DEMAREST

Oncology in Brazil: From Innovation to Access





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Introduction

Innovation in oncology and the subsequent need to expand patients' access to new technologies have driven significant changes in oncology care in Brazil.

In recent years, regulations, public policies, and mechanisms for funding, technology adoption, and procurement have evolved to address the challenges of oncology care throughout the patient journey, from prevention and diagnosis to treatment and follow-up.

This guide provides a comprehensive overview of the legal, regulatory, and institutional landscape for innovation in oncology in Brazil. It maps key regulatory milestones and initiatives aimed at assessing, funding, and enabling access to new technologies. It also explores the challenges of expanding access to innovation and ensuring the sustainability of both the public and supplementary health systems, as well as the trends shaping the sector's future.



1 Advances in Oncology

Cancer treatment has moved beyond conventional methods such as chemotherapy, radiation therapy, and surgery. New therapeutic and diagnostic approaches to oncology care have expanded the toolkit for preventing, diagnosing, and treating cancer.

CHEMOTHERAPY | RADIATION THERAPY | SURGERY

Targeted Therapies	Medicines designed to target specific molecular or genetic alterations in tumors, enabling more precise and personalized treatment.
Immunotherapies	Therapies that stimulate the immune system to detect and target cancer cells.
Personalized Medicine	An approach that uses a patient's clinical, molecular, and genetic data to inform individualized diagnosis and treatment decisions.
Cell and Gene Therapies (CAR T)	Treatments that use modified cells or genetic material to fight cancer, including CAR T-cell therapies that rely on the patient's own lymphocytes.
Advanced Diagnostics and Biomarkers	Diagnostic methods that identify biomarkers capable of aiding in the detection, characterization, and monitoring of tumors.
Radiopharmaceuticals and Theranostics	Radiopharmaceuticals are medicines that use radioactive substances to diagnose or treat diseases. In oncology, they enable theranostic approaches that integrate diagnosis and treatment to target the tumor.



01 • ADVANCES IN ONCOLOGY

Advances in oncology have enabled increasingly precise diagnoses and personalized treatments, often leading to significant improvements in patient survival and quality of life.

These innovations, however, are generally more complex and costly, as they may require specific testing, specialized facilities, and dedicated logistics. **This creates a paradox: as scientific advances expand therapeutic possibilities, they also increase the challenges of translating innovation into effective access for patients.**

2 The Legal Landscape of Oncology

Brazil's Federal Constitution recognizes access to healthcare as a fundamental right and a duty of the State, to be guaranteed through social and economic policies.[1] In oncology, patient care is governed by specific laws, including:

- Cancer Patient Rights Act[2]
- National Policy for Pediatric Oncology Care[3]
- National Policy for Cancer Prevention and Control (PNPCC)[4]

Law No. 15.385/2026 expanded the concept of cancer-related technologies set out in the PNPCC to include products, equipment, procedures, and other technological solutions used in cancer prevention, early detection, diagnosis, treatment, and monitoring. As a result, the PNPCC now encompasses not only medicines but also other technologies relevant to oncology care, such as vaccines, medical devices, diagnostic tests, and advanced therapy products.

Despite addressing different aspects of cancer care, these regulations share common guidelines aimed at prevention, early diagnosis, access to **comprehensive care** , and the reduction of cancer-related mortality.

1 Article 196 of the Brazilian Federal Constitution.
2 Law No. 14,238/2021.
3 Law No. 14,308/2022.
4 Law No. 14,758/2023 and Decree No. 12,060/2024 – regulated by Ordinance GM/MS No. 6,590/2025.

Comprehensive care for cancer patients



Implementing these guidelines, however, largely depends on the capability of health systems to evaluate, fund, procure, and provide technologies used in oncology care. In this context, the discussion on access to cancer-related technologies has led to initiatives by various branches and levels of government.

WAIT TIMES FOR ONCOLOGY CARE IN THE BRAZILIAN UNIFIED HEALTH SYSTEM (SUS)

30 DAYS

Diagnostic tests for malignant neoplasms

Law No. 13,896/2019

60 DAYS

Start of the first cancer treatment

Law No. 12,732/2012

180 DAYS

Supply of new oncology technology incorporated into SUS

Law No. 14,758/2023

EXECUTIVE BRANCH

Measures to incorporate, procure, and provide access to oncology technologies, including the regulation of the PNPCC and initiatives to organize pharmaceutical care, such as the **Pharmaceutical Care Component in Oncology (AF-Onco)**.

JUDICIAL BRANCH

Judicialization of public and private healthcare before higher courts, notably Federal Supreme Court **Topics 500, 6, and 1234** and **Direct Action for the Declaration of Unconstitutionality No. 7,265**.[5]

LEGISLATIVE BRANCH

Bills aimed at funding innovation, stimulating research, and expanding access to oncology technologies, including initiatives to:

- Establish permanent funding instruments
- Advance scientific research
- Incorporate new technologies into SUS
- Expand access to diagnostic and therapeutic methods

Understanding this landscape is essential for analyzing the mechanisms for technology incorporation, funding, and acquisition discussed next.

5 Federal Supreme Court Topics 500, 6, and 1234 address, respectively, the supply of medicines without ANVISA's marketing authorization, requirements for court-ordered provision of medicines not incorporated into SUS, and rules governing the jurisdiction and funding of these claims. Direct Action for the Declaration of Unconstitutionality No. 7,265, on the other hand, established criteria for covering treatments not included in the ANS's list of mandatory procedures.

3 From Innovation to Access

1 Research and Development
Discovery and development of new technologies through laboratory studies and clinical trials to gather safety, efficacy, and quality evidence.
Research institutions, the pharmaceutical industry, research sites, researchers, and study subjects

2 Marketing authorization
Safety, efficacy, and quality assessment, culminating in the marketing authorization.
Brazilian Health Regulatory Agency (ANVISA)

3 Pricing
Fixing of the maximum sales price for the government and the market.
Pharmaceutical Market Regulation Chamber (CMED)

4A Incorporation into SUS
Evaluation of efficacy, safety, cost-effectiveness, and budgetary impact evidence.
National Committee for the Incorporation of Technologies into SUS (CONITEC)

4B Coverage in Supplementary Health
Evaluation for inclusion in the ANS's List of Mandatory Health Procedures and Events.
National Supplementary Health Agency (ANS)

5 Acquisition and funding
Implementation of mechanisms for acquiring, funding, and distributing technology.
Federal government, states, and municipalities (SUS); health insurance operators, healthcare providers, and other stakeholders in the supplementary health system

6 Patient access
Effective access to the technology within the healthcare system.
Patient

INNOVATION

EVALUATION AND REGULATION

INCORPORATION AND COVERAGE

IMPLEMENTATION

ACCESS

Research and Development

The path from innovation to access begins with the research and development of new technologies. According to the IQVIA Institute's Global Oncology Trends 2025 report,[6] oncology accounted for **41%** of all clinical trials started worldwide in 2024, with **2,162 new studies**. Cancer medicines account for 38% of the global medicine development pipeline.

41%	2,162	38%
of all clinical trials started worldwide in 2024	new studies	of the global medicine development pipeline

Clinical research plays a central role in oncology, given the complexity and heterogeneity of cancer types and the ongoing need to develop more effective, safe, and personalized treatments. The field stands out for its intense research activity and the increasing use of biomarkers, genetic testing, and personalized medicine strategies, which enable the identification of specific patient populations and help guide the assessment of clinical outcomes.

One of the PNPCC's goals is to expand oncology research, which is directly associated with Brazil's first law on research involving human subjects.[7] In this regard, Brazil is engaging more proactively in the global landscape of clinical studies by ensuring:

- ✓ Greater legal certainty for the clinical research environment in Brazil
- ✓ Set timeframes for the ethical and regulatory review of research protocols
- ✓ Reorganization of the CEP/CONEP system[8]
- ✓ Clear rules regarding informed consent, data use, and post-study supply

Studies involving advanced therapy products — cell and gene therapies — are particularly relevant in oncology. Given their specific characteristics, these studies are subject to specific ANVISA regulations, notably regarding subject selection and safety monitoring.[9]

6 Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2025

7 Law No. 14,874/2024.

8 Research Ethics Committees (CEPs) and the National Research Ethics Committee (CONEP).

9 Currently governed by Collegiate Board Resolution No. 506/2021, which must be revised to comply with Law No. 14,874/2024.

Marketing Authorization and Pricing

ANVISA's marketing authorization authorizes the sale of medicines and diagnostic products in Brazil. Approval is contingent upon ANVISA's evaluation of the technical dossier and quality, safety, and efficacy evidence.

In addition to the synthetic medicines traditionally used in cancer treatment, oncology also relies on biologics, advanced therapy medicinal products (ATMPs), radiopharmaceuticals, medical devices and equipment, and diagnostic tests designed to identify tumor biomarkers and support patient selection for personalized therapies.

Each product category is governed by a specific regulation that sets out the marketing authorization requirements:

Category	Main Regulation	Highlights
Synthetic Medicines	Collegiate Board Resolution No. 753/2022	Provides for the general structure of dossiers and the quality, safety, and efficacy requirements to issue marketing authorizations for medicines with synthetic and semisynthetic active ingredients, across the “new,” “innovative,” “generic,” and “similar” categories.
Biological and biosimilar products	Collegiate Board Resolution No. 55/2010	Establishes a specific regulatory framework for biological products and introduces the standalone and comparability development pathways.
Advanced therapy products	Collegiate Board Resolution No. 505/2021	Establishes marketing authorization requirements, using a risk-based approach, as well as post-authorization monitoring requirements for gene and cell therapies. Defines an authorization or prior notification regime for certain individualized products.
Radiopharmaceuticals	Collegiate Board Resolution No. 738/2022	Establishes a specific regulatory framework for radiopharmaceuticals, which are increasingly important in theranostics. It distinguishes between products that require marketing authorization and those that require notification.
Medical devices and equipment	Collegiate Board Resolution No. 751/2022	Establishes the regulatory framework for medical devices, including risk-based classification and differentiated notification or marketing authorization requirements, depending on the product category.
In vitro diagnostics	Collegiate Board Resolution No. 830/2023	Establishes the regulatory framework for in vitro diagnostics, including risk-based classification and specific requirements applicable to diagnostic tests and biomarkers used in personalized medicine.

Mechanisms such as priority review, the use of preliminary data, and regulatory reliance are designed to expedite the evaluation of innovative technologies. In this context, Law No. 15.385/2026 included cancer-related technologies among the priority categories for review, establishing a **120-day deadline for marketing authorization** and a **60-day deadline for post-authorization adjustments**. Both periods start from the filing date.[10]

120 DAYS
for marketing authorization

60 DAYS
for post-authorization changes

Once the marketing authorization has been granted, a medicine must also undergo price approval by CMED before it can be marketed[11]. CMED is responsible for setting the maximum prices applicable to companies that produce, import, and distribute medicines, the maximum retail price, and the mandatory discounts for public entities. The price-setting process takes into account international price benchmarks and the prices of available therapeutic alternatives.

Incorporation into SUS

A marketing authorization allows a technology to be sold, but its availability in Brazil's Unified Health System (SUS) requires additional procedures, such as incorporation, the establishment of clinical protocols and therapeutic guidelines, and the implementation of funding and acquisition mechanisms.

Under the law, technologies incorporated into SUS must be made available to patients within 180 days[12] . In practice, however, several implementation challenges may affect their effective availability.

180 DAYS
to make SUS-incorporated technologies available to patients

Under the PNPCC, the Ministry of Health must ensure that treatments incorporated into SUS are available to patients, regardless of which entity is responsible for their care.[13]

Still, cancer medicines often remain unavailable even after being incorporated into SUS. Delays may arise from coordination challenges among SUS authorities, including within the Tripartite Inter-Agency Commission (CIT), as well as from difficulties in updating clinical protocols and ensuring funding, procurement, distribution, and supply.

10 Article 17-A, paragraph 2, item I, of Law No. 6,360/1976.
11 Pursuant to Law No. 10,742/2003 and CMED Resolution No. 3/2025.
12 Article 25 of Decree No. 7,646/2011 and Article 10 of Law No. 14,758/2023.
13 Article 15, item III, of Ordinance GM/MS No. 6,590/2025.

In this context, through Ordinance GM/MS, the Ministry of Health established the **Pharmaceutical Care Component in Oncology (AF-Onco)**, which aims to develop an access strategy for cancer medicines within SUS.

The following topics examine key aspects of technology incorporation, clinical protocols, and the rules governing access to and funding for oncology care within SUS.

• Health Technology Assessment (CONITEC)

As part of the SUS incorporation process, technologies are assessed by CONITEC for safety, efficacy, cost-effectiveness, and budget impact. This may include medicines, diagnostic and molecular tests, medical devices, and other technologies used in oncology care.

180 + 90 DAYS Final decisions on incorporation rest with the Ministry of Health, and the administrative proceeding must be completed within 180 days, extendable for 90 days.[14]

In oncology, this assessment is increasingly relevant as new and more personalized therapies emerge. The process follows a defined procedure that includes public participation:

SUS'S TECHNOLOGY INCORPORATION PROCEDURE

1. CONITEC's Executive Secretariat receives the application and evaluates the documentation.
2. The secretariat reviews the scientific studies and, if necessary, requests supplementary studies.
3. The secretariat drafts reports on the technology, its indication, alternatives available in SUS and the critical assessment of data.
4. Based on the reports, CONITEC's committees evaluate the material, issue their recommendation and submit it to public consultation.
5. The secretariat organizes the contributions and includes them in the technical report.
6. The committees review the updated report and ratify or rectify the recommendation.
7. The Secretary of Science, Technology, and Innovation in the Ministry of Health receives the report and evaluates the recommendation from the committees.
8. If deemed necessary, the secretary may conduct a **public hearing** and, based on the contributions received, refer the matter back to CONITEC for reassessment.
9. The final decision is published in the Federal Official Gazette of Brazil.

14 Article 19-R of Law No. 8,080/1990.

Clinical Protocols and Therapeutic Guidelines

Making incorporated technologies available within SUS may also require the development or update of Clinical Protocols and Therapeutic Guidelines. These protocols establish criteria for diagnosis, treatment, monitoring, and patient follow-up, and define how incorporated technologies are used within SUS. For example, the Clinical Protocol and Therapeutic Guideline for breast cancer guides treatment decisions based on the biological and molecular characteristics of the tumor.

In oncology, however, the Diagnostic and Therapeutic Guidelines stand out. Unlike the Clinical Protocols and Therapeutic Guidelines, these guidelines specify care for each tumor type and enable authorized services to determine the most appropriate therapeutic strategy for each case, considering the resources and alternatives available within the SUS.

Funding

Within SUS, oncology care funding falls under Medium- and High-Complexity Outpatient and Inpatient Care.[15] Historically, cancer treatments have been funded through general mechanisms applicable to medium- and high-complexity care, with no specific component for cancer medicines.

According to the law establishing the PNPCC, federal funding for oncology care must prioritize additional resources to reduce regional disparities in access. This law also allows states, the Federal District, and municipalities to provide additional reimbursement for procedures or services where availability remains insufficient.

In this context, two funding elements stand out:

MAC

Medium- and High-Complexity Funding Limit (MAC)

It covers medium- and high-complexity outpatient and inpatient care and services through the regular transfer of funds from the National Health Fund to state, district and municipal funds. To date, this component has funded the bulk of oncology care within SUS.

FAEC

Strategic Actions and Compensation Fund (FAEC)

It funds actions and procedures deemed strategic by the Ministry of Health, often including procedures and technologies recently incorporated into SUS during a transition period, until they are eventually contemplated in the regular MAC funding framework.

15 Ministry of Health Consolidation Ordinance No. 6/2017.

In the outpatient setting, oncology care is managed through the Authorization for High-Complexity Procedures, which is used to authorize, log, and reimburse high-complexity procedures. Through this system, facilities accredited to provide high-complexity oncology care (UNACONs and CACONs)[16] log the procedures performed for reimbursement by state or municipal authorities at SUS rates.

Prior to the establishment of AF-Onco, cancer medicines did not fall under a specific component of pharmaceutical care. As a rule, cancer medicines were purchased by oncology facilities using funds transferred by SUS to finance medium- and high-complexity actions and services, in line with the MAC component's reimbursement system.

AF-Onco and the Reorganization of Pharmaceutical Care in Oncology

AF-Onco[17] established a specific pharmaceutical care component in oncology, setting rules for the funding, acquisition, distribution, dispensing, and monitoring of oncology medicines incorporated into SUS, in accordance with the Clinical Protocols and Therapeutic Guidelines, the protocols for use, and the clinical and care guidelines.

The initiative aimed to organize access to oncology medicines and ensure comprehensive treatment in accordance with the National Policy for Cancer Prevention and Control (PNPCC) and the clinical guidelines and protocols adopted by the Ministry of Health.

KEY AF-ONCO PRINCIPLES:

01 Prioritizing technologies

The federal government, states, and municipalities collaborate to establish healthcare priorities based on clinical, scientific, economic, and operational criteria, such as:

- Severity of the disease
- Unmet therapeutic needs
- Expected clinical benefits
- Quality of data
- Cost-effectiveness
- Budgetary impact
- Feasibility of implementation
- Litigation

Contributions by public officials, scientific societies, and patient organizations are considered in addition to alignment with the National Policy for Chronic Disease Care and SUS sustainability.

16 High-Complexity Oncology Care Facility and High-Complexity Oncology Care Center, respectively.

17 Ordinance GM/MS No. 8,477/2025.

02 Medicine acquisition methods

METHOD	HOW IT WORKS	WHAT IT IS FOR
Centralized procurement by the Ministry of Health	The Ministry of Health acquires and supplies medicines to state, district, and municipal health departments that operate authorized services under its oversight, as well as to federal hospitals, such as the National Cancer Institute and the Grupo Hospitalar Conceição. The Ministry of Health conducts the planning, storage and distribution jointly with local administrators.	This approach is intended, among others, for medicines: • that have a single patent holder and a high budgetary impact • linked to Health Economic-Industrial Complex (CEIS) initiatives • eligible for risk-sharing agreements • indicated for highly complex neoplasms or those with a higher prevalence
National negotiation[18]	The Ministry of Health conducts price negotiations at the national level, which are formalized in price registration records that state and local governments may adopt. The state and district secretariats are responsible for acquiring and distributing medicines. Funding is provided through fund-to-fund transfers.	This approach is intended for technologies whose scale of use or demand profile warrants national negotiation—for example, those with high aggregate demand, low individual use by authorized services, or a history of regional shortages.
Decentralized procurement	Oncology services (CACONs and UNACONs) remain responsible for the planning, purchasing, storage, dispensing, and administration of medicines.	It covers medications not included in other categories, including those with established use that have not yet been added to the National List of Essential Medicines (RENAME), provided their costs are covered by the corresponding SUS-funded procedure.

18 Framework established in Joint Ordinance SCTIE/SAES/MS No. 3/2026.

03 Distribution and Dispensing

Establishment of workflows to ensure that medicines reach authorized services and patients, with clear responsibilities for each entity.

04 Exclusive APAC Onco

Created to log and monitor the dispensing and administration of medicines covered by AF-Onco. This model links each treatment to a specific clinical indication recognized by SUS and enables the monitoring and control of the use of incorporated oncology medicines.[19]

05 Compounding facilities

Facilities authorized to handle and prepare cancer medicines. They are intended to serve, on a regional basis, healthcare providers within the oncology care network.

The facilities aim to improve the efficiency of medication use, especially for medicines administered via intravenous infusion, including by optimizing doses and reducing waste.[20]

06 Ultra-high-cost cancer medicines

These medicines are treated according to a specific set of procedures.[21] They can be provided to authorized oncology services through regional compounding facilities.

07 Prior authorization

System that conditions the supply of centrally procured or ultra-high-cost medicines on verification of compliance with Clinical Protocols and Therapeutic Guidelines (PCDTs), use protocols, or Conitec recommendations, carried out by a multidisciplinary team.[22]

08 Monitoring of inventories, costs, and supply

Monitoring mechanisms to predict shortages and track spending.

19 Regulated by Ordinance SAES/MS No. 4,331/2026.

20 Ordinance GM/MS No. 12,085/2026 set out the criteria for registering compounding facilities, as well as the operational, health, and liability requirements applicable to their implementation and operation.

21 List established by Joint Ordinance SCTIE/SAES No. 2/2026.

22 Regulated by Ordinance SAES/MS No. 4,329/2026.

AF-Onco: What changes for those involved in oncology care?

Pharmaceutical industry

increased federal government involvement in the acquisition of medicines covered by AF-Onco, with potential impacts on commercial negotiations, demand planning, and access strategies.

Public administrators

new pharmaceutical care monitoring, traceability, and management mechanisms, along with operational responsibilities and coordination among the state and local governments.

Authorized services (UNACONs and CACONs)

adaptation to new workflows for the recording, dispensing, and monitoring of medicines covered by AF-Onco, including specific control mechanisms, where applicable.

Patients

the implementation of AF-Onco may reorganize access pathways for certain oncology medicines incorporated into SUS.

Incorporation into Supplementary Health

In supplementary health, the ANS's List of Mandatory Health Procedures and Events provides for minimum coverage factoring in the contracted insurance plan and the applicable Guidelines of Use.

In oncology, coverage includes appointments, diagnostic tests, surgeries, treatments, and medicines specified in the ANS's list, including oral antineoplastic medicines for home use, which must be supplied **within ten days of the physician's prescription.**[23]



23 Law No. 9,656/1998.

The Guidelines of Use play an important role in establishing clinical criteria for coverage of technologies, including criteria relating to the line of treatment, biomarkers, disease characteristics, and patient eligibility.

The list is continuously updated with new medicines, tests, procedures, and medical devices. This process can start through proposals to the ANS, internal ANS demands, or incorporation of technologies into SUS following a favorable recommendation from CONITEC. In these cases, the ANS must update the list within 60 days.

In all other cases, the deadline is 180 days, which can be extended by an additional 90 days. A 120-day deadline, extendable by 60 days, applies to oral antineoplastic medicines and radiation therapy procedures. The review considers clinical evidence, safety considerations, economic assessments, and the technology's impact on the sector.

60 DAYS

Incorporation into SUS following a favorable recommendation from CONITEC

180 + 90 DAYS

In all other cases

120 + 60 DAYS

Oral antineoplastic medicines and radiation therapy procedures

In precision oncology, access often relies on combining therapies with diagnostic tests to identify specific biomarkers or molecular variants. Therefore, the coverage analysis should be comprehensive, encompassing medicines, diagnostic tests, molecular tests, procedures, and other technologies necessary to define and monitor the course of treatment.

The incorporation of new technologies also broadens discussions on funding and sustainability in supplementary health, especially in a field marked by rapid therapeutic advances and the growing complexity of cancer treatments.

Litigation

Litigation has become a key pathway for accessing cancer-related technologies in Brazil, especially amid rapid scientific advances and the inherent urgency of cancer treatment. In this context, legal claims often concern unincorporated or unavailable medicines, technologies lacking marketing authorization, and requests for off-label use.

57.5%

INTERFARMA SURVEY

Cancer medicines are among the most frequently litigated technologies in Brazil. According to an Interfarma survey,[24] 57.5% of legal claims in this sector concern medicines that have already been incorporated into SUS, or whose incorporation has been recommended, but are not yet available to patients.

The complexity of these lawsuits led the Brazilian Federal Supreme Court to establish key parameters:

TOPIC

500

Topic 500: addressed the supply of medicines that lack ANVISA's marketing authorization.

TOPIC

6

Topic 6: established criteria for the supply of medicines that have a marketing authorization but have not been incorporated into SUS.

TOPIC

1234

Topic 1234: established rules on the jurisdiction and allocation of responsibilities among state and local governments in claims concerning technologies not incorporated into SUS.

The implementation of AF-Onco began to align directly with this judicial governance framework. New rules for the acquisition, distribution, and funding of oncology medicines incorporated into SUS were taken into account in the interfederative agreement approved by the Federal Supreme Court under Topic 1234. These affected the responsibilities of the federal government, the states and municipalities for medicine supply and reimbursement methods.

Regarding private health insurance, the Federal Supreme Court upheld the constitutionality of Law No. 14,454/2022,[25] ensuring coverage of treatments not included in the ANS's list of mandatory procedures, provided they meet the cumulative criteria established by the Court.

24 Available at: https://www2.camara.leg.br/atividade-legislativa/comissoes/comissoes-permanentes/cssf/apresentacoes-em-eventos/eventos-2025/02-12-2-025-public-hearing-evidence-based-medicine-in-the-context-of-health-judicialization-in-brazil/association-of-the-pharmaceutical-research-industry-interf-arma/view

25 Ruling on Direct Action for the Declaration of Unconstitutionality No. 7,265.

4 Innovation in Oncology: Access Strategies

The debate on access to innovation in oncology has progressively moved beyond incorporating new technologies to also establishing mechanisms that enable their sustainable use.

Given these challenges, several strategies are under discussion to expand access to therapeutic advances in oncology, with a focus on securing funding, generating data, implementing the necessary infrastructure to use these technologies, and strengthening innovation and production in the healthcare sector.

Funding and incorporation

Enabling the sustainable adoption of new technologies

- Risk sharing
- Confidential pricing
- Value-based agreements
- Payment based on clinical outcomes

Evidence and data

Reducing uncertainty and improving decision-making

- Collecting post-incorporation evidence
- Real-World Data (RWD)
- Real-World Evidence (RWE)

Healthcare infrastructure

Capabilities required to supply and monitor innovative technologies

- Diagnostics and precision medicine
- Data infrastructure and patient records
- Specialized facilities and care networks

Innovation and Development

Strengthening research, production, and the supply of strategic technologies

Instruments of the Health Economic-Industrial Complex

- Productive Development Partnerships
- Local Development and Innovation Program
- Procurement of Strategic Technologies for SUS

Concluding Remarks

Expanding access to innovation in oncology does not depend on any single measure, but rather on coordinating a set of regulatory, economic, and healthcare instruments. As oncology advances toward increasingly personalized and complex treatments, the discourse extends beyond simply making technologies available; it also involves ensuring the conditions required to use them effectively and sustainably.

Cooperation among the industry, healthcare providers, insurers, public administrators, regulators, and other stakeholders in the oncology care ecosystem is essential to **translate innovation into access and, in turn, convert access into better outcomes for patients.**

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