White Paper

FIFARMA Patient W.A.I.T. Indicator & Root Causes 2026 — Latin America

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Overview of the study

- Improving the availability of innovative medicines in Latin America is a priority for all stakeholders in the healthcare system, especially policymakers, pharmaceutical manufacturers, and patients. Since 2004, the European pharmaceutical industry association (E.F.P.I.A.) has run the Patients W.A.I.T. (Waiting to Access Innovative Therapies) Indicator, enabling stakeholders to measure the availability rate of innovative medicines in 37 European countries. This study has been replicated to understand availability rate in ten Latin American Countries.
- The first EFPIA Patients W.A.I.T. Indicator was developed to understand the "availability" of innovative molecules, by creating a standardized method of comparing access to innovative medicines across distinct healthcare systems, and across years. FIFARMA (Federación Latinoamericana de la Industria Farmacéutica) developed indicators in a similar vein in Colombia (2016), Chile (2018) and Peru (2019), eventually leading to the first official LATAM W.A.I.T. Indicator study conducted in 2022.
- This year's FIFARMA Patient W.A.I.T. survey marks the fifth regional edition and measures the level of availability to innovation across ten Latin American countries, covering >80% of the LATAM population. These countries are: Argentina (AR), Brazil (BR), Chile (CL), Colombia (CO), Costa Rica (CR), Dominican Republic (DO), Ecuador (EC), Mexico (MX), Panama (PA), and Peru (PE).
- The following pages feature analyses that benchmark the rate of availability and accessibility of innovative medicines in each of the ten LATAM countries, including analysis on regional availability, and how it has evolved over the period of investigation. This year's study includes 447 innovative molecules globally approved* from 2014-2025, which represent >80% of the globally approved NAS** in this period. These molecules span treatments across five therapeutic areas (TA): oncology, inflammation and immunology, central nervous system, cardiometabolic, and transversally, orphan drugs.
- Local pharmaceutical member associations (eight in total, see appendix for more details of the methodology and associations participating) worked in partnership with FIFARMA and IQVIA to develop the W.A.I.T Indicator study, chiefly in ensuring local market nuance is captured within parameters for the study, as well as local/regional directors of market access from manufacturer organizations who provided and validated the relevant aspects of the dataset.
- Ultimately, the goal of this reoccurring study is to create a lens into what access looks like across LATAM, with a specific eye towards understanding if, why, and in what direction the needle has moved in recent years. The learnings that are outlined are intended to serve as a catalyst for meaningful discussions across stakeholders to improve access to innovative medicines.

*'**Availability**' is used throughout to permit **standardized measurement** across 10 healthcare systems; **availability** represents the local reimbursement of a globally approved innovative medicine*

*Global approval is defined as a molecule that has regulatory approval in the United States of America by the FDA, or in Europe by the EMA
**NAS refers to New Active Substances as defined by the IQVIA Institute, see appendix for definitions and selection criteria
Acronyms: FDA: US Food & Drugs Administration; EMA: European Medical Agency

Additional scope and validation

- Access to innovative medicines across LATAM remains highly uneven, with notable disparities between countries and between public and private healthcare sectors. To further understand these disparities, this year's report includes a Root Causes section that adds quantitative and qualitative insight into the structural drivers of access delays and barriers. It focuses on the tension between innovation development and the healthcare systems and processes that govern access at the country level, as well as broad regional trends.
- Key areas explored include:
  - High-level disease burden, innovation, and novel medicine development trends
  - Structural features of healthcare systems that influence access
  - A deeper view into how these dynamics translate into access outcomes and the challenges faced along the route to access
  - Series of core principles to support constructive, multi-stakeholder dialogue and initial ideas to explore and build upon
- Together, the WAIT Indicator and its Root Causes section aim to support more informed, collaborative, and equitable decision-making across LATAM, ultimately contributing toward the multi-faceted effort to improve patient access to innovative medicines across the region.

The study is undertaken with private/public sector validation through multiple sources:

Added in 2026

"It's an optimistic view still, there are more challenges for real-life access than what we see here."

- ex-Minister of Health

Drug usage and spend analysis

- In addition to evaluating access, the 2026 WAIT report incorporates an analysis of drug usage (units) and spending (USD). Leveraging the FIFARMA WAIT Indicator 2025 alongside IQVIA MIDAS and country-level usage and spending datasets, this analysis quantifies not only availability but also extent of investment at a high level to reflect adoption of innovative therapies across LATAM.
- **Data sources and scope*:** Pharmaceutical spending and utilization data are derived from IQVIA MIDAS, and IQVIA country-level NRC databases, representing standardized estimates of market activity adjusted to support international comparability. Data reflects spend estimates based on list prices and projections, not net spending. It quantifies total market activity (all drugs) versus WAIT-specific activity (403 innovative drugs). The analytic period corresponds to MAT October 2025 (Moving Annual Total), a standardized measure representing cumulative sales or volume observed over the preceding twelve months, ensuring alignment with the WAIT reference window. A constant exchange rate (local currency to USD) methodology is applied for most countries; an exception is made for Argentina, where inflationary pressure and controlled exchange rates required a variable exchange rate methodology.
- **Channel segmentation*:** Usage and spending data are segmented between Retail and Non-Retail distribution channels. In many LATAM countries, Non-Retail channels are predominantly financed by government sources, while Retail channels are largely private and funded through patient out-of-pocket expenditures. This segmentation provides a useful proxy for assessing public-sector involvement and drug funding. In Brazil, only the public Non-Retail channel is considered, removing private payer (HMO) activity. Argentina and Colombia may show less direct correlation between channel and financing due to some public/private funding of Retail channels, but financing source separation is not possible in these cases. Data is also segmented into prescription and Over-the-Counter (OTC) drugs, with OTC defined as products that do not require a prescription and may be dispensed directly to consumers.
- **Normalization and context*:** Macroeconomic and demographic indicators were obtained from the WHO Global Health Expenditure Database (GHED) and the World Bank. These enable normalization of pharmaceutical spending across countries, allowing consistent evaluation of metrics such as drug spending per capita and drug spending as a share of GDP, providing essential economic framing for interpreting access and market behavior.

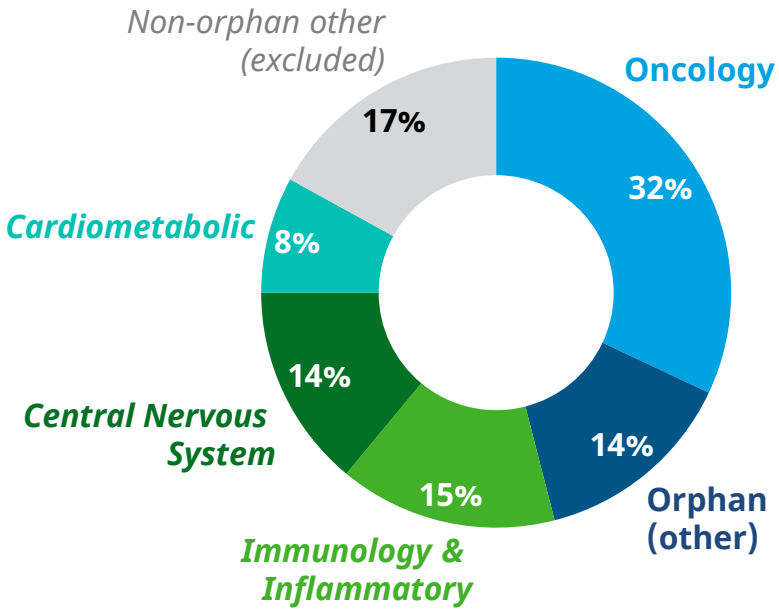
Full scope of the FIFARMA 2026 WAIT report

*See appendix for definitions, exchange rates, and indicators

Methodological considerations

A total of 447 new active substances approved between 2014-2025 by FDA/EMA across five therapeutic areas are analyzed

Molecule selection by therapeutic area 2026



The selection accounts for >80% of new active substance (NAS) in the study period (see appendix for further detail)

- A total of 447 molecules were selected based on several primary criteria:
  - New active substance
  - FDA or EMA approved between 2014-2025 (with no generics/biosimilars available in LATAM)
  - Global launch in the US, EU, UK, JP, so as to reflect molecules that are most likely to reach the global market, excluding agents that are launched predominantly for a given local market (e.g., local Chinese PDL1 inhibitors)
  - Utilization in treatment of disease (i.e., diagnostics, imaging agents, etc. are excluded)

Additional detail is outlined in the appendix

After initial filtering of NAS molecules based on primary criteria, therapeutic areas were selected in conjunction with FIFARMA to optimize the percentage of NAS included in the study, as well as the representativity and comparability of the molecules. Three main criteria were used:

- Percentage of NAS molecules
- Procurement e.g., TAs with percentages of supranational purchases like infectious disease, were excluded
- Global sales as per IQVIA MIDAS data

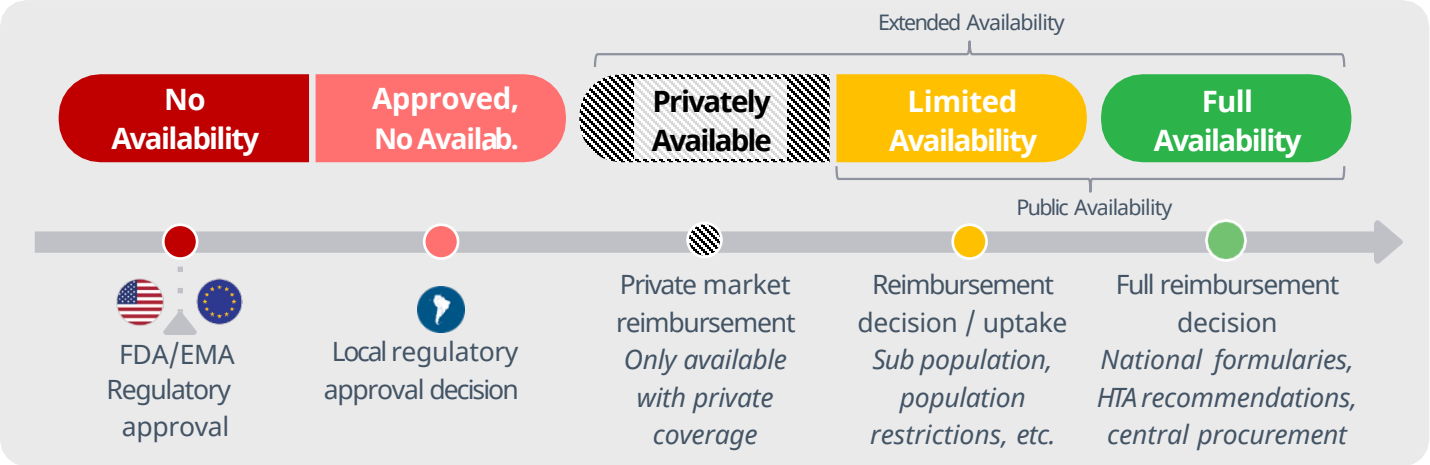
Orphan status may be determined by either the FDA or EMA, as per the first-approved indication

Acronyms: JP: Japan; US: United States; EU: European Union; UK: United Kingdom; PDL1: programmed death-ligand 1; FDA: US Food & Drug Administration; EMA: European Medical Agency; NAS: New Active Substance; Therapeutic Area;

Methodological considerations

Results from the study are shown in terms of different levels of availability and compared across countries

Availability definitions



NO AVAILABILITY

Not submitted, or in regulatory evaluation process

Marketing authorization is not granted either because it is in process of regulatory review, or not submitted for local approval

APPROVED, NOT AVAILABLE

Commercially available, but not reimbursed

Molecules that have obtained regulatory approval but are not available through either private or public healthcare; patients typically pay fully out-of-pocket, importations or compassionate use

PRIVATELY AVAILABLE

Reimbursed in the private market only

Medicines available only in the private market but not the public sector, generally limiting the overall patient population that has access

LIMITED AVAILABILITY

Reimbursement but not for a broad population, or uptake

The molecule is available to some extent in the public sector, but not to the broad population either because of discrepancies sub-nationally, or it is limited to specific patient sub-populations, limited number of treatment centers, or has significant volume of legal injunctions / administrative processes that result in a meaningful level of uptake

FULL AVAILABILITY

Broad, national reimbursement

Medicines are fully available at national level for a broad population in both the public and private sectors; full availability is frequently tied to national formulary listing, positive HTA recommendations, and/or central procurement

Extended Availability

Availability in either public or private sector; in a bottoms-up access paradigm, is indicative of the system reach and potential but not broad access

Public availability

Availability either via limited or full availability; indicative of the level of access to the broader national population, and where governments are investing

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; SoC: Standard of care

Methodological considerations

Each geography in scope has a local definition of availability such that, to the extent possible, results can be compared regionally

		AR	BR	CL	CO	CR	DO	EC	MX	PA	PE
Availability Definition	Full	PAMI/ SURGE or PAMI / PMO	CONITEC and centralized purchases	Ley Ricarte Soto or GES	PBS-UPC	CCSS (LOM)	PBS-SISALRIL	Essential list e.g., MSP, IESS	Compend-ium, and federal inst. purchases	CSS and ION (LOM)	PNUME, and RENETSA/ RM purchases
	Limited	1+ country formulary and broad coverage by OSN / prepaid	CONITEC, no centralized purchasing	Limited FONASA reimb-ursement, special programs	ADRES / MIPRES	Special purchases	DAMAC LOM	Typically exception processes	De-centralized form-ularies	Special Purchases	Typically exception processes
	Private	Broad prepaid coverage	ANS ROL placement	CAEC, ISAPREs	n/a	Prepaid plans	Prepaid plans	n/a	Large private form-ularies	Prepaid plans	n/a
Data	Public	ANMAT, SURGE Drug Banks	CONITEC, ANVISA, ANS ROL	ISPCH, MOH public data, tenders	INVIMA, MinSalud circulars	MOH, CCSS	SISALRIL, PDSS, DAMAC	MSP, IESS	COFEPRIS, Compend-ium, INEFAM, tenders	MOH, CSS, ION	DIGEMID, PNUME, IETSI, INEN
Caveats		Data coverage for sub-national plans not compre-hensive	Limited availability definition adjusted to reflect stricter criteria	Private coverage data is highly limited	n/a	Public data limited, relies on IQVIA expertise and laboratory part-icipation	Public data limited, relies on IQVIA expertise and laboratory part-icipation	n/a	n/a	Public data limited, relies on IQVIA expertise and laboratory part-icipation	n/a

Definitions were aligned on and refined by the working group of local trade association representatives, IQVIA local consulting teams, and FIFARMA; full availability definitions can be found in the appendix

Where not otherwise stated, date of sustained sales (after 3mos with country-specific thresholds) was used to indicate time to reimbursement
Acronyms: PAMI: Programa de Asistencia Médica Integral; SURGE: Sistema Único de Reintegros por Gestión de Enfermedades; PMO: Programa Médico Obligatorio; OSN: Obras Sanitarias de la Nación; ANMAT: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica; ANS ROL: Agencia Nacional de Saúde list of procedures of mandatory reimbursement; CONITEC: National Committee for Technology Incorporation; ANVISA: Agencia Nacional de Vigilancia Sanitaria; GES: Garantías explícitas en Salud; FONASA: Fondo Nacional de Salud; ISPCH: Instituto de Salud Pública de Chile; CAEC: Cobertura Adicional para Enfermedades Catastróficas; ISAPREs: Instituciones de Salud Previsional; PBS-UPC:Plan De Beneficios En Salud Con Cargo A La UPC; ADRES: Administradora de los Recursos del Sistema General de Seguridad Social en Salud; INVIMA: Instituto Nacional de Vigilancia de Medicamentos y Alimentos; CCSS: Caja Costarricense De Seguro Social; MOH:Ministry of Health; PBS-SISALRIL: Plan Básico de Salud - Superintendencia de Salud y Riesgos Laborales; PDSS: Plan de Servicios de Salud; DAMAC: Dirección de Acceso a Medicamentos de Alto Costo; MSP:Ministerio de Salud Pública; IESS:Instituto Ecuatoriano De Seguridad Social; COFEPRIS: Comisión Federal para la Protección contra Riesgos Sanitarios; INEFAM: Instituto Farmacéutico de México; CSS: Caja de Seguro Social; ION: Instituto Oncológico de Panamá; LOM: Lista Oficial de Medicamentos; PNUME: Petitorio Nacional Único de Medicamentos Esenciales; RENETSA:Red Nacional de Evaluación de Tecnologías Sanitarias; ANVISA: Agencia Nacional de Vigilancia Sanitaria; MOH:Ministry of Health; IETSI:Instituto de Evaluación de Tecnologías en Salud e Investigación; INEN: Instituto Nacional de Enfermedades Neoplásicas

Methodological considerations

The study focuses on four key metrics that provide a panorama of availability of innovative medicines to patients in LATAM

Metric	Research Question	Content
1 Availability Status	***What is the availability of innovative medicines across LATAM?***	Breakdown of availability across the region, by country and by therapeutic area
2 Time to Availability	***How long does it take for innovative medicines to become available?***	Time from global regulatory approval to local approval, and local availability
3 Availability Over Time	***What is the maturity of innovative medicines available?***	Evolution of availability status by year of global approval
4 Improvement Index	***At what rate does availability for innovative medicines improve?***	Comparison of availability status of molecules from 2025 W.A.I.T. to 2026 W.A.I.T.

Important considerations

1. The study results reflect a snapshot of the **current availability of innovative medicines in LATAM** as of April 2026, and aims to increasingly shed light on its evolution over the years

2. The five therapeutic areas selected allow for an ample view of innovative medicines **with >80% of global, new active substance approvals (NAS)*** captured, and >80% of Latin America's population across ten countries

3. The study considers the **first locally approved indication** for analysis at the molecule level as the most consistent comparison subsequent indications are not captured due to inconsistent availability of data (public or otherwise)

4. **Comparability by countries to the extent possible** is ensured through rigorous validation across a wide group of local and regional experts, and further detail can be found in accompanying country-level reports

*NAS refers to New Active Substances as defined by the IQVIA Institute, see appendix for definitions and selection criteria

Summary of key W.A.I.T. metrics

Time to Availability

Represents the length of time from both global and local market authorization until full, limited, or private availability is reached

- Total time to availability is on average 68 months between the countries in scope, which reflects the total of time to marketing authorization and time to reimbursement (full or limited), as of FDA/EMA approval
- Time to availability, post-marketing authorization, is 32 months on average between the countries in scope
- As with regional availability, wide disparities also exist between countries in terms of time to availability, with AR on the low end at an average of 63 months, and PA on the high end, with an average of 91 months
- Comparing across TAs, orphan and CNS drugs are typically the fastest to reach availability after local marketing authorization, although there is variability by country

Patients on average have been waiting over 5.7 years to get access to an innovative medicine in LATAM; meanwhile they may have no means of obtaining it in their country, or face significant out of pocket costs

Availability Status

Represents the degree of availability of an innovative medicine in a given country according to regional definitions

- 60% of molecules that are globally approved are approved in at least one of the geographies in scope in LATAM, though wide disparities exist between countries
- 34% of molecules have a degree of availability in the public market in at least one market, whilst a further 27% are only available with private coverage

Availability Over Time

Pinpoints the degree of current availability according to global market authorization year to estimate the maturity of available molecules

- <50% of molecules from 2018 onwards have public availability in at least one country
- <50% of molecules from 2021 onwards are approved, driven by BR and AR

Improvement Index

Outlines the extent that molecules have changed availability status from year to year between reports

- From 2025 to 2026, 89% of molecules did not change in availability status
- 7% of molecules improved availability status

Acronyms: AR: Argentina; PA: Panama; BR: Brazil; LATAM: Latin America; TA: Therapeutic Area; CNS: Central Nervous System1; FDA: US Food & Drug Administration; EMA: European Medical Agency

Summary of Root Causes and Opportunity

Innovation is outpacing system capacity, driving saturation and delays

The volume and complexity of globally approved innovative medicines have both been rising over the past decade, compounding challenges for regulatory and HTA agencies across Latin America that lack proportional capacity gains. As a result, approval timelines have lengthened, backlogs have grown, and the gap between global and regional access has widened, particularly over the last 5 years.

Low investment constrains institutions, fragments processes, and reduces competitiveness

Chronic underinvestment in healthcare—averaging well below WHO and OECD benchmarks—limits institutional capacity, erodes transparency and coordination, and signals operational risk to innovators. These structural deficits compound access delays, reduce equity, and undermine the region's ability to attract pharmaceutical investment or deliver sustainable access to innovation.

Access improves when clinical value and system readiness are mutually reinforcing

Approval and recommendation do not guarantee access; progress occurs when local evidence, diagnostic infrastructure, delivery capacity, and budget-impact mechanisms align to ensure real-world access. Where these elements converge, supported by early engagement and strategic sequencing, access becomes more predictable, scalable, and equitable, unlocking investment opportunities.

Emerging opportunities signal potential for strategic repositioning

Rising pharmaceutical spending, growing use of innovative therapies, geopolitical realignment, and advances in AI create openings for Latin America to strengthen its role in the global pharmaceutical ecosystem. If systems invest in capacity, governance, and regional collaboration, these shifts can translate into improved access, greater investment, and enhanced system readiness for future innovation.

Sustained progress requires collaboration, integration, and forward planning

Achieving sustainable access demands concerted action across three pillars: collaboration (among countries, sectors, and institutions); integration of emerging technologies to improve efficiency and transparency; and disciplined planning to reduce saturation, prioritize high-impact therapies, and optimize long-term system potential. Only through coordinated, multi-stakeholder effort can Latin America move from fragmented, reactive access to proactive, equitable delivery of innovation.

LATAM's access gap is not driven by lack of innovation, but by misalignment between accelerating innovation and constrained system readiness; yet current investment momentum and structural shifts create a clear opportunity to change course

Acronyms: HTA: Health Technology Assessment; OECD: Organization for Economic Co-operation and Development; WHO: World Health Organization

Key takeaways

Innovation is accelerating as disease burden evolves

Disease burden in LATAM is significant and changing; driving innovation toward more targeted and high-impact therapies to address these challenges

Access challenges are intensifying as innovation grows

Access is a key challenge, with difficulties that worsen year after year; reliance on fragmented, bottom-up pathways is increasingly inadequate

Structural underinvestment amplifies access inefficiencies

Low spending on healthcare and innovative medicines constrains capacity and creates inefficiencies, compounding delays and misalignment across the access pathway

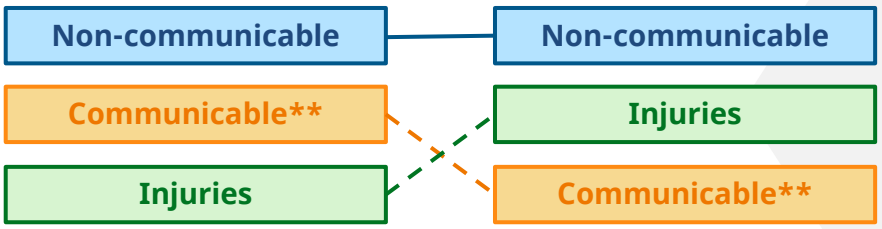
A window for transformation is emerging

Amidst global shifts and the rise of AI, a significant opportunity exists today to stimulate the pharmaceutical sector for growth and impact

Non-communicable diseases drive LATAM's health burden

The epidemiological transition toward chronic conditions creates rising demand for innovative medicines and sustainable access pathways

Evolution of Disease Burden in Latin America - DALYs per 100,000



Diseases with the Highest Burden of Morbidity Classified by Level 2, 2023, excl. injuries

1	Cardiovascular disease
2	Neoplasms
3	Diabetes and chronic kidney disease
4	Musculoskeletal disorders
5	Respiratory infections and tuberculosis
6	Mental disorders
7	Other non-communicable diseases
8	Neurological disorders
9	Digestive disorders
12/13	Maternal and neonatal

- Non-communicable diseases (NCDs) now account for approximately two-thirds of global mortality and morbidity, with cardiovascular disease, neoplasms, and diabetes leading the burden.
- This shift has critical implications for healthcare systems and pharmaceutical needs. Unlike acute infectious diseases, NCDs are chronic in nature, requiring long-term management, often with multiple therapies over extended periods.
- Many of the most significant advances in NCD treatments have come from innovative medicines (e.g., targeted oncology therapies, novel immunomodulators for inflammatory diseases, advanced treatments for metabolic and cardiovascular conditions) that address unmet needs and improve survival, function, and quality of life; key drivers of productivity.
- As NCD burden rises, so does the demand for access to both new and existing treatments. The therapeutic areas prioritized in this report are those most aligned with the region's disease profile.
- However, the growing need for innovative therapies comes at a time when healthcare budgets face competing pressures, regulatory and HTA systems manage increasing submission volumes, and access pathways remain fragmented. The alignment between disease burden and pharmaceutical innovation underscores the urgency of understanding where and why access gaps persist.

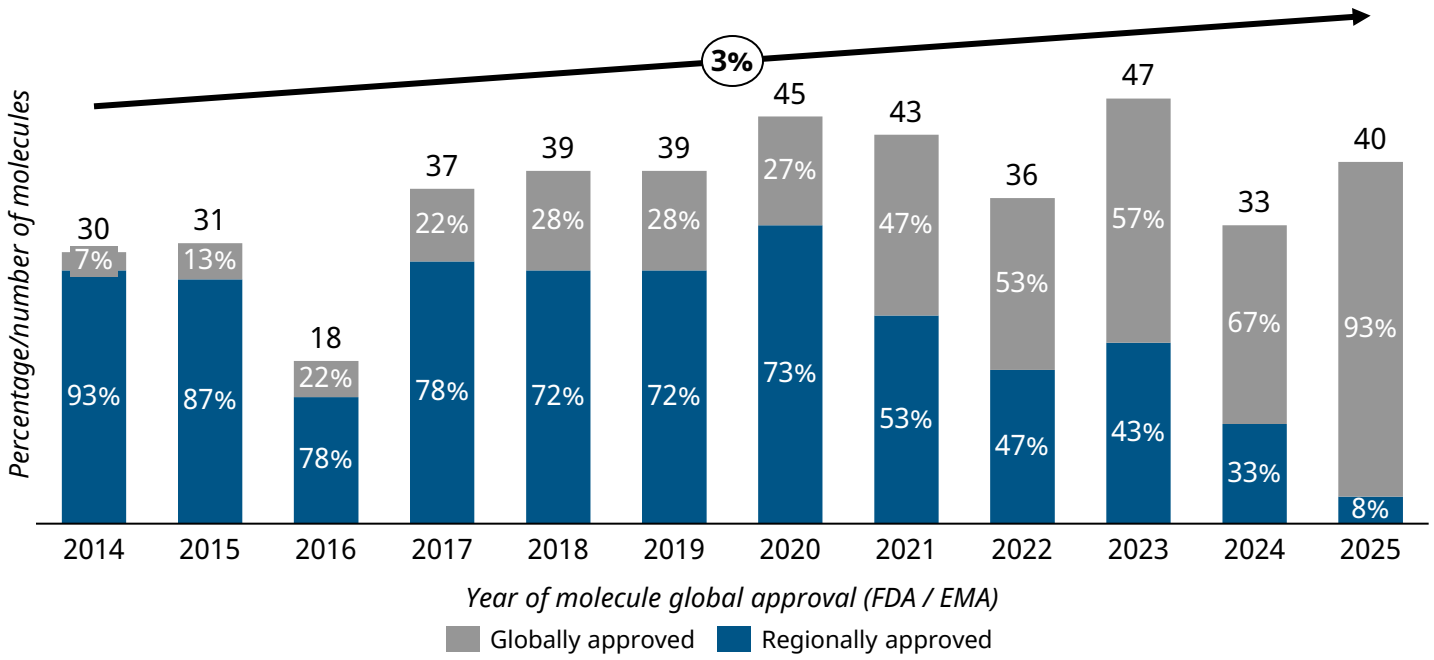
LATAM's disease profile justifies the focus on innovative medicines for NCDs, while the rising burden underscores the importance of timely access to novel therapies

Acronyms: DALYs: disability-adjusted life year; NCD: non-communicable diseases; HTA: Health Technology Assessment
Sources: Institute for Health Metrics and Evaluation

In response, pharma innovation is increasing and evolving

There has been a 3% YoY increase in medicines globally approved, though after 2020 there is a drop in the number approved for LATAM patients

Global vs. Regional Approved Therapies (2014 - 2025) – Combined



- Overall, globally approved molecules have been increasing, despite significant dips in approvals in 2024 and 2025
- From 2014-2019, the rate of initial regional approval is >70%, showing that given enough time, molecules are generally approved in at least one country in the region
- From 2019 to 2021, it drops from 72% to 53%, and then drops more quickly to 33% in 2024, and 8% in 2025
- Over the past decade, the number of novel medicines successfully completing pivotal trials and entering the global pipeline has continued to grow. However, before reaching patients, these therapies must navigate local regulatory systems, where the first major bottlenecks emerge in LATAM
- While global approvals have risen steadily, regional approvals remained flat until 2020 and then declined sharply. This divergence reflects broader delays in regulatory timelines and highlights growing difficulty for local agencies to keep pace with innovation, particularly after the pandemic, when resource constraints and operational disruptions further slowed progress.

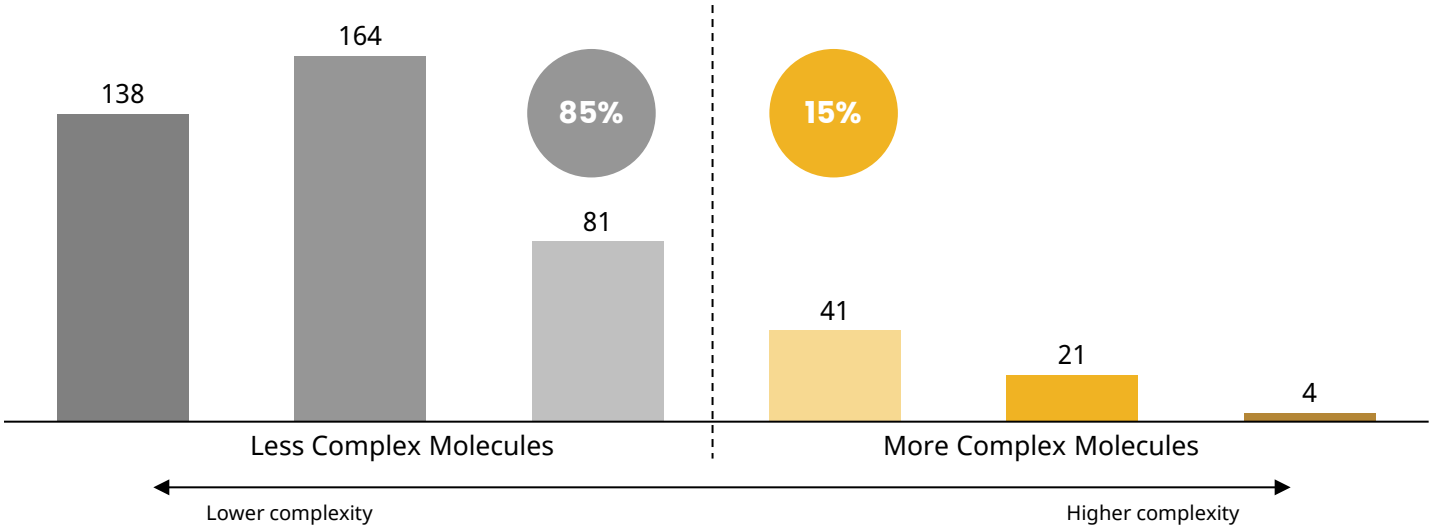
Regulatory agencies face increasing submission volumes, creating saturation and reducing efficiency; with increasing innovation and delays, comes the threat of compounding upon an existing backlog

Acronyms: YoY: Year over Year; FDA: US Food & Drug Administration; EMA: European Medical Agency; SoC: Standard of care

Complexity introduces additional considerations for systems

Differences in therapeutic design, evidence needs, and delivery requirements place varying technical and operational demands on regulators, payers, and providers

Complexity of Globally Approved Molecules – WAIT Dataset



- The complexity levels shown reflect a set of factors that place additional strain on health systems and require capabilities or expertise beyond standard regulatory, HTA, and implementation processes.
    - Biologic or next generation therapies (e.g., nucleotide, RNAi, gene, cell, tissue, immunotherapy): Require specialized manufacturing, handling, and regulatory expertise beyond small-molecule drugs
    - Innovative / first-in-class therapies: Novel mechanisms may lack precedent, requiring deeper reviews and raising uncertainty around long-term safety and real-world efficacy
    - Precision medicine (i.e., diagnostic required): Companion diagnostics require parallel validation and infrastructure deployment before therapies can be administered effectively
    - Orphan population: Often target smaller populations, making large-scale trials difficult and limiting the availability of robust comparators
    - Route of administration: Complex routes (e.g., infusion, intrathecal, one-time delivery) demand specialized infrastructure, trained staff, and coordinated care pathways
- From a system-facing perspective, complexity magnifies capacity constraints. From a technical perspective, complex molecules pose greater challenges in evidence generation and interpretation.
- Limited expertise in novel modalities, HTA frameworks ill-suited to uncertainty and long-term value, and uneven readiness of delivery infrastructure all slow decisions, while high unit costs drive conservative responses.

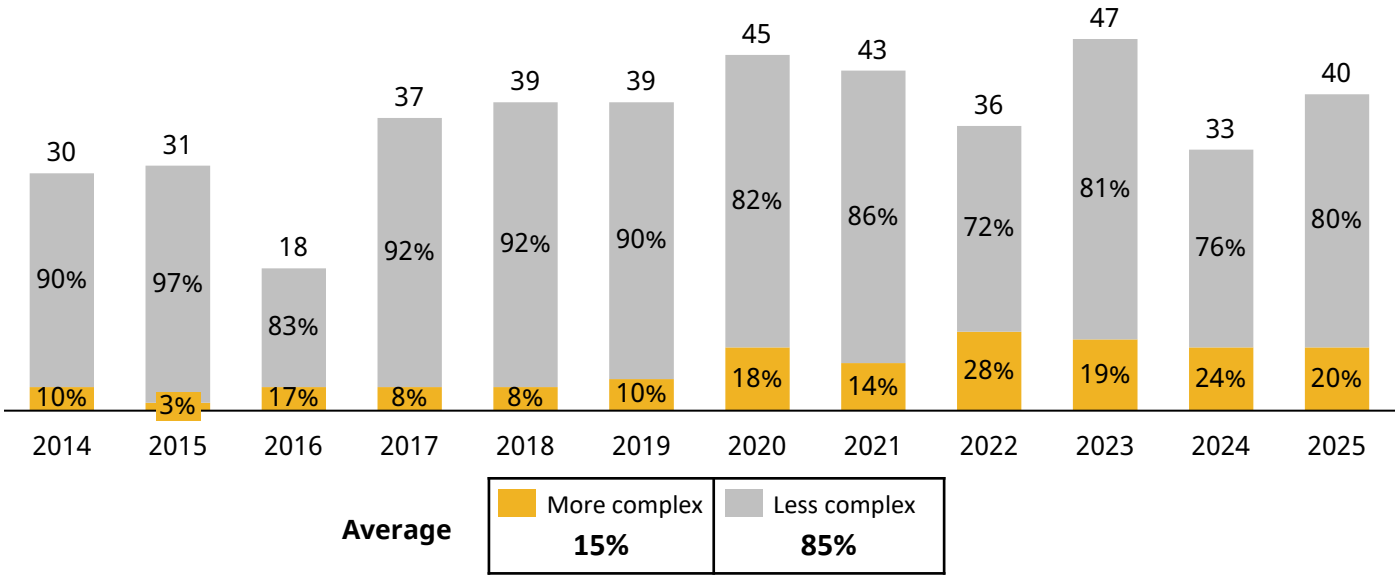
Innovation often introduces technical challenges during evaluation and creates downstream system constraints for regulators, payers, and providers in resource-limited settings

Acronyms: HTA: Health Technology Assessment

Innovation is also becoming more complex

The share of complex therapies among global approvals has doubled since 2014, creating evidence and assessment challenges for regulatory and payer systems

Complexity of Global Approvals - WAIT Dataset



- Among globally approved molecules in this study, the proportion of complex molecules has risen from 10% in 2014 to 20% in 2025. This increase reflects growing reliance on precision medicine, orphan disease therapies, novel mechanisms of action, and advanced modalities (e.g., gene and cell therapies)
- While these innovations address persisting unmet needs and offer transformative benefits, they also introduce challenges across the access pathway
- Complex therapies often face inherent difficulties in evidence generation, related to demonstrating efficacy and safety in sufficient patients, over sufficient timeframes, and versus a relevant clinical comparator. Thus, creating additional operational and technical challenges for regulators and payers
- This can increase uncertainty around real-world efficacy, long-term safety, and budget impact, creating tension between the desire to provide early access and the need for robust evidence to inform reimbursement decisions
- For regulators and payers in LATAM, rising complexity compounds existing operational and technical challenges. Regulatory agencies may lack specialized expertise to evaluate novel modalities or interpret endpoints and accelerated approval pathways. Systems often rely on traditional frameworks, which may not adequately address uncertainty, value over time, or broader societal benefits
- As complexity increases without matching capacity-building, timelines risk lengthening, and access decisions may become more conservative or inconsistent across systems. Each additional point on the scale, to some extent, reflects an additional layer of uncertainty to contend with

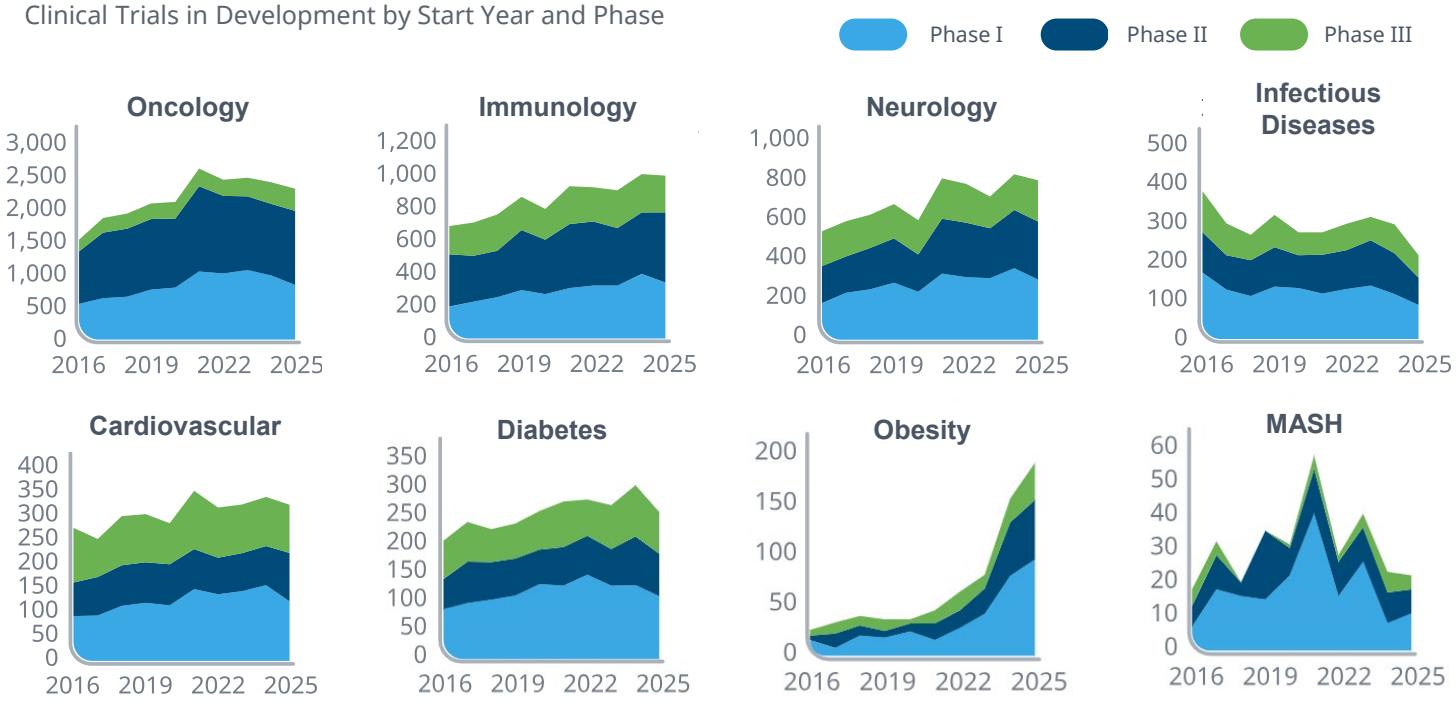
Rising therapeutic complexity requires evolution of regulatory and HTA frameworks in LATAM as well as renewed focus on technical capacity; without adaptation, complexity becomes an additional barrier

Acronyms: HTA: Health Technology Assessment

A robust global pipeline signals sustained innovation and mounting system pressure

This continued innovation creates opportunity, but only if access bottlenecks are eased

Clinical Trials in Development by Start Year and Phase



- The global pharmaceutical pipeline remains strong, with a sustained flow of new treatments expected in the short and long term. Ongoing clinical trial activity suggests that the number of innovative medicines reaching regulatory review will continue to grow rather than level off.
- Advances in biologics, precision medicine, gene-based therapies, and novel small molecules are expanding treatment options across a wide range of chronic and complex diseases
- Pipeline concentration closely aligns with LATAM's disease burden. These areas reflect global priorities in addressing cancer, cardiovascular disease, diabetes, obesity, and related metabolic conditions, many of which require long-term treatment and sustained system engagement.
- While this innovation momentum represents progress for patients, the increasing volume of molecules, often with novel mechanisms and higher uncertainty, will further strain already saturated health systems. As more therapies seek regulatory approval, pricing, reimbursement, and delivery within existing capacity constraints, access challenges are expected to intensify, particularly in systems with limited sources, fragmented pathways, and budgetary pressures.
- The continued expansion of the pipeline underscores the importance of ensuring that access frameworks evolve alongside innovation

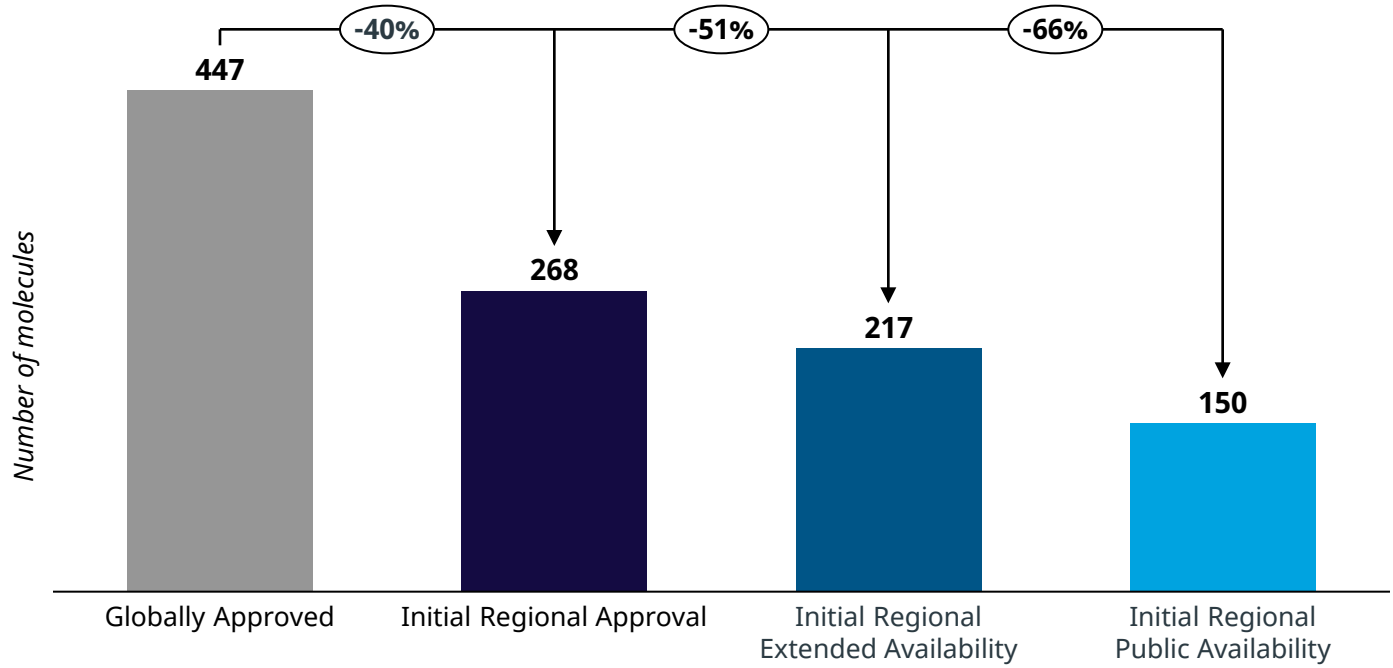
A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed

Acronyms: MASH: Metabolic dysfunction-associated steatohepatitis
Sources: IQVIA – Global R&D Trends 2026

There are significant barriers to accessing innovation

Regional availability is broken down into subtypes, with <50% of molecules included in the study available in at least one country regionally

Breakdown of Initial Regional Availability (2014 - 2025) — Combined



- Initial regional approval and availability represents where a molecule is approved or is available in at least one country in the region
- Overall, there is a large gap between globally approved molecules and those that become available in the region in even just one country, reflecting review backlogs, HTA and pricing delays, and challenges in translating global approvals into local access
- Out of 447 molecules, 60% of these are approved for commercialization in at least one of the ten LATAM countries in scope
- 49% have extended availability, meaning these molecules have some level of availability between public (full or limited) and/or private markets in at least one country, often affected by timing of HTA decisions, pricing negotiations and reimbursements
- 34% of globally approved molecules are available publicly, whether that be limited or full availability, in at least one country in the region
- Drivers of lower rates of approval and availability include: regulatory backlogs and lengthy submission and review processes, HTA assessment timelines and pricing negotiations delaying extended availability, funding constraints and procurement processes limiting public-sector availability

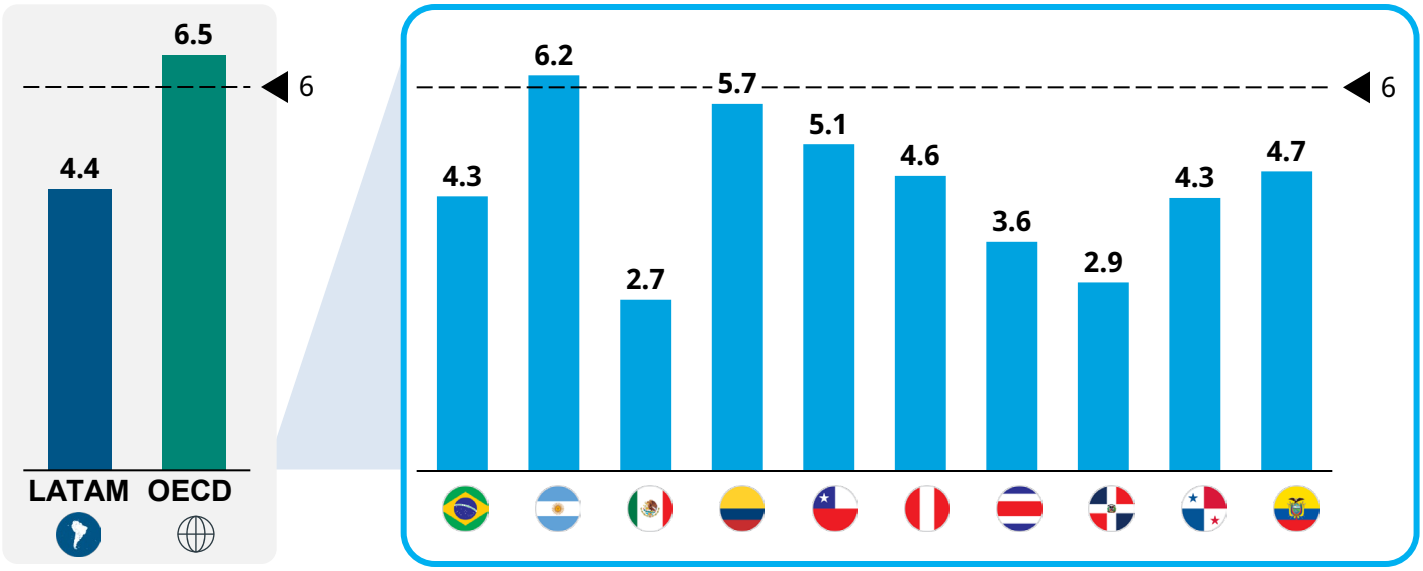
Patients across LATAM have access to almost half of the globally available innovative medicines in the private sector, that trend is worsened when looking at the public sector where the majority of patients are covered

Acronyms: HTA: Health Technology Assessment

LATAM’s health spending is below the OECD target

Public spending on health as a proportion of GDP remains below 6%—the benchmark recommended by the WHO—as well as below the average for OECD countries

Average Public Spending on Health (% of GDP)



- Public spending on health across LATAM remains materially below international benchmarks. WHO recommends that countries allocate at least 6% of GDP to health to ensure universal health coverage and adequate service delivery, while the OECD average stands at approximately 6.5%
- Most LATAM countries fall short of these thresholds, with some operating on budgets closer to 4–5% of GDP. Even among higher-income countries in the region, health spending as a share of GDP often lags behind global peers with comparable economic development
- This underinvestment has profound system-level consequences. Limited budgets constrain the capacity of regulatory/HTA agencies and procurement systems to evaluate and incorporate innovative medicines in a timely manner.
- Chronic underfunding also affects workforce availability, infrastructure, and the ability to maintain robust supply chains and distribution networks. These structural weaknesses slow decision-making, reduce transparency, and create bottlenecks across the access pathway.
- Over time, underinvestment in health is likely to translate into worse health outcomes, avoidable disease progression, and greater downstream healthcare costs

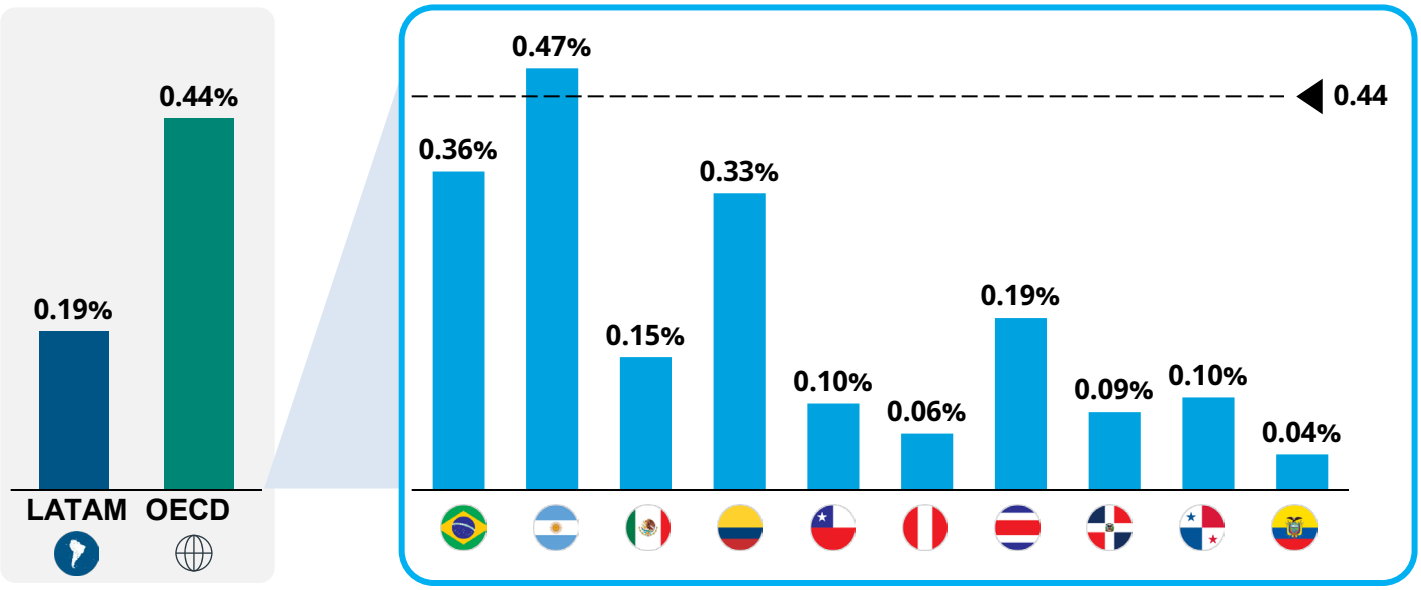
Underinvestment in health limits both system capacity and population reach, creating structural barriers to timely and equitable access

Acronyms: GDP: Gross Domestic Product; WHO: World Health Organization; OECD: Organization for Economic Co-operation Development

There is a similar trend for innovative treatments

Latin America falls even further behind the OECD, highlighting that the most innovative and high-value therapies face additional access barriers in the region

Average Public Spending on Innovative Treatments – WAIT (% of GDP)



- Public expenditure on innovative medicines in LATAM is materially lower than in OECD. On average, countries in the region allocate approximately 0.19% of GDP to innovative treatments, compared to around 0.44% across OECD nations
- This disparity reflects both overall lower health spending and conservative prioritization of budget allocation toward newer, higher-cost therapies. Variation within the region is also pronounced, with some countries investing closer to OECD levels while others dedicate a fraction of that share
- Low spending on innovative medicines directly constrains capacity to incorporate technologies; budget limitations force stricter prioritization, often favoring therapies with higher certainty or lesser budget impact
- Beyond immediate access, this also reflects challenges in aligning financing models with the realities of modern medicine, where value may be delivered upfront or over long-time horizons though with high uncertainty, and where traditional cost-effectiveness frameworks may inadequately capture broader benefits

"Health is not the priority; it is viewed more as a burden or an expense—rather than as it should be: an investment."

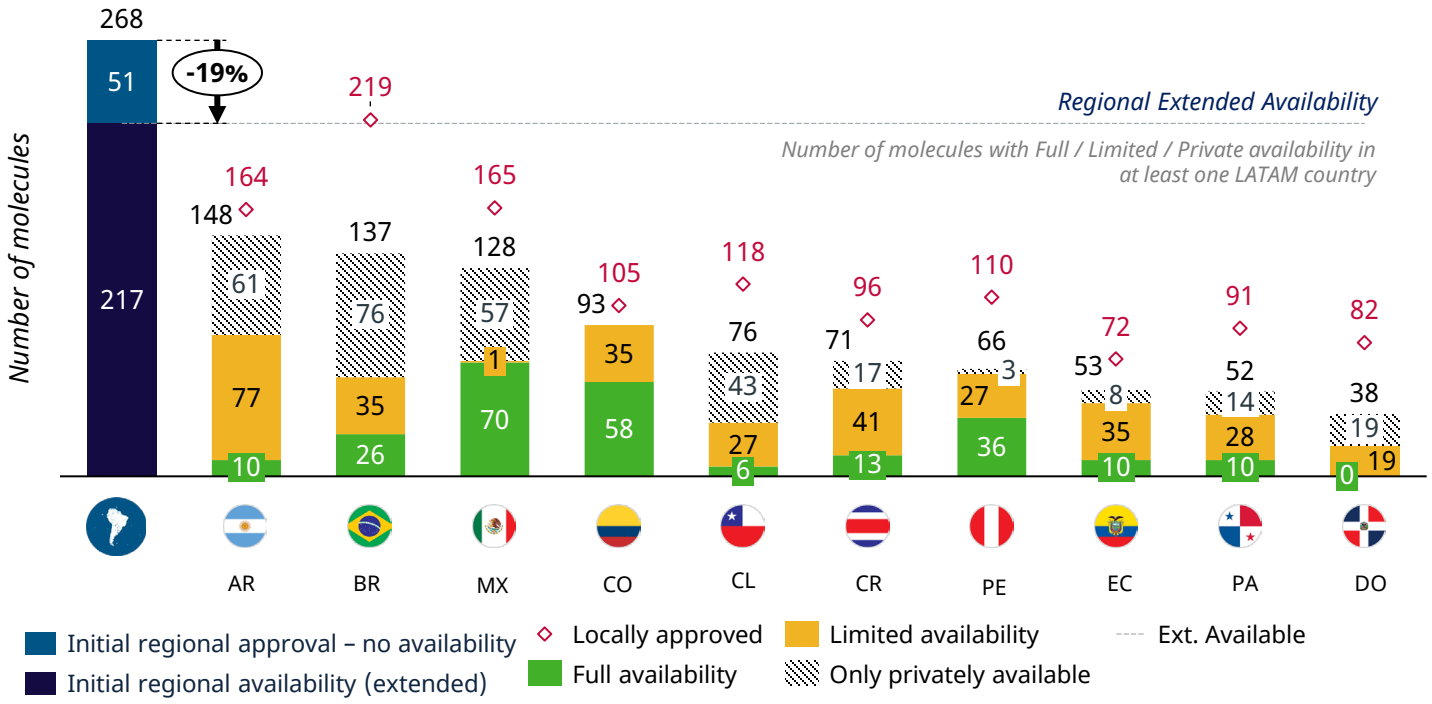
- ex-Minister of Health

Acronyms: OECD: Organization for Economic Co-operation Development

Availability rates vary widely by country

Brazil drives initial regional approval, Colombia has historically been a leader in public availability but Mexico has made strides recently that have resulted in the highest full availability rate

Breakdown of Local Availability (2014 - 2025) — Combined



- There is a gap of 19% between molecules that are approved in at least one country in LATAM, and those that are available
- The trend in approvals vs. availability is not consistent across countries; Brazil, Chile, Dominican Republic and Panama show a more pronounced gap between approvals and availability
- Argentina and Brazil have a disproportionately high contribution from the private sector vs. the public sector, helping bridge the gap between regulatory approvals and availability, but also potentially exacerbating the delay in time to public availability
- Mexico has the highest levels of full availability by a wide margin, followed by Colombia and Peru
- These patterns reflect underlying system characteristics, where high private contribution is typically associated with fragmented systems and limited public budgets, high public availability aligns with centralized structures and more mature processes, and approval–availability gaps point to regulatory capacity being outpaced by HTA and pricing delays driven by process saturation and limited transparency

Patients face different challenges by country: where private coverage is high it affords better access but for a subset of patients, whereas where there is a high rate of public coverage, typically there are fewer molecules available, heightening inequalities

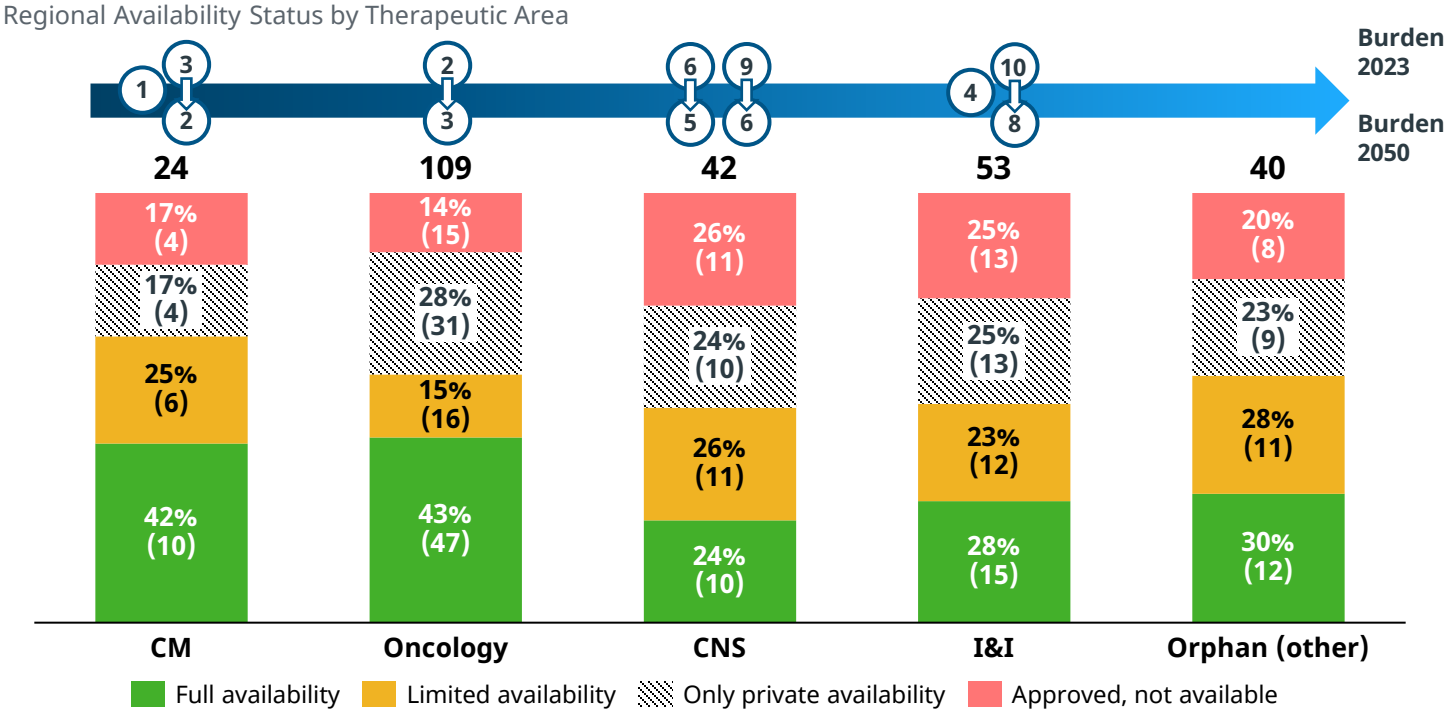
*See appendix for further detail

Acronyms: AR: Argentina; BR: Brazil; MX: Mexico; CO: Colombia; CL: Chile; CR: Costa Rica; PE: Peru; EC: Ecuador; PA: Panama; DO: Dominican Republic; HTA: Health Technology Assessment

Significant differences also exist by therapeutic area

CNS and I&I exhibit lower full availability of approved treatments, while CM and oncology demonstrate broader access, even if a significant portion of oncology access is supported privately

Regional Availability Status by Therapeutic Area



- Access varies materially by therapeutic area, with CM and Oncology showing the broadest access among approved treatments. Oncology has the highest full availability share at 43%, while CM is close behind at 42%, indicating relatively stronger conversion of approvals into access.
- Oncology's stronger access profile is partly offset by a heavy reliance on private access. While Oncology has high full availability, 28% of approved treatments remain only privately available, suggesting that headline access overstates the extent of broad, equitable patient reach.
- CNS and I&I lag in broad access, with lower full availability and a larger share of treatments remaining constrained
- CNS shows only 24% full availability, with the remainder spread across limited availability (26%), only private (24%), and approved but not available (26%); I&I performs somewhat better but still reaches only 28% full availability
- Orphan in the middle: meaningful progress, but broad access remains limited. Full availability reaches 30%, yet 48% of approved treatments are still either limited (28%) or approved but not available (20%), underscoring persistent access friction even after approval.

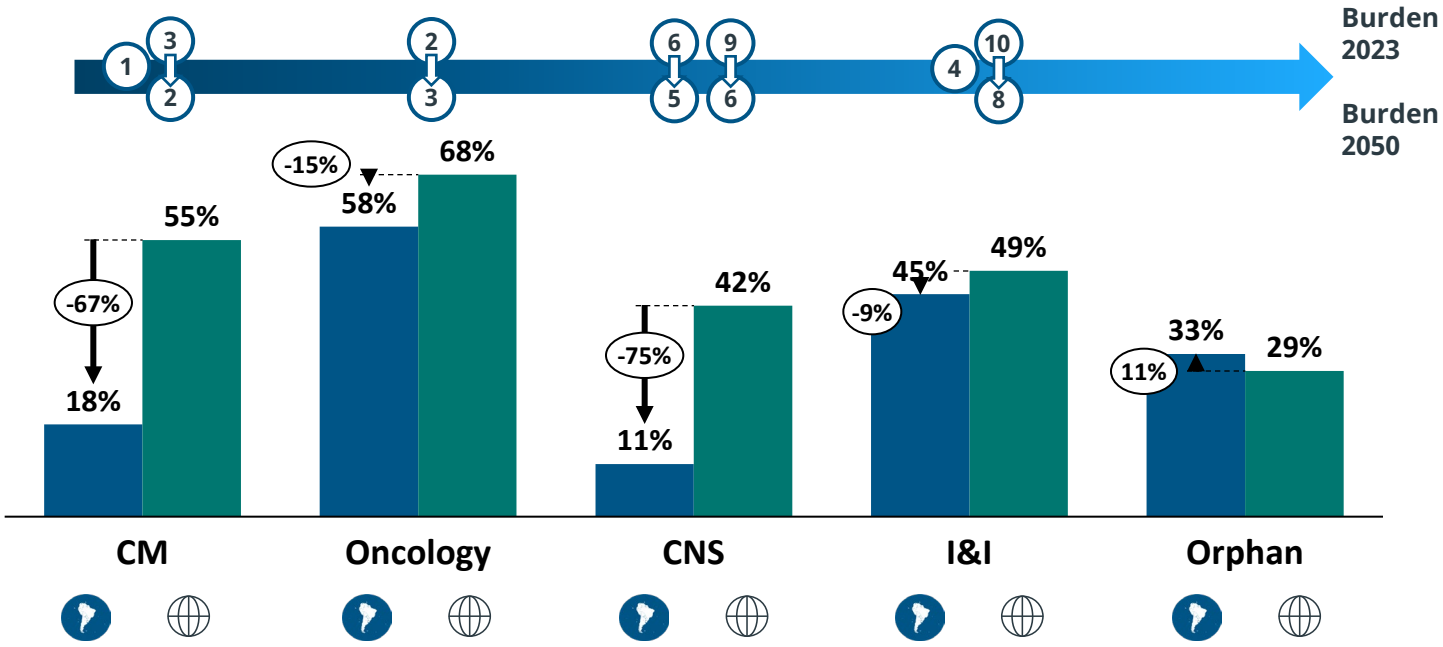
Therapeutic area remains a major determinant of access: CM and Oncology show broader availability, but Oncology still depends heavily on private channels, while CNS and I&I continue to face more constrained access even after approval

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology

The trend in public spending differs from that of access

Public spending in Latin America is lower—in some cases significantly so (CM/CNS)—compared to the OECD average, while the spending on orphan diseases is higher

Average Public Spending on Innovative Treatments – WAIT (% of Spending on RX Drugs by TA)



- Public spending on innovative treatments in LATAM remains materially below OECD levels across most major therapeutic areas, reflecting constrained budgets and conservative prioritization
- In CM disease, LATAM public systems spend ~67% less than OECD countries, the widest gap observed. CNS disorders show a similar pattern, with LATAM at roughly 11% vs OECD's ~42%, underscoring limited public investment despite rising disease burden in these areas
- The gap narrows in oncology, where LATAM reaches approximately 58% compared with OECD's ~68%, and in I&I, where the region achieves roughly 45% vs ~49% in OECD markets
- Notably, orphan diseases represent an exception, with LATAM at approximately 33% vs OECD's ~29%, suggesting relatively stronger public commitment in select markets or therapeutic categories, though absolute availability for rare diseases remains limited as shown in prior analyses
- These disparities reveal how budget constraints and prioritization decisions shape which innovations reach patients. Therapeutic areas with the largest gaps represent major contributors to regional disease burden, yet public systems allocate proportionally less to their innovative treatments

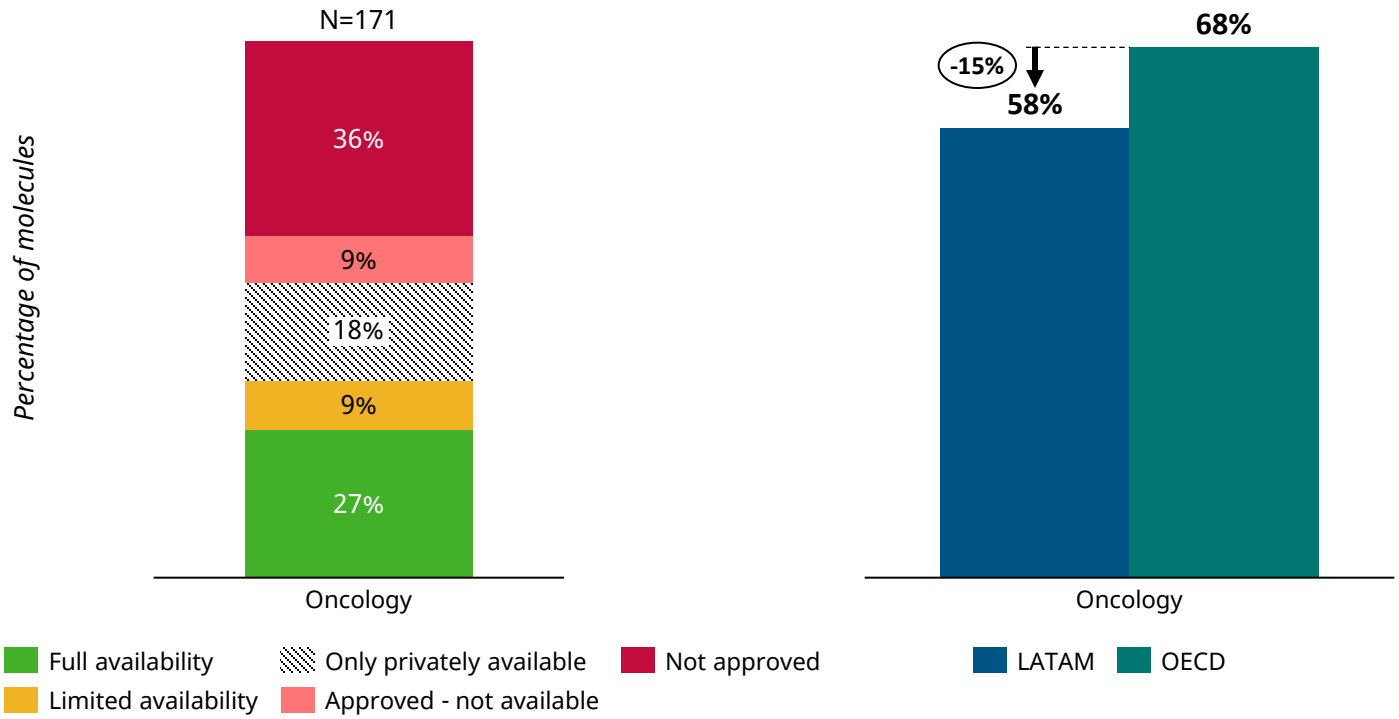
LATAM's TA spending gaps highlight misalignment between burden, innovation availability, and public investment priorities

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; OECD: Organization for Economic Co-operation Development

Oncology leads in access, and in public spend on innovation

LATAM shows limited broad access (27% fully available) alongside a lower public spending share compared to OECD

Initial Regional Availability and Public spend (2014 – 2025) – Oncology



- Oncology is a leader amongst therapeutic areas in the region in both quantity of molecules, and regional full availability, though only 27% of oncology molecules are *fully available* in LATAM, meaning nearly 3/4 face access limitations
- Around 36% of oncology molecules are *not approved* and a similar share (~ 36%) are approved but still not fully accessible, indicating that closing the approval gap alone would not translate into broader access without stronger public financing, which is consistent with the lower public spend shown for LATAM
- Approximately 18% of molecules are only accessible through private channels, indicating that insufficient public funding or restricted reimbursement pushes access toward out-of-pocket or private insurance pathways
- Public oncology spending is lower in LATAM (58%) compared to OECD (68%) by 15%, though amongst TAs it is a significant percentage on innovative therapies, which is in line with the relatively broader access that corresponds with it

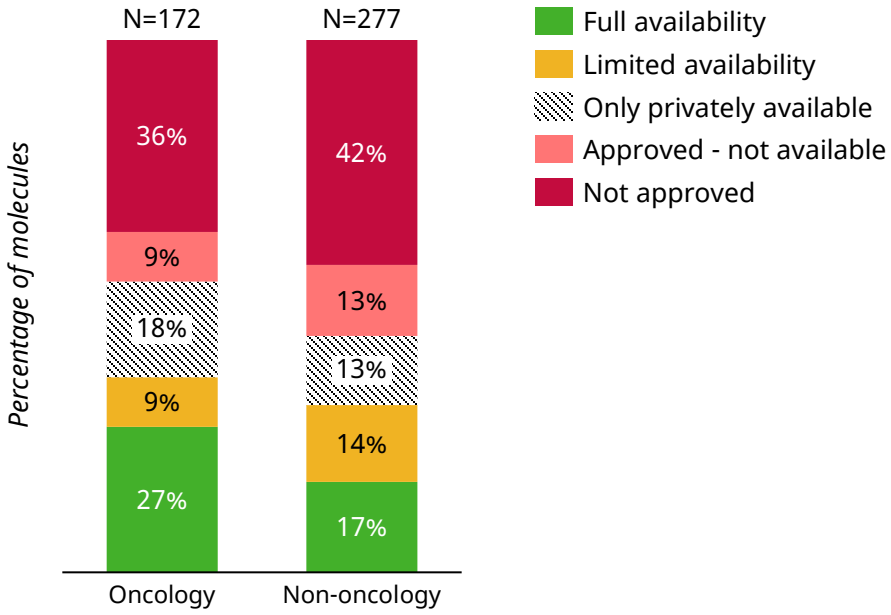
Oncology is the TA with broadest access, and the highest spend on innovative treatments, though gaps are still pronounced

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Oncology leads vs. non-oncology, with persistent access gaps

While oncology achieves stronger full availability (27% vs. 17%), access remains uneven with higher reliance on private and partial pathways and a larger share of molecules not approved

Initial Regional Availability (2014 – 2025) – Oncology vs. Non-oncology



- Oncology demonstrates higher full availability vs. non-oncology (27% vs. 17%), indicating stronger conversion of approved molecules into access
- However, oncology still faces stiff obstacles, with a high share of molecules not approved (36% vs. 42% for non-oncology) and persistent gaps post-approval
- Despite higher depth of access in oncology, both segments are dominated by non-approval and constrained access states (>60%), underscoring that systemic barriers continue to limit overall availability irrespective of therapeutic area
- Access pathways differ: oncology relies more on private availability (18% vs. 13%), highlighting more dependence on non-public channels
- Non-oncology therapies show greater presence in intermediate access states, with higher limited availability (14% vs. 9%) and approved-but-not-available (13% vs. 9%), reflecting slower progression to broad access
- Overall, both segments remain predominantly concentrated in sub-optimal access tiers, limiting consistent, population-level access across LATAM

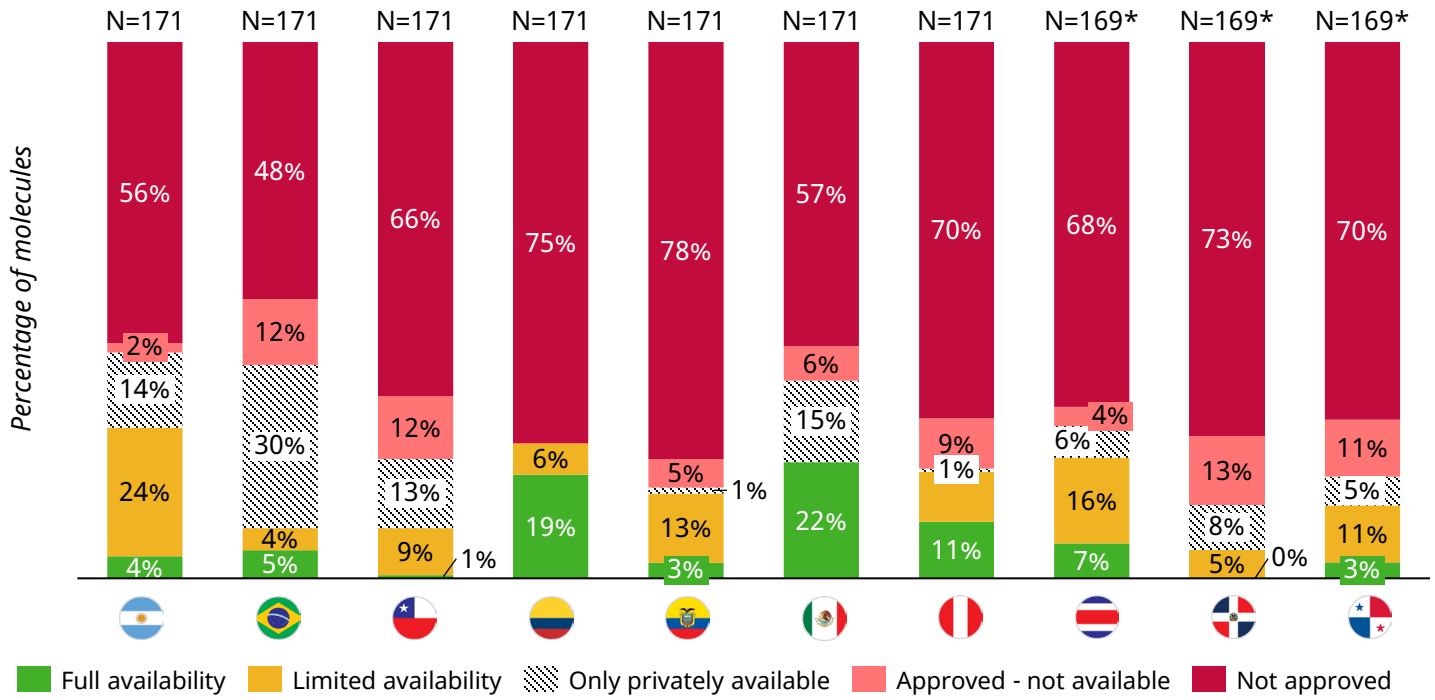
Stronger oncology access vs. non-oncology is tempered by higher private-channel dependence, limiting equitable population reach

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Regional availability is limited or private for oncology molecules

The oncology access landscape in LATAM is characterized by high regulatory constraints and fragmented post-approval availability

Initial Regional Availability (2014 – 2025) – Oncology



- Oncology availability is generally highest amongst TAs across all countries though with wide ranges, with *full availability* from 1% in Chile to 22% in Mexico
- Most oncology molecules remain unapproved across LATAM markets, with the *not approved* share exceeding ~50% in every country except Brazil where it is 48%, and rising above 70% in Colombia and Ecuador
- Brazil demonstrated the broadest overall oncology access, reflecting the lowest proportion of *not approved* molecules (48%) and the highest combined availability (52%). Mexico, however, leads in depth of access, exhibiting the highest share of fully available oncology molecules (22%).
- Private-only access constitutes a meaningful access pathway in several countries, particularly Brazil (30%), Mexico (15%), and Argentina (14%), indicating that oncology uptake often relies on out-of-pocket or private-sector channels as a stop-gap or path toward public systems
- Limited availability consistently exceeds full availability across countries, reflecting restrictive access or procurement it common to manage spend

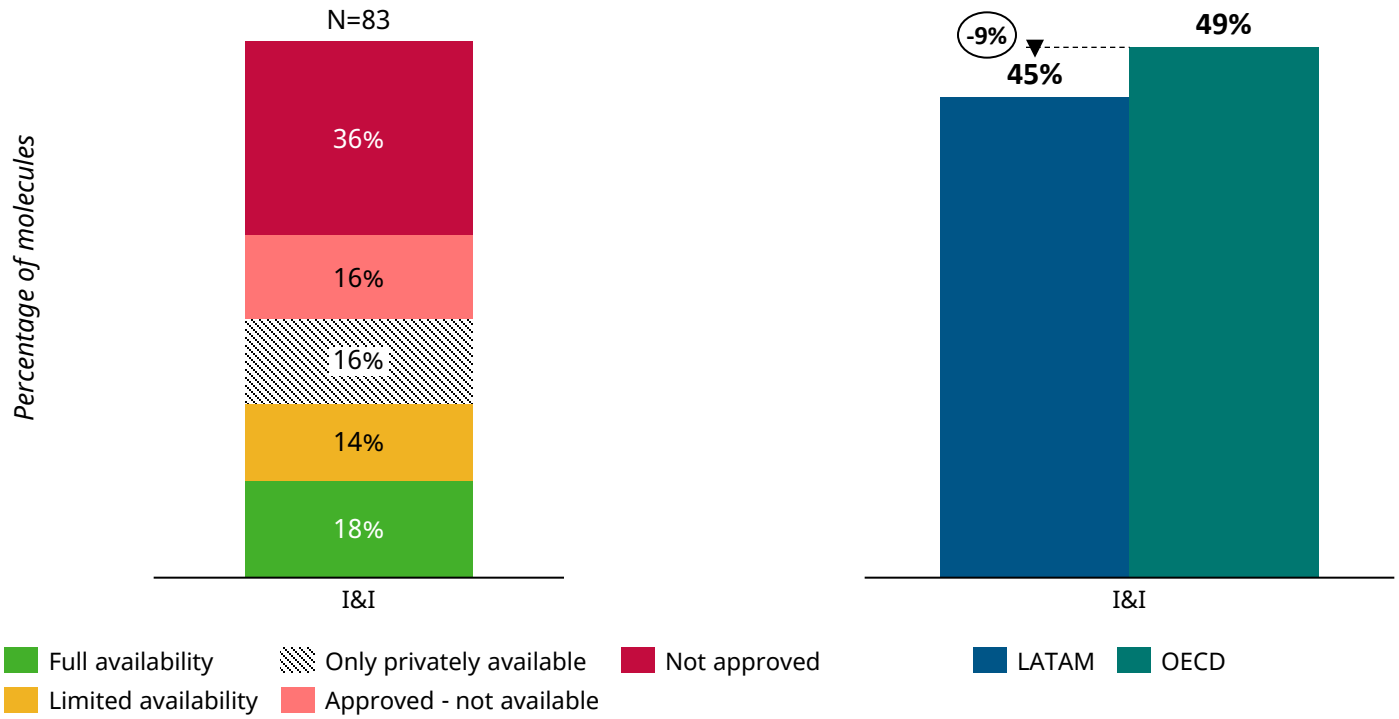
Most oncology molecules in LATAM remain unapproved (>50%), and even when approved, access is largely limited or private

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Access to I&I is fragmented despite high public spending

I&I molecules in LATAM show a predominantly "partial-access" profile, with only 18% fully available, and many molecules stalled in post-approval or restricted states

Initial Regional Availability and Public spend (2014 – 2025) – Immunology & Inflammatory



- Only 18% of I&I molecules reach *full availability*, indicating that most of the molecules do not translate into consistent "standard-of-care" access across LATAM markets
- A notable 16% are approved but not available suggesting that operational steps after approval, such as listing or procurement, are a frequent point where access gets delayed
- Near half of the molecules (46%) sit in "in-between" access states (14% limited, 16% private-only, 16 approved-not-available) showing access is commonly partial or conditional
- Overall, 64% of molecules are at least approved, although only 48% are available in practice (full, limited and private-only)
- Public spending is relatively close to OECD (45% LATAM vs 49% OECD; 9% lower), yet full availability remains low (18%), implying coverage design and implementation dynamics may be limiting broader access
- With public funding at 45% and 16% of molecules only privately available, the mix suggests I&I access often relies on multi-channel pathways where patient access varies by payer route and practical coverage conditions

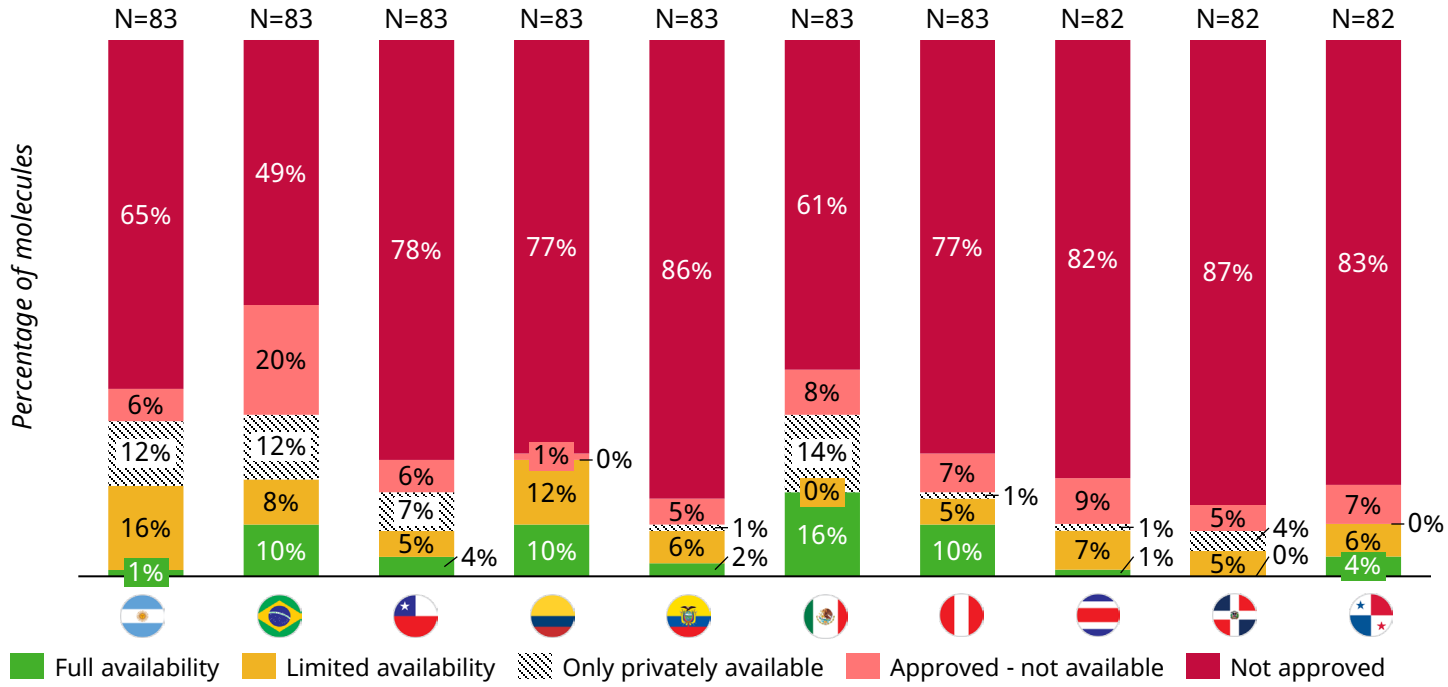
Despite LATAM public spend being relatively close to OECD, 46% of molecules have at least some restrictions as part of the route to access

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

I&I availability varies widely across LATAM markets

The I&I access landscape in LATAM is driven by strong-county heterogeneity, with uneven regulatory reach and a greater reliance on private and limited-access pathways

Initial Regional Availability (2014 – 2025) – Immunology & Inflammatory



- *Not approved* molecules range from 49% in Brazil to over 80% in Ecuador, Costa Rica, Dominican Republic, and Panama; indicating access, as well as market size is an influencer of submission
- Brazil stands out as the leading market for regulatory approvals, with the lowest share of molecules not approved (49%); however, post-approval access remains limited, indicating downstream barriers that may be related to budget impact assessment, pricing negotiations, and procurement processes are stalling access
- Full availability does not surpass 16% in any given country, reflecting the relatively challenging state of access in I&I
- Private-only availability represents an important access channel in selected markets, accounting for 14% of molecules in Mexico and 12% in Argentina and Brazil, reflecting earlier uptake through private insurance or out-of-pocket mechanisms
- Extended availability remains limited across countries, with 30% in Brazil and Mexico the pinnacle underscoring the severe gaps

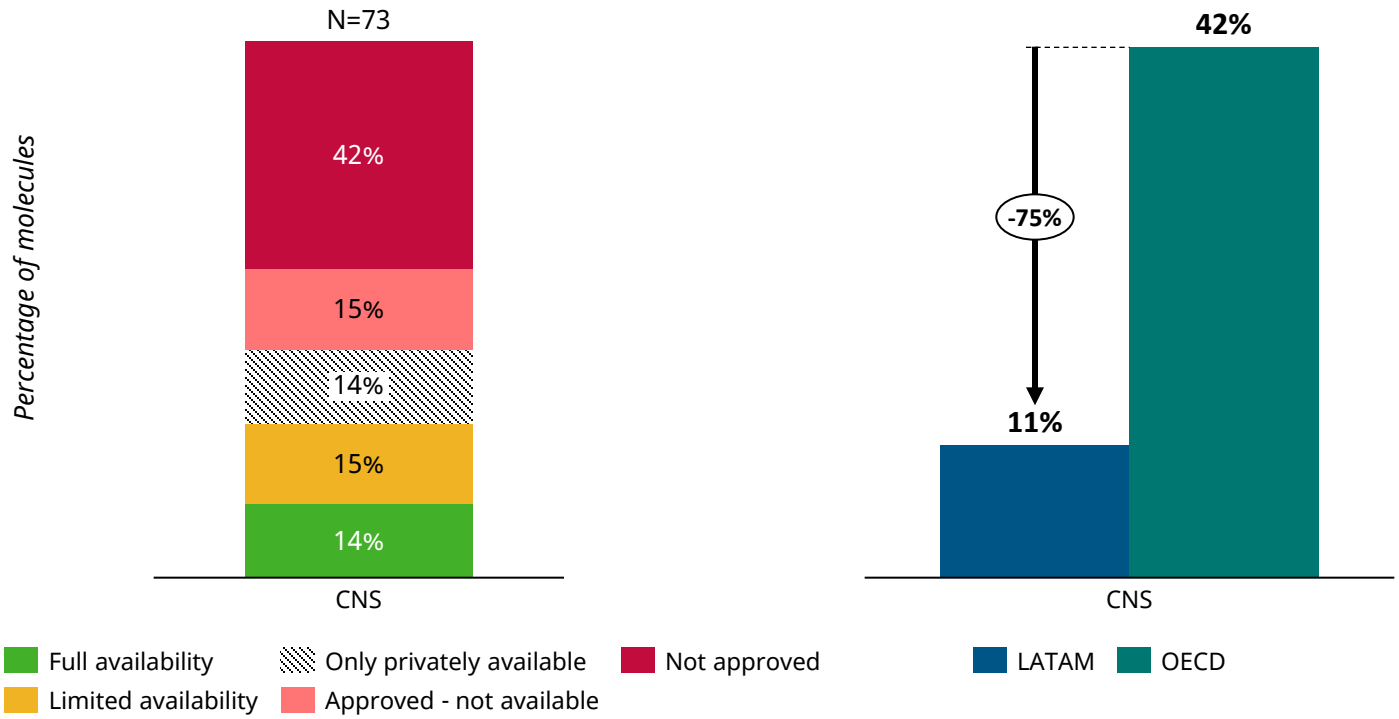
Post-approval barriers to access play an important role in determining submission, resulting in low public availability and continued reliance on private pathways

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Innovative CNS therapies have the lowest public spend

CNS molecules in LATAM combine a high "not approved" share (42%) with an exceptionally low public spending share (11% vs 42% OECD), reflecting a critical gap for healthcare systems

Initial Regional Availability and Public spend (2014 – 2025) – Central Nervous System



- A small share of molecules reaches broad, routine access across LATAM markets, with only 14% of the molecules achieving *full availability*
- 15% of CNS molecules have limited availability, meaning that while these molecules are present in the market, their use is restricted to specific settings or patient groups, preventing broad and consistent access
- CNS shows a highly fragmented access profile with more than half of the molecules with some type of accessibility; 14% full and only privately available, as well as 15% limited and approved not available suggest a scattered access landscape, which necessarily contributes to uptake that is inconsistent across markets and channels
- LATAM public innovative CNS spending is 11% highlighting very small public share of financing compared to other therapeutic areas
- When comparing LATAM public spending with OECD, we can see a 75% difference, highlighting a pronounced deprioritization of novel CNS therapies that is out-of-step with developed markets

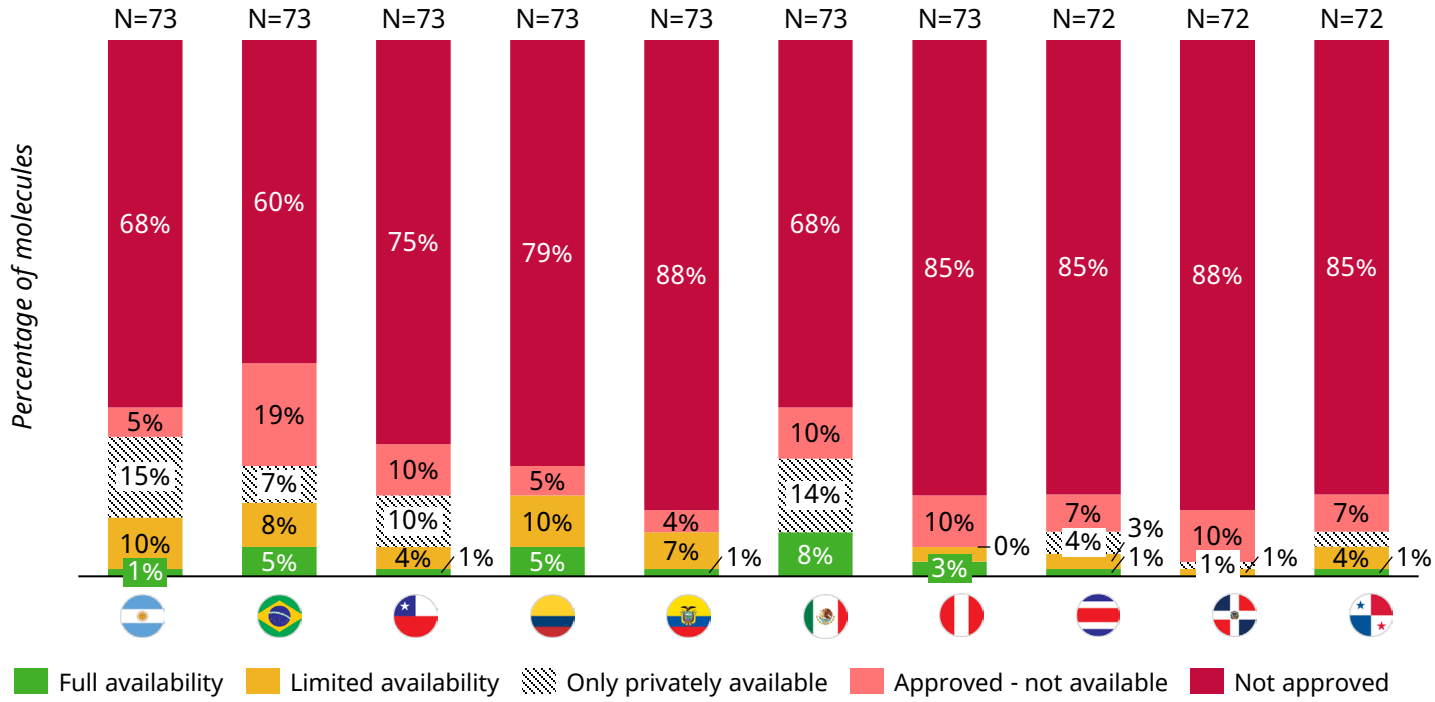
CNS access is highly fragmented, with only a small minority of molecules fully available and many restricted, mirroring the very low public spend

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Approved CNS molecules remain largely unavailable

CNS access landscape in LATAM is primarily limited by weak progression beyond regulatory approval, resulting in minimal full availability and heavy reliance on restricted access pathways across markets

Initial Regional Availability (2014 – 2025) – Central Nervous System



- Regulatory approval is the dominant bottleneck for CNS molecules, with *not approved* molecules accounting for most products in all markets, ranging from 60% in Brazil to 88% in Ecuador and Dominican Republic
- Brazil emerges as the most advanced market at the regulatory level; however, most CNS assets fail to progress beyond registration even in the most mature market
- Across most countries, post-approval access remains highly constrained, as full availability is consistently low (0-5 % in most markets), peaking only at 8% in Mexico and 5% in Colombia and Brazil)
- Limited availability is more common than full access in Argentina, Brazil, Chile, and Colombia, suggesting CNS molecules are more often subject to restricted coverage or sub-population use
- CNS access pathway shows weak conversion from approval to meaningful availability, highlighting structural challenge in translating regulatory success into sustained public-sector access in the region

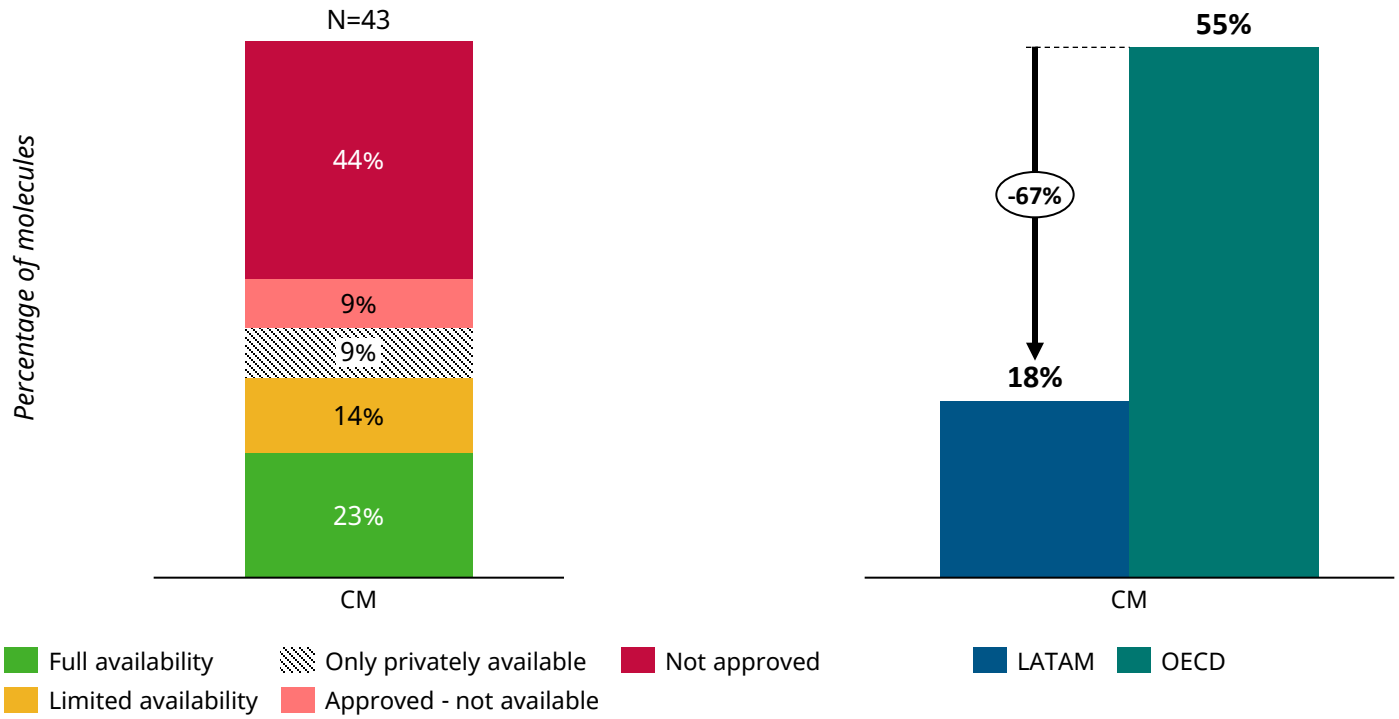
CNS molecules in LATAM face significant access constraints, where high non-approval rates and weak post-approval conversion result in consistently low full availability

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Innovative CM treatment access is a critical gap in the region

CM molecules in LATAM have the highest non-approval share (44%) of the TAs (except orphan-other), and a low public spend compared to OECD; in stark contrast to the disease burden it represents

Initial Regional Availability and Public spend (2014 – 2025) – Cardiometabolic



- CM availability is primarily constrained upstream, with 44% of the molecules not approved, meaning the biggest gap is in submission, despite the high burden of cardiovascular disease and diabetes in the region
- Among molecules that are approved (56%), a meaningful share translate into broad access, with 23% fully available, implying that once CM molecules are submitted and clear entry hurdles, a sizable fraction can reach routine availability
- Post-approval stalling exists but is not the dominant pattern, as only 9% of the molecules are approved but not available, indicating fewer molecules have restraints after approval
- Public CM financing plays a much smaller role in LATAM (18%) than in OECD (55%), with 67% lower public spend, highlighting a substantial funding gap that limits the ability of public systems to support broad and consistent access
- The spending profile suggests innovative treatments for CM with access are likely those that have more narrow populations, as opposed to broader population interventions that also can drive significant population health impact

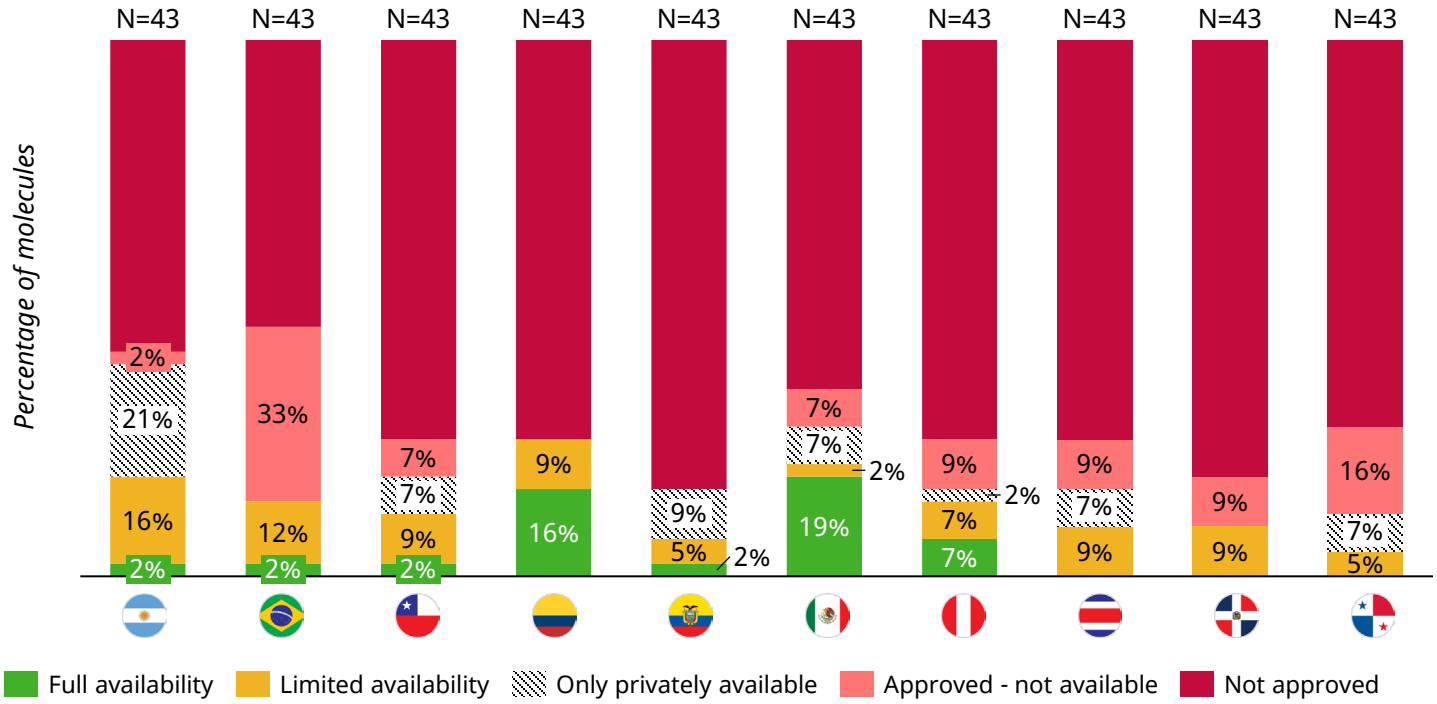
CM molecules access in the public sector is relatively high vs. other TAs, though the public spend on innovative treatments is very low

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Full availability of CM therapies remains low and concentrated

CM access landscape in LATAM is highly uneven, with regulatory barriers, delayed post-approval launches, and reliance on limited rather that full availability

Initial Regional Availability (2014 – 2025) – Cardiometabolic



- CM access shows pronounced cress-country heterogeneity, with the share of not-approved molecules ranging from 53% in Brazil to over 80% in Ecuador and Dominican Republic, showing uneven prioritization
- Brazil stands out as the strongest entry market for CM molecules, with the lowest proportion of *not-approved* molecules (53%), however, it has a high share of assets that are approved but not available (33%), pointing to delays between approval and launch
- Full availability peaks in Mexico with 19% of the molecules, followed by Argentina with 16%, while all other markets remain low, ranging between 0% and 7%
- Limited availability represents a significant access outcome, reaching 16% in Argentina, 12% in Brazil, and 9% in Chile, Colombia, Costa Rica, and Dominican Republic and in some cases exceeding full availability
- Overall, CM molecules show limited progression to mature access states, as the combined share of full and limited availability remains a minority across markets, underscoring the structural difficulty of translating regulatory entry into sustained and broad access

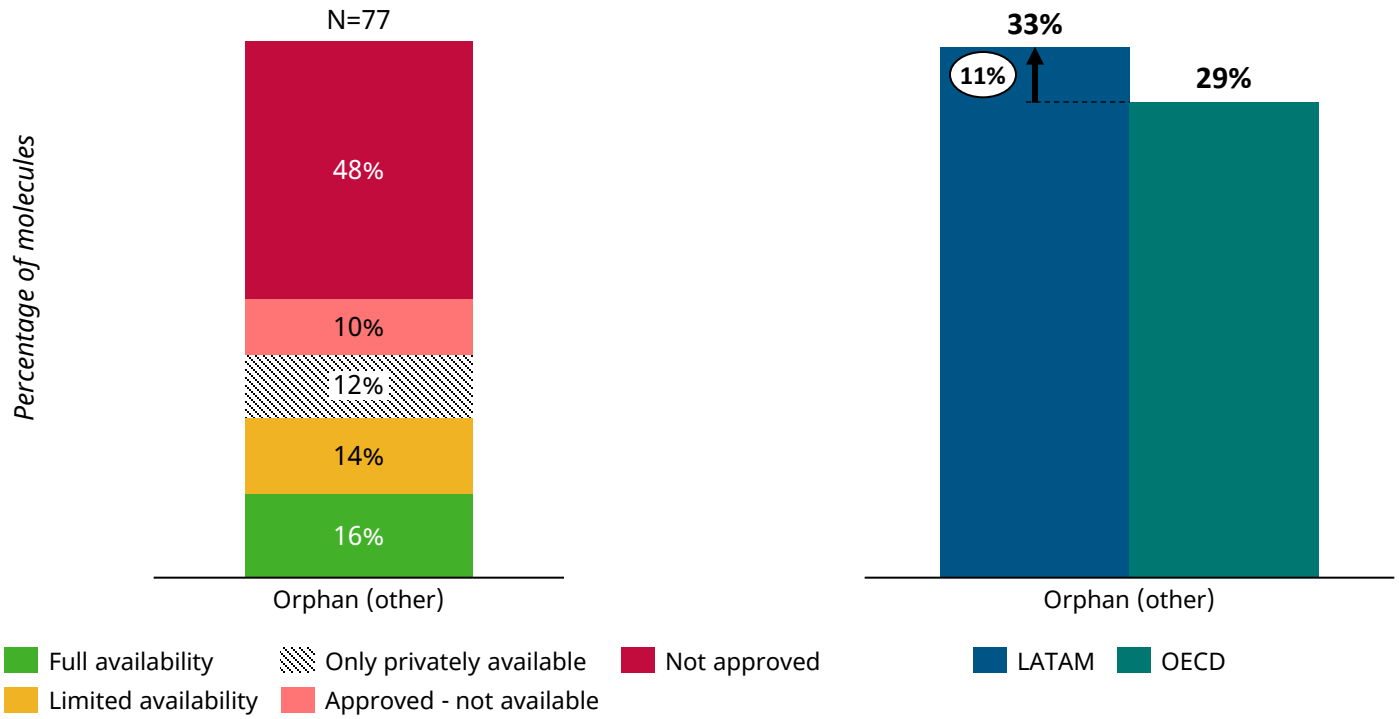
CM molecules in LATAM show high uneven access, with many molecules either not approved, or approved but not available

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Orphan therapies combine low access with modest public spend

Orphan drugs in LATAM face limited opportunities, indicated by the dominant not-approved segment, however, they show a unique pattern with a slightly higher public financing share than OECD

Initial Regional Availability and Public spend (2014 – 2025) – Orphan (other)



- Opportunity for orphan molecules in LATAM is primarily constrained at the entry stage, with 48% of molecules *not approved*, likely as a result of challenging access and funding pathways
- Among the 52% of molecules that achieved approval, 16% are fully available, suggesting that even withing the approval segment, broad and routine access remains selective, despite small eligible population sizes in first instance
- A further 36% of molecules fall into the intermediate access categories (14% limited availability, 12% privately available, and 10% approved but no available), reflecting a system where access in frequently conditional, though not inconsistent for high-cost therapies targeting narrow populations
- Public funding for orphan molecules in LATAM (33%) exceeds that of OECD markets (29%) by approximately 11%, making orphan the only therapeutic area in this analysis where LATAM demonstrates a relatively stronger public funding role, however in both approx. 2/3 of patients are receiving older generations of treatments
- Despite 30% public sector access, orphan disease therapies are characterized by exception processes, driving disproportionate public spend

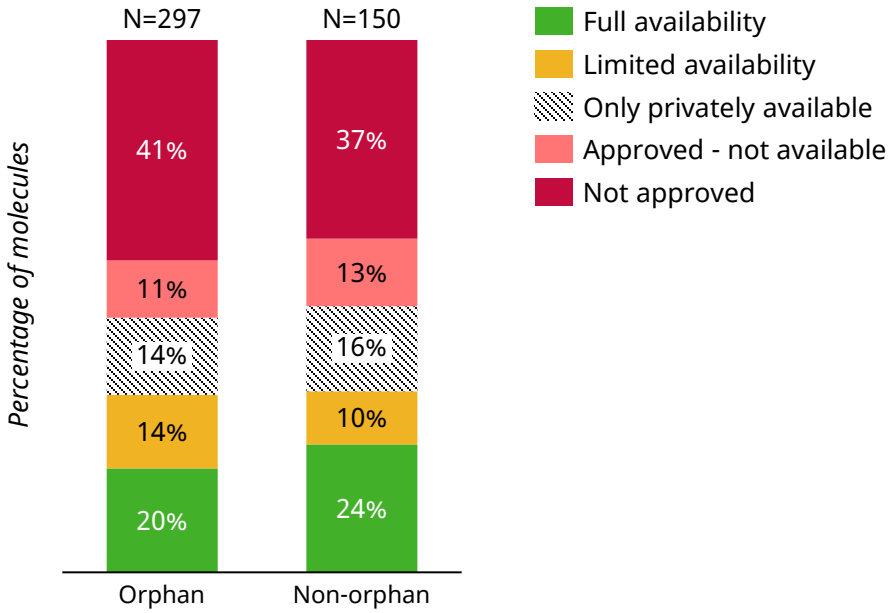
Orphan molecules face multiple constraints that limit their progression to full availability, with exceptional purchases likely contributing to public spend despite low access

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Availability varies by therapeutic area

Orphan drugs generally have lower availability vs non-orphan drugs, and account for two thirds of the overall cohort of molecules

Initial Regional Availability (2014 – 2025) – Orphan vs. Non-orphan



- ~2/3 of the molecule cohort is orphan-designated by the FDA or EMA, underlining the importance of access pathways for therapies initially launched in smaller populations and then expanding to broader populations with subsequent indications
- Non-orphan molecules have higher broad public availability (24% vs. 20%) but lower limited availability, highlighting more cautious approach to access for orphan disease
- Extended availability stays near ~40% across both categories, though the private channel is more widely used for non-orphan drugs; there are also more drugs approved in total for non-orphan (63% vs. 59%)
- The lower availability observed for orphan therapies likely reflects a combination of smaller populations, greater uncertainty, more technical evaluations, and budget impact concerns, which can complicate processes both during regulatory processes and access pathways down the line
- Non-orphan therapies may benefit from broader evidence and clearer clinical positioning, but their larger eligible populations can also trigger stronger affordability and budget scrutiny

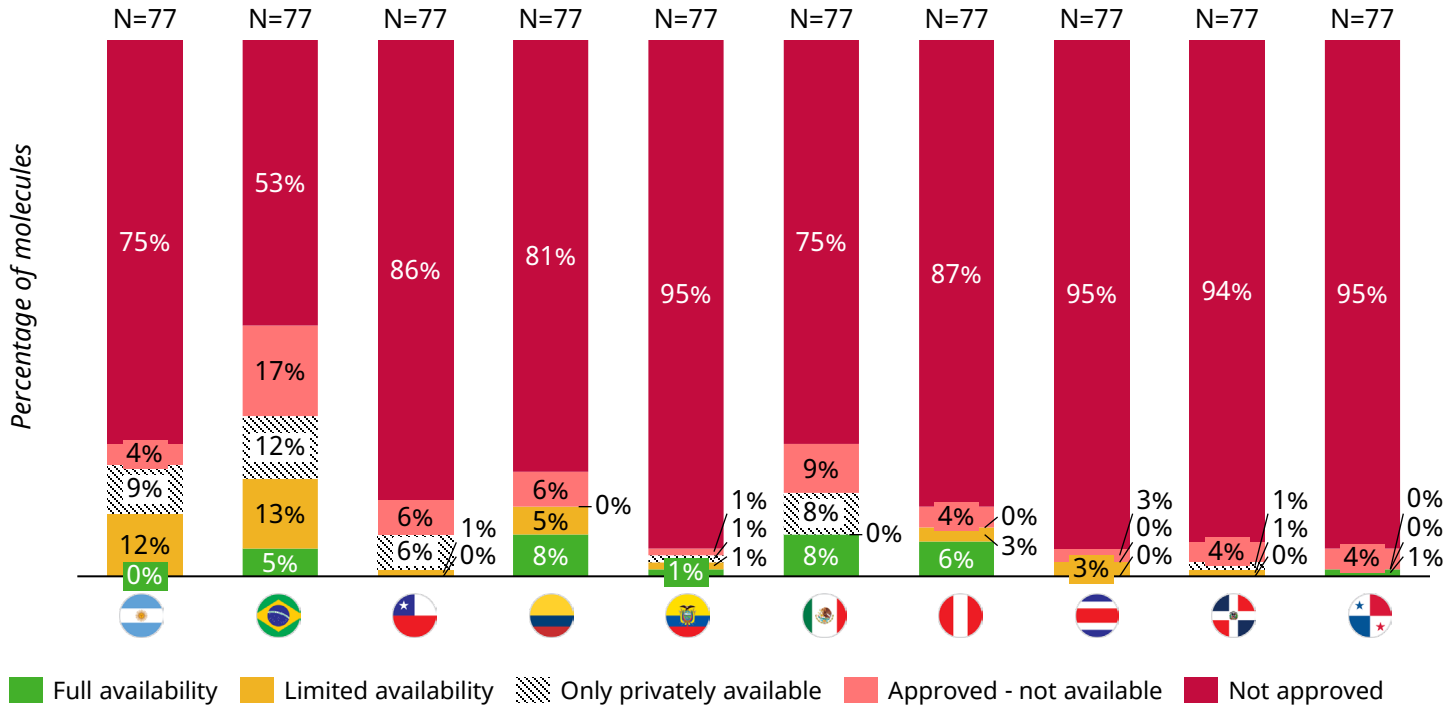
For at least two thirds of molecules, patients in LATAM need to rely on means outside of public healthcare for medications for orphan disease

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Orphan access is strong in some markets but weak in others

Orphan molecule availability remains limited across LATAM, with approvals only partially translating into real patients access across countries

Initial Regional Availability (2014 – 2025) – Orphan (other)



- Orphan molecule availability remain limited across the region, with no country exceeding ~50% total approval rates, and several markets remaining in the single-digit range (generally driven by market size and access potential)
- Brazil stands out with the highest overall availability (~47%), but access is largely restricted, as only 5% of molecules achieve *full availability* while significant share remains approved but not available (17%)
- Argentina demonstrates moderate access (25%), but this does not translate into meaningful access, as *full availability* is completely absent and most molecules are confined to limited or private channels
- Mexico shows a similar level of total availability (25%) as Argentina, but with a fragmented access profile where only 8% of molecules are fully available and comparable share remains limited to private access or not yet commercially available, despite approval
- Smaller markets such as Ecuador, Costa Rica, Dominican Republic, and Panama exhibit very low penetration overall, with a recurring pattern of molecules being approved but not effectively reaching patients

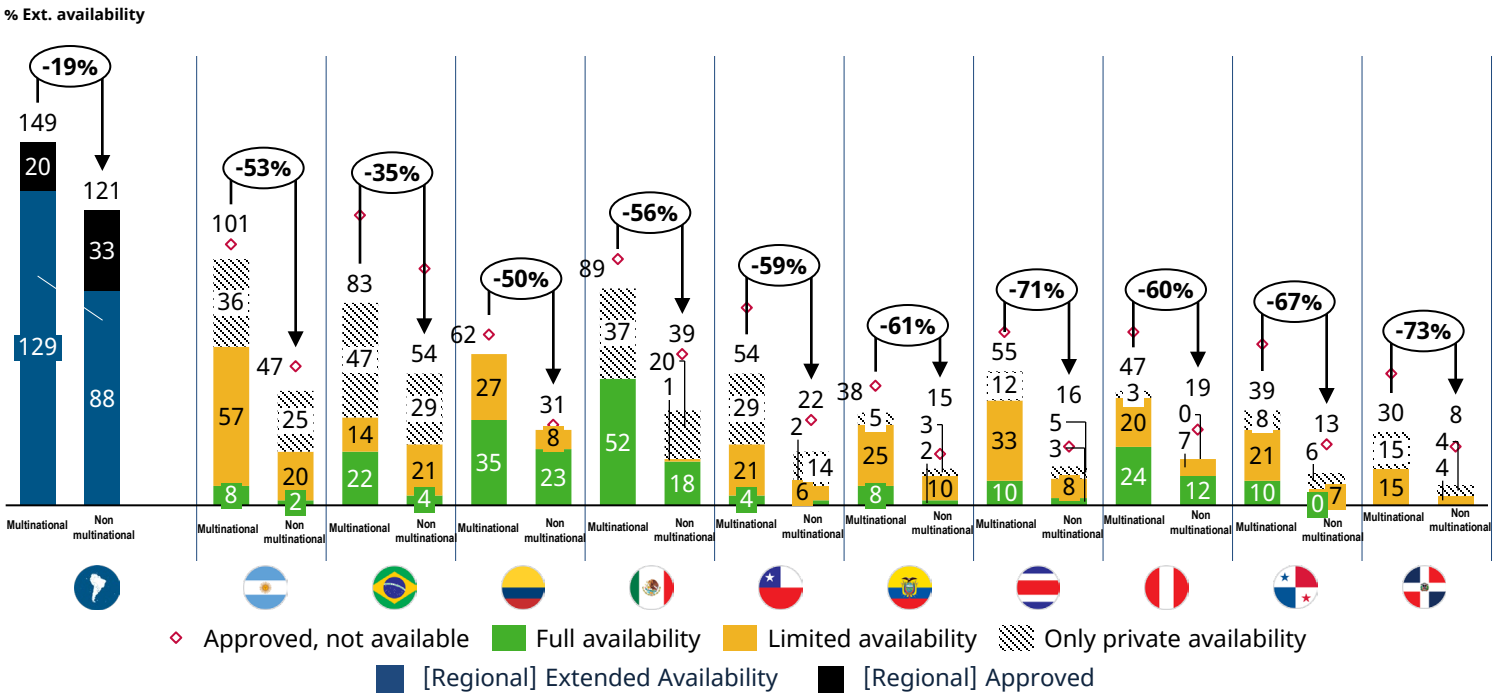
Patient support programs may be helping to bridge some of the gaps, but generally approvals and access are at their lowest for orphan disease treatments

Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; FDA: US Food & Drug Administration; EMA: European Medical Agency

Multinational manufacturers lead in availability

Multinational portfolios show consistently higher availability rates than medium-small biopharma, with smaller markets seeing the widest gaps

Breakdown of Local Availability (2014 - 2025) — Multinational vs. Non-multinational



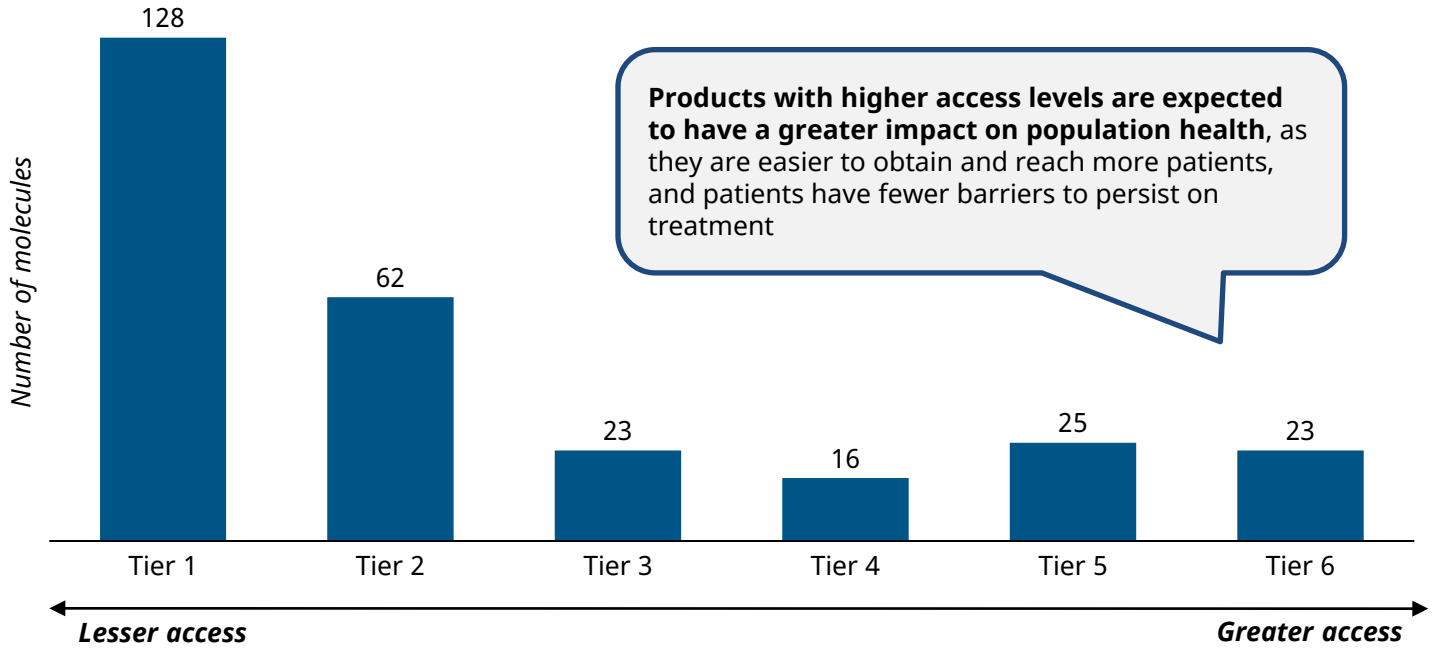
- At the regional level, molecules from multinational manufacturers are more prevalent and more available than those from non-multinational manufacturers, with 149 multinational vs. 121 non-multinational molecules and a higher extended-availability count
- This multinational advantage in extended availability is consistent across all countries displayed, indicating that non-multinational manufacturers trail multinational manufacturers in local availability in each market
- The magnitude of the multinational advantage varies substantially by country, with comparatively smaller gaps in some markets (Brazil) and very large gaps in others (Dominican Republic), suggesting that country-specific access dynamics amplify or dampen the multinational advantage.
- Drivers behind this gap go beyond ability to invest, and highlight the importance of local know-how, relationships and experience in navigating access processes
- Despite the stronger performance of multinational manufacturers, full availability remains limited in many markets and access is often concentrated in limited and private-only availability, indicating that even multinational presence does not consistently translate into broad, fully available access

Molecules from multinational manufacturers show higher local availability than those from non-multinational manufacturers

Access is concentrated among a few molecules, limiting reach

Only a small subset of innovative molecules achieve broad access; the majority remain at lower access tiers, limiting real-world impact and deepening inequities

Access Level of Regionally Approved Molecules – WAIT 2026



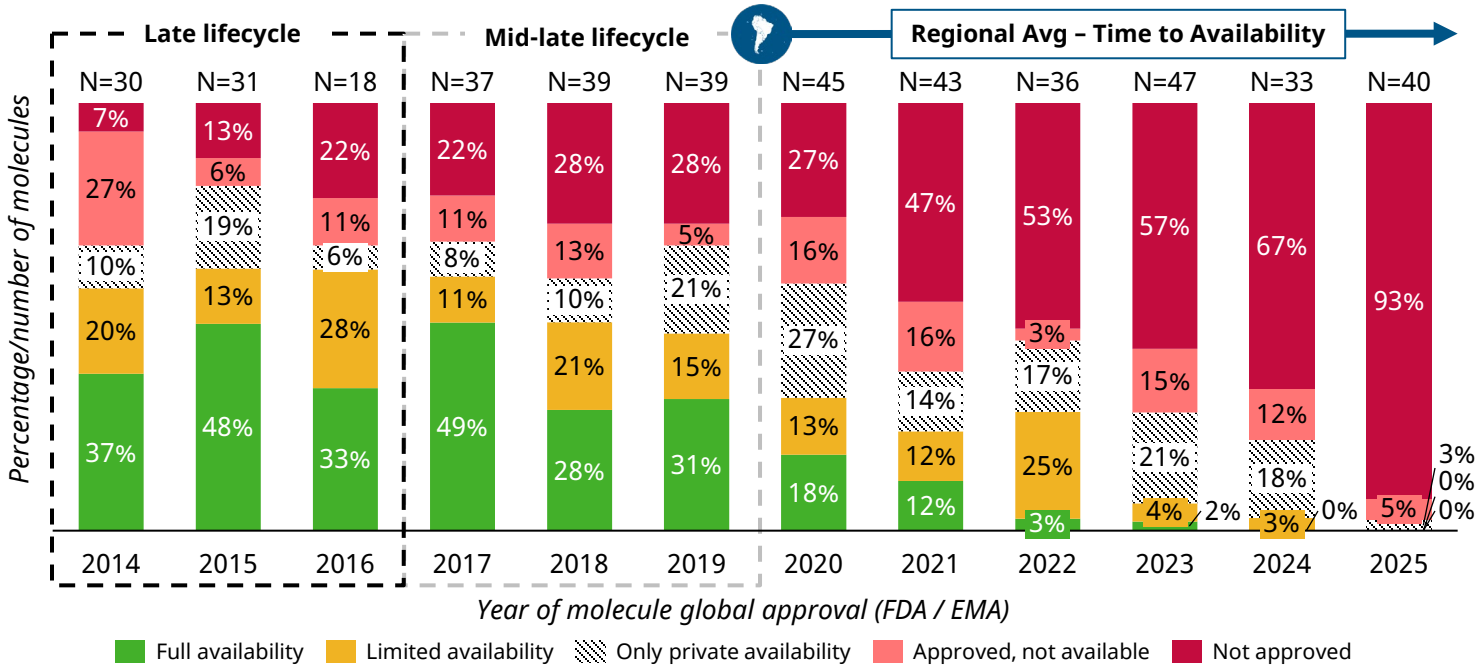
- The access levels shown above reflect both a product's availability in a given country and said country's extent of healthcare coverage
- Access remains heavily skewed toward the lowest tiers, with Tier 1 alone containing 128 molecules, by far the largest concentration in the distribution and reflective of significant gaps in availability post-approval
- Tier 2 is the second largest group at 62 molecules, reinforcing that a substantial share of regionally approved products are available less-than fully, in a subset of countries (usually BR/MX/AR)
- The sharp drop from Tier 2 to Tier 3 (62 vs. 23 molecules) suggests that relatively few products transition from approval /private availability, into meaningful population-access levels in a critical mass of countries
- Access level is not just a product level measure; it also reflects each country's healthcare coverage, meaning lower-tier concentration points to barriers to patient reach
- The real-world impact of innovation is likely constrained not only by whether a molecule is approved, but by whether it can move into the upper tiers where access becomes materially broader

The imbalance across tiers suggests that innovation is entering the region, but its effective reach remains concentrated among a narrower subset of molecules that successfully convert approval into broader access

Access focuses on medications launched before 2020

Regional availability drops drastically after 2020, with less than 50% medications available from 2021 onwards

Broadest Molecule Availability Status Over Time (2014 - 2025) – Combined



- The overall trend, shows a general decrease in public availability and increase in molecules not approved from 2014-2025. Even older molecules have not achieved universal availability. Products approved between 2014–2018, now well beyond launch and clinical maturity, continue to show fragmented access, demonstrating that time does not automatically translate into broad availability.
- The highest variability, besides molecules not approved, is derived from broad public availability ranging from 49% for molecules that received global approval in 2017 where it's at its highest, to 0% in 2024 and 2025, highlighting the significant hurdles in reaching the broader population
- Private availability and limited availability percentages do not have such wide ranges at a regional level, with only privately available molecules ranging from 6% in 2016, to 27% in 2020, and limited availability ranging from 0% in 2025 to 28% in 2016, though this trend varies significantly between countries
- Systems are not catching up to past innovation peaks, the sustained presence of older molecules in lower access tiers points to a growing backlog, where newer launches accumulate on top of unresolved access gaps

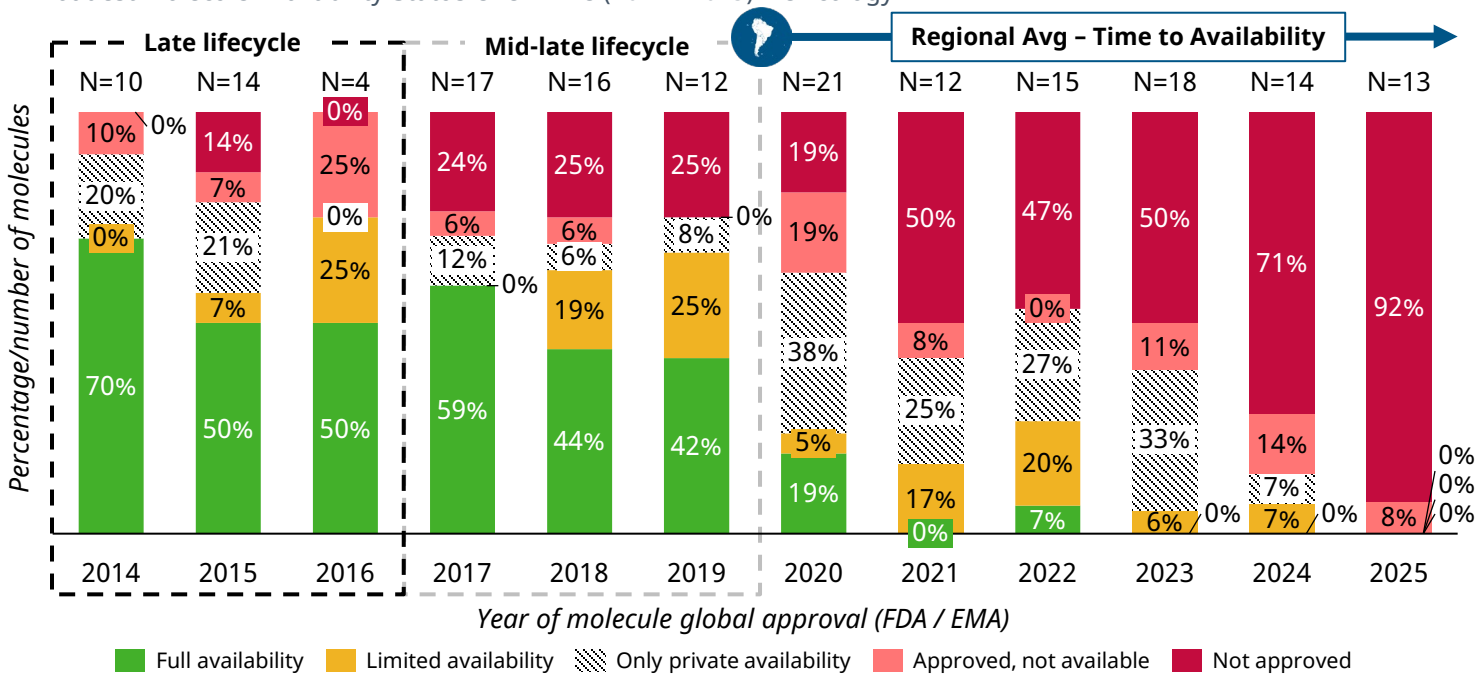
"These technologies being incorporated are older, and I don't know how we can get to the newer ones; there's a backlog."

- ex-Minister of Health

Access to new oncology therapies drives regional trend

Regional availability drops sharply after 2020, with fewer than 50% of oncology drugs approved since 2021 reaching any LATAM market, but accounting for the vast majority of regional access vs. other TAs

Broadest Molecule Availability Status Over Time (2014 - 2025) – Oncology



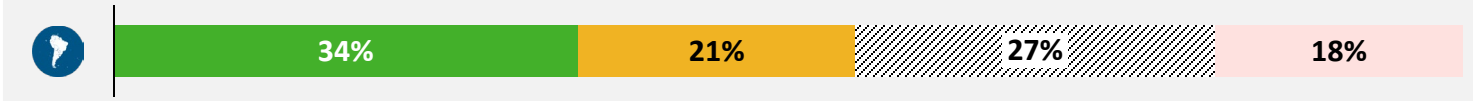
- Before 2020, most globally approved oncology medicines achieved some availability (public or private) in at least one Latin American country.
- Since 2021, however, fewer than 50% have any regional availability, marking a severe drop in patient access.
- The vast majority of oncology drugs approved in 2024–2025 remain unapproved and unavailable in all 10 LATAM countries as of early 2026, this indicates a widening gap where nearly all of the latest cancer treatments have yet to reach patients region-wide
- 1 post-2020 oncology launch has attained full public reimbursement in the region, public availability does not exceed 27% over this period either though in 2014-2019 it reaches 75% and does not drop below 57%
- The few newer therapies that are available tend to rely on private insurance or niche programs, underscoring the delays for public health systems in incorporating innovation
- Latin American systems are not catching up with past innovation peaks; older globally-approved oncology drugs still linger in lower access tiers and newer launches are piling onto this unresolved backlog. This trend highlights a structural lag – recent breakthroughs accumulate on top of persistent access gaps without swift integration into public care.

Less than half of global oncology launches (2021–2025) are available in Latin America, vs. the majority of pre-2020 launches.

Less-than Full Availability often leads to inefficient spend

Where there is a lower level of investment in broad access, affordability challenges also increase, limiting the potential benefit of a new medication introduced into the system

Access to Innovative Treatments in Latin America – WAIT 2026



Full Availability

Reducing barriers to access results in improved persistence and adherence to treatments, which correlates with better clinical outcomes.

Limited Availability

Partial access increases the administrative burden on systems (e.g., additional steps at the regional or clinical level) and, in many cases, leads to legal injunction

Only Private Availability

It allows for the incorporation of new technologies, but only for a segment of the population; barriers are higher outside metropolitan areas

Approved, Not Available

It restricts access to out-of-pocket spending, or to treatment-specific programs (e.g., managed access)—which should serve as an intermediate step

Full availability | Limited availability | Only private availability | Approved, not available

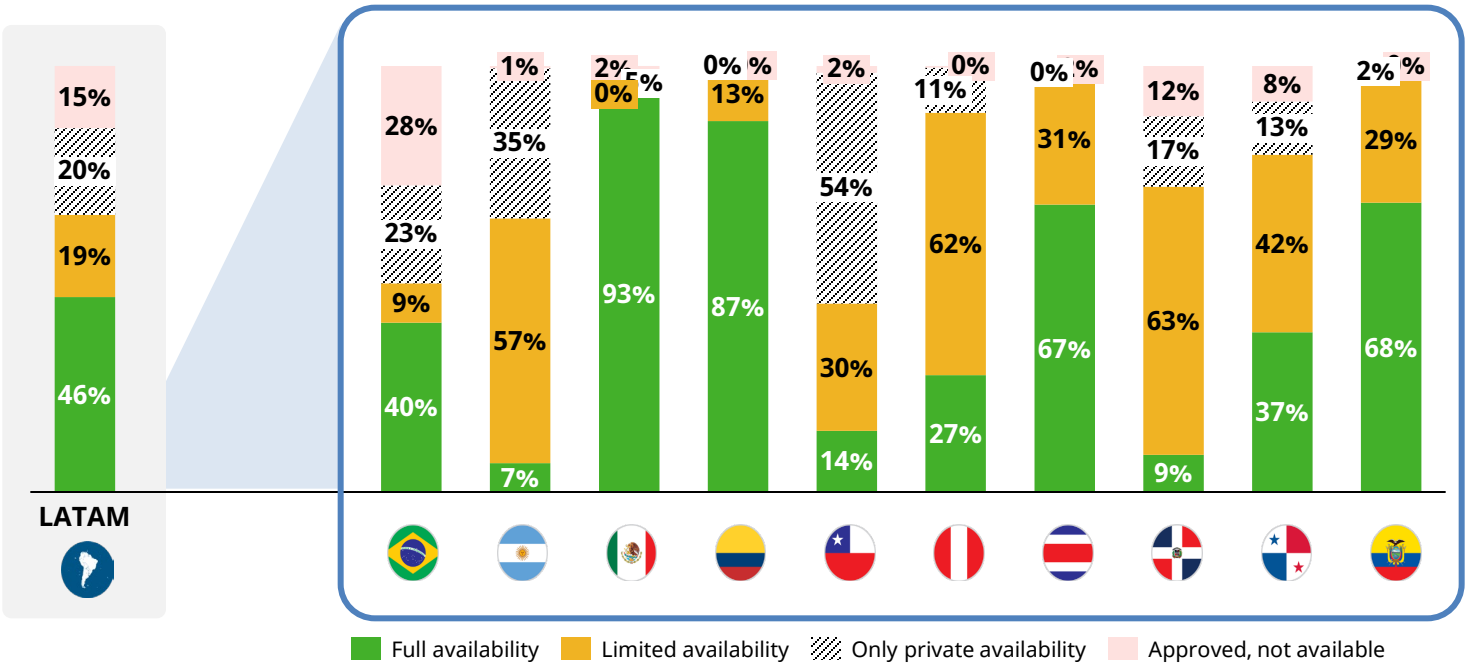
- Broad, equitable access remains the exception rather than the norm, with only 34% of innovative treatments reaching full availability. The remaining 66% are concentrated in lower-access tiers, limiting population-level impact even after products enter the market
- A substantial share of access remains either partial or financially restrictive. 21% of treatments are only limitedly available, increasing administrative burden and often creating fragmentation in patient access, while 27% are available only through private channels, restricting access to the segment of the population able to pay or covered privately
- Approval alone does not translate into meaningful patient access. Another 18% of innovative treatments are approved but not available, meaning they remain outside broad reimbursement pathways and are instead restricted to out-of-pocket spending or interim access mechanisms

Less-than-full availability drives inefficiency: when innovative treatments do not achieve broad access, systems face higher administrative friction, greater reliance on private or out-of-pocket funding, and a reduced ability to capture the full clinical value of innovation

There is disproportionate public spend by availability status

Public expenditure should be highly concentrated across public-availability status, however in some countries the spend on molecules not publicly available indicates high use of legal injunction

Public Expenditure on Innovative Treatments – WAIT 2026 by Availability Status (% of Total Expenditure)



- In a well-functioning access system, public spending on innovative medicines would be concentrated in categories with full or broad availability, reflecting coordinated decision-making and transparent reimbursement. However, across LATAM meaningful public expenditure is observed even in lower availability tiers. This suggests that spending does not flow exclusively through planned, formulary-based channels but also occurs widely through alternative access pathways

- Alternative mechanisms (e.g., patient groups, judicial orders, exception protocols) can enable access outside formal frameworks, creating unpredictability and lacking traditional transparency, cost control, and equity safeguards. Over time, susceptibility to these pathways can undermine budget planning, distort prioritization, and delay systemic reforms; it is also a highly inefficient spend

- This misalignment also reflects inefficiencies. It unveils a paradox where systems are funding innovation but not capturing it within official metrics or governance structures, limiting accountability and making it difficult to assess if spending achieves intended health outcomes

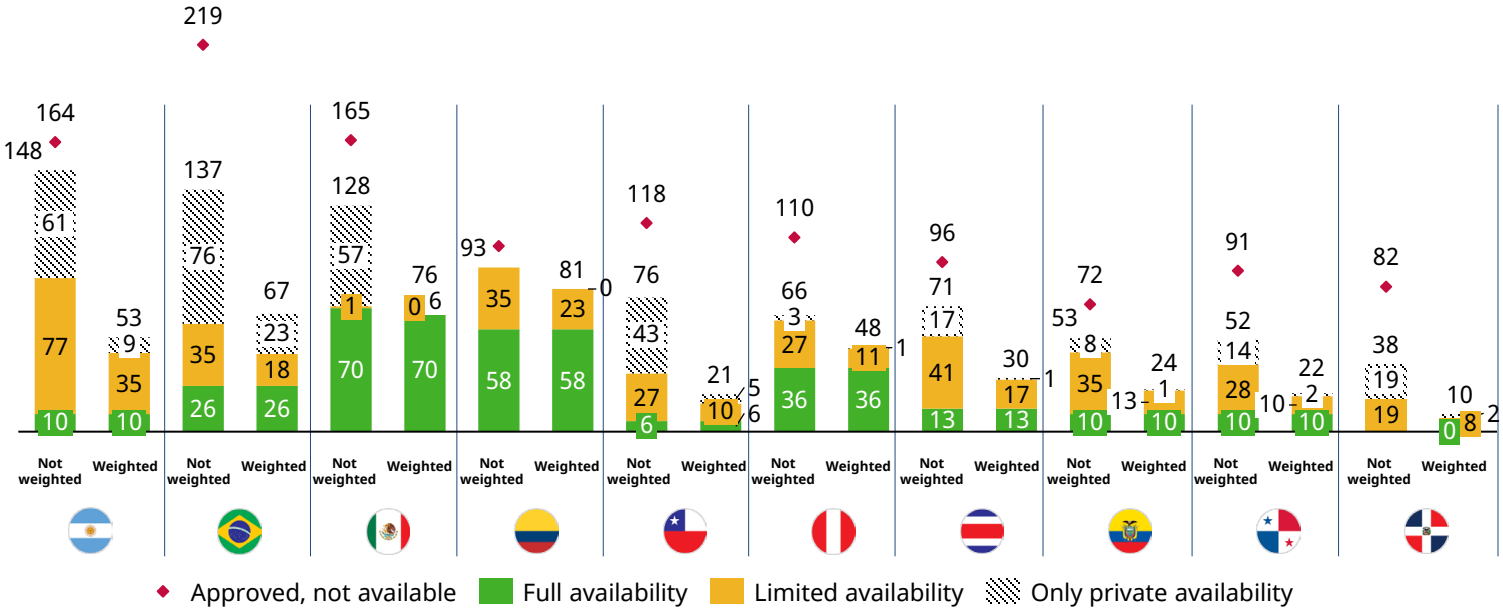
"When spending is insufficient, it becomes inefficient."

- ex-Minister of Health

Inequalities are widespread

Once healthcare coverage and system reach are considered, large gaps emerge between approved availability and what the majority of populations can access across LATAM

Breakdown of Local Availability (2014 - 2025) — Illustratively Weighted by Country Healthcare Coverage*



◆ Approved, not available Full availability Limited availability Only private availability

- Availability metrics based on regulatory and reimbursement status provide an important but incomplete picture of patient access, when availability is weighted by the share of each country's population covered by the relevant healthcare system or insurance mechanism, substantial additional gaps emerge
- Products classified with limited availability may be formally reimbursed but accessible to only a small fraction of those who could benefit clinically; similarly, molecules available solely through private insurance reach only those with financial means or employer-sponsored coverage, often representing a minority of the total population in LATAM
- This dynamic is particularly pronounced in countries with fragmented healthcare systems, where public coverage is incomplete, segmented by employment status, or varies significantly across states and municipalities
- In such contexts, even molecules with regulatory approval and reimbursement may have minimal population-level impact because the majority of patients are not covered, resulting in a disconnect between the extent of access for the population
- Weighting availability by coverage also reveals that higher extended availability rates driven by private-sector participation do not translate into broad population reach, instead, they highlight inequities, where innovation benefits a small, economically advantaged segment while the majority, often those with the highest disease burden, remain without access

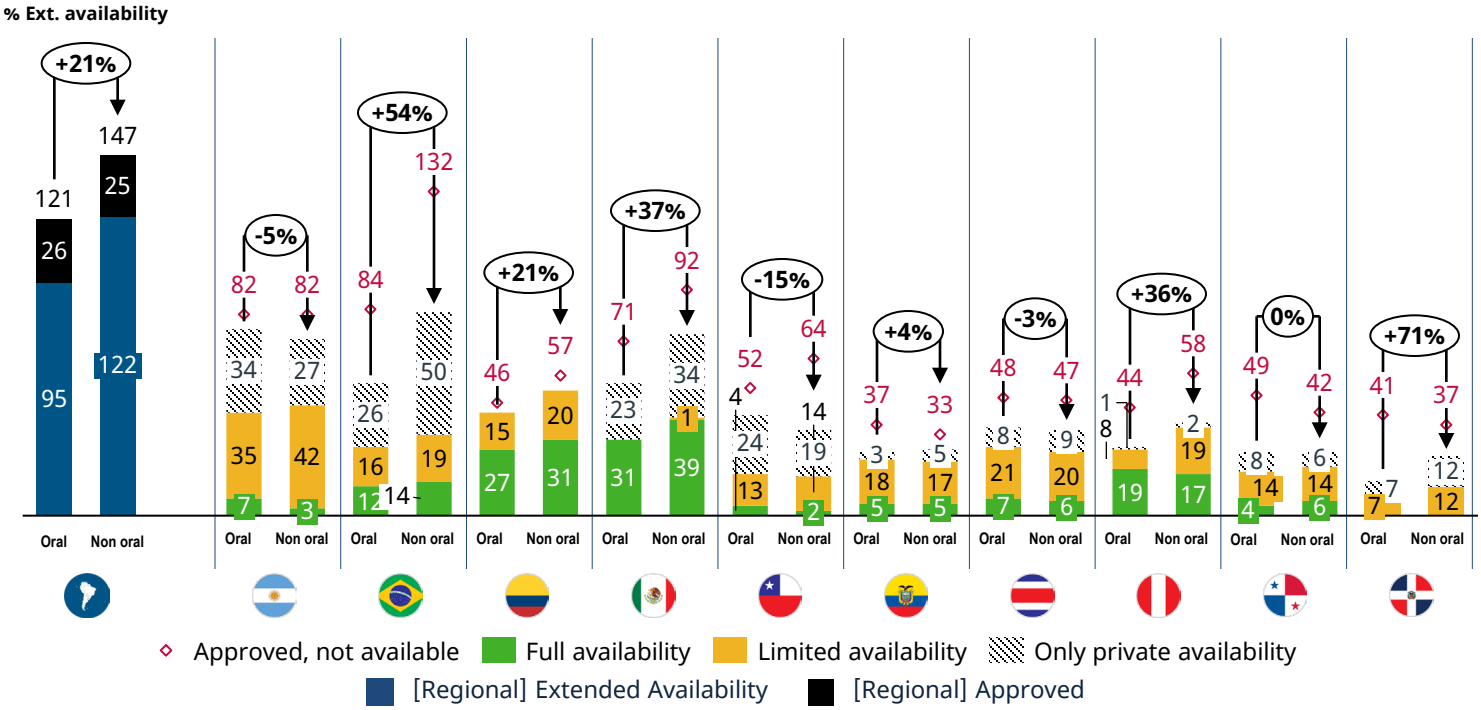
Coverage-weighted availability reveals that formal access often reaches only a fraction of patients, limiting innovation's real population impact

*See appendix for further detail

Non-oral therapies show higher availability

Availability differences between oral and non-oral molecules are inconsistent across countries and are primarily driven by limited and private-access only

Breakdown of Local Availability (2014 - 2025) — Oral vs. Non-oral



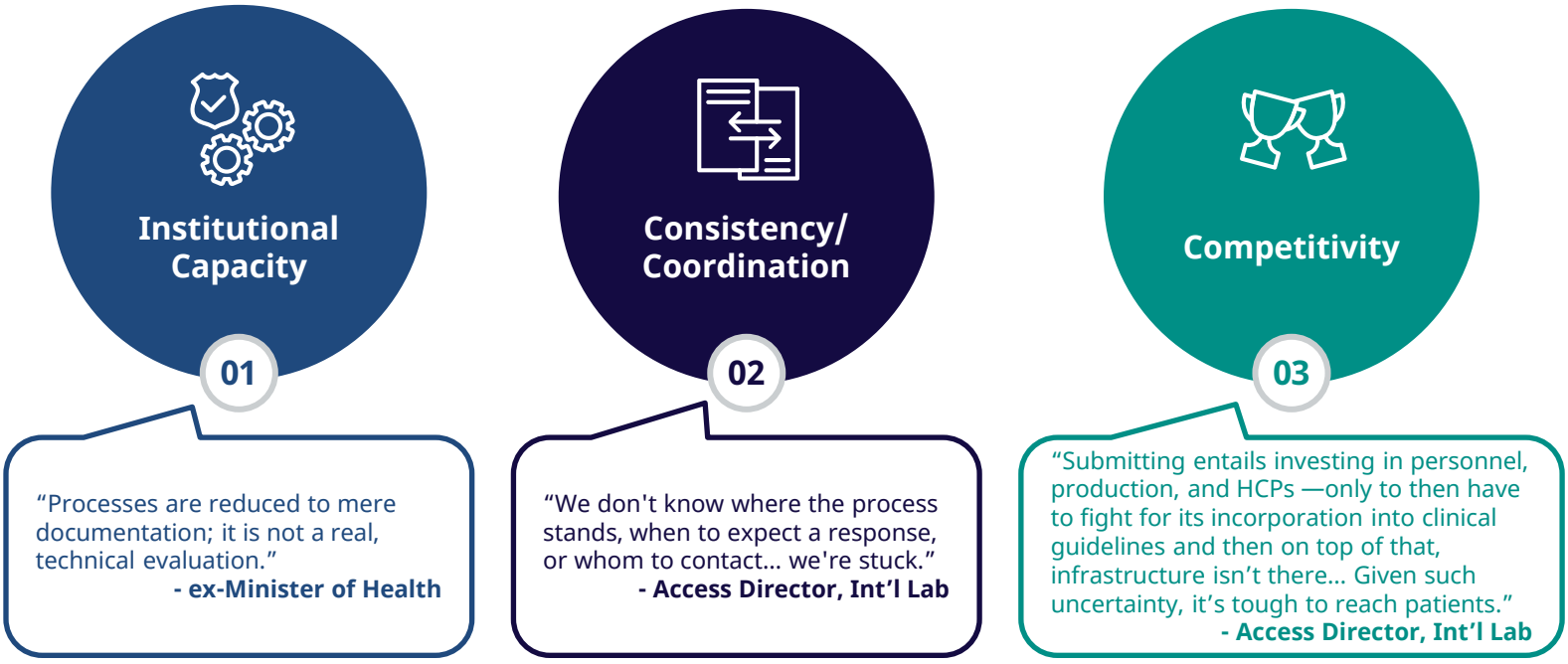
- Across countries, non-oral molecules generally exhibit higher extended availability than oral molecules, with several markets showing sizeable non-oral advantages, including +54% and +71%
- The relative availability difference by administration route varies substantially by country, ranging from markets where oral molecules outperform non-oral molecules (Argentina, Chile, and Costa Rica) to markets where non-oral molecules clearly lead (Dominican Republic with +71%)
- In many markets, orals and injectables have different purchasing, distribution and sales routes, that in theory don't change access, they play an important role in the economics of a given product, which in turn impacts the indirect costs and opportunity for innovative treatments
- The inconsistency across countries indicates that route of administration interacts with country-specific access conditions and "innovation" in and of itself may take second-tier importance
- In Brazil for example, an infused drug can gain private access immediately, whereas there are additional challenges in registering a biologic when compared with chemically synthesized agents e.g., Chile
- Moreover global development has shifted to biologics in due to the "pill penalty" imposed as part of the Inflation-Reduction Act

Wide variability across countries by route of administration indicate significant impact of distribution dynamics, which can overshadow innovation and access

The challenges associated with low investment are varied

Limited resources cause significant gaps in health systems in the region, which in turn lead to drawn-out processes as a result of saturation, and insufficient means to handle high uncertainty

Key Challenges Associated with Underinvestment



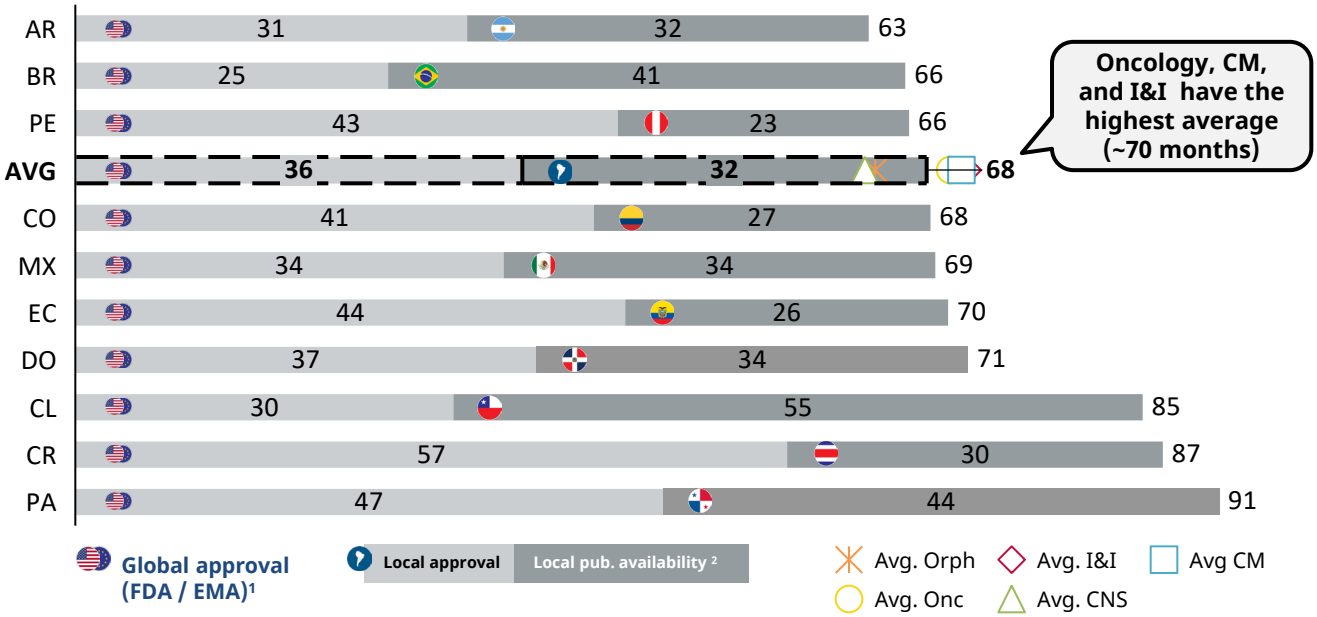
- Low investment in health systems generates cascading challenges across three interconnected dimensions. Institutional capacity is constrained by limited human resources with uneven experience and expertise to carry out processes, alongside digital infrastructure still under development. This undermines the ability to manage rising volumes, assess complex evidence, and make timely, evidence-based decisions. The result is prolonged review cycles, inconsistent evaluations, and growing backlogs that delay access.
- Consistency and coordination are weakened as underinvestment limits transparency around evaluation criteria and decisions and reduces structured interaction among ecosystem actors, fragmenting pathways and increasing uncertainty for patients and stakeholders. The lack of clear pathways complicates planning and undermines trust in the ability to deliver equitable access.
- Competitiveness is undermined when commercialization conditions remain risky or unpredictable. Opaque processes, uncertain timelines, and constrained budgets dampen incentives and capacity to invest, prompting delayed launches, narrower indications, or market deprioritization.
- Together, these dynamics reinforce a cycle in which low investment diminishes capacity, coordination, and confidence, constraining access today and discouraging the investment needed to improve access tomorrow

Low investment weakens institutions, fragments processes, and deters innovation participation, compounding delays and limiting patient access

Access is a long and fragmented process

The time to availability averages 5.7 years, with a time to approval of 3 years and a time to availability of 2.7 years

Time to Availability from Global Approval (2014 - 2025) – Combined



[1] Global approval date considered the earliest date between FDA or EMA
[2] Considering molecules with Full and/or Limited Availability

- The average time to local approval is 36 months, 3 years after global regulatory approval (first of FDA or EMA), though this does not consider at what time the laboratory filed a submission
- Wide disparities exist across countries in both approval and availability timelines, although in total, most of them are close to the average of 68 months for the region, with only Panama as an outlier at 91 months reflecting uneven system readiness and access processes
- The average time from local approval to first availability is 32 months, or ~2.6 years; this considers between the date of local approval and the date of first availability (public or private), and only considers the first indication
- Countries differ greatly in time to availability after local approval. Peru sees formulary listing relatively shortly, at an average of 23 months, whereas Chile and Panama are toward the high end, above 3.5 years
- Though both approval and availability timelines vary by country, overall time to availability ranges from approximately 5- 6 years across the region
- Differences in regulatory capacity, process maturity, funding, and purchasing delays likely contribute to this fragmented pathway

First availability captures only a small part of the patient experience, as for many molecules it marks access to only an initial indication and often only for a limited subset of the broader eligible population

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency

Timelines lengthened in 2026, driven by post-approval delays

While regulatory timelines remained stable or improved in some markets, availability delays increased across most countries, signaling growing system strain beyond approval

Time to Availability from Global Approval vs. 2025 – Combined

	Approved	Available	Total
AR	-6%	+23%	+7%
BR	-	+5%	+3%
PE	+2%	+5%	+3%
AVG	-5%	+10%	+1%
CO	-	+8%	+6%
MX	-	-8%	-
EC	-	+8%	+4%
DO	+19%	-	-
CL	+3%	+58%	+34%
CR	+10%	-3%	+5%
PA	+2%	-	-

- Comparing WAIT 2026 to 2025, overall time to availability increased in most markets, with the most pronounced delays occurring after regulatory approval rather than during approval. This pattern signals that bottlenecks shifted downstream, concentrating in the reimbursement, pricing, procurement, and implementation stages.
- Chile saw a 3% setback in approval speed along a considerable 58% increase in post-approval delays, producing a 34% overall slowdown.
- Argentina achieved a modest 6% improvement in time to approval, yet experienced a 23% increase in time to availability post-approval, resulting in a net 7% slowdown in total access timelines.
- Mexico, Dominican Republic and Panama retained a stable total time to availability.
- These trends point to system strain shifting more toward HTA, pricing, and procurement; rising innovation volumes and complexity exacerbate backlogs, capacity limits, and budget pressure.
- The implications for patients are direct and significant: longer waits mean delayed treatment initiation, prolonged disease progression, and reduced quality of life, particularly for chronic and progressive conditions where early intervention is critical. For manufacturers and health systems, lengthening timelines increase uncertainty, complicate launch planning, and reduce the efficiency of healthcare investments.

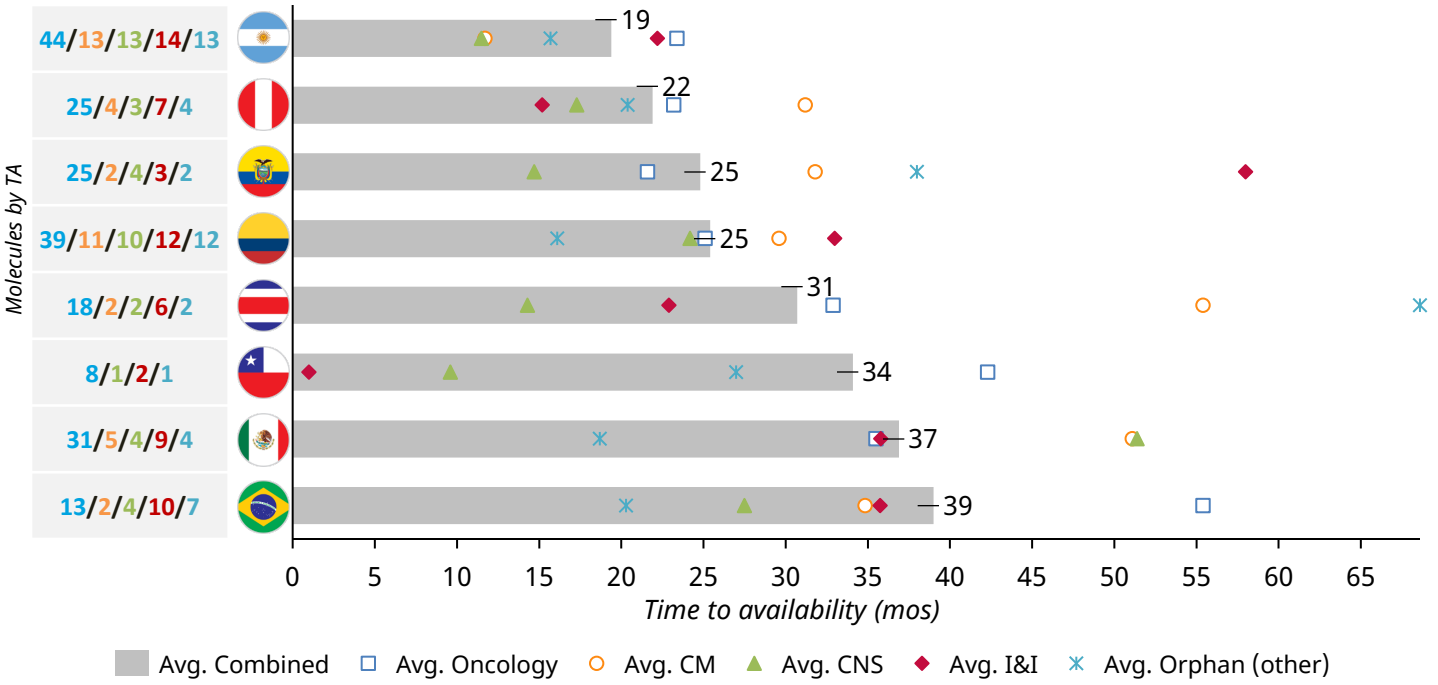
Post-approval delays drove overall timeline increases in 2026, highlighting that system strain has shifted beyond regulation to reimbursement and implementation

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency

Time to availability varies widely by therapeutic area

Orphan molecules tend to have a shorter time to availability after approval, compared to non-orphan molecules; cardiometabolic faces longest delays in general

Time to availability from local market authorization (2014 - 2025) – by TA



- Time to availability differs materially across countries and therapeutic areas, pointing to meaningful variation in how quickly post-approval access is translated into patient availability.
- Oncology and cardiometabolic therapies are above the country average in most markets, suggesting that higher disease burden does not necessarily translate into faster availability.
- Costa Rica has the widest range, where orphan (other) drugs is on average 68 months vs. CNS at 14 months (although sample sizes are small). For Brazil, Colombia, and Mexico, orphan drugs are the types of molecule with shortest time to availability when compared to other TAs; in Costa Rica, Ecuador, and Argentina, it is CNS drugs
- Therapeutic area patterns appear linked to system features: oncology timelines are likely shaped by treatment complexity and budget impact, while broader public availability remains slower in systems where access depends heavily on public adoption.
- Oncology does not feature amongst the fastest times to availability in any of the countries

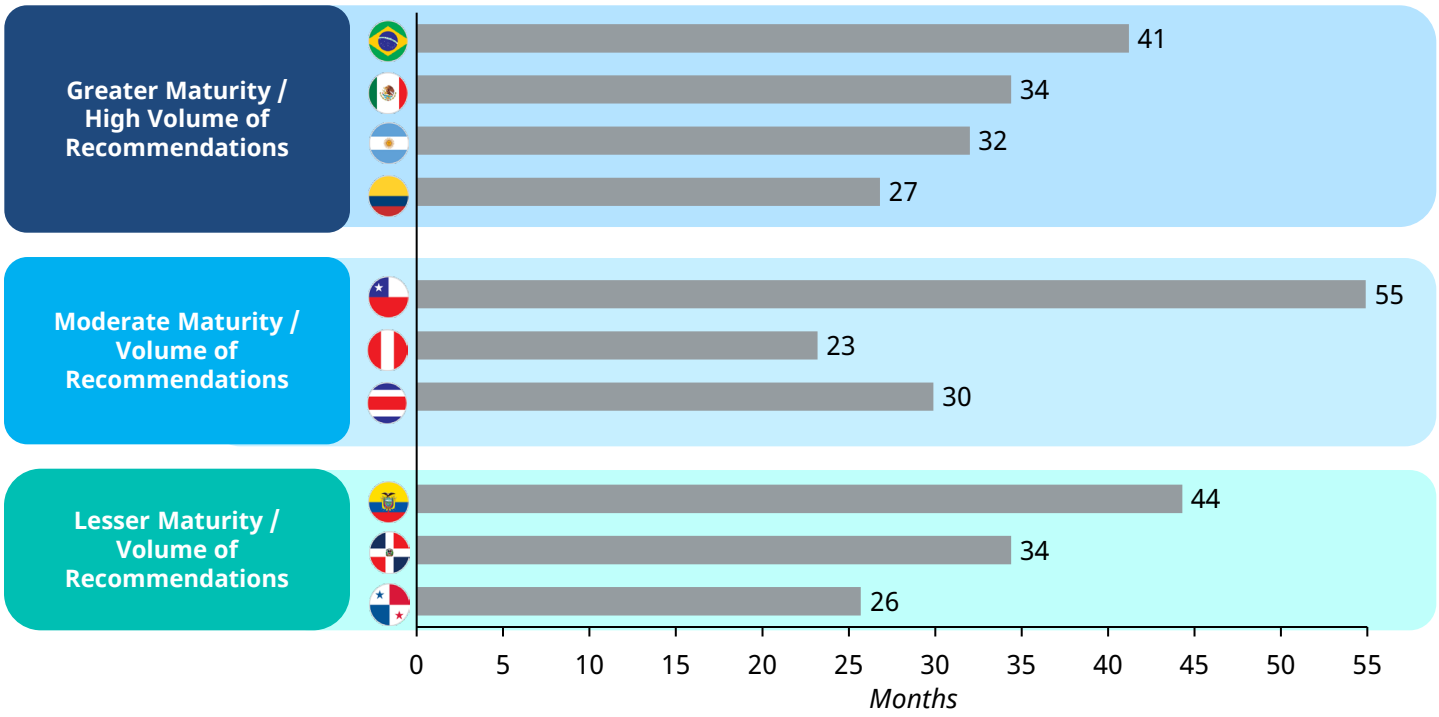
Broader, public availability is typically a drawn-out process, particularly in countries where there is a relatively large private market participation, underscoring challenges for patients in the public system more broadly

* DO and PA have no sample dates for availability
Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammatory and Immunological

Saturation results in longer processes

The maturity of HTA improves consistency, but may slow down access if adequate resources are not available

Time to Availability Based on the Maturity of Evaluation Processes



- The relationship between innovation volume and timelines is mediated by a system's maturity, specifically, design and resourcing of its processes
- More mature systems (i.e., longer track record) typically employ formalized review structures, clear criteria, and standardized pathways that reduce subjectivity and improve transparency. However, processes may become bottlenecks when capacity does not scale with demand, leading to backlogs and extended wait times despite procedural rigor.
- In contrast, less mature systems, characterized by less structured processes, may achieve faster initial decisions in some cases. However, it often comes at the cost of consistency, transparency, and predictability. Over time, these systems may struggle to manage complexity or rising volumes, leading to delays or stagnation without procedural safeguards that mature frameworks provide.
- This dynamic highlights a critical trade-off: maturity brings rigor and equity, but without adequate resourcing it can slow access; informality may enable short-term speed, but undermines long-term sustainability
- Addressing saturation in mature systems requires investment in capacity, expanding personnel, upgrading information systems, and optimizing workflow prioritization. For less mature systems, the path forward involves strengthening governance and process design to balance speed with consistency and transparency.

Maturity enables rigor but can delay access under saturation; optimizing capacity, prioritization, and process design is key to balancing both

New standards of care take significant time to establish

Even for some of the most prominent classes of innovative treatments that were established as standard of care in multiple indications have taken time above the average to reach the region

Case Studies – WAIT 2026

Case Study (MoA)	Countries with Approval (highest)	Avg Time First to Last Local Approval	Countries with Availability (highest)	Avg Time First to Last Availability	Access Tier* (highest)
PD1s	10	81 months	10	54 months	6
CDK4/6s	10	43 months	10	63 months	6
ALKs	8	41 months	8	51 months	4
JAK1s	9	17 months	7	29 months	4
ILs	10	69 months	8	46 months	6
FVIII mAb	10	66 months	10	59 months	6
CD-20 mAb	10	63 months	10	38 months	6
Gene therapy (SMN1)	5	52 months	4	18 months	3

- The classes of innovative treatments represented above generally were established as the prevailing standard of care in their respective indication/s
- In LATAM, a similar peak level of access was reached for many of the treatments, indicative of the consensus in the high clinical value that they represent for healthcare systems and further demonstrating the slow, steady, bottoms-up trend
- However, despite high clinical value and, for many of these agents, strong competition, the span of time between first regional approval and last is over 5 years for 4 of the classes
- Adding to that, time to availability was slightly lesser, but still wide span, with 4 classes with an average time of more than 4 years to availability
- In Brazil, the ALKs case illustrates the challenges of real world access in spite of clinical value: despite CONITEC recommending SUS incorporation in 2019 delays in clinical guideline updates, purchasing, and diagnostic practices led to minimal real world access; underscoring challenges beyond the decision
- These treatments form the basis of future standards of care, incorporation is critical to enable the next generation of medicines

Case studies show that even for breakthrough therapies, the road to access remains fragmented and long, though broad availability can be attained

*Tiers represent access level: 1 (lesser access) – 6 (greater access); Acronyms: MoA: Mechanism of action, PD1s: programmed cell death protein 1 inhibitors, CDK4/6s: Cyclin-dependent kinases 4 and 6 inhibitors, ALKs: Anaplastic Lymphoma Kinase inhibitors; JAK1s: Janus Kinase 1 inhibitors, ILs: Interleukins, FVIII mAb: Factor VIII monoclonal antibody, CD-20 mAb: CD20 monoclonal antibody, SMN1: Survival Motor Neuron 1; SUS: Sistema Único de Saúde

PD-1s show system readiness may constrain breakthroughs

PD-1s included in the analysis: pembrolizumab, nivolumab, atezolizumab, cemiplimab, durvalumab

PD-1/PD-L1 inhibitors are immune checkpoint therapies that block tumor immune-evasion signals, allowing the immune system to recognize and attack cancer cells. They are used across many cancers, including lung, melanoma, renal, and head and neck, and are now core standards of care, making timely access central to modern oncology outcomes

Access Tier* (highest)

6

High level of access

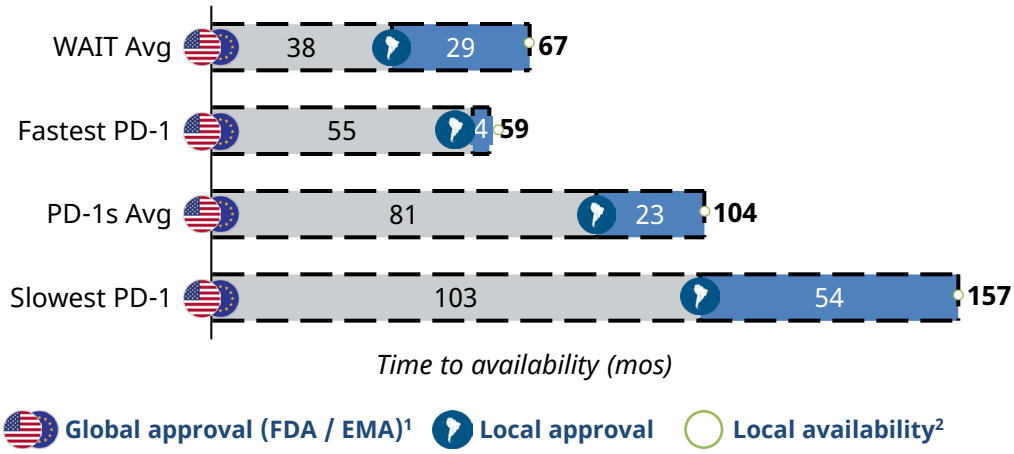
Average time from first to last local approval

81 months

Average time from first to last local availability

54 months

Time to availability from global approval (2014 - 2025) – PD-1s



- Local investment emerges as a key access driver; PD-1s with early LATAM investment (RWE, HEOR, diagnostics, clinical engagement) achieved faster and broader access, highlighting the critical nature of public-private partnership in paving access for novel classes of therapy
- However, the class also shows that clinical value alone does not mean broad, quick access; despite strong survival and QoL benefits in high-burden cancers, approval-to-availability gaps remain large due to system readiness constraints rather than lack of efficacy
- Affordability is an important structural barrier, in spite of cost-effectiveness and competition, the sheer volume of indications as well as additional costs e.g., infusion clinics, represented substantial hurdles for real-world access
- Confidential discounts, managed entry agreements, performance-based schemes and alternative funding channels enabled access in select countries but were imperfect means to institutionalize region-wide
- The PD1 class has forever changed oncology, and the next generation e.g., PDxVEGF is coming; it is an opportunity to catalyze the local industry, draw investment in studies and pave the way for important future treatments

PD-1s show that LATAM access delays are structurally driven by affordability, system readiness, and depth of local engagement, not by innovation level

*Tiers represent access level: 1 (lesser access) – 6 (greater access)
Sources: PAHO/WHO , PMC, ISPOR, Value in Health, IARC

CDK4/6s represent another heavy-hitting class facing delays

CDK4/6 inhibitors included in the analysis: ribociclib, palbociclib, abemaciclib

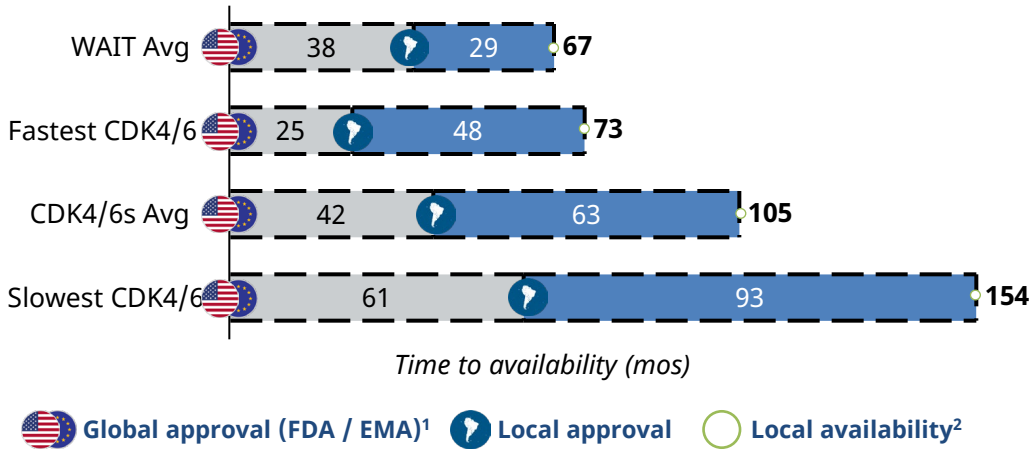
CDK4/6 inhibitors are targeted therapies that slow cancer cell division by blocking key cell-cycle proteins in hormone receptor–positive, HER2-negative breast cancer. Widely used with endocrine therapy, they are standard of care in early and advanced disease, so access delays can directly affect survival and disease control

Access Tier* (highest)
6
High level of access

Average time from first to last local approval
42 months

Average time from first to last local availability
63 months

Time to availability from global approval (2014 - 2025) – CDK4/6s



- Large clinical relevance, high system pressure, HR+/HER2– disease accounts for ~70% of breast cancer, the most prevalent female cancer in LATAM
- Younger populations and later diagnosis increase reliance on advanced therapies, amplifying affordability challenges but also the potential economic gain from treating these patients for the sake of their families, their productivity, and the healthcare system
- As a class, CDK4/6 inhibitors deliver meaningful PFS gains, with overall survival benefit demonstrated within the category and recurrence reduction in high-risk early disease. Despite guideline-defined standard of care status, chronic use and large eligible populations drive budget resistance
- Local real-world and economic evidence confirms effectiveness in LATAM populations, however, HTA assessments consistently conclude the category is not cost-effective at list prices, limiting public coverage without more extensive commercial agreements, and price-volume tradeoffs
- Widespread regulatory approval contrasts with delayed public reimbursement, shifting access toward private insurance, assistance programs, or judicialization and reinforcing inequity

CDK4/6 inhibitors again exemplify a high benefit class, with high opportunity for systems, but budget concerns become the main friction point

*Tiers represent access level: 1 (lesser access) – 6 (greater access)
Sources: LATAM RWE, Value in Health, WHO assessment of CDK4/6 inhibitors

ALKs showcase the hurdles in leveraging precision medicine

ALK inhibitors included in the analysis: alectinib, lorlatinib, brigatinib

ALK inhibitors are targeted therapies that block ALK-driven tumor growth in ALK-positive non-small cell lung cancer. They are the standard of care for this molecular subgroup, often replacing chemotherapy, so limited access can leave patients without an effective treatment option.

Access Tier* (highest)

6

High level of access

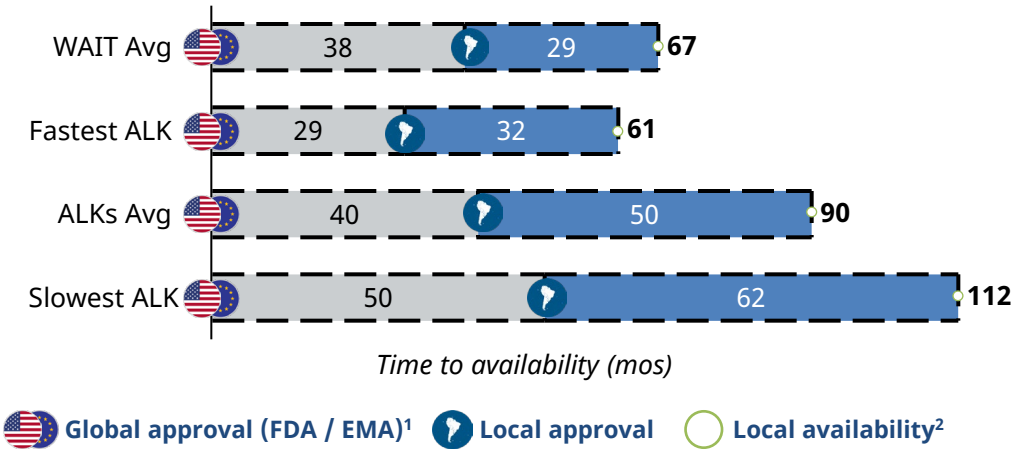
Average time from first to last local approval

40 months

Average time from first to last local availability

50 months

Time to availability from global approval (2014 - 2025) – ALKs



- ALK inhibitors are global standards of care with strong survival and CNS benefits, but in LATAM their impact is limited by insufficient access to molecular diagnostics, particularly in public systems, delaying treatment despite regulatory approval, and even with reimbursement decisions in place
- Across the category, access barriers are driven by affordability, HTA outcomes, and system constraints rather than clinical uncertainty, reflecting a core WAIT root cause: high therapeutic value without sustainable reimbursement alignment
- Variation in efficacy, CNS activity, and monitoring requirements across ALKs results in de facto prioritization driven by budget impact rather than clinical guidelines, with higher-cost options facing greater access friction
- Despite being well suited for managed entry or outcomes-based agreements, ALKs have largely relied on private access, litigation, or ad-hoc decisions, reinforcing inequities across health systems
- ALK also had multiple generations of agents with improvements in the efficacy/safety, but showing how in absence of strong pullthrough, the class can be hindered, and infrastructure built over the course of years to support access

Gaps in diagnostics, HTA alignment, and sustainable financing. have hindered multiple generations of ALKs, though with consistent improvement broad access can be reached on paper, and in the real world

*Tiers represent access level: 1 (lesser access) – 6 (greater access)
Sources: Clinical evidence, Epidemiology, ICCP, Value in Health

Oral admin. and competitive TA likely supported JAKs access

JAK inhibitors included in the analysis: barcitinib, upadacitinib, abrocitinib

JAK inhibitors are oral therapies that suppress inflammatory signaling pathways involved in immune-mediated diseases such as rheumatoid arthritis, atopic dermatitis, and ulcerative colitis. They are important options for patients with inadequate response to other treatments, and access affects long-term disease control and quality of life.

Access Tier* (highest)

6

High level of access

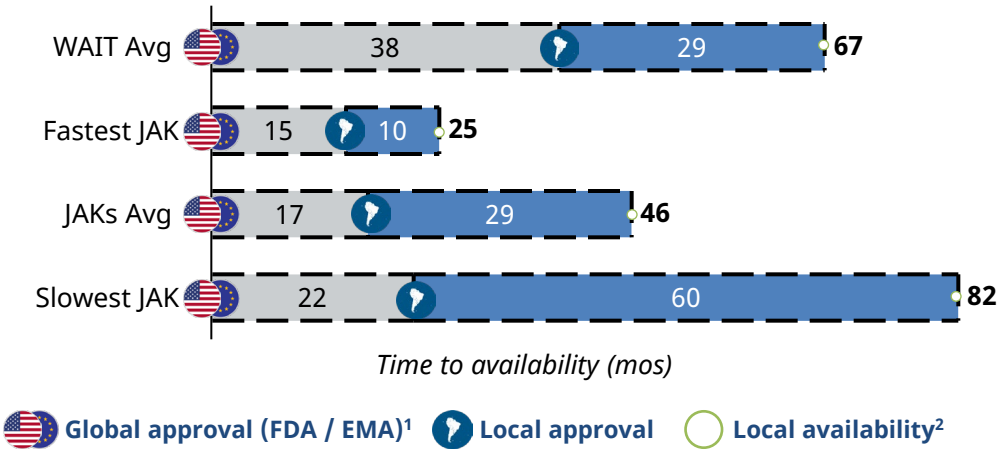
Average time from first to last local approval

17 months

Average time from first to last local availability

28 months

Time to availability from global approval (2014 - 2025) – JAKs



- As a class, JAKs reached LATAM faster than many specialty immunology therapies, indicating openness to innovative, oral targeted treatments; payer adoption lagged significantly, with reimbursement decisions trailing approvals by several years in many countries
- JAKs target chronic, disabling immune-mediated diseases with major quality of life and productivity impact, despite this, they are rarely positioned as early or standard therapy, remaining restricted to later lines after failure of conventional and biologic treatments
- The well-established prior lines of therapy naturally limit the patient population for JAKs, which may have led to a less-than-average time to availability for the class
- Class-wide safety concerns and international boxed warnings translated into cautious HTA and payer behavior in LATAM, reinforcing restrictive coverage criteria and slowing expansion despite clinical efficacy
- The oral route lowered infrastructure barriers compared with biologics and supported regulatory diffusion across countries, nevertheless, budget impact and pricing remain the dominant constraints to equitable access, where competition likely led to rapid access for the later entrants

JAKs were able to gain access faster than average, likely driven by well-established treatment paradigms, competition, oral admin, and a natural restriction to patient population by virtue of late-line use

*Tiers represent access level: 1 (lesser access) – 6 (greater access)
Sources: Budget Impact, ICER Report, Value Assessment

ILs act as an example of high-value biologics where price and not innovation determines access

IL inhibitors included in the analysis: guselkumab, risankizumab, secukinumab

Interleukin (IL) pathway inhibitors are biologics that target IL-17 or IL-23 cytokines driving inflammation in diseases like psoriasis and psoriatic arthritis. As standard treatments for moderate-to-severe disease, delays in access can prolong symptoms, disability, and healthcare burden.

Access Tier* (highest)

6

High level of access

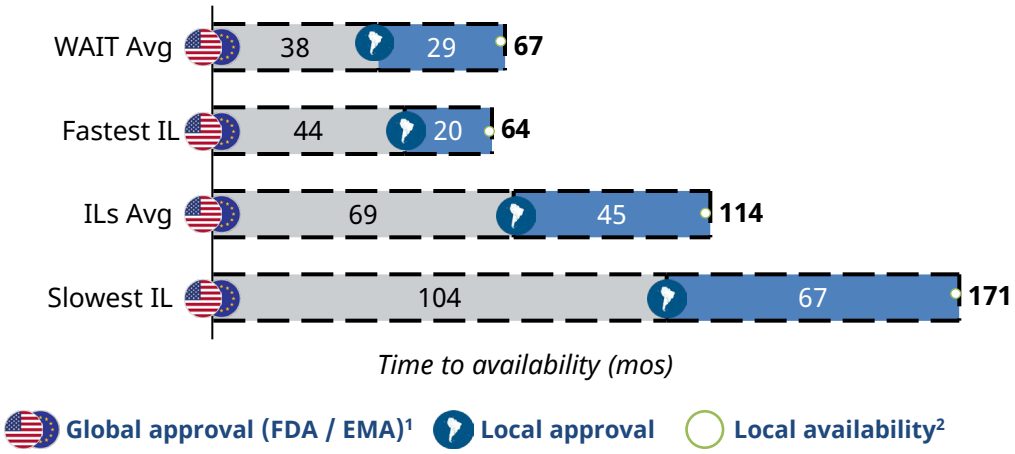
Average time from first to last local approval

69 months

Average time from first to last local availability

45 months

Time to availability from global approval (2014 - 2025) – ILs



- ILs reached LATAM relatively quickly after global approval, reflecting strong clinical pull and regulatory efficiency, but the gap between first approval and broad, sustainable access remains substantial
- High unmet need persists in a large chronic population, as moderate-to-severe psoriasis carries a substantial quality-of-life burden while biologic access remains structurally low across LATAM
- As a class, ILs deliver superior efficacy, durable responses, and more convenient dosing versus earlier biologics still, long-term use creates strain on budgets, and create high uncertainty in modeling economic outcomes, thus access was eventually broad, but slow in reaching that point for the class
- Financial agreements have been decisive, with consistent push from clinical and patient communities to drive access as key drivers that over the long run, prevail
- Fragmented health systems, limited dermatology specialist capacity, and reliance on private insurance or judicial pathways continue to shape access, even where approved, ILs remain concentrated in urban and higher-income populations

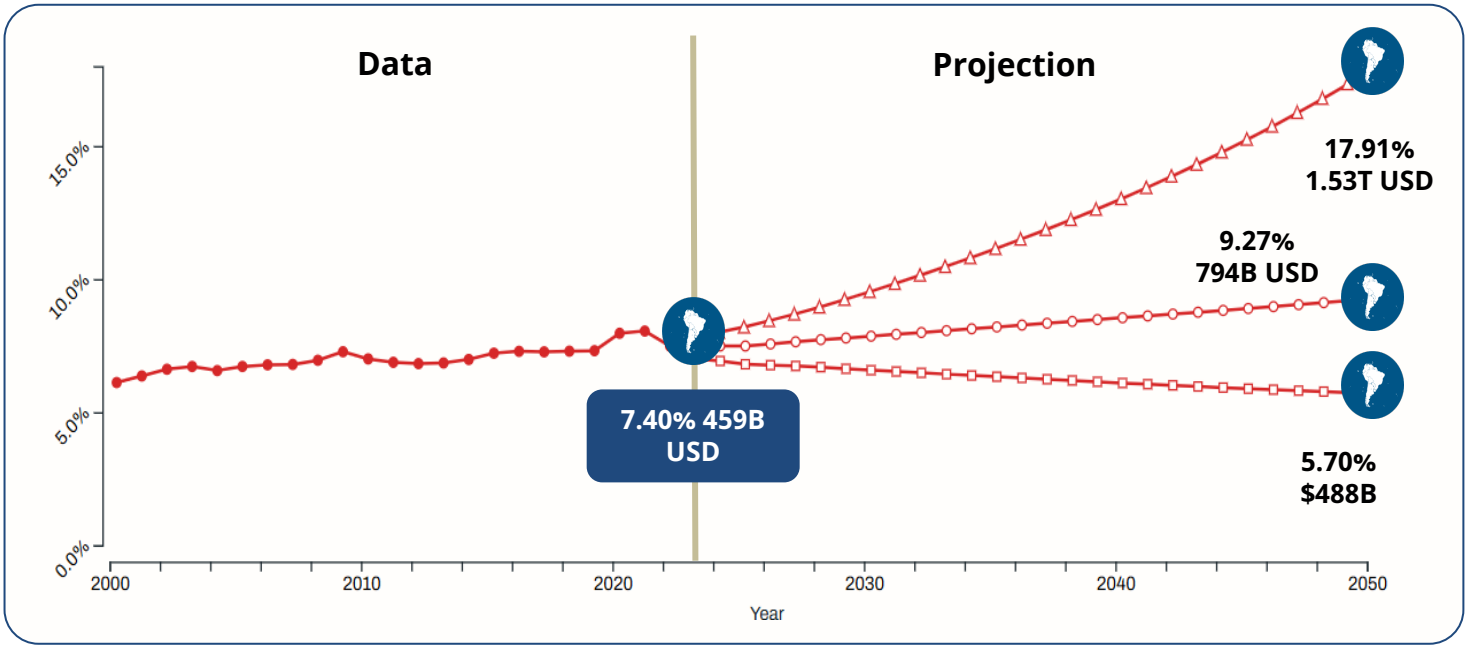
Public access to ILs has been achieved after significant price realignment, highlighting the challenges in financing chronic, biologic treatments, but high promise for QoL and productivity in this population

*Tiers represent access level: 1 (lesser access) – 6 (greater access)
Sources: RWE LATAM, CONITEC Report, Value in Health

The growing burden of disease creates divergent scenarios

The baseline forecast projects an increase in health expenditure to 9.27% by 2050 in the region

Total Health Expenditure for All Causes (Expenditure as % of GDP - (2000-2050)



- Health expenditure in LATAM is projected to rise substantially over the coming decades, driven by aging populations, rising non-communicable disease prevalence, and increasing uptake of innovative treatments
- Under a baseline scenario, which assumes current policy trajectories and moderate investment growth, health spending as a share of GDP is expected to increase from ~7.4% today to ~9.3% by 2050. However, this trajectory is sensitive to policy and system design choices
- An alternative lower scenario, reflecting constrained budgets and limited innovation uptake, would see spending stabilize near 5.7% of GDP, while a higher scenario, incorporating universal health coverage expansion and broader access to innovation, could push spending toward 17.9%
- In the near term (2025–2030), systems will face pressure from complex, high-cost therapies amid tight budgets and political volatility. Without capacity-building, bottlenecks will intensify and access gaps widen
- In the mid term (2030–2040), rising chronic demand will require aligned financing and capabilities. Failure to plan risks fiscal stress and deepening inequities
- In the long term (2040–2050), sustainability will depend on maturity and spending efficiency. Optimized processes and integrated innovation will achieve better outcomes per dollar

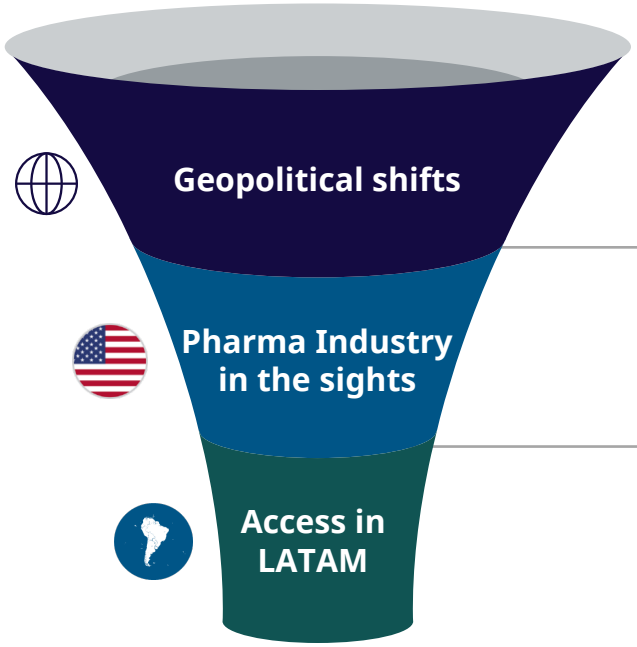
Increasing investment in systems is critical to avoid exponential growth in future expenditure; sustainability depends on governance, prioritization, and efficiency to align investment with impact

Acronyms: GDP: Gross Domestic Product

2025 & 2026 have brought significant change, and opportunity

Amidst global changes, the opportunity in the region can be repositioned to attract investment and stimulate the sector

Key Recent Market Changes Influencing the Pharmaceutical Landscape



2025: A New Global Geopolitical Order

Pressure on Global Drug Prices

A Different Approach for LATAM

- The global landscape is undergoing significant transformations which are prompting stakeholders to reassess dependencies and diversify supply, creating opportunities for LATAM to position itself as a strategic partner
- At the geopolitical level, recent US policy changes have marked the end of the post–Cold War and altered the industry's status quo through tariffs and withdrawal from key international bodies. This introduces volatility into global trade and supply chains, but also opens space to reassert strategic autonomy and negotiate new partnerships.
- At the same time, the pharmaceutical industry faces intensified scrutiny, with a global lens on R&D spending and the "Most Favored Nation" approach exerting downward price pressure in developed markets, prompting companies to reassess launch sequencing and pricing strategies
- While LATAM is not explicitly referenced in MFN frameworks, it is receiving increased attention within broader National Security Strategy discussions, particularly around resilience and nearshoring. As laboratories seek alternatives to mitigate MFN impacts, the region is gaining relevance for differentiated pricing, partnerships, and investment.
- These shifts create openings for LATAM countries to position themselves strategically, leveraging regulatory maturity, market size, and geographic proximity to attract investment and negotiate more favorable access terms

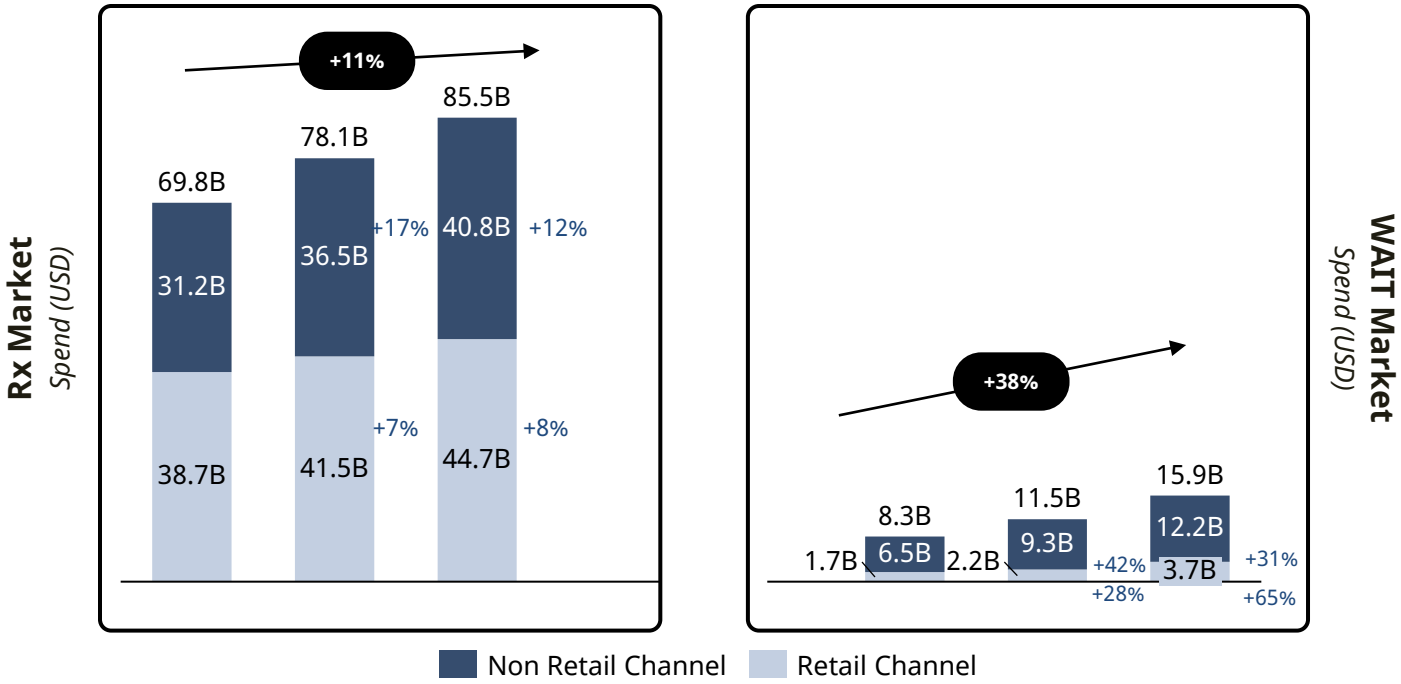
Global shifts in developed markets are reshaping pharma strategies, creating an opportunity to improve LATAM's positioning in the global pharma sector

Acronyms: R&D: Research and Development; MFN: Most Favored Nation

There has been growth in spending over the last three years

Spending on innovative treatments has increased considerably over the past two years, with institutional purchases assuming greater significance

Prescription Rx and WAIT Market Spend – MAT Oct 2025



- Pharmaceutical spending across LATAM has grown significantly, reflecting increased incorporation of innovative therapies and evolving treatment paradigms. Total prescriptions expenditure has risen 11%, while spending on medicines in the WAIT cohort has grown almost 40% over 3 years.
- Much of this growth is driven by non-retail, institutional channels, rather than traditional retail pharmacy. This shift reflects the nature of recent innovation (e.g., biologics, specialty therapies) which are administered in controlled settings and managed through centralized purchasing.
- The entry of high-cost biologics, precision oncology agents, specialty immunomodulators, and advanced therapies is starting to shift the composition of spending, though it is still a recent trend with older technologies dominating
- The implications are multifaceted. On one hand, rising spending signals improving access to innovation and greater willingness by payers to invest in newer treatments. As budgets expand to accommodate costly therapies, systems must ensure that spending growth is matched by governance capacity, monitoring and administration to ensure spend is strategically administered to maximize benefit and continue expansion.

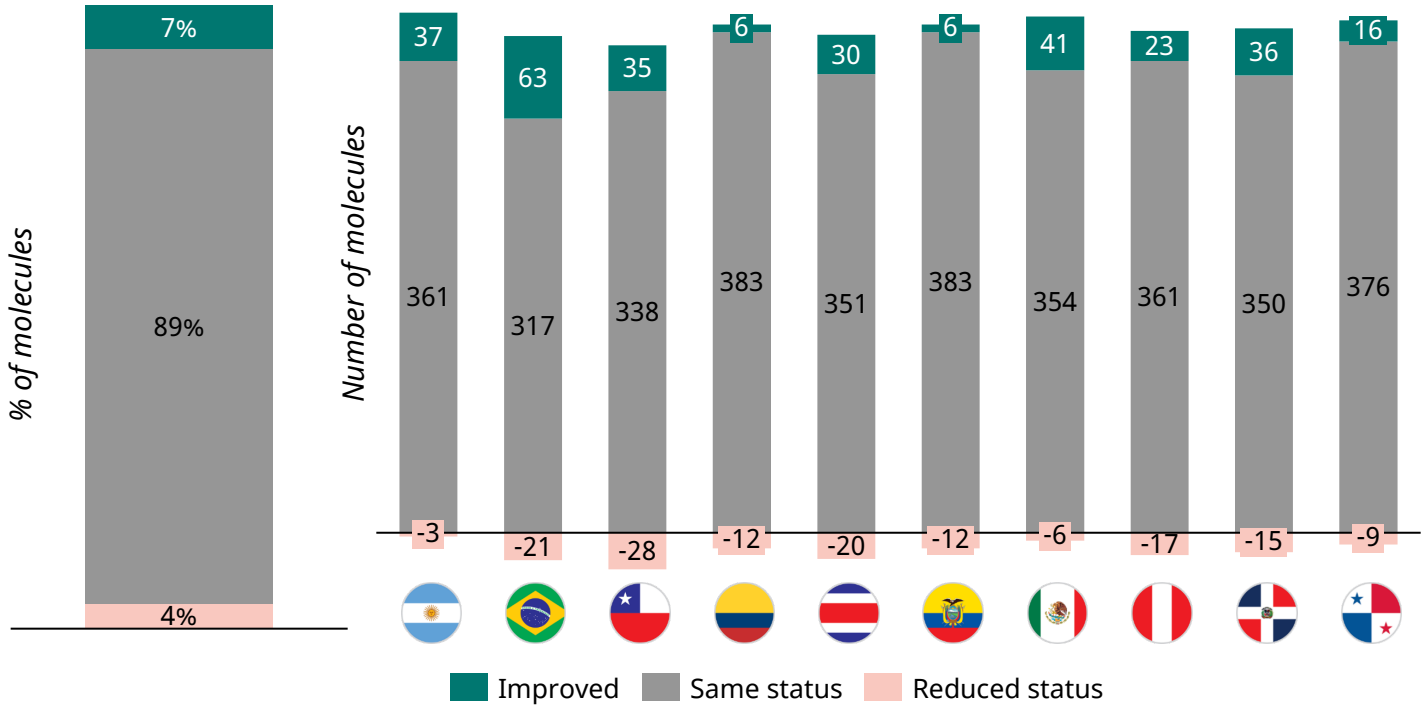
Rising innovative treatment spending signals progress but demands governance, prioritization, and equity to ensure sustainable, broad patient impact

MAT Oct 2025 – USD Fixed Price (Brasil, Mexico, Colombia, Chile, Costa Rica, Peru, Dominican Republic, Panama) and USD Mix Price (Argentina);
Acronyms: MAT: Moving Annual Total; Sources: Fifarma – Drug Spend

Improvement rate is generally incremental year to year

7% of molecules advanced in access compared to 2024-2025; BR and MX R stood out in terms of improvements, together with CR/DR while CO shows a noticeable slowdown from previous years

Improvement Index by Country (2026 vs 2025)



- Overall, movement between availability status classifications varied by country, with Brazil leading in access expansion with 63 improvements
- Mexico and Argentina saw a consistent upward trajectory with a high net access gain as political continuity and traction allow for incremental gains
- Costa Rica and Dominican Republic, especially considering the size of the markets, saw considerable gains too, approaching larger markets in terms of net improvement
- Colombia and Ecuador saw near-stagnant progress, reflective of broader systemic challenges that divert attention and political will to healthcare
- Reductions typically reflect changes in access and/or purchases due to competition, redundancies as newer technologies or generics/biosimilars become available, and on occasion, withdrawals from manufacturers

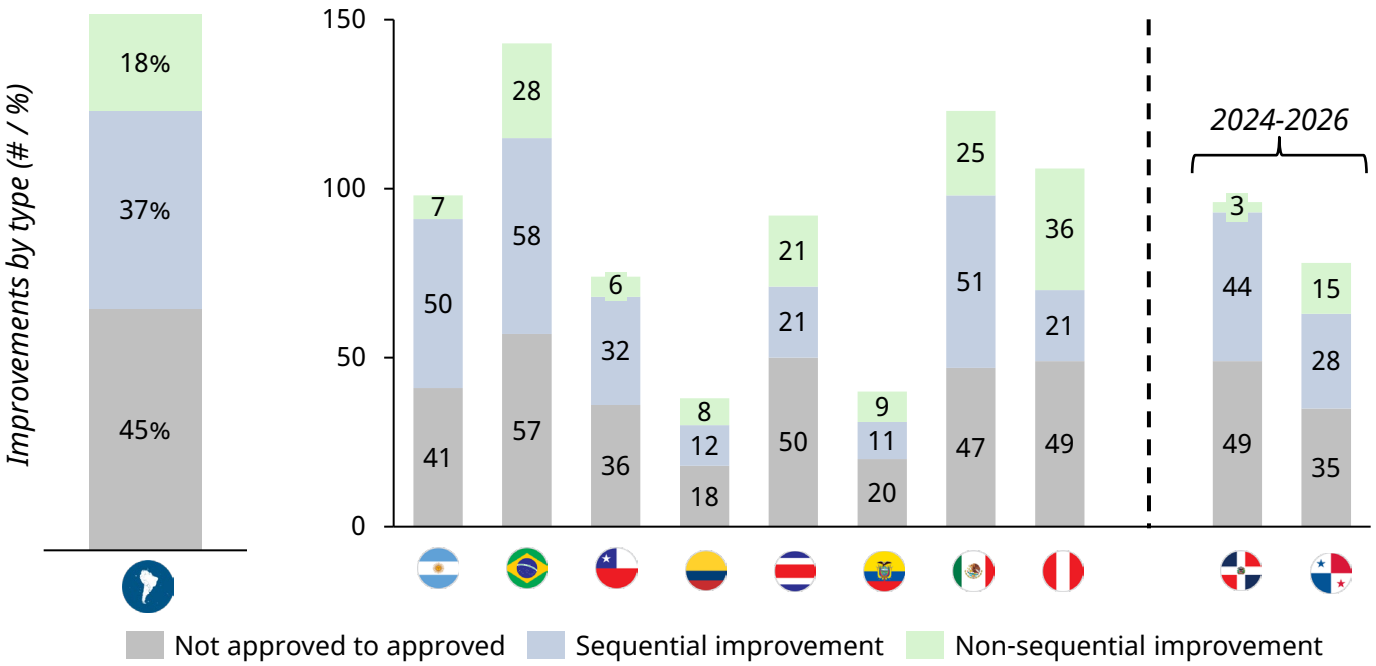
With increasing clinical innovation, regulatory and HTA agencies may have increasing backlogs of assessments, compounding challenges for patients in gaining access to innovative molecules

*See local definitions for further detail

The improvements are primarily sequential

Over 80% of the observed improvements consist of new approvals or sequential access changes, demonstrating a "bottom-up" approach

Cumulative Improvement Index (2023-2026)



- Access improvements in LATAM follow a consistent pattern with most progress coming from new regulatory approvals and sequential movements through availability tiers (bottoms-up)
- Between 2023 and 2026, cumulative improvement has been steady and increasing, with an average of 37% of gains attributable to sequential transitions e.g., approved, not available to privately available, or privately available to limited public availability
- Initial approvals account for ~45% of improvement, reflecting the entry of newer molecules. Non-sequential jumps, remain rare and are concentrated in select markets like Mexico and Peru, where policy interventions or centralized procurement enabled accelerated inclusion
- While sequential processes can provide governance rigor and allow for incremental evidence generation, they also extend timelines for the majority of patients
- The cumulative strengthening of improvement over time suggests that systems are gradually incorporating more molecules, though the pace remains slow relative to innovation volume; for laboratories and patients, this underscores the importance of understanding pathway structure and engaging early across stakeholders

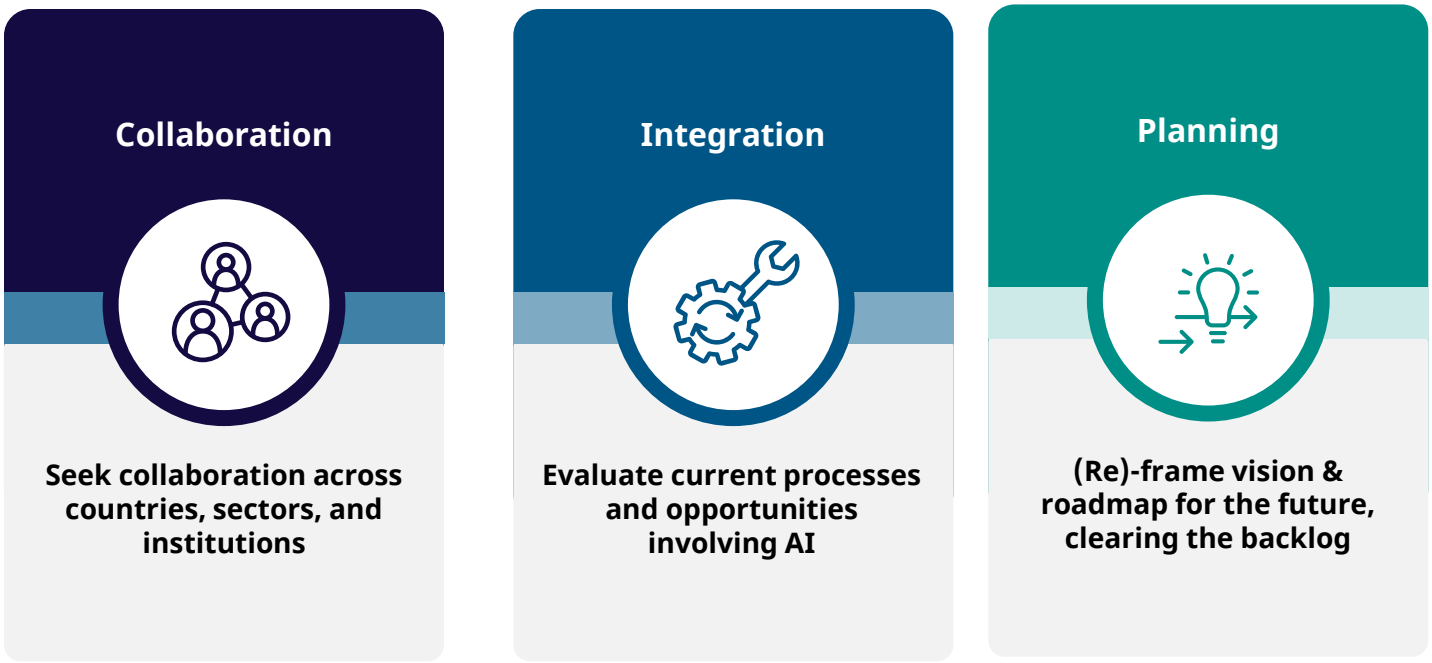
"With better access, we can manage much of the burden far better; otherwise, it will spiral out of control..."

- ex-Minister of Health

Investment must underpin key activities to drive improvement

It is possible to advance toward a more sustainable state of access by taking these measures today, and striving toward a leap in access as opposed to incremental improvements

Key Strategies Towards Innovation and Access in LATAM



- A path toward more sustainable access is emerging, grounded in three strategic pillars: collaboration, integration, and planning. These levers, if pursued with intent and coordination, can strengthen institutional capacity, improve process efficiency, and align stakeholder interests in ways that translate global shifts into tangible health gains.
- Collaboration offers opportunities to pool expertise, share learnings, and coordinate action across borders and sectors. Regional mechanisms (e.g., PAHO, RedEtsa) provide platforms for harmonizing regulatory standards and coordinating procurement. Strategic public-private partnerships can attract investment, accelerate local manufacturing, and enable innovative financing models. Greater integration of the local innovation ecosystem amplifies capacity and creates a virtuous cycle of innovation uptake and reinvestment.
- Integration of emerging technologies, particularly AI, presents efficiency opportunities. Use cases in regulatory assessment and HTA can reduce timelines and resource burdens. It also enables re-evaluation of latent opportunities, such as risk-sharing agreements, which can align incentives while managing uncertainty.
- Planning is foundational. Immediate interdisciplinary dialogue can break down silos and improve coordination. Reducing short-term saturation through prioritization of technologies and initiatives will prevent backlogs. In the long-term, targeted investments will optimize system potential to manage future innovation waves.

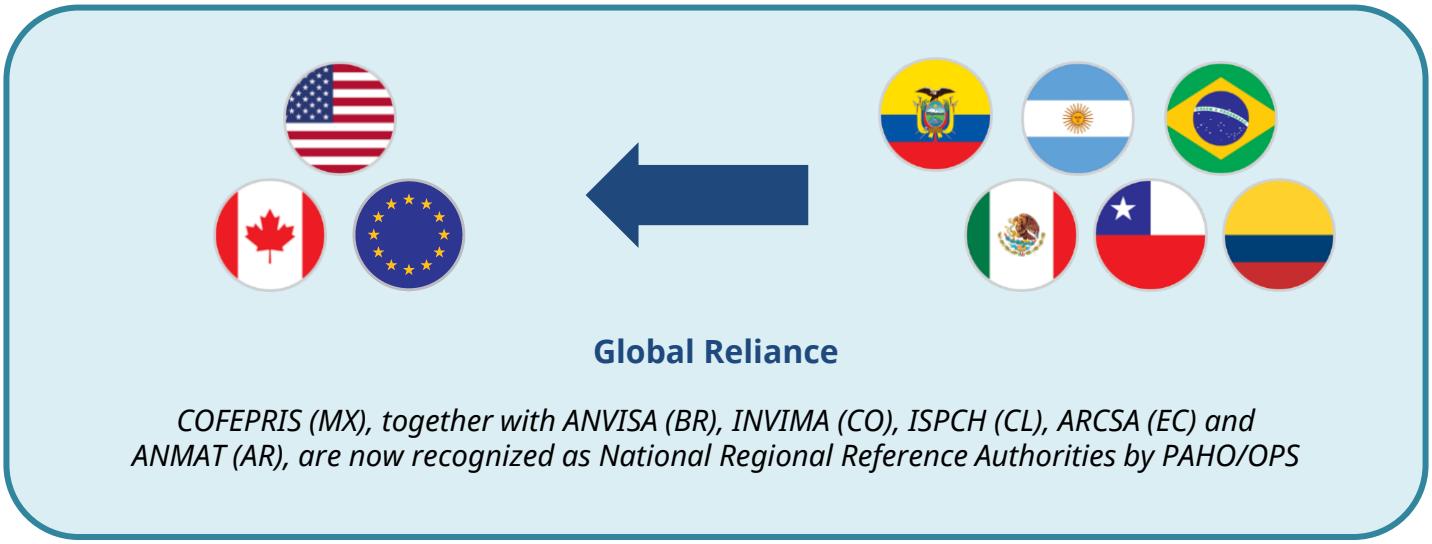
Sustainable access advances through collaboration, integration, and planning that reduces saturation and attracts investment

Acronyms: AI: Artificial Intelligence; PAHO: Pan American Health Organization; RedEtsa: Health Technology Assessment Network of the Americas

LATAM's regulatory agencies are gaining global recognition

Six LATAM agencies are now recognized as National Regional Reference Authorities by PAHO/OPS, strengthening global reliance on LATAM regulatory capacity

Global Reliance of Latin American Health Agencies



- Several agencies have been recognized as National Regional Reference Authorities (NRAr) by PAHO/OPS, signaling their maturity, technical rigor, and alignment with international standards.
- The implications for the region are significant. Global reliance strengthens credibility, positioning LATAM agencies as trusted partners in the international regulatory ecosystem and increasing their influence in shaping global standards and guidelines.
- It also creates opportunities for regional collaboration and harmonization: countries with less mature systems can leverage NRAr decisions to expedite approvals, reduce duplication of effort, and improve consistency across markets. This can shorten timelines, reduce submission burdens for manufacturers, and improve predictability for patients and stakeholders, particularly for innovative therapies where rapid access is critical
- However, realizing the full benefits of NRAr status depends on continued investment and coordination; sustained progress will require regional coordination mechanisms, shared data platforms, and capacity-building initiatives that extend NRAr standards and practices across the broader LATAM regulatory landscape
- Looking ahead, NRAr recognition positions LATAM to play a more strategic role in global pharmaceutical development and access if agencies continue to strengthen processes, share learnings, and collaborate regionally, global reliance can translate into faster, more predictable access pathways and improved system readiness for the next generation of innovation

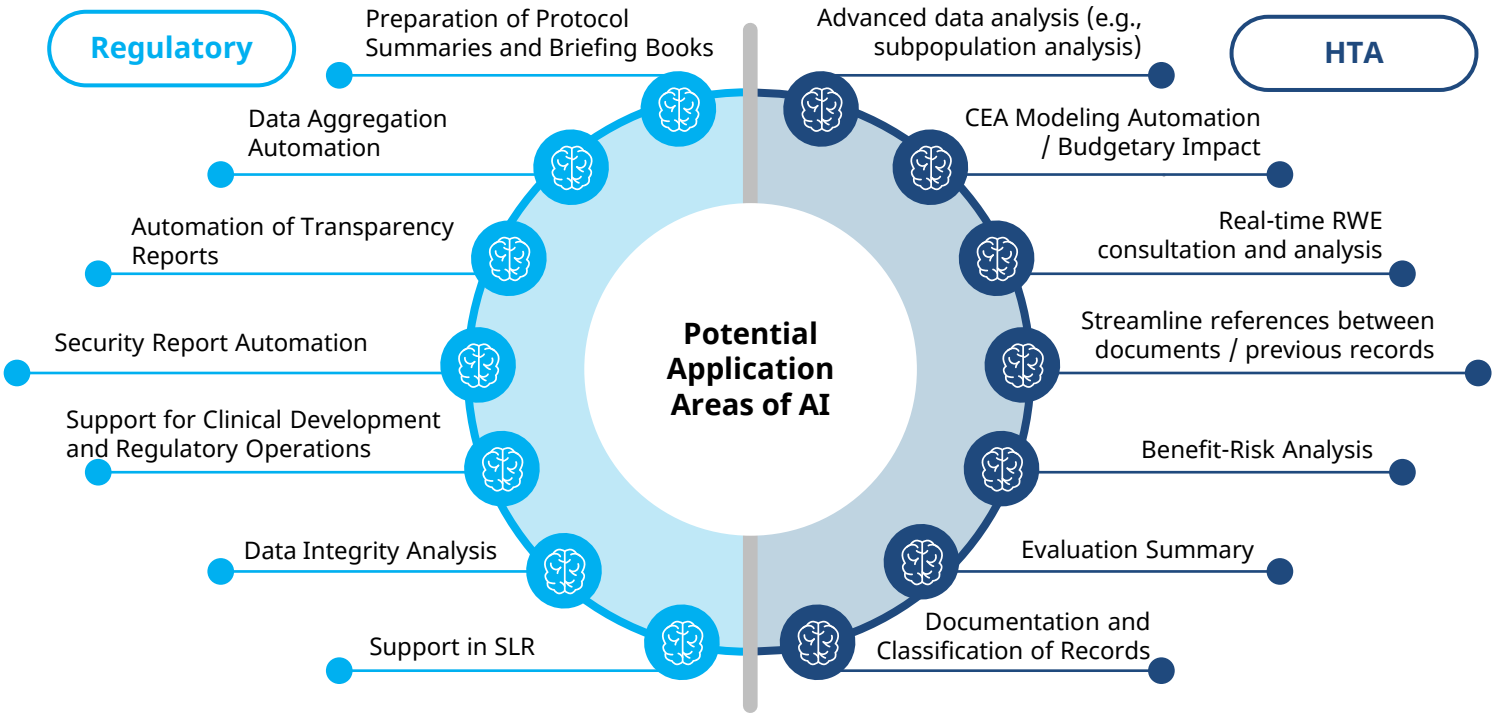
NRAr recognition strengthens LATAM's global regulatory credibility and creates pathways for harmonization

Acronyms: COFEPRIS: Comisión Federal para la Protección contra Riesgos Sanitarios, ANIVISA:Agência Nacional de Vigilância Sanitária, INVIMA:Instituto Nacional de Vigilancia de Medicamentos y Alimentos, ISPCH: Instituto de Salud Pública de Chile, ANMAT: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, NRAr: National Regional Reference Authorities, PAHO/OPS: Pan American Health Organization

The possibilities with artificial intelligence are numerous

Both in regulatory processes and in technology assessment, there is significant potential to utilize AI to enhance efficiency and ensure quality in technology evaluation processes

Potential Applications of AI in Health Regulatory Processes



- Artificial intelligence is emerging as a practical lever to address persistent bottlenecks in regulatory and HTA processes across LATAM
- Near-term applications such as automated literature review, evidence extraction, and dossier triage can reduce manual workload, improve consistency, and shorten review timelines. AI-enabled tools can also support real-world evidence synthesis, budget impact forecasting, and prioritization by analyzing historical and administrative data, helping systems focus resources on therapies with the highest potential impact.
- Looking ahead, AI can strengthen transparency and governance by identifying patterns in timelines, decisions, and outcomes, and by enabling real-time visibility into backlogs and process performance
- These capabilities are particularly relevant as innovation volumes and complexity continue to rise. However, realizing AI's benefits depends on foundational enablers, including data readiness, clear governance frameworks, and workforce capabilities to interpret and validate outputs. Without these, AI risks adding opacity rather than efficiency. For LATAM, AI represents a scalable opportunity to amplify limited institutional capacity and improve access performance, if adopted strategically.

AI can accelerate regulatory and HTA processes and improve consistency, but requires investment in data, governance, and workforce to deliver sustainable impact

Acronyms: AI: Artificial Intelligence, HTA: Health Technology Assessment, CEA: Cost Effectiveness Analysis, RWE: Real-World Evidence

Recent system reforms are creating tangible opportunities

Targeted policy updates, stronger HTA processes, and procurement reforms are beginning to emerge and may translate into broader, more predictable patient access

Recent Health Reforms in Latin America

LATAM countries continue to advance initiatives to strengthen health systems and expand patient access

- Policy updates across therapeutic areas
- Updates to HTA materials and increased rigor
- Efforts towards a more universal health system
- Streamlining waiting lists
- Support of oncology innovations
- Dedicated funding and centralized procurement
- Dedicated registries for rare diseases
- Enhancement of institutional capacities
- Expansion of the private sector

- Healthcare systems are dynamic in the region, seeking to evolve to address issues, with now being a critical juncture for growth and improvement
- LATAM is witnessing a wave of reforms that signal meaningful progress toward strengthening access pathways for innovative medicines
- In Brazil, updates to the national cancer policy are strengthening access pathways for oncology and changes allowing selected drugs to bypass waiting lists could accelerate access. These updates may translate approval into faster, real-world uptake.
- Mexico´s consolidated "mega-purchases" and movement toward a more universal system may improve access, a national rare disease registry could signal stronger focus on orphan disease, and increased HTA rigor is also supporting more structured, evidence-based decisions
- In Peru RENETSA strengthened evaluation and prioritization of oncology innovations, and dedicated funding and centralized procurement have enabled broad public access
- Costa Rica's HTA manuals have been updated, improving clarity and consistency, while workforce expansion strengthens capacity
- In Colombia and Ecuador, private-sector expansion is acting as a complementary access channel though driven by patient out of pocket spend in systems where significant gaps exist

These reforms support more predictable timelines, transparent decision-making, and broader patient reach, positioning the region to better manage rising innovation

Acronyms: RENETSA: Red Nacional de Evaluación de Tecnologías Sanitarias

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Silvana has over fifteen years of management experience. Silvana is a forestry Engineer with a Master of Business Administration (M.B.A.) focused on International Business from Tulane University - A.B. Freeman School of Business.

Local trade associations also supported in the development and validation of the study

AMIIF, MX

CAEME, AR

AFIDRO, CO

CIF, CL

ARAPF, RD

FEDEFARMA, CAC

INTERFARMA, BR

ALAFARPE, PE

IFI–Promesa, EC

Definitions and additional notes on methodology

Assumptions and rules to identify a NAS

- A NAS must be an active moiety and therefore cannot be a purified biologic entity (e.g., biosimilar, bio-betters, certain tissue products
- If the new approval is a combination, it needs at least one new compound in the product
- The NAS may be a pro-drug (i.e., a substance which is inactive when administered and which requires metabolism to produce an active metabolite). In such case, the active metabolite may not be novel. However, provided that the pro-drug is novel (i.e., not previously approved by any regulatory authority and not available for commercial sale), the pro-drug would be a NAS
- A different ester form of an existing substance would also not be precluded from consideration for NAS status
- New salts, polymorphs, enantiomers, isoforms, solvates, hydrates, crystalline forms, or other noncovalent derivatives of previously approved substances are not NASs unless they are deemed to be by a regional or national regulatory authority

Selection of NAS molecules

1. NAS with FDA/EMA approval 2014-2025 in relevant TAs
2. Global launch rest of world - (without US launch): Products that are typically not exposed to the global market e.g., homegrown PD-1s in China, endemic response in Africa etc.
3. Pandemic response - outbreaks (e.g., COVID), and respective treatments may be subject to exceptional routes to access and procurement dynamics
4. Vaccines - also have different routes to access, confounding comparison; FIFARMA Time to Vax study in development to assess these separately
5. Other non-comparable agents e.g., imaging/diagnostics - agents not directly used in treatment and also not directly comparable
6. Withdrawn/not launched - typically a repeal of conditional approval based on not meeting evidence requirements and resulting in global withdrawal/or not launched

	Overview of additional TAs selected		
	I&I	**CNS**	**CM**
ATC2 Examples**	L4, M1, D5, A7	N3-7, L04	B1, C2, C10, A10
Class Examples	ILis, JAKis	CGRPis, antiamyloid mAbs	PCSK9i, GLP1s, GH
Product Examples	Skyrizi, Olumiant, Cibinqo, Ultomiris, Tremfya	Leqembi, Zurzuvae, Nurtec, Ubrelvy	Ozempic, Ngenla, Repatha
Indication Examples	RA / CD / UC / PSO / PSA	AD / MS / ALS / DMD	HF / Diabetes / GHD

Notes on sources and validation process

THIS REPORT IS BASED ON THE SOURCES DETAILED BELOW

IQVIA NRC/ MIDAS™ is a unique platform for assessing worldwide healthcare markets. It integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and provides estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history. IQVIA MIDAS was used by each local IQVIA team to provide the existing data

PUBLICLY AVAILABLE INFORMATION for each market was incorporated in the study from HTA agencies and regulatory bodies

LABORATORY INTERNAL DATA was asked via a Smartsheet survey and collected from each of the manufacturers included in the study, as well as via interviews to understand underlying dynamics

LOCAL TRADE ASSOCIATION DATA was collected from associations and validated, in addition to the development of the definitions for their respective countries

Former **Ministry of Health stakeholders** were interviewed across a number of countries in scope to provide additional perspective and validation

THE DEVELOPMENT OF THE REPORT FOLLOWS A PROCESS OF MULTI-STAKEHOLDER INPUT AND VALIDATION

The initial selection of molecules as described on page 20 is made the core IQVIA project team and validated by FIFARMA

Definitions for availability are developed/updated by the local IQVIA consulting teams and validated by local trade associations

The approval/availability data is then gathered by IQVIA local consulting teams leveraging the data sources outlined (to the left)

This data is validated by IQVIA and FIFARMA and, in a confidential manner, shared to the respective, marketing-authorization laboratories for validation and complementing

IQVIA local consulting teams perform a final validation of the data and IQVIA core project team performs the relevant analyses

IQVIA core project team develops the preliminary report for final validation by the FIFARMA and local trade organization representatives prior to publication

For local country reports, trade associations perform a further validation prior to publication

Healthcare coverage by country (% of population covered)

Country	Public Healthcare Coverage	Private Healthcare Coverage*
Argentina	61.07%	14.43%
Brazil	44.15%	29.62%
Chile	48.52%	12.33%
Colombia	99.00%	15.49%
Costa Rica	70.70%	5.17%
Dominican Republic	64.95%	9.99%
Ecuador	62.22%	6.89%
Mexico	48.63%	10.13%
Panama	48.00%	12.00%
Peru	63.60%	9.40%

**Private insurance, excludes population with access limited to out-of-pocket payment*
Weighted access weights molecules by country and coverage level as follows: full availability = 1; limited availability = private coverage + 50% of public coverage; only private availability = private coverage; approved-not-available = 10% of private coverage

Sources: World Health Organization - Global Health Expenditure Database; World Bank; PAHO – Health in the Americas Country Profiles

Exchange rates used by country and period

Country	MAT OCT 23	MAT OCT 24	MAT OCT 25
Brazil	5,34	5,34	5,34
Chile	935,02	935,02	935,02
Colombia	3.773,58	3.773,58	3.773,58
Costa Rica	1,00	1,00	1,00
Dominican Republic	53,81	54,16	53,98
Ecuador	1,00	1,00	1,00
Mexico	18,42	18,42	18,42
Panama	1,00	1,00	1,00
Peru	3,37	3,37	3,37
Argentina	256	858	1.182

General Definitions from spend report

General Definitions

- **Retail Channel:** Pharmaceutical sales channel comprising medicines dispensed directly to patients through retail pharmacies and drugstores.
- **Non-Retail Channel:** Pharmaceutical sales channel covering institutional distribution settings, including public and private hospitals, clinics, and other healthcare institutions. In many Latin American countries, this channel is predominantly publicly financed. In Brazil, expenditure within the non-retail channel can be distinctly segmented between public and private sector financing.
- **OTC drugs:** Over-the-Counter (OTC) drugs are defined as pharmaceutical products that may be dispensed directly to consumers without the requirement of a medical prescription, based on an assessment by regulatory authorities that such products are safe and effective for use without direct supervision by a prescriber, provided they are used in accordance with approved labeling and instructions. Internationally, OTC drugs are understood as medicines intended for the prevention, relief, or treatment of mild, self-limiting conditions.
- **Public Health Expenditure (GHED):** In the WHO Global Health Expenditure Database (GHED), Government Health Expenditure refers to Domestic General Government Health Expenditure (GGHE-D) and is defined as public expenditure on health financed from domestic government revenues, including resources managed through central, state, and local governments, as well as compulsory social health insurance schemes classified within the general government sector. It encompasses all current health spending by government entities on health care goods and services, irrespective of the provider, and excludes health expenditures financed by households, voluntary private insurance, corporations, or external donors. The metric is compiled in accordance with the System of Health Accounts 2011 (SHA 2011) framework, ensuring consistent tracking of public resource flows for health across countries and over time
- **MAT:** Moving Annual Total (MAT) is a time-series metric that represents the sum of values accumulated over the most recent rolling 12-month period, updated continuously as new data points become available. Rather than being tied to a fixed calendar year, MAT recalculates the annual total at each observation point by adding the latest month (or period) and dropping the corresponding period from the previous year. This approach smooths short-term volatility, mitigates seasonal effects, and provides a more stable view of underlying trends in indicators such as expenditure, utilization, or sales over time.
- **Therapeutic Area (TAs):** A grouping of medicines based on the diseases or conditions they treat, used to organize pharmaceutical market**.** This study used the same divisions proposed in the FIFARMA WAIT study.

Spend report appendix

Calculation of the main indicators	
Total drug spend	Total drug sales in USD
Total drug use	Total drug sales in units. For OECD countries it was considered sales in Standard Units (SU)
WAIT drug spend	Sales in USD only for molecules included in the FIFARMA 2025 WAIT study
WAIT drug use	Sales in Units only for molecules included in the FIFARMA 2025 WAIT study
KPIs on product sales	Market data was obtained from IQVIA audits considering the most recent MAT (Moving Annual Total) – MAT OCT 2025
Averages (Avg)	The averages presented are simple averages between countries, not weighted by population or expenditure
Per capita metrics	For per capita metrics, population data for countries were obtained from GHED
GDP	GDP data were obtained from the World Bank
Health expenditure indices	Health expenditure indices were obtained from GHED

This report is based on the sources detailed below

- **IQVIA PM LATAM** is a database that consolidates information from local audits in each IQVIA country, capturing pharmaceutical market sales from both retail and non-retail channels.
- **IQVIA MIDAS** is a global pharmaceutical market audit system that consolidates and harmonizes national sales and volume data for medicines, enabling comparable analyses of market performance across countries, therapeutic classes, products, and companies. The data represents standardized estimates of market activity, derived from local sources and methodologically adjusted to support international comparability.
- **WHO Global Health Expenditure Database (GHED)** is the World Health Organization's official repository of internationally comparable data on health expenditure. It provides standardized, open-access information on health spending across countries and over time, covering total health expenditure and its breakdown by financing sources, financing schemes, providers, and health care functions. The database is compiled and updated annually in collaboration with WHO Member States, using national health accounts, government financial records, and official statistics, complemented where necessary by WHO estimates to ensure cross-country and temporal consistency

LATAM countries macro data assumptions

Country	Population	GDP per Capita – USD	Health Expenditure per Capita
Brazil	211 M	10,378	1,010
Argentina	46 M	14,182	1,457
Mexico	130 M	13,826	761
Colombia	52 M	7,001	571
Chile	20 M	17,424	1,760
Costa Rica	5 M	16,942	1,163
Peru	34 M	7,902	446
Dominican Republic	11 M	10,630	489
Panama	4 M	18,701	1,558
Ecuador	18 M	6,738	509

Sources: GHED, 2023 (Population and Health Expenditure); World Bank, 2024 (GDP/CAP)

Spend report appendix

Table 3 - Report 10 Latin American countries macro data assumptions and sources

Country	Population	GDP per Capita – USD	Health Expenditure per Capita
Australia	26 M	67,129	5,142
Austria	9 M	56,956	-
Belgium	12 M	54,898	4,369
Canada	40 M	56,394	4,477
Czech Republic	11 M	31,653	-
Estonia	1 M	31,109	-
France	68 M	46,184	3,645
Germany	83 M	55,837	-
Greece	10 M	23,382	994
Hungary	10 M	22,295	1,042
Ireland	5 M	107,889	-
Italy	59 M	40,236	-
Japan	124 M	33,876	3,086
Latvia	2 M	22,609	978
Lithuania	3 M	29,393	-
Netherlands	18 M	68,414	-
New Zealand	5 M	49,912	-
Norway	5 M	87,985	7,144
Poland	37 M	24,977	-
Portugal	11 M	29,012	-
Slovenia	2 M	34,127	-
Spain	48 M	33,692	2,274
Sweden	11 M	57,822	-
Switzerland	9 M	100,793	3,898
Turkey	87 M	12,814	416
UK	69 M	52,637	-
USA	343 M	80,706	7,269

Sources: GHED, 2023 (Population and Health Expenditure); World Bank, 2024 (GDP/CAP)

To achieve a more accurate analysis, KPIs and metrics were also calculated for a list of countries from Organization for Economic Co-operation and Development (OECD) – an intergovernmental organization founded in 1961 to advise governments and stimulate economic progress and world trade. The Latin American countries that are OECD members (Chile, Colombia, Costa Rica and Mexico) were removed from this analysis, and countries without IQVIA sales data were cut as well, leaving 27 countries OECD members to be analyzed (Table 3).

It should be noted that in these countries, the division between funding sources and distribution channels does not necessarily have the same correlation as in Latin America. For this reason, channel split will not be explored for this group.

To set a reference number to compare the Latin American countries versus the group of the most developed countries in the world, was used the average of the OECD countries KPIs and metrics as base values. To ensure consistency and comparability across the groups analyzed, the assessment relied on simple, unweighted averages. This methodological choice was deliberately adopted to avoid disproportionate influence from large economies within each group. By excluding weighting effects, the analysis prevents countries with substantial economic or demographic scale – such as the United States within the OECD and Brazil within Latin America – from unduly skewing aggregate results.

Additional references

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16. Economic Evaluation of Brigatinib in Brazil https://www.valueinhealthjournal.com/article/S1098-3015(24)00799-X/fulltext
17. Real-World Evidence (LATAM)Brigatinib Real-World Effectiveness in Argentina (Drugs Real World Outcomes, 2025)https://pmc.ncbi.nlm.nih.gov/articles/PMC12173969/

Argentina - CAEME

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**[1,2,3]	*Multiple national formularies (PAMI and SURGE, or PAMI and PMO formularies) with reimbursement values aligned to treatment cost in case of bundled (e.g., SURGE) National Oncology Drug Bank*	**SURGE** *(Therapeutical Area Bundles Not Always Molecule Specific)* **Drug Banks** *Publicly Available Drug Banks of Relevant Obras Sociales (e.g., IOMA, OSECAC, OSDE)*	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited[1,2,4]	*Listed in at least one of country formularies (e.g., PAMI, PMO, SURGE formularies), and Broad coverage by OSN and prepaid* *Conditions included on SURGE formulary, but with a treatment cost substantially higher than SURGE bundle are considered limited availability*		
	Only Private	*Broad coverage by prepaid plans*		
	Not Available	*ANMAT Approval, no broad coverage by prepaid plans, no national formulary or National Oncology Drug Bank listing* *Only OOP sales, mostly in the Retail Setting*	ANMAT Website	

[1]SUR / SURGE date of inclusion considered the date when the updated Superintendencia de Servicios de Salud (SSS) resolution is published
[2] PAMI contract execution considered as the date of PAMI formulary inclusion
[3] Full Availability: Consider the date of the most recent formulary inclusion as the date of full availability (i.e., if the product is first included on PAMI and further on SURGE, consider SURGE date as the reference for full availability
[4] Limited Availability: Consider the first formulary date as the reference for limited availability (i.e., if the product is included on PAMI but have a restricted coverage on SURGE, consider PAMI contract date as the reference for Limited Availability)

Brazil - Interfarma

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full[1]**	*Positive CONITEC recommendation with centralized purchasing or subnational guidelines (oncology), Central Purchasing or Subnational Guidelines to be validated using IQVIA sales data and Gov. Tenders*	CONITEC website & subnational guidelines	**Retail:** *Available* **Hospital / Non-Retail:** *Available*
	Limited	*Positive CONITEC recommendation, no centralized purchasing or restricted subnational guidelines* *Subnational / state level uptake considering a minimum and recurrent volume but restrict to the main treatment centers*		
	Only Private[2]	*ANVISA Approval and ANS ROL placement, no positive CONITEC decision, no centralized purchasing* *ANS DUT publishing date is the reference for all products except Oncology IV, which considers ANVISA label update date*	ANVISA Website & ANS ROL	
	Not Available	*ANVISA Approval, no ANS ROL placement, no positive CONITEC decision, no centralized purchasing* *Mostly OOP or Legal Injunctions*		

Note: Approval dates consider ANVISA, not CMED
[1]The date of first contract (central proc.) or subnational uptake considering a minimum and recurrent volume across multiple treatment centers (e.g., States Secretaries, CACONs)
[2]Oncology IV products are automatic reimbursed in the private setting; therefore marketing authorization date is considered as the reference if the reimbursed indication is the first, or the label update date found on ANVISA label change tracking for the specific indication

Note: change vs. 2024 edition to use stricter criteria on uptake/sales thresholds in private / public sectors, in absence of CONITEC decision, to approximate and adjust for use of legal injunction. For limited availability: 10% or more of its total institutional sales in the public sector, and 50% or more of the public sales in the Government Channel. For only privately available: 5% or more of its institutional private sector sales in the HMO channel. If criteria were not met, they were classified as approved, not available.

Chile - CIF

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*Broad reimbursement through FONASA formularies (e.g., GES, Ricarte Soto), accounting for approx. >80% of the patient population*	Ricarte Soto website GES website AUGE clinical guidelines, DAC listings Cenabast purchases Public tenders	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available* *Restricted to Public Tenders*
	Limited	*Limited reimbursement of through national reimbursement system (<80% approx.); availability through a specialized programs e.g., DAC – centralized, ministry of health programs, or decentralized local/regional programs* *GES formularies also applies for private insurance companies, but they only reimburse 80% of the total cost* *Also applies whilst decision is pending, where use is restricted to specialists*		
	Only Private	*Covered in multiple ISAPREs, partial or full reimbursement only for patients via CAEC or extracontractual benefit*	Not available	
	Not Available	*Available in the out of pocket market, or is not reimbursed until the evaluation or decision*		

Costa Rica - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*CCSS Basic Formulary (LOM)*	MOH website CCSS Document	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Purchased via Special purchases negotiations, and through judicialization initiated by the patient*		
	Only Private	*Broad coverage by prepaid plans, no special purchase negotiations, no CCSS formulary*		
	Not Available	*Ministerio de salud approval, no CCSS, no special purchases negotiations, no broad coverage by prepaid plans, Only OOP sales, mostly in the Retail Setting*	Not available	

Colombia - AFIDRO

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full[1]**	*Medicines listed on PBS-UPC and EPI (PAI)*	MinSalud website PBS-UPC Circular	**Retail:** *Available* **Hospital / Non-Retail:** *IQVIA SISPRO / SISMED & NRC*
	Limited[2]	*Medicines available via ADRES / MIPRES, not listed on PBS-UPC* *ADRES / MIPRES uptake considering a minimum and recurrent volume using SISMED information*	MinSalud website ADRES / MIPRES Circular	
	Only Private	*Not Applicable* *Assuming MIPRES overlaps Pre-Pagadas, eventual coverage*	Not available	
	Not Available	*No INVIMA Approval, no MIPRES, not listed on PBS-UPC* *Only OOP sales, mostly in the Retail Setting*	INVIMA Website	

[1]PBS / UPC date of MinSalud Circular containing the updated PBS / UPC drug list to be considered as the date of Full Availability
[2]ADRES / MIPRES date of first minimum and recurrent sales based on SISMED and IQVIA NRC data to be considered as the date of limited availability – in some cases, there might be a delay between INVIMA regulatory approval and date of limited availability

Dominican Republic - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**[1]	*Medicines listed on PBS-SISALRIL*	SISALRIL PDSS[1] (document) DAMAC Website	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Medicines available via High-Cost Medicine Program (DAMAC), not listed on PBS-SISALRIL Listed on DAMAC LOM*		
	Only Private	*Broad coverage by prepaid plans, no special purchase negotiations, no DAMAC/SISALRIL coverage*		
	Not Available	*Ministerio de salud approval, no DAMAC/SISALRIL coverage, no special purchases negotiations, no broad coverage by prepaid plans Only OOP sales, mostly in the Retail Setting*	Not available	

[1]PDSS containing the updated PBS medicines list to be considered as the date of Full Availability

Note: Drugs with non-government importation purchases were categorized as only privately available, in absence of additional information provided by manufacturer

Ecuador – IFI-Promesa

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*Essential list including national institutions (e.g., MSP, IESS, Army)*	MSP IESS (where data is available)	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Not listed but with limited access, typically evaluated through an exception process*		
	Only Private	*Products covered OOP with no possibility for reimbursement, no essential listing*	Not available	
	Not Available	*Pending or not approved by ARCSA, no listing or other access*	ARCSA website	

Mexico - AMIIF

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full[1]**	*CGS National Compendium & Federal Institution Acquisitions* *Date of first contract (central proc.)* *Federal Institutions contracts to be validated using IQVIA / INEFAM sales data*	Compendium Government Tenders INEFAM (where data is available)	**Retail:** *Available* **Hospital / Non-Retail:** *IQVIA GSDT/Gov Analytics* & NRC*
	Limited[2]	*Decentralized formularies (SENDA, SEMAR, PEMEX, ISSEMYM, ISSSTESON) and/or patient purchase outside of compendium* *Purchasing to be validated using IQVIA other channels data*		
	Only Private	*Large private formularies (GNP, AXA, and MetLife)*	Not available	
	Not Available	*COFEPRIS Approval, no private, decentralized formularies, no compendium, no federal institutional acquisition* *Only OOP sales, mostly in the Retail Setting*	COFEPRIS website	

[1]Date of the first sales to federal institutions IMSS / ISSSTE, assuming a minimum volume, will be considered the date of full reimbursement reflecting the central purchasing or broad but individual federal institutions contracts
[2]A minimum of 2-3 institutions purchasing will be considered as Limited Access, date of the first institution purchasing considered to be timeline benchmark for limited access

Panama - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*Listed on CSS and ION* Basic Formulary (LOM)*	MOH website CSS Document (LOM) ION Document (LOM)	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Medicines available via special purchase process for non-LOM medicines on CSS / ION*		
	Only Private	*Broad coverage by prepaid plans, no special purchase negotiations, no CSS formulary*		
	Not Available	*Ministerio de salud approval, no CSS, no special purchases negotiations, no broad coverage by prepaid plans Only OOP sales, mostly in the Retail Setting*	Not available	

**ION Basic Formulary is only for oncologic medicines.*

Peru - ALAFARPE

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*National petition (PNUME) and its complementary listings, RENETSA/RM purchases*	MOH website PNUME document IETSI dictum INEN evaluation	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Not listed but with limited access*		
	Only Private	*Products covered OOP with no possibility for reimbursement, no essential listing*	Not available	
	Not Available	*DIGEMID approval, no listing or other access*	DIGEMID Website	

Patient W.A.I.T. Indicator & Root Causes 2026 – Brazil

FIFARMA | IQVIA

Measuring availability and understanding the barriers to access to innovative medicines

The FIFARMA Patient W.A.I.T. Indicator 2026 – Brazil is the fifth edition of this study that measures the availability of innovative medicines in the country and explores the root causes behind access delays. This year's study includes 447 innovative molecules approved globally between 2014–2025 across 5 therapeutic areas and orphan drugs.

Key Takeaways

Low Availability

Only 19% of innovative molecules are fully available in Brazil (public and private sectors).

Long Time to Access

Median time to availability
Public sector: 66 months (5.5 years)
Private sector: 24 months (2 years)

Modest Improvement

Improvement index 2024–2026
16% for the public sector
41% for the private sector

Patient Impact

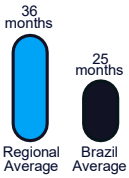
Delays in access limit treatment options and contribute to worse health outcomes and productivity losses.

Availability Snapshot (2026) Molecules approved globaly

Status	Molecules	%
Not available	231	51.7%
Out of pocket	79	17.7%
Private	76	17.0%
Limited availability	35	7.8%
Full availability	26	5.8%
Total	447	100%

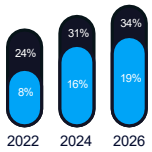
More than half of innovative molecules (51.7%)are not available to Brazilian patients.

Time to Approval by the Local Authority



Brazil presents an approval time of 25 months, compared to the regional average of 36 months

Time to Availability (Median Months)



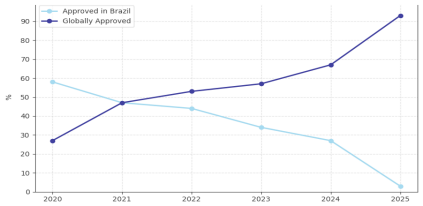
Full availability improved, **but from a low baseline.**

Availability by Therapeutic Area (2026)

Therapeutic Area	Public Sector	Private Only	Extended Availability (public+private)
Oncology	18%	58%	76%
Inflammation & Immunology	36%	24%	60%
Central Nervous System (CNS)	35%	17%	52%
Cardiometabolic	30%	0%	30%
Orphan Drugs	39%	25%	64%

Oncology and orphan drugs show higher availability, while Cardiometabolic and CNS remain among the most challenging areas.

Approval of Innovative Medicines (2020-2025)



Public spending in Brazil remains lower than the recommended 6% GDP shared by WHO and the OECD average, but remains in line with its LATAM peers, indicating structural underfunding

Root Causes: Main Barriers to Access

These structural factors create delays and prevent patients from accessing innovation in a timely manner.

Regulatory & HTA Complexity
Multiple assessment bodies, lack of alignment and transparency,and evolving HTA criteria.

Pricing & Budget Constraints
Insufficient and inflexible budgets and challenges in value assessment and price negotiations.

Procurement & Supply Chain
Centralized purchasing, lengthy tender processes and local uncertainties.

Inequity of Access
Large disparities between regions and between public and private healthcare.

Data & Monitoring Gaps
Limited real-world data and monitoring to support decision-making and track access.

Opportunities to Improve Access

Collaborative, multi-stakeholder action is essential to accelerate patient access to innovative medicines in Brazil.

Align & Streamline Processes
Harmonize requirements across agencies and increase transparency and predictability.

Strengthen Value-Based Decisions
Adopt sustainable funding models and incorporate health technology value and outcomes.

Modernize Procurement
Simplify and accelerate tender processes and improve planning and supply chain management.

Promote Equity
Expand access programs and reduce regional disparities within the public health system.

Invest in Data & Monitoring
Build robust data infrastructure to inform and monitor access and outcomes.

Better data. Better decisions. Better access. Innovation only transforms lives when patients can access it.

Source: FIFARMA & IQVIA. (2026). FIFARMA Patient W.A.I.T. Indicator 2026: Brazil.

Learn more: w.fifarma.org

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