing, the funding mechanism established for blinatumomab suggests that alternatives to the traditional APAC model may represent an opportunity to improve access to oncological treatments within the SUS.

Conclusion

Em conclusão, a análise indica que, apesar dos avanços, a incorporação de medicamentos antineoplásicos enfrenta barreiras que comprometem a disponibilidade de tratamentos essenciais, sugerindo a urgência de estratégias mais eficientes de financiamento e gestão no sistema de saúde.

Authors' Contributions:
BSP and MFM: project conception; BSP and JB: methodological design; BSP and JB: data collection; BSP and JB: data analysis and interpretation; BSP and JNSC: review of the scientific literature; BSP, JB, and JNSC: manuscript drafting; JB, JNSC, MSN, and MFM: critical review; BSP, JB, JNSC, MSN, and MFM: final approval of the manuscript.

Conflict of Interest:
The authors of this article are currently employed by the company that funded the study, Moka Info.

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Data Availability Statement:
The datasets generated and analyzed during the current study are available upon request from the corresponding author.

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