Judicialization of health: profile of demands for oncological medicines in a state in the central region of Brazil

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Abstract

Background: The significant increase in access to oncological medicines through court cases suggests that constitutional guarantees of integral and universal care in the Brazilian public health system are uncertain.

Methods: A retrospective observational study was conducted to analyze data from lawsuits requesting oncological medicines from 2014 to 2020 in the State of Goiás, Brazil, in state and federal courts. Sociodemographic, medical, and legal variables were statistically examined using descriptive, association, and correlation methods.

Results: Women brought more than half (54%) of the 301 processes analyzed. The most frequent age group was over 55 years, with income below 3 × the minimum wage (total about USD$600/month), and their cases were promoted through the public minister and public defender’s offices. The most requested medications, not on official public health system lists, were indicated for multiple myeloma and brain cancer.

Conclusions: Improved quality of life, frequently used as a justification, could be conceptually confused with increased survival. Finally, judicialization itself indicates that individual health needs arise even with properly defined and adequately implemented public policies. These needs should be considered for the adequate provisioning of services by the state to ensure the right to health.

Keywords: Judicialization of health, Antineoplastic Agents, Quality of life

Introduction

Health care is a constitutional right in Brazil, and article 196 of the constitution states that health is a “right of all and also a duty of the State, guaranteed through social and economic promotion, protection, and recovery policies aimed at reducing the risk of disease and guaranteeing access to services” [1].

The Brazilian government is organized into three harmonious and independent branches, executive, legislative, and judicial, with typical and atypical executive, legislative and jurisdictional functions. In addition, the essential functions of justice are the Public Prosecutor’s Office (Ministério Público) and the Public Defender’s Office (Defensoria Pública), which operate independently in the states and from the Union. The Executive branch is responsible for managing the public health system—SLIS, as the executor of constitutional guidelines to guarantee integral health care [1].

Brazil is one of about a hundred countries recognizing the constitutional right to health, emphasizing...
comprehensive pharmaceutical care [2]. In addition, using a judicial process to access health services also occurs in other countries, such as Chile, Colombia, and Costa Rica [3–5]. However, improving the quality of medications offered in SUS and ensuring access to medications presents several challenges, such as increased life expectancy and the aging population, the demand of patients for treatments to be included, and offering health interventions [6]. These challenges contribute to the process of “medicationization” or “medicalization” [7], or even “pharmaceuticalization” [2] when medications are used in situations that cannot be considered diseases or the effects are overestimated. These processes are closely linked to the current economic-social model, where the use of medicines in society is separate from scientific medical-health criteria and rational use [8].

Through SUS, universal access to comprehensive health care was provided, aiming at prevention and health promotion, focused on quality of life for the population [9]. Quality of life refers to an individual’s perception of essential aspects of their standard of living, such as their physical health, vitality, social relationships, the environment they are inserted into, emotional health, and spirituality. In addition, with chronic diseases, such as cancer, quality of life is a predictor of morbidity and mortality and a measure for evaluating treatment effects [10–12].

Through a presidential decree in 2000, the Executive branch designated the National Cancer Institute (INCA) as the formulator and developer of policies to prevent and control cancer in the country [13, 14]. Furthermore, to integrate resources to prevent and fight cancer, the federal government created the national cancer care support program (PRONON) in 2012 [15]. PRONON consists of the organization of lines of care at all levels, including promotion, prevention, diagnosis, rehabilitation, and palliative care [16].

The SUS pharmaceutical service in basic, strategic, and specialized components does not include the supply of oncologic drugs [17]. Moreover, SUS has no single list of antineoplastic drugs, and oncology clinical guidelines contemplate only some types of cancer [18]. The SUS path to oncological treatment, including drugs and other health technologies, is unique: An individual diagnosed with a neoplasm must be referred to a High Complexity Oncology Care Unit (UNACON) or a High Complexity Oncology Care Center (CACON), institutions linked to the Ministry of Health, distributed throughout the country to treat various types of cancer [19, 20]. Currently, there are 317 qualified care units and care centers in the country, with five units in the state of Goiás [21, 22].

Pharmaceutical care in cancer treatment is specially designated as oncological care and is included in medium and high-complexity health care funding. Cancer treatment is reimbursed by specific procedures (surgical, radiotherapy, chemotherapy, and iodotherapy), depending on the stage of the disease, histological type, treatment objectives (curative or palliative), and the therapeutic means to be used [17]. SUS does not restrict or establish a specific chemotherapy drug. That is, reimbursement does not depend on the therapeutic regimen. Thus, the responsibility for acquiring, standardizing, and supplying chemotherapy drugs belongs to the qualified public or private institution (UNACON or CACON) [23, 24].

In Brazil, structural limitations create obstacles to financing the health care system through public–private incentives. Therefore, Brazil is the only country with a comprehensive and universal health system with higher private spending than public spending [25, 26].

Not many studies address oncology in Brazil. However, public spending on medicines impacts SUS, and a large part of these costs is due to advanced-stage treatment, requiring more procedures and medications. Therefore, early diagnosis is promoted to save lives and minimize the financial impact on public health expenditures [27].

Controlling environmental risk factors and lifestyle changes can reduce the incidence of new cancer cases, and in developed countries, the reduction can vary from one-third to two-fifths [28–30]. Despite the importance of prevention with proven effective interventions, by reducing exposure to known causes of human cancer or by interrupting the progression in various stages of tumors, national and international policymakers still need encouragement to recognize the benefits and advances achieved [30, 31].

From 2010 to 2015, there was a 66% increase from R$2 billion to R$3.5 billion (1 BRL is about 5 USD), including surgical procedures, chemotherapy, radiotherapy, hormone therapy, and palliative care. There was also an increase in the number of individuals undergoing treatment, from about 292,000 to about 393,000 [32]. In 2017, public spending on treatments (chemotherapy, radiotherapy, and hormone therapy) totaled R$4.5 billion reais, 25% of total expenses. In 2018, expenses were 4.6 billion reais, and chemotherapy alone was responsible for 49% of expenses. On average, each individual with cancer cost SUS around R$9000 in 2018 [33].

In 2019, the total monthly burden on the individual in cancer treatment and their caregiver was, on average, from R$290 to R$300, indicating a high financial impact on the average Brazilian family income [25].

Health expenditures represent 8.2% of the GDP. However, less than 50% of this total is for the cost of the public system [34]. Per capita spending on health in 2017 was comparatively higher than in Latin American countries, such as Colombia, but three times lower than in OECD
countries [35]. The latest data from the OECD show that Brazil’s 2019 health expenditure was 9.59% of GDP. The breakdown of health expenditure by type of financing is distributed as follows: public (40%); voluntary health insurance (30%); direct out-of-pocket expenses (25%); other (5%) [36].

SUS has been underfunded since it was created. For example, social welfare transfers were interrupted in 1993, and part of the health budget provided by the Social Emergency Fund was de-funded when federal revenues were unlinked. Later, the CPMF (a tax on financial transactions) was intended to subsidize public health expenses, resulting in the government adding additional budgetary items to the Ministry of Health. Federal funding of SUS through Constitutional Amendment 29 (EC-29) took eight years and allocated perpetually insufficient resources to SUS, further complicated by the approval of Constitutional Amendment 86 in 2015 [37, 38].

Moreover, the approval of Constitutional Amendment 95 (EC-95) in 2016 freezes the federal government’s primary expenditure and its minimum application in health actions and services, in real terms, until 2036 and represents an obstacle to the expansion of SUS funding by preventing the allocation of more resources to health without de-funding other policies at the federal level [39]. De-funding estimates approached R$22.5 billion between 2018 and 2020 [40].

It is important to note that the inclusion of health as a fundamental constitutional right was not enough to guarantee it [41]. Indeed, these medications are not always available, and this is especially relevant to the current topic because the patient must then resort to judicial intervention to safeguard their constitutionally protected right [42]. As the right to health is a subjective fundamental right, the legal system allows this right to be asserted in the judiciary [1].

Judicialization of health refers to an intervention in Public Administration by the judiciary to guarantee the constitutional right to care, such as provisioning medications and products and services [43, 44] or even mediating the supply–demand relationship to secure constitutional guarantees [45].

Despite all the regulations on each political entity that implements pharmaceutical care, the judiciary has come to understand that federal entities have a joint responsibility to provide medications and health treatments [13, 46]. However, only the federal government must be sued when it comes to medications that are not registered with the National Health Surveillance Agency (ANVISA) [47].

Data made available by the National Council of Justice reveal that the supply of medicines is the leading cause of litigation against SUS, indicating that the issue requires the coordinated action of all health and justice actors [48]. However, judicialisation is not something new. The first lawsuits were filed in 1990 requesting medication for HIV/AIDS treatment, and since then, the judiciary has become the means for acquiring high-cost drugs for more diverse treatment options [49].

There is no consensus on the definition of high-cost medication. However, some conceptual approximations have been made using qualitative indicators like medicines with high health risks and quantitative indicators like regulating the cost of treatment. Others still use it as a synonym for highly complex and costly medicines, with precise use conditions and expensive medicines from limited sources [50].

Judicialization is already institutionalized as an alternative form of access to new technologies through SUS [51]. However, it is undeniable that this avenue of entry often violates the right to equality in a community that is supposed to be served by SUS [52].

The expansion of adequate public health services depends on the commitment of the State and its leadership [53]. Many of these lawsuits seek to ensure patients’ right to high-cost medicines that are not always available in SUS and often without proven benefits, or even, in some cases, with deleterious/side effects and adverse impacts on quality of life [33]. The Judiciary has self-compositional methodologies for conflict resolution from the Judicial Centers for Conflict and Citizenship Solutions (CEJUSC), in addition to the possibility of opinions from health professionals by the Judiciary Technical Support Center (NATJUS) as subsidies for the judicial decision [54, 55].

From 2015 to 2020, there were more than a million new lawsuits concerning medicines in Brazil. In 2020, this figure included 196,000 new lawsuits, most seeking new drugs not provided by SUS or private insurance [41].

The imbalance in SUS pharmaceutical care resulting from the judicialization of oncological medicines has a high impact due to the high cost, the complexity of the treatment, and pressure from the pharmaceutical industry [56].

The phenomenon of judicialization can be understood by analyzing relevant aspects of lawsuits and their impact on quality of life to help mitigate the phenomenon and fill the gap in broader studies on the subject in the Midwest Region of Brazil. Therefore, the study’s objective was to analyze the results of lawsuits on requests for oncological drugs in the State of Goiás from 2014 to 2020.

Method

A retrospective analytical study was conducted from July to October 2021, with data obtained from individual lawsuits requesting high-cost cancer drugs at the Goiás State
The present study is part of a larger project entitled: Quality of life of oncological drug claimants in administrative and judicial proceedings in Goiás.

The data were obtained from the Technical Analysis Sector of the Central de Medicamentos de Alto Custo Juarez Barbosa / Center for High-Cost Medications (CEMAC) through the registration of oncological medicines and the respective users in the judicial process of granting the supply. In addition, the lawsuits were also checked in the judicial demand protocol system of TJGO (Digital Judicial Process—PROJUDI) and TRF-Goiás (Electronic Judicial Process—PJe) for confirmation and double-checking.

CEMAC is the referral center in the state of Goiás, Brazil, for dispensing drugs from the Specialized Pharmaceutical Service Component (CEAF) located in the city of Goiânia, Goiás. The list of individuals registered to receive oncological medicines was obtained in the Pharmacy Sector of the Judiciary. The judicial processes were accessed in the Technical Analysis Sector of CEMAC, where two researchers with law qualifications collected the data presented in this study. The data obtained were confirmed in the procedural search in PROJUDI and PJe.

All current processes that requested oncological medicines were included. The process initiated from 2014 to 2020. Duplicate processes at TJGO and TRF-Goiás and processes requesting medical or nutritional products, procedures, medical consultations, surgery, and diagnostic tests were excluded.

The study variables were based on the Manual of Indicators for the Evaluation and Monitoring of Judicial Demands for Medicines of the National School of Public Health/FIOCRUZ [57]. They were separated into 3 groups: sociodemographic, medical-health, and legal. The sociodemographic variables were gender, age, income, education, and declared occupation. The medical-health variables were the ICD-10 [58], name and quantity of the medication requested, the origin of the prescription, and the origin of the medical report (public or private). Finally, the legal variables were the promoter or office that filed the action (Public Prosecutor, Public Defender, or Private Lawyer), dates of filing, preliminary decision or anticipation of protection and first-degree ruling, request for expertise, presence of NATJUS or CEJUS opinion and justifying the request using quality of life.

The statistical analysis consisted of descriptive statistics with a distribution of simple and relative frequencies and analysis of measures of central tendency (mean, mode and median), and respective analyzes of variability or dispersion measures (amplitude, interquartile range, variance, standard deviation, minimum and maximum). Microsoft® Excel 2019 was used for data tabulation. Statistical Package for Social Sciences software (SPSS® Windows® version 28.0.1, IBM Company, Chicago, IL) was used for data analysis. To evaluate the legal variables and the relationship with the variables of the sociodemographic profile with more than two groups, variance analysis (ANOVA) was used, and for the other cases, Student’s t-test was used. In addition, Pearson’s correlation coefficient was calculated for comparative detailing. Finally, a statistical significance of \( p < 0.05 \) was used for all tests.

The research involved data from human beings and complied with the National Health Council according to Resolutions No. 466/2012 and No. 510/2016. It was approved on August 20, 2018, by the Research Ethics Committee of the Federal University of Goiás, Brazil, under opinion no. 2.831.905 and no 4.558.046 – CAAE 93,238,318.7.0000.508351–52 [59, 60], part of the project entitled Quality of life of cancer drug claimants in administrative and judicial proceedings in Goiás.

**Results**

This study identified 549 cases in the study period; 301 met the inclusion criteria and were analyzed. The excluded cases were related to requests for special facilities (26), surgeries (45), medical consultations (49), diagnostic tests (43), medical products (49), and cases where access was prevented by judicial secrecy (36). Of the 301 cases analyzed, 264 (88%) were filed in the state courts (TJ) and 37 (12%) in the federal courts (TRF(GO)) (Fig. 1).

All actions were individual. The complainants were primarily women (54%). The predominant age bracket was 65 years or more (30%). However, most were in the age bracket above 55 years (52.5%). The occupations described were diverse, highlighting retirees (27%) and domestic workers (11%). The family income, when declared, was up to 3 minimum wages (33%). Notably, none of the cases analyzed reported a family income higher than 3 minimum wages (Table 1).

The number of cases in the TRF(GO) was comparatively lower than TJ. Table 1 also shows a majority of women and retirees in both channels, with a difference in the predominant age groups, being > 55 years in the TJ and > 65 years in TRF(GO), and family income, being in the TJ < 1 minimum wage and TRF(GO), between 1 and 3 minimum wages.

The most requested drugs were temozolomide (14%) and bevacizumab (13%), followed by rituximab (9%), pazopanib (8%), ibrutinib (5%), pembrolizumab (5%) and bortezomib (3%). Regarding the ICD-10 [58], the most frequent codes used were C71 (malignant neoplasm of brain) and C90 (multiple myeloma and malignant plasma cell neoplasms) (Table 2).
Fig. 1 Study data collection flowchart. Goiania, 2020. Source: Study data

Table 1 Sociodemographic profile of participants (complainants)

| Variables            | All groups | TJ | TRF (GO) |
|----------------------|------------|----|----------|
|                      | n          | %  | n        | %  | n        | %  |
| Gender               |            |    |          |    |          |    |
| Male                 | 138        | 46%| 123      | 41%| 15       | 5% |
| Female               | 163        | 54%| 141      | 47%| 22       | 7% |
| Age                  |            |    |          |    |          |    |
| 0–17                 | 10         | 3% | 8        | 3% | 2        | 1% |
| 18–24                | 8          | 3% | 6        | 2% | 2        | 1% |
| 25–34                | 25         | 8% | 21       | 7% | 4        | 1% |
| 35–44                | 41         | 14%| 39       | 13%| 4        | 1% |
| 45–54                | 59         | 20%| 50       | 17%| 7        | 2% |
| 55–64                | 67         | 22%| 86       | 29%| 7        | 2% |
| 65 years or older    | 91         | 30%| 54       | 18%| 11       | 4% |
| Occupation           |            |    |          |    |          |    |
| Retiree              | 81         | 27%| 70       | 23%| 11       | 4% |
| Social Assistance or pensioner | 6  | 2% | 5       | 2% | 1     | 0% |
| Student              | 5          | 2% | 4        | 1% | 1       | 0% |
| self-employed professional | 28 | 9% | 26      | 9% | 2     | 1% |
| Rural worker         | 11         | 4% | 10       | 3% | 1       | 0% |
| domestic worker      | 32         | 11%| 30       | 10%| 2       | 1% |
| Others               | 138        | 46%| 119      | 40%| 19      | 6% |
| Family income        |            |    |          |    |          |    |
| Less than 1 SM (up to USD 209) | 48 | 16%| 43      | 14%| 5       | 2% |
| 1–3 SM (between USD 209–627) | 51 | 17%| 40      | 13%| 11      | 4% |
| Above 3SM (more than USD 627) | 0  | 0% | 0       | 0% | 0     | 0% |
| Not Specified        | 202        | 67%| 181      | 60%| 21      | 7% |

*a Family income: The national minimum wage (SM) in 2020 was R$1045.00, 1USD = (apx) R$5.00 [61]*
The medical record presented as technical evidence of the need for oncologic medicine was mainly from SUS (public origin), both in the TJ and in the TRF (GO), representing 90%, while the report of private origin had a frequency of 10% (Table 2).

| Variables                     | All groups | TJGO | TRF (GO) |
|-------------------------------|------------|------|----------|
| Drug                          |            |      |          |
| temozolomide                  | 42         | 14%  | 0%       |
| bevacizumab                   | 39         | 13%  | 2%       |
| rituximab                     | 26         | 9%   | 1%       |
| pazopanib                     | 25         | 8%   | 2%       |
| pembrolizumab                 | 15         | 5%   | 0%       |
| ibrutinib                     | 15         | 5%   | 0%       |
| bortezomib                    | 10         | 3%   | 0%       |
| Others                        | 129        | 43%  | 6%       |
| ICD-10                        |            |      |          |
| C-71 malignant neoplasm of brain | 40     | 13.3%| 0.3%     |
| C-90 multiple myeloma and malignant plasma cell neoplasms | 38 | 12.7% | 1.7% |
| C-53 malignant neoplasm of cervix uterin | 28 | 9.3% | 1.3% |
| C-64 malignant neoplasm of kidney, except renal pelvis | 26 | 9% | 2.0% |
| C-43 malignant melanoma of skin | 15     | 5%   | 0.0%     |
| C-91 lymphoid leukemia         | 15         | 5%   | 1.0%     |
| C-18 malignant neoplasm of colon | 13    | 4.3% | 0.3%     |
| C-50 malignant neoplasm of breast | 12    | 3.7% | 0.7%     |
| C-81 Hodgkin lymphoma          | 8          | 2.7% | 1.7%     |
| C-82 Follicular lymphoma       | 5          | 2%   | 0.0%     |
| Others                        | 101        | 33.3%| 3.3%     |
| Origin of the report           |            |      |          |
| Public                        | 271        | 90%  | 11%      |
| Private                       | 30         | 10%  | 1%       |

*ICD-10: International Classification of Diseases, version 10 [58]*

There were more judicial requests for NATJUS opinions (24%) than intermediation by the CEJUSC (7%) (Table 3). In TRF (GO), there were no opinions from CEJUSC, which was expected because intermediation by the CEJUSC is within the scope of the state courts of justice.
Included in this analysis were requests for opinions, but they were not necessarily present in all the cases.

The justification that the supply of medication would promote improvement in quality of life was used in 47% of the cases in TJGO (41%) and TRF (GO) (6%) (Table 3).

The preponderant representative, appearing in 47.74% of the cases, was the Public Prosecutor, followed by the Public Defender’s Office with 35.80% of the claims, and finally, Private Lawyers brought 16.45% of the cases. Medical reports originated in the SUS in 97.88% of cases and 2.12% in the private system (Table 3). In addition, there was a significant difference between (p = 0.0007) and between the public prosecutor and public defender (p = 0.000001). In addition, a statistically significant difference was found in medication type and time of care in TJGO (p = 0.042) and regarding the ICD-10 described in the process and time of care in TJGO (p = 0.015) (Table 4).

**Discussion**

In the lawsuits studied, it was identified that most of the claimants for oncological medications were women, representing 54%. Similar studies have found this association between women and health services [62–65]. In addition, this statistic highlights cancer as a family disease and the role of women as formal and informal caregivers of individuals with cancer who could have filed these lawsuits on their behalf [64, 66–69].

The most frequent age groups were people over 55 (52%), with those over 65 representing 30% of the total. In addition, adult and elderly women appear as claimants in other studies [65, 69, 70].

The average income of the plaintiffs in the lawsuits was 1–3 × the minimum wage. Considering that the cost of treating an individual with cancer can exceed R$300.00 per month, the impact of treatment on the family’s finances is high, resulting in suffering and stress [25, 71].

All actions were individual, with the same result found in other studies [44, 65, 72]. The preponderant procedural representative was the Public Prosecutor with 47.74% of the cases, followed by the Public Defender’s Office with 35.80%, and finally, private lawyers with 16.45% of cases. It is important to emphasize that in the requests made by the Public Prosecutor and the Public Defender, the rate of granting preliminary relief is high. Furthermore, preliminary orders

| Table 3 | Study legal variables |
|---------|----------------------|
| Variables | All groups | TJGO | TRF (GO) |
|          | n | % | n | % | n | % |
| **Organization** | | | | | | |
| CEJUSC | 21 | 7% | 21 | 7% | 0 | 0% |
| NATJUS | 72 | 24% | 52 | 17% | 20 | 7% |
| Not specified | 208 | 69% | 191 | 63% | 17 | 6% |
| **Sponsorship** | | | | | | |
| Public ministry | 138 | 46% | 137 | 46% | 1 | 0.3% |
| Public defense | 103 | 34% | 68 | 23% | 35 | 11.6% |
| Private lawyer | 60 | 20% | 59 | 20% | 1 | 0.3% |
| **Justification improved QOL** | | | | | | |
| Yes | 141 | 47% | 124 | 41% | 17 | 6% |
| No | 160 | 53% | 140 | 47% | 20 | 7% |

QoL = Quality of life
Table 4  Correlation between study variables and service times at TJGO and TRF-Goiás

| Variables                | Service time (days) | Service time TJGO (days) | Service time TRF-Goiás (days) |
|-------------------------|--------------------|--------------------------|-------------------------------|
|                         | Mean   | Standard Deviation | p-value | Mean   | Standard Deviation | p-value | Mean   | Standard Deviation | p-value |
| Gender                  |        |                   |         |        |                   |         |        |                   |         |
| Male                    | 13.91  | 16.87             | 0.74    | 8.59   | 5.86             | 0.85    | 46.75  | 38.77             | 0.32    |
| Female                  | 12.92  | 20.02             |         | 8.78   | 6.12             |         | 32.35  | 32.12             |         |
| Age                     |        |                   |         |        |                   |         |        |                   |         |
| 0–17                    | 11.62  | 17.49             | 0.69    | 6.83   | 6.91             | 0.54    | 26     | 36.77             | 0.73    |
| 18–24                   | 4.6    | 4.72              |         | 5.25   | 5.18             |         | 2      | NA                |         |
| 25–34                   | 16.18  | 24.08             |         | 9.67   | 6.22             |         | 35.75  | 45.58             |         |
| 35–44                   | 11.36  | 16.82             |         | 7.56   | 4.6              |         | 55     | 46.67             |         |
| 45–54                   | 13.76  | 14.58             |         | 10.35  | 8.85             |         | 31.17  | 26.64             |         |
| 55–64                   | 10.94  | 8.7               |         | 9.29   | 6.07             |         | 28     | 14.8              |         |
| 65 years or older       | 16.79  | 25.7              |         | 8.17   | 5.81             |         | 54.5   | 42.46             |         |
| Income                  |        |                   |         |        |                   |         |        |                   |         |
| Less than 1SM           | 12.87  | 14.11             | 0.96    | 8.89   | 4.96             | 0.904   | 28.2   | 25.74             | 0.48    |
| Greater than 3SM        | 12.89  | 15.09             |         | 8.14   | 6.58             |         | 29.5   | 24.19             |         |
| Not Specified           | 13.72  | 20.13             |         | 8.77   | 6.05             |         | 46.4   | 41.19             |         |
| Sponsorship             |        |                   |         |        |                   |         |        |                   |         |
| Public prosecutor       | 7.86   | 5.86              | 0*      | 7.9    | 5.87             | 0.06    | 4      | NA                | 0.32    |
| Public defense          | 26.72  | 29.81             |         | 11.18  | 6.54             |         | 40.4   | 35.36             |         |
| Lawyer                  | 9.25   | 5.33              |         | 9.25   | 5.53             |         | NA     | NA                |         |
| Medication              |        |                   |         |        |                   |         |        |                   |         |
| temozolamide            | 12.7   | 9.93              | 0.245   | 11     | 5.46             | 0.042*  | 52     | NA                | 0.121   |
| bevacizumab             | 14.09  | 20.33             |         | 10.68  | 7.01             |         | 25     | 41.06             |         |
| Rituximab               | 16.87  | 31.02             |         | 6.84   | 3.57             |         | 82     | 59.39             |         |
| Pazopanib               | 22.56  | 25.51             |         | 9.5    | 6.22             |         | 44.33  | 31.2              |         |
| pembrolizumab           | 8.7    | 5.47              |         | 8.7    | 5.47             |         | NA     | NA                |         |
| ibrutinib               | 22.5   | 35.48             |         | 10.14  | 6.64             |         | 109    | NA                |         |
| pembrolizumab           | 8.7    | 5.47              |         | 8.7    | 5.47             |         | NA     | NA                |         |
| Bortezomibe             | 12.06  | 11.51             |         | 9.88   | 7.08             |         | 49     | NA                |         |
| Others                  | 9.84   | 12.48             |         | 6.34   | 5.26             |         | 24.9   | 21.44             |         |
| ICD-10                  |        |                   |         |        |                   |         |        |                   |         |
| C‑90                    | 14.3   | 12.4              | 0.0388  | 10.88  | 6.83             | 0.015   | 45     | 5.66             | 0.276   |
| C‑71                    | 12.73  | 10.15             |         | 10.95  | 5.58             |         | 52     | NA                |         |
| C‑53                    | 13.7   | 29.38             |         | 5      | 2.78             |         | 3454.58| NA                | 0.172   |
| C‑64                    | 18.79  | 19.86             |         | 9.44   | 6.6              |         | 35.6   | 25.39             |         |
| C‑43                    | 13.7   | 29.38             |         | 5      | 2.78             |         | 34     | 54.58             |         |
| C‑91                    | 34.2   | 44.84             |         | 9.85   | 6.54             |         | 91     | 44.8              |         |
| C‑18                    | 10     | 9.96              |         | 10     | 9.96             |         | NA     | NA                |         |
| C‑50                    | 20.83  | 12.56             |         | 15.25  | 8.46             |         | 32     | 14.14             |         |
| C‑81                    | 11.85  | 15.24             |         | 5      | 1.73             |         | 17     | 19.49             |         |
| C‑82                    | 8.25   | 3.77              |         | 8.25   | 3.77             |         | NA     | NA                |         |
| Others                  | 9.27   | 14.13             |         | 6.59   | 4.74             |         | 31.17  | 35.98             |         |
| Origin of the report    |        |                   |         |        |                   |         |        |                   |         |
| Public                  | 20.43  | 12.89             | 0.701   | 15.83  | 5.96             | 0.726   | 38.44  | 35.99             | 0.69    |
| Private                 | 10.43  | 12.86             |         | 7.6    | 6.25             |         | 53     | NA                |         |
| QOL justification       |        |                   |         |        |                   |         |        |                   |         |
| Yes                     | 23.508 | 21.4              | 0.534   | 24.49  | 28.13             | 0.4024  | 7      | 9.18              | -       |
| No                      | 20.69  | 21.4              |         | 20.69  | 21.4             |         | NA     | NA                |         |

*p-value < 0.05
have a definitive and irreversible character [73]. Therefore, it could be thought that judicialization is not a tool to promote equity in access to cancer drugs [74].

Regarding the judicial entity, the state of Goiás (88%) was preferred over the federal government (12%) in the present study. In addition, time may have been a determining factor in the choice since, as it turned out, the average time from filing to the delivery of judicial resolution in the state court (8.45 ± 0.87 days) was shorter than in the federal court. (43.5 ± 12.90 days), which could explain the choice. Health-related claims are based on pressing health needs; injunctive relief must be granted to improve life, demonstrating a conceptual mismatch between procedural urgency and medical urgency/emergency [75].

Colombia is also judicializing access to health care through its supreme court, and there has been a growing use of injunctions to protect social rights such as health care indirectly. For example, the judiciary can protect a social right if its non-enforcement causes a violation of a fundamental right, such as life, physical integrity, or human dignity. This understanding is called the doctrine of connection [76] and underpins judicial decisions on the subject in Brazil.

The joint liability of federative entities expands access to judicial intervention. However, the federal government will always be in better financial shape to protect the fundamental right to health concerning the supply of high-cost medicines than states and municipalities [77].

Protecting social rights involves different interpretations according to ideological convictions and the interpreter’s point of view. The judicialization of health, in this context, must be analyzed as a consequence of a hermetic phenomenon involving the need for inter-institutional dialogue and integrated action, whether concerning the current international intellectual property system or policy discussions on research, development, and innovation, whether in price regulation in the pharmaceutical market or assessing which health technologies to include on official lists [78].

The judicialization of health challenges judges to mediate a non-legal conflict between politics and services, impacting public health policies. At the Public Defender’s Office, the challenge is smaller, as this office has practically specialized in demands for comprehensive health care since its implementation in the state in 2016. Before that, through the Chamber of Deputies Technical Assessment in Health (CATS) 2009, the state Public Prosecutor analyzed medication demands with a team composed of health professionals [48, 79–81]. These organizations’ specialized case sponsors and free service could explain the greater appearance of public organization sponsors in the study (public defender and public prosecutor) to the detriment of sponsorship by private lawyers and the high number of preliminary orders confirmed in decisions [63, 69].

A medical report must be presented to request medicines in court [43, 48]. In most processes (97.88%), the medical report originated in the public system. In some studies, most reports originated in the private system (38%) [69]. In addition, the medical report or prescription of public origin, issued by a professional from SUS, has greater weight as the primary evidence that the health system recognizes the need [73, 82]. Medical reports of public origin combined with the income of the participants demonstrate that judicialization is yet another way for individuals with low family income to access needed medications [6].

One notable aspect of the judicialization of access to medicines is the ability of the magistrate to request an opinion from the Center of Technical Support of the Judiciary (NATJUS) before deciding. NATJUS aims to provide technical support for decision-making based on scientific evidence in health-related actions. In addition, the Judicial Centers for Conflict Resolution and Citizenship (CEJUSC) act to self-compose available rights to resolve conflicts consensually within the state courts of justice [54, 55]. Although not binding, in its use, it can serve as technical support to support judicial decisions [48].

In Goiás, NATJUS started its activities in 2012, evaluating public and private health demands, verifying clinical protocols and therapeutic guidelines within the scope of SUS, and guidelines for use established by the National Agency for Supplementary Health (ANS) [83]. However, despite the recommendations, only 24% of the processes analyzed in the study used the opinion of NATJUS and CEJUSC.

In cooperation with the Ministry of Health, the National Council of Justice has created a National Opinion Bank, the digital platform (E-NATJUS System) for NATJUS opinions throughout the country. The system is available for consultation by magistrates. The objectives of the platform include reducing the possibility of conflicting judicial decisions on issues related to medicines and treatments and the concentration in a single database to avoid the formalization of requests whose treatments are not recommended by official health agencies [41, 84]. In Goiás, in 2020, there were 2016 consultations and 2081 opinions formulated, originating from requests from 1st-degree magistrates, mostly [83].

The most prevalent neoplasm in the lawsuits was brain cancer, followed by multiple myeloma. In the study by CERVI et al. [44], in 2020, in the state of Rio Grande do Sul and by Santos (2021) [65] in São Paulo, the most frequent neoplasm was also multiple myeloma.

Of the most requested drugs in the study, bevacizumab is indicated for metastatic colorectal cancer, advanced or metastatic lung, metastatic breast, renal, ovarian, and metastatic cervical cancer. In addition, bevacizumab was considered the agent of choice in clinical protocols and therapeutic guidelines for managing diabetic retinopathy, glaucoma, and
The addition of bevacizumab as a molecular therapy to palliative chemotherapy in patients with recurrent, persistent, or metastatic cancer was associated with a 3.7-month improvement in overall survival. Even so, this improvement would not be considered cost-effective in the United States, given the price of the current treatment [86]. Indeed, in the study by GOMES et al. (2021) [25], the total average cost of treatment was R$531.87, estimated per procedure session.

In the present study, in most of the legal requests for bevacizumab, it was prescribed for AMD when it was legal for off-label use [69, 87].

The drug temozolomide was, together with bevacizumab, the most requested. However, CONITEC, in a 2014 recommendation report on temozolomide for the adjuvant treatment of patients with High-Grade Gliomas, stated that using the temozolomide as an adjuvant in the treatment of brain neoplasia increased survival but decreased quality of life. Thus, the basis for improving the quality of life for access to high-cost oncological drugs is a paradox that deserves reflection since the administration of drugs in individuals with cancer can often worsen the desired quality of life in patients with cancer due adverse drug reactions [88].

Concerning the reasons for the judicial processes, 47% identified quality of life as the justification for requesting cancer medication. There are several concepts of quality of life. The World Health Organization (WHO) suggests this complex concept as a subjective way for individuals to perceive their lives, defining their goals and perspectives, including their satisfaction with life, cultural context, social, environmental, and value systems in which they are inserted [89, 90]. Notably, in 1995, the Food and Drug Administration (FDA) included the need to assess the quality of life for the approval of oncological drugs [91].

Considering that medical and pharmaceutical practice shows that oncological drugs cause many adverse reactions, are difficult to adapt to, and in most cases reduce the quality of life of patients, there seems to be a terminological confusion between improvement in quality of life and increased survival [92].

In order to be considered beneficial, an increase in survival must be accompanied by improved quality of life. Otherwise, it would prolong suffering and pain for the individual and their family. Indeed, prolonging life must respect the interests and dignity of the individual in question as an active participant in their care process, overcoming professional interests of trying to extend life at any cost with experimental treatments, prolonged hospital stays, and invasive procedures that increase the suffering they already experienced, in addition to being resource-intensive [93–95].

The judiciary cannot avoid the debate about resource allocation in health and its relationship with the principles of universality, equity, and integrality that guide SUS. However, it must also weigh this social protagonism with individual decisions that significantly impact the entire State structure [77]. For granting access to medications and other health technologies through judicial protection, the cost-utility analysis (CUA) should be suggested as an alternative. The CUA is more suitable for health-related quality of life, focusing mainly on the quality of the health outcome produced or avoided and introducing the QALY concept – quality-adjusted life years [96]. QALY is a cost-to-effectiveness threshold calculation that aims to maximize years and quality of life from a utilitarian perspective.

CONITEC suggests that the economic evaluation and cost-effectiveness parameters for approving new technologies for SUS should be based on quality-adjusted life years (QALY). However, a cost-effectiveness threshold and the QALY cannot be obstacles that hinder other relevant decision-making criteria when it comes to adding new technologies to SUS approval lists [97].

Indeed, the experience of countries like Australia (Medical Service Advisory Committee—MSAC), Canada (Canadian Agency for Drugs and Technology in Health—CADTH), and the United Kingdom (National Institute for Health and Clinical Excellence—NICE) in the adoption of cost-effectiveness thresholds. However, it should be noted that these value definitions are context-specific, depending on local wealth, health system characteristics, availability, ability to pay, and social preferences. Therefore, such issues must be considered while issuing the regulations in art. 19-Q, §3, of Law No. 8.080/90 [98].

Indeed, health benefits can be maximized, including cancer drugs, through cost-effectiveness (or utility) weightings based on quality of life, achieving the ideals of justice without abdicating the primary public interest [73].

Conclusions

The lawsuits analyzed in the study were brought by women aged over 55 years, of low income, and sponsored by public prosecutors and public defenders to request, mainly, medications prescribed for multiple myeloma and brain cancer that are not included on SUS official lists, with few requests for opinions from NATJUS and mediation from CEJUSC.

Using quality of life to justify these medication requests presents a dubious understanding when it comes to increased survival. The apparent confusion disregards the
deleterious effects of oncological therapy and its negative impact on quality of life. Increased survival is important and should not be neglected in this assessment if it improves an individual’s quality of life, but the erroneous use of non-synonymous expressions, quality of life, and increased survival should be avoided.

There are many financial challenges to fully implementing oncologic care. SLIS has been underfunded since it was created 34 years ago, with federal budget cuts below the minimum required to meet constitutional guarantees. The market is overvalued, and state power has been reduced. Only broad, profound changes in the current economic model and social structures that break neoliberal paradigms will ensure medium and long-term sustainability.

It should be noted that greater profits are guaranteed to the pharmaceutical industry through expanded access to medications by lower-income patients. Even if severe questions of inequity are not raised, it can be argued that industry profits are driving this process, not access to medications.

Finally, the judicialization of health indicates that specific health needs arise even with defined and equitably implemented public policies. These needs must be considered for the state’s effective provision of public services to guarantee the right to health.

The present work has strengths and limitations. One of the strengths is being the first study in the central region of Brazil and having a relatively large sample size. The size may suggest the generalizability of the results obtained. However, as a possible limitation, cancer stages and previous treatment protocols were not considered relevant, as they do not interfere with the court’s response.

| Frequency table: |
|------------------|
| Decision         | Quality of life | < Mean | > Mean |
| No               | 32              | 14     |
| Yes              | 83              | 41     |
| Pearson’s Chi-squared test |
| Data: Table      | X-squared = 0.10602, df = 1, p-value = 0.7447 |
|                  | There was no association between time and quality of life |

| Welch Two Sample t-test: |
|-------------------------|
| Data: Time by Quality of life |
| t = -0.69995, df = 103.67, p-value = 0.4855 |
| Alternative hypothesis: true difference in means between the No group and Yes group is not 0 |
| 95 percent confidence interval: |
| -10.780632               | 5.155807 |
| Sample estimates:        |
| Mean in No group         | Mean in Yes group |
| 20.69565                 | 23.50806 |

Abbreviations
SUS: Brazilian Public Health / Sistema Único de Saúde; CONEP: National Ethics Committee; FDA: Food and Drug Administration; WHO: World Health Organization; CF: Federal Constitution / Constituição Federal; INCa: National Cancer Institute / Instituto Nacional do Câncer; UNACON: High-Complexity Oncology Care Unit / Unidade de Assistência de Alta Complexidade em Oncologia; CACON: High Complexity Oncology Care Center / Centro de Assistência de Alta Complexidade en Oncologia; M.S.: Ministry of Health / Ministério da Saúde; DDT: Diagnostic and Therapeutic Guidelines / Diretrizes Diagnósticas e Terapêuticas; PCDT: Clinical Protocols and Therapeutic Guidelines / Protocolos Clínicos e Diretrizes Terapêuticas; PIB: Gross Domestic Product / Produto Interno Bruto; ANVISA: Brazilian National Health Surveillance Agency / Agência Nacional de Vigilância Sanitária; TJGO: Goias State Court of Justice / Tribunal de Justiça do Estado de Goiás; TRF: Regional Federal Court / Tribunal Regional Federal; CEMAC: Center for High-cost Medications / Centro de Medicamentos de Alto Custo; PROJUDI: Digital Judicial Process / Processo Judicial Digital; PIE: Electronic Judicial Process / Processo Judicial Eletrônico; CEAF: Specialized Pharmaceutical Assistance Component / Componente Especializado da Assistência Farmacêutica; NATIUS: Center for Judicial Technical Support / Núcleo de Apoio Técnico do Judiciário; CEJUSC: Judicial Centers for Conflict Resolution and Citizenship / Centros Judiciários de Solução de Conflitos e Cidadania; CID: International Classification of Diseases / Classificação Internacional de Doenças; CATS: Chamber of Technical Evaluation in Health / Câmara de Avaliação Técnica em Saúde; DP: Public Defender / Defensoria Pública; MP: Public Prosecutor / Ministério Público; DMR: Age related macular degeneration / Degeneração Macular Relacionada à Idade; ACU: Cost-effectiveness analysis / Análise de custo-efetividade; QV: Quality of life / qualidade de vida; QALY: Quality-Adjusted Life Years; SM: National minimum wage (Salário-Mínimo).

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Authors’ contributions
LAS, MAB conceived and designed the research question; LAS, FCR was responsible for collecting research data, JEM analyzed the data, prepared the tables and figure; LAS prepared the data for analysis; and LAS, FCR, RMG, JHSL, NAS, RRP, MAB provided input on data analysis and interpretation of results; EPO and PAML initially revised the manuscript; All authors revised the manuscript critically for important intellectual content and read and approved the final manuscript.

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Availability of data and materials
All data generated or analyzed during this study are available from the corresponding author on reasonable required.

Declarations
Ethics approval and consent to participate
Administrative permission to use the raw data was provided by the State Health Secretariat after the author registered the research for approval by the Research Ethics Committee of the Federal University of Goiás (Protocol No. 4.558.046- CAAE 91238318.7.0000.5083). Access was granted on compliance with the following: that the data were used only by the author and only for the purpose of the registered research or study; the data should be treated as confidential, and no effort should be made to identify any cases granted and finally, the author is required to submit a copy of any reports/publications resulting from the use of the cases granted. The institutional review board waived informed consent because it used secondary data.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.
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