

White Paper

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

Chile

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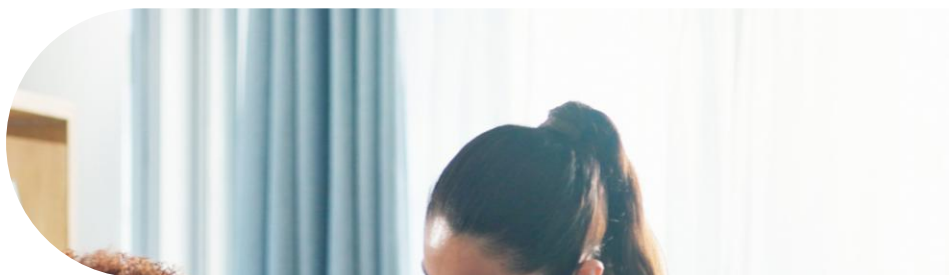


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Overview of the study

- 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

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:



Based on public and IQVIA data (MIDAS / NRC, hospital audits, gov't sites, etc.)



Aligned with FIFARMA, local trade assoc., e.g., Interfarma, AFIDRO, AMIIF, etc.



Participation from laboratories via data validation, interviews, and project steering



Interviews with ex ministers of health and other high-level MoH officials

Added in 2026



Multiple formats and cuts of data (local, by TA)

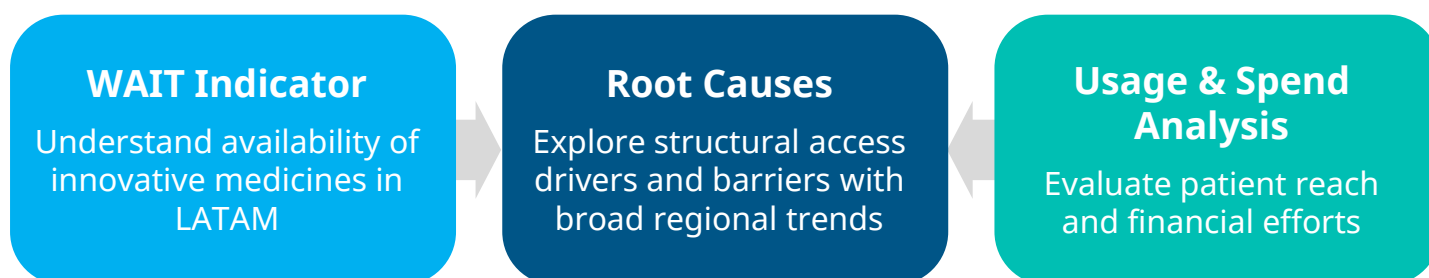
"It's an optimistic view still, there are more challenges for real-life access than what we see here."

- 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



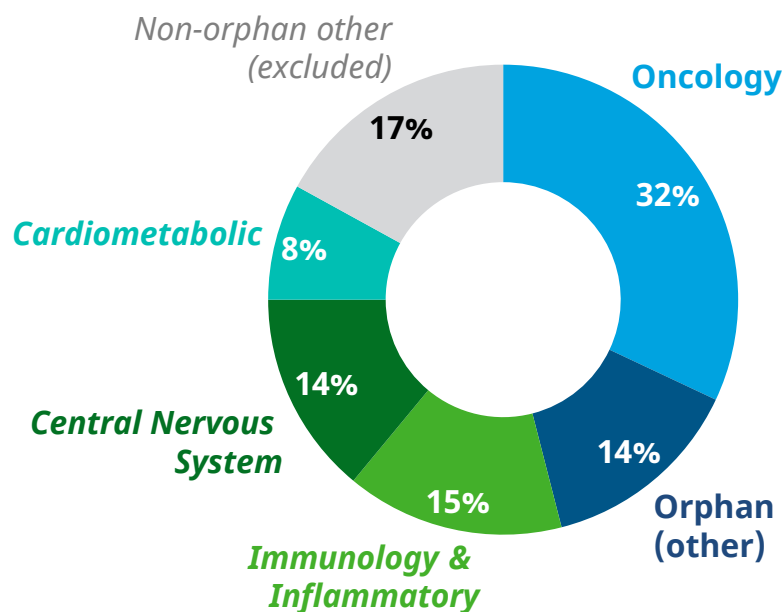
*See appendix for definitions, exchange rates, and indicators

Acronyms: NRC: Non-retail Channels; USD: US dollars; WHO: World Health Organization

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:

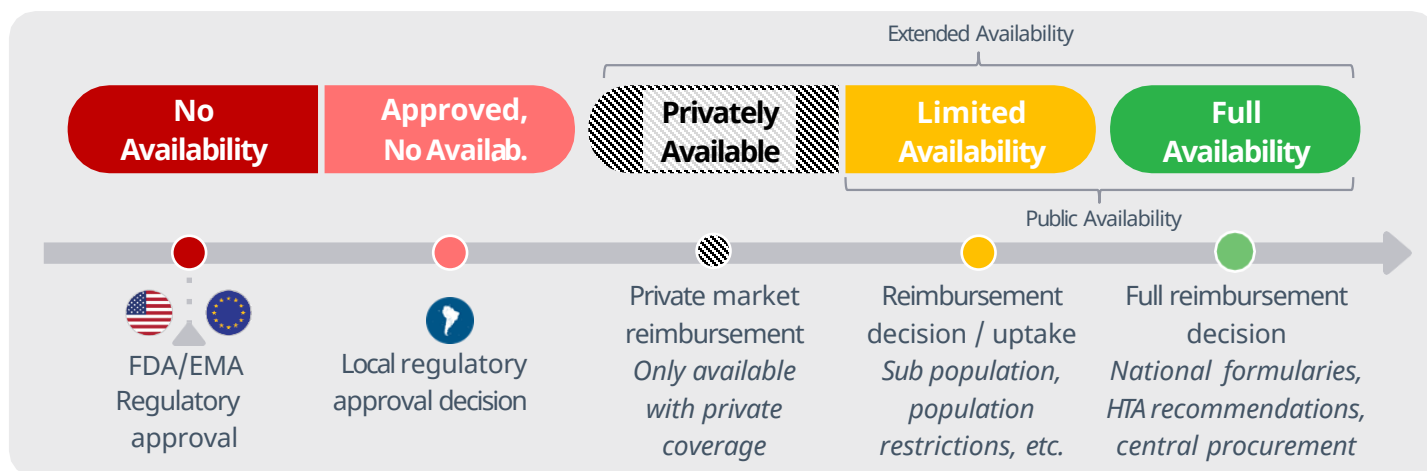
- Percentage of NAS molecules
- Procurement e.g., TAs with percentages of supranational purchases like infectious disease, were excluded
- Global sales as per IQVIA MIDAS data

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

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

Methodological considerations

The detailed definitions for molecules' availability status in Chile involved inclusion to public health formularies, centralized purchases, and ISAPREs coverage

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		

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	<i>What is the availability of innovative medicines across LATAM?</i>	Breakdown of availability across the region, by country and by therapeutic area
2 Time to Availability	<i>How long does it take for innovative medicines to become available?</i>	Time from global regulatory approval to local approval, and local availability
3 Availability Over Time	<i>What is the maturity of innovative medicines available?</i>	Evolution of availability status by year of global approval
4 Improvement Index	<i>At what rate does availability for innovative medicines improve?</i>	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 - Chile

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
- The average time to local availability, post-marketing authorization, is 32 months between the countries in scope, approximately 2.7 years
- Chile's time to approval is lower than the regional average (30 vs 36 months), but local time to availability is 30 months over the regional average (62 vs 32 months)
- Time to availability varies substantially in Chile across therapeutic areas, with CM showing the longest delays taking ~138 months to become locally available compared to ~32 months of the regional availability. CNS therapies become available the fastest

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; out of these regionally approved, 43% are approved in Chile
- 22% of molecules with regional public availability (limited or full availability) have public availability in Chile
- 43% of molecules approved in Chile have some level of availability; out of this extended availability, only 8% have reached full availability status
- The TA with highest fully available therapies is I&I (3), while there aren't any orphan therapies with this availability status

Availability Over Time

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

- Over 28% of molecules that received global approval from 2014 to 2018 are approved in Chile, and have a very low level of availability
- For therapies approved globally after 2018, approval and availability rates decline even further, both approval and availability reaching 0% by 2025

Improvement Index

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

- 9% of the molecules in Chile have improved their availability status over the past year, 2% above the regional average of 7%
- Chile had 22 newly approved molecule this year

Summary of Regional Root Causes and Opportunity

Innovation is outpacing system capacity, driving saturation and delays

The volume and complexity of globally approved medicines continue to rise, creating mounting challenges for Chile's regulatory and healthcare systems, which have not expanded capacity at the same pace. As a result, approval timelines have lengthened, backlog pressures persist, and gaps between global innovation and local access remain evident—despite recent improvements in approval activity.

Low investment constrains institutions, fragments processes, and reduces competitiveness

Chile's overall public healthcare spending is broadly aligned with regional benchmarks but remains below OECD levels. However, spending on innovative treatments is significantly lower than both LATAM and OECD averages, indicating a more constrained prioritization of innovation. This gap limits the system's ability to fund and scale access to newer therapies, contributing to slower uptake and continued reliance on restricted access pathways

Access improves when clinical value and system readiness are mutually reinforcing

Regulatory approval alone does not ensure access in Chile. Timely uptake requires alignment between local evidence generation, diagnostic infrastructure, delivery capabilities, and budgetary frameworks. When these elements are in place, access becomes more predictable and scalable; when they are not, complexity translates into delays and restricted availability.

Emerging opportunities signal potential for strategic repositioning

Growing pharmaceutical investment, increased adoption of innovative therapies, and gradual system modernization present an opportunity for Chile to strengthen its position within the global landscape. Targeted improvements in governance, infrastructure, and cross-sector collaboration could translate into faster access, improved outcomes, and greater readiness for complex innovation.

Sustained progress requires collaboration, integration, and forward planning

Delivering sustainable access in Chile will depend on coordinated action across regulatory authorities, payers, and providers. Priorities include improving institutional collaboration, integrating new technologies to enhance efficiency and transparency, and strengthening long-term planning to manage rising complexity and demand.

Chile's access challenges are not due to a lack of innovation, but rather a mismatch between accelerating therapeutic complexity and the system's ability to absorb it. While progress is underway, closing this gap will require sustained investment, structural reforms, and a proactive approach to managing complexity across the healthcare ecosystem.

Key regional takeaways



Innovation is accelerating as disease burden evolves

A growing and complex disease burden in Chile is driving demand for more targeted and advanced therapies, placing additional pressure on the system to adapt to higher-impact innovation



Access challenges are intensifying as innovation grows

As the volume and complexity of innovation increases, Chile's reliance on fragmented, sequential processes is becoming less effective, contributing to delays and variability in patient access



Structural underinvestment amplifies access inefficiencies

Persistent capacity constraints and relatively low healthcare investment limit Chile's ability to absorb innovation efficiently, leading to delays, operational misalignment, and uneven access outcomes

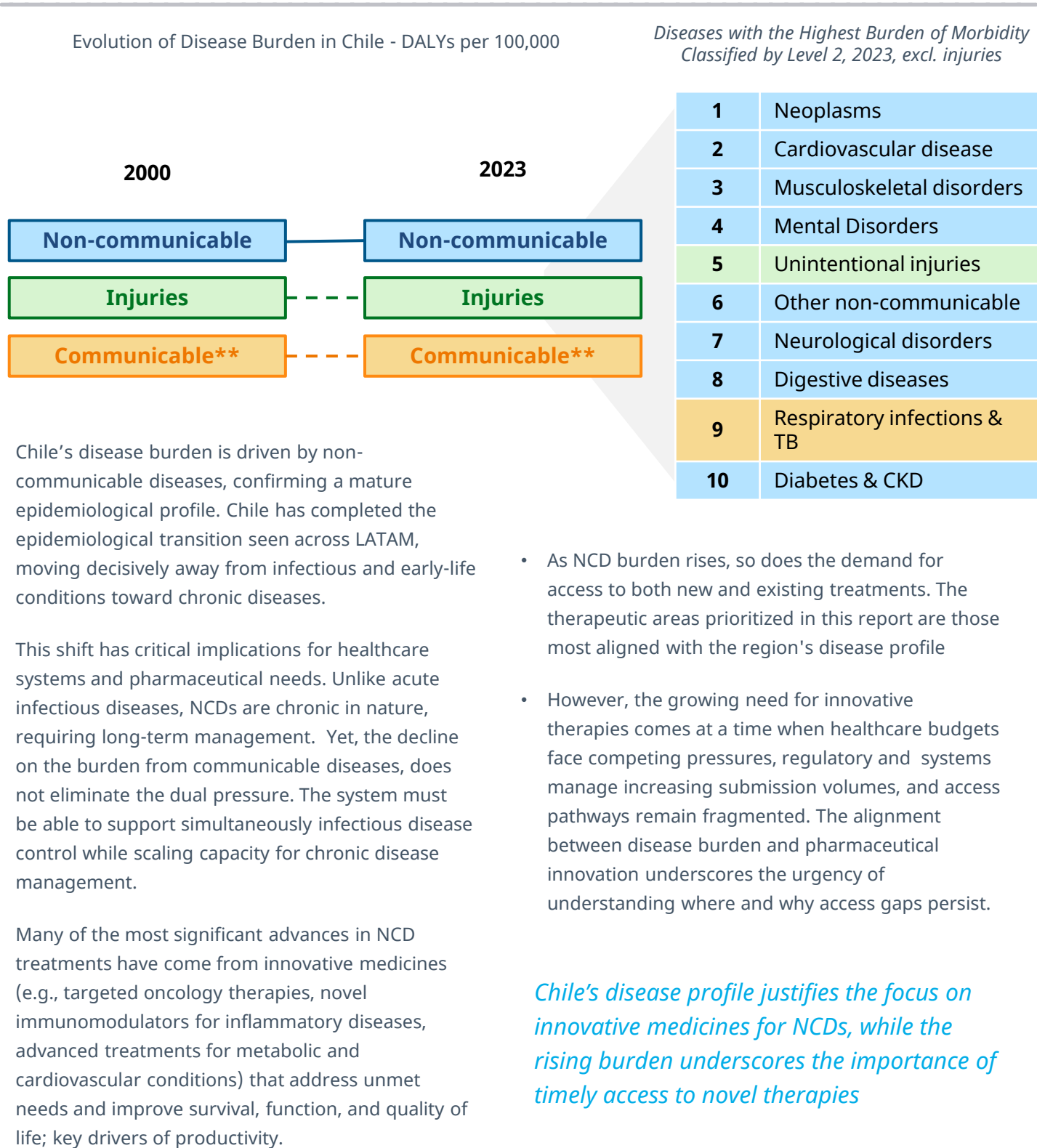


A window for transformation is emerging

Ongoing system evolution, increasing focus on innovation, and gradual investment growth create a timely opportunity to improve access pathways, and enhance readiness for more complex therapies

Non-communicable diseases drive Chile’s health burden

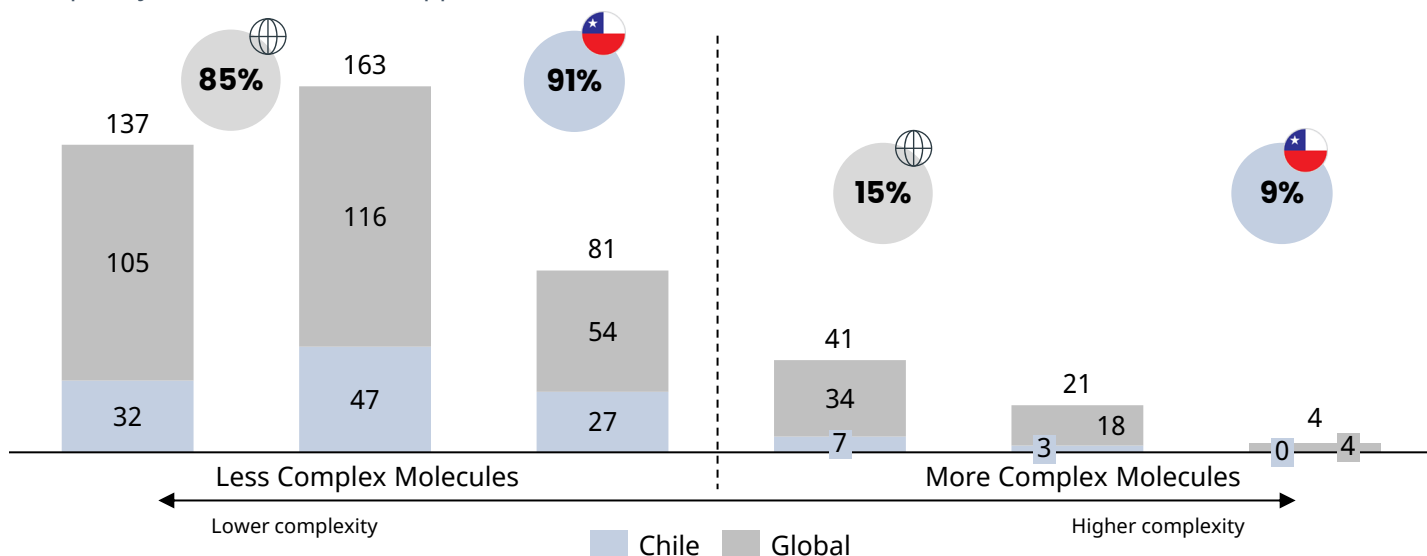
The epidemiological transition toward chronic conditions creates rising demand for innovative medicines and sustainable access pathways



Complexity introduces additional considerations for systems

Chile follows the LATAM complexity distribution, with ~91% of molecules approved concentrated in lower-complexity segments

Complexity of Global and Local Approved Molecules – WAIT Dataset

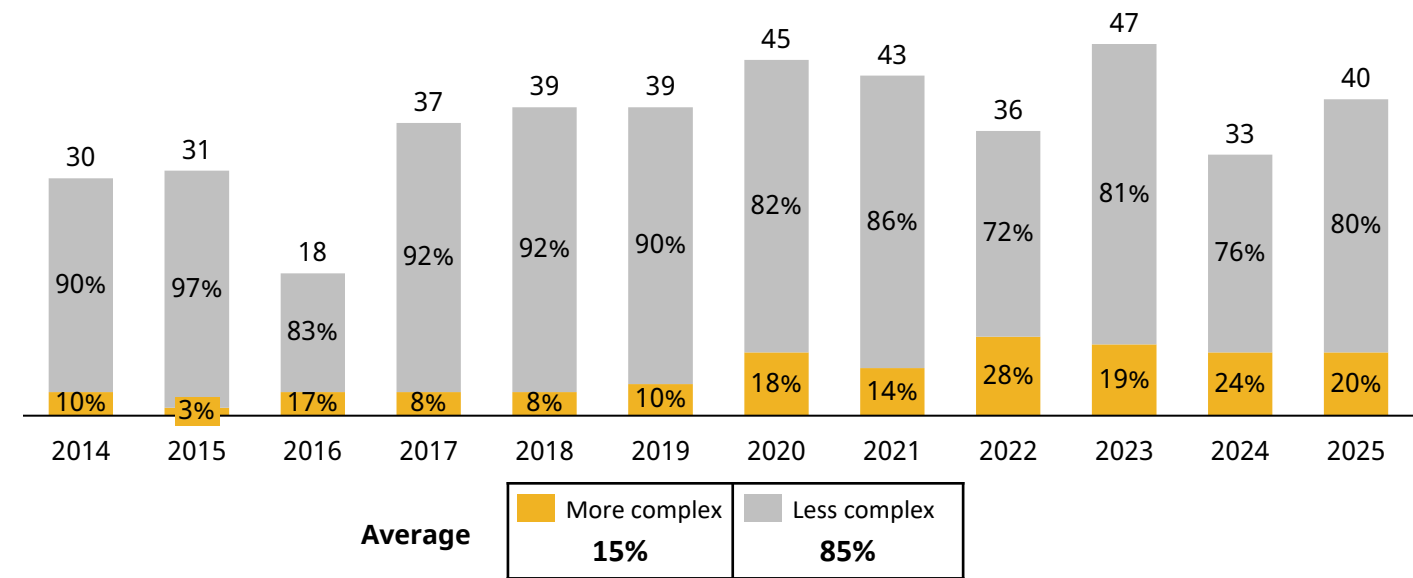


- The complexity levels shown reflect a set of factors that place additional strain on health systems and require capabilities or expertise beyond standard regulatory, and implementation processes
 - Biologic or next generation therapies (e.g., nucleotide, RNAi, gene, cell, tissue, immunotherapy): Require 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.
 - Chile's complexity index closely mirrors LATAM, with ~91% of molecules concentrated in the lower-complexity side versus ~9% in higher complexity, indicating a consistent regional distribution pattern, with slight skew to less complex molecules
- Innovation often introduces technical challenges during evaluation and creates downstream system constraints for regulators, payers, and providers in resource-limited settings*

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

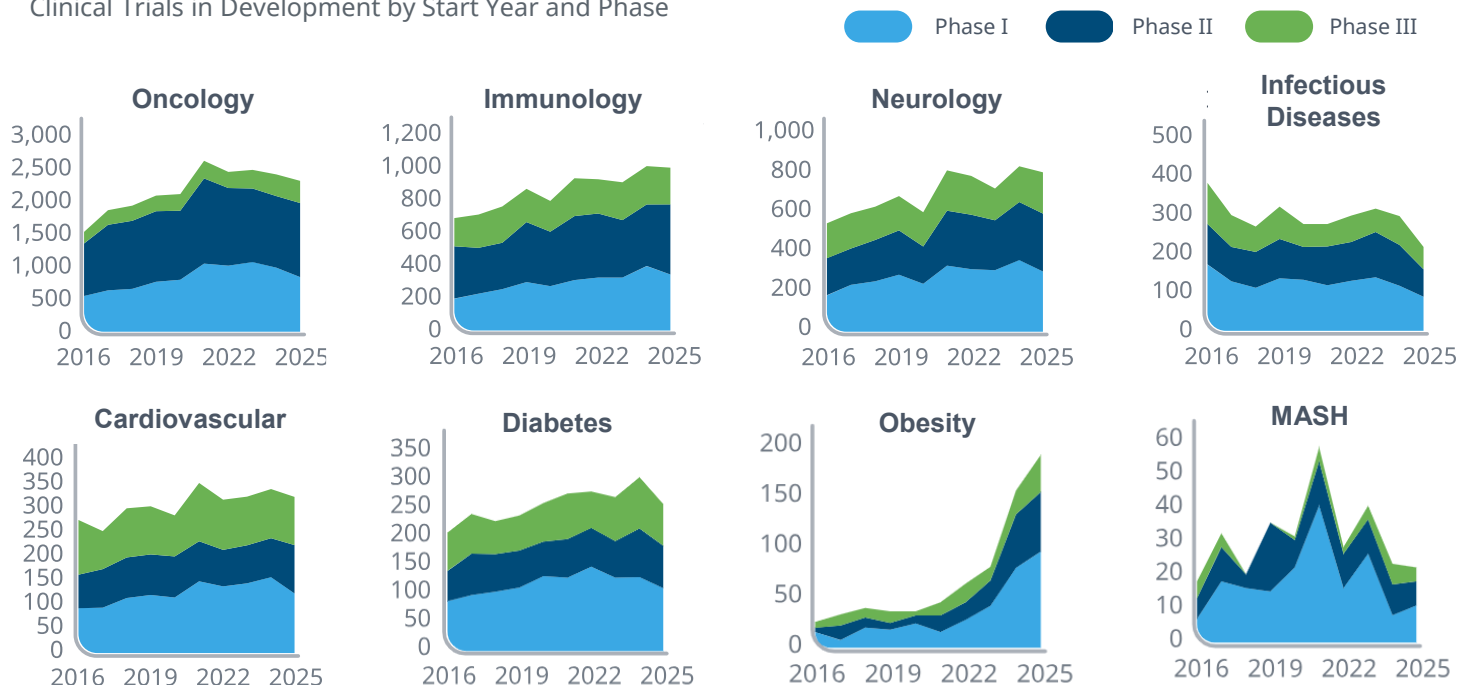


- Among globally approved molecules in this study, the proportion of complex molecules has risen from 10% in 2014 to 20% in 2025. This increase reflects growing reliance on precision medicine, orphan disease therapies, novel mechanisms of action, and advanced modalities (e.g., gene and cell therapies)
 - 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 frameworks in LATAM as well as renewed focus on technical capacity; without adaptation, complexity becomes an additional barrier*

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

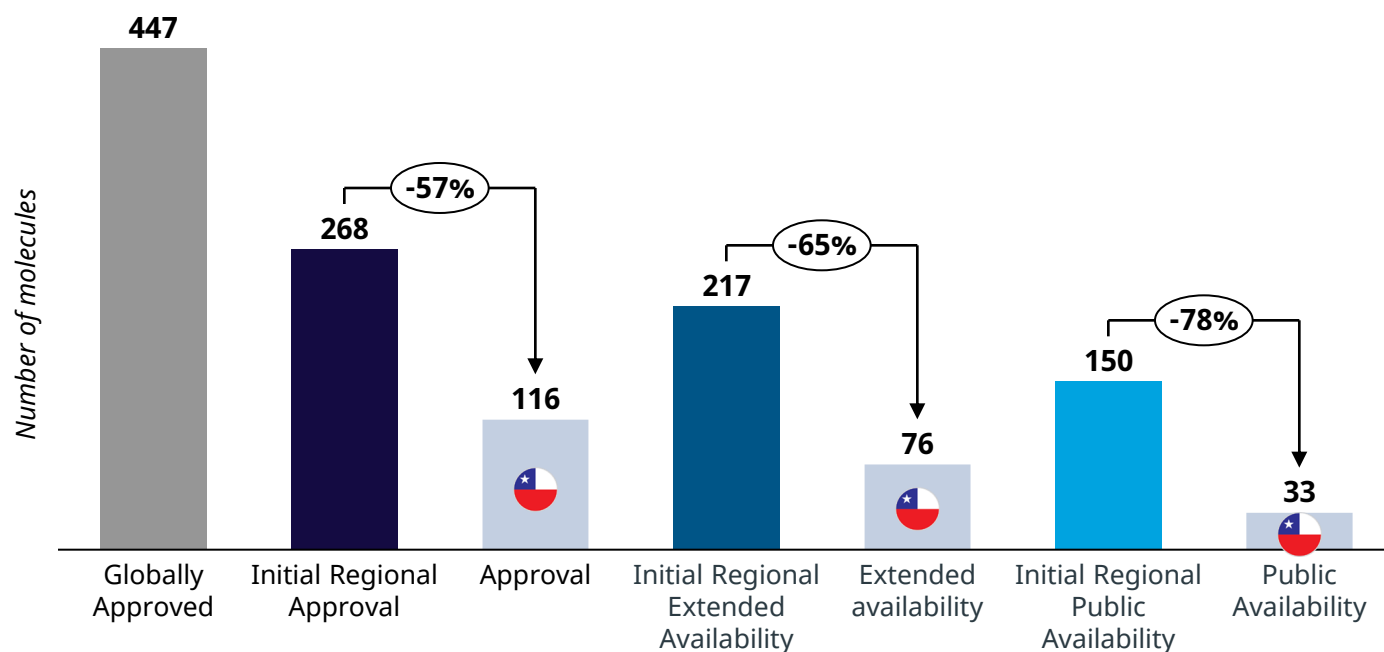
A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed

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

Chile's approval stage significantly limits final access

While Chile experiences losses at the approval stage, the most significant attrition occurs after approval, with sharp declines in extended and public availability

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



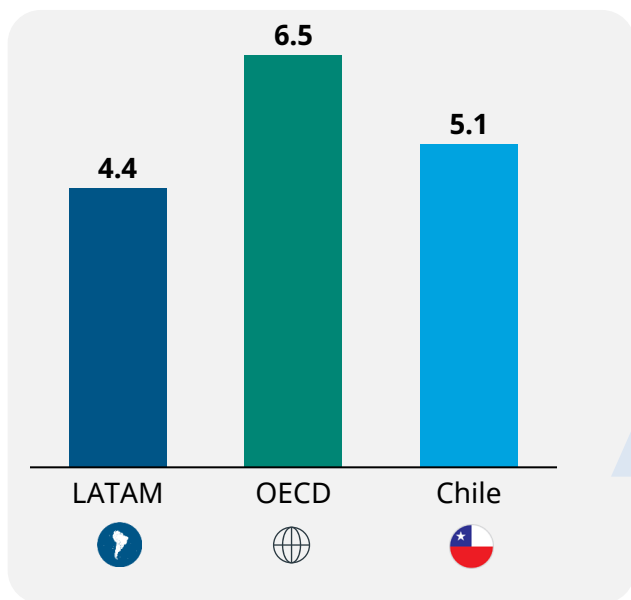
- Initial regional approval and availability represents where a molecule is approved or is available in at least one country in the region, the comparative graph represents Chile's status
- Chile show a lower proportion of molecules with only ~43 of the regions total, this rate diminishes further when considering broader availability, indicating specific constraints
- The conversion from approval to extended availability is limited, with only 76 molecules reaching broader availability, which reflects delays in the processes and systematic adoption
- The most pronounced gap is shown when considering public availability. Where only ~22% of the molecules are available compared to the regional benchmark
- Chile in general, has areas of opportunity in the approval stage, furthermore, it underdelivers on the public availability limiting patient access significantly
- The system has limitations when translating approvals into availability, particularly within the public sector; This indicates barriers such as reimbursement and incorporation

Chile experiences gaps at the approval stage, but the most significant losses occur after approval, where limited conversion into extended and public availability drives low final access

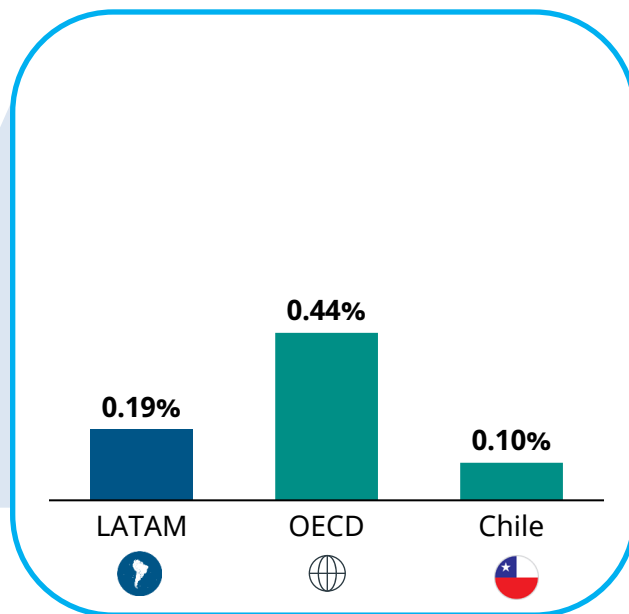
Chile's health spending is below the OECD target

Public and innovation-specific health spending in Chile remain below OECD benchmarks, constraining system capacity and limiting access to innovative therapies

Average Public Spending on Health (% of GDP, MAT October 2023-2025)



Average Public Spending on Innovative Treatments (% of GDP, MAT October 2023-2025)



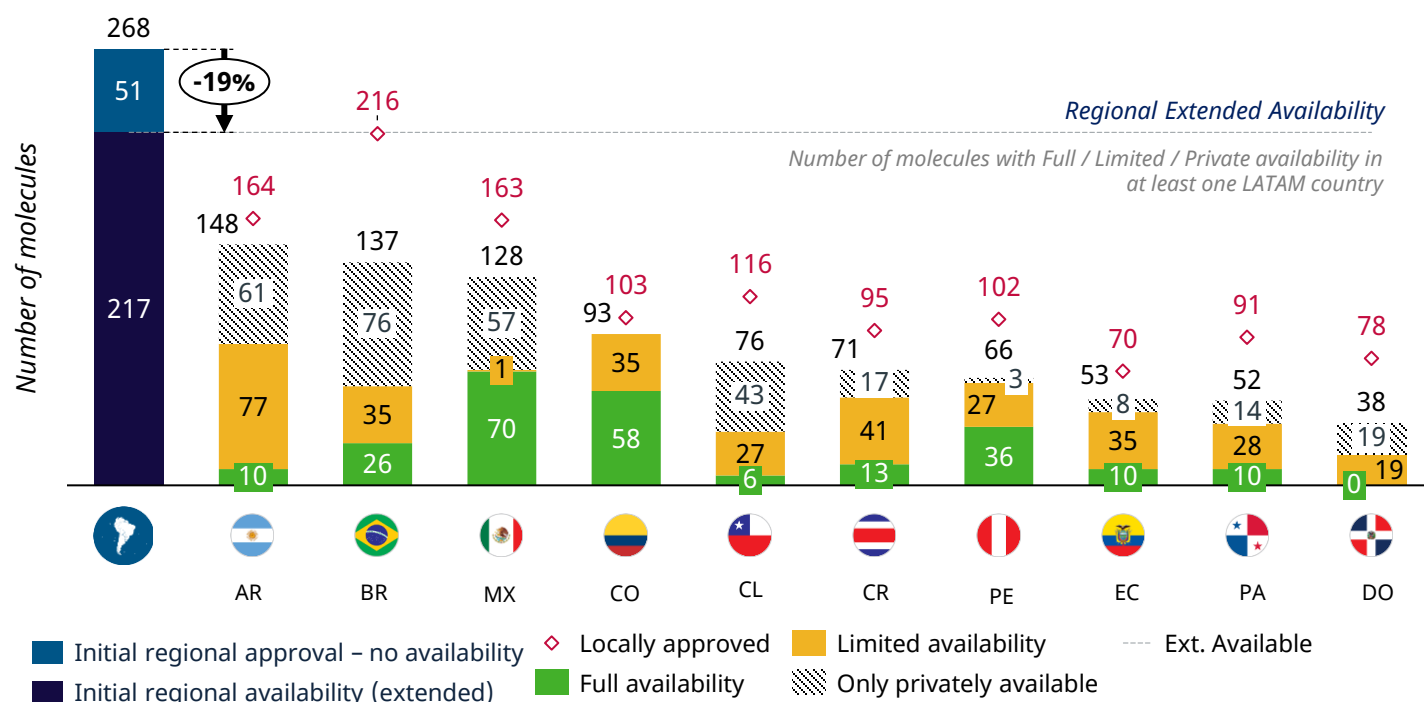
- Public spending in Chile (5.1%) remains lower than the recommended 6.5% GDP share by WHO and the OECD average, although it remains above its LATAM peers, indicating stronger baseline investment
- Chile allocates a lower share of GDP (~0.10%) to innovative treatments compared to the regional (~0.19%) and OECD (0.44%) benchmark, limiting the system capacity to grant access to innovation
- This imbalance suggests that while Chile maintains solid overall health system funding, allocation toward innovative therapies remains constrained, potentially delaying patient access to advanced treatments
- The funding gap reflects prioritization challenges, with resources focused on sustaining coverage rather than expanding access to innovative therapies
- Broader fiscal and budgetary constraints continue to limit Chile's ability to increase dedicated funding for innovative treatments, impacting the speed of adoption and reimbursement decisions
- Lower investment in innovation may also influence the extent of private sector participation, reducing incentives for manufacturers to prioritize the Chilean market for early access launches

While Chile outperforms LATAM peers in overall health expenditure, its significantly lower investment in innovative treatments highlights a critical gap in funding prioritization, underscoring the need to better align resource allocation

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

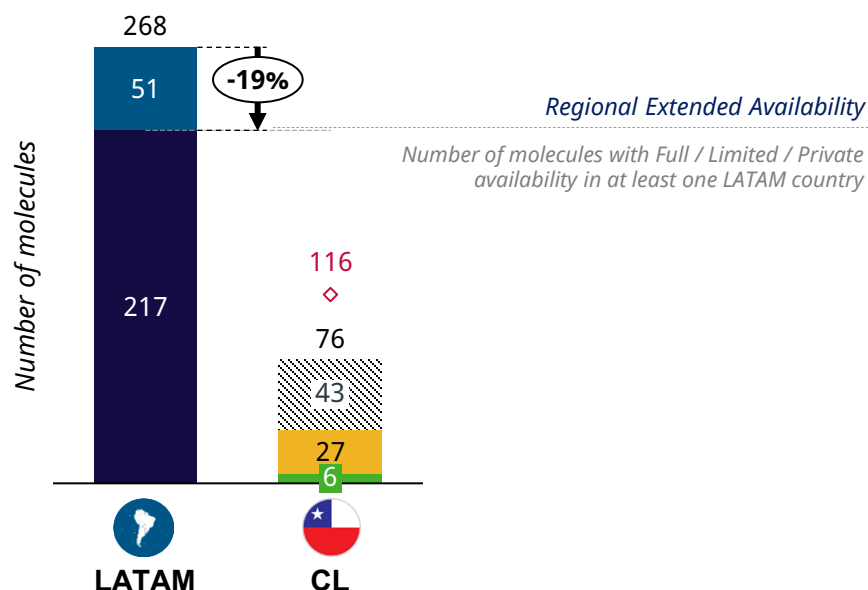
*See appendix for further detail

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

Chile's availability continues to lag behind approvals

Strong approval rates contrast with limited public access and reliance on private-sector availability in Chile

Breakdown of Regional and Local Availability (2014 - 2025) — Combined



■ Initial regional approval - no availability ◇ Locally approved ■ Limited availability --- Ext. Available
■ Initial regional availability (extended) ■ Full availability ▨ Only privately available

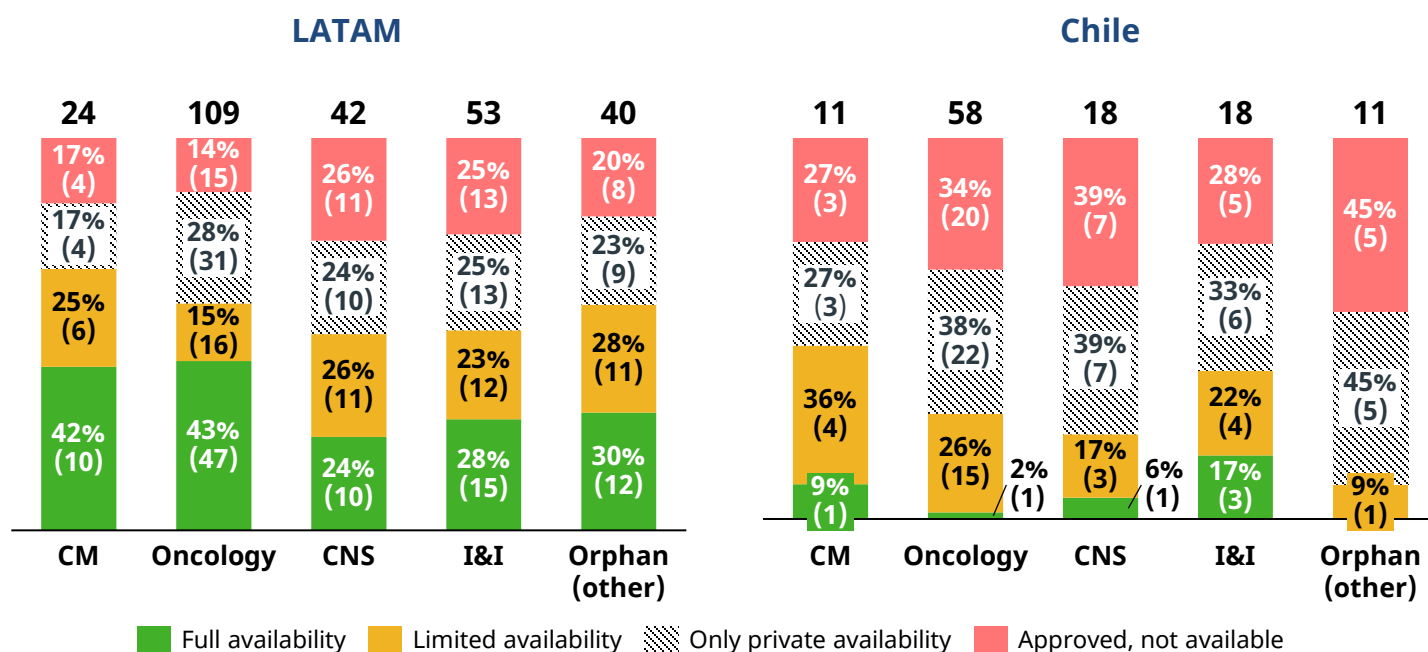
- There is an important gap between the approval and the extended availability in Chile, where only ~65% of the approved molecules have extended availability
- The composition of availability reveals a structural imbalance, where more than half of the therapies with extended availability (~56%) are restricted to private-sector access, indicating that innovation is present in the market but not equitably distributed across the population
- Public system uptake remains very limited, as only 6 therapies achieve full availability, demonstrating that ISP faces significant limitations in scaling access to innovative medicines, driven by funding constraints, prioritization, and implementation capacity
- This dynamic reflects systematic delays in translating approvals into public access, driven by funding and reimbursement constraints
- The reliance on private availability suggests innovation is present but not broadly accessible, reinforcing inequalities in access pathways

In Chile, strong regulatory approvals are not matched by system-wide access, with limited public funding and high reliance on private availability restricting equitable access to innovative therapies

Significant differences also exist by therapeutic area

Chile diverges from regional trends, with consistently low full availability and high shares of therapies either private-only or not available across most therapeutic areas

Regional and Local Availability Status by Therapeutic Area



- Chile demonstrates a more limited access profile relative to LATAM across all therapeutic areas, with consistently lower levels of full availability, particularly in CM (9% vs. 42%), Oncology (2% vs. 43%), and CNS (6% vs. 24%)
- The distribution of availability points to a clear structural imbalance, with a large share of therapies concentrated in private-only or not available categories, especially in Oncology (72%), CNS (78%), and Orphan diseases (90%), constraining broad patient access
- In key high-burden areas such as Oncology and CNS, access remains particularly restricted, with minimal full availability and strong reliance on private channels, highlighting systemic limitations in converting approvals into widespread availability

- High shares of private-only availability reflect reliance on OOP or private channels, limiting equitable access across the population
- Therapeutic areas with high unmet need, such as Oncology and CNS, show particularly high “not available” shares, suggesting delays in translating approvals into patient access
- While I&I shows relatively better performance, access remains fragmented, with only 17% full availability and significant dependence on private-sector pathways

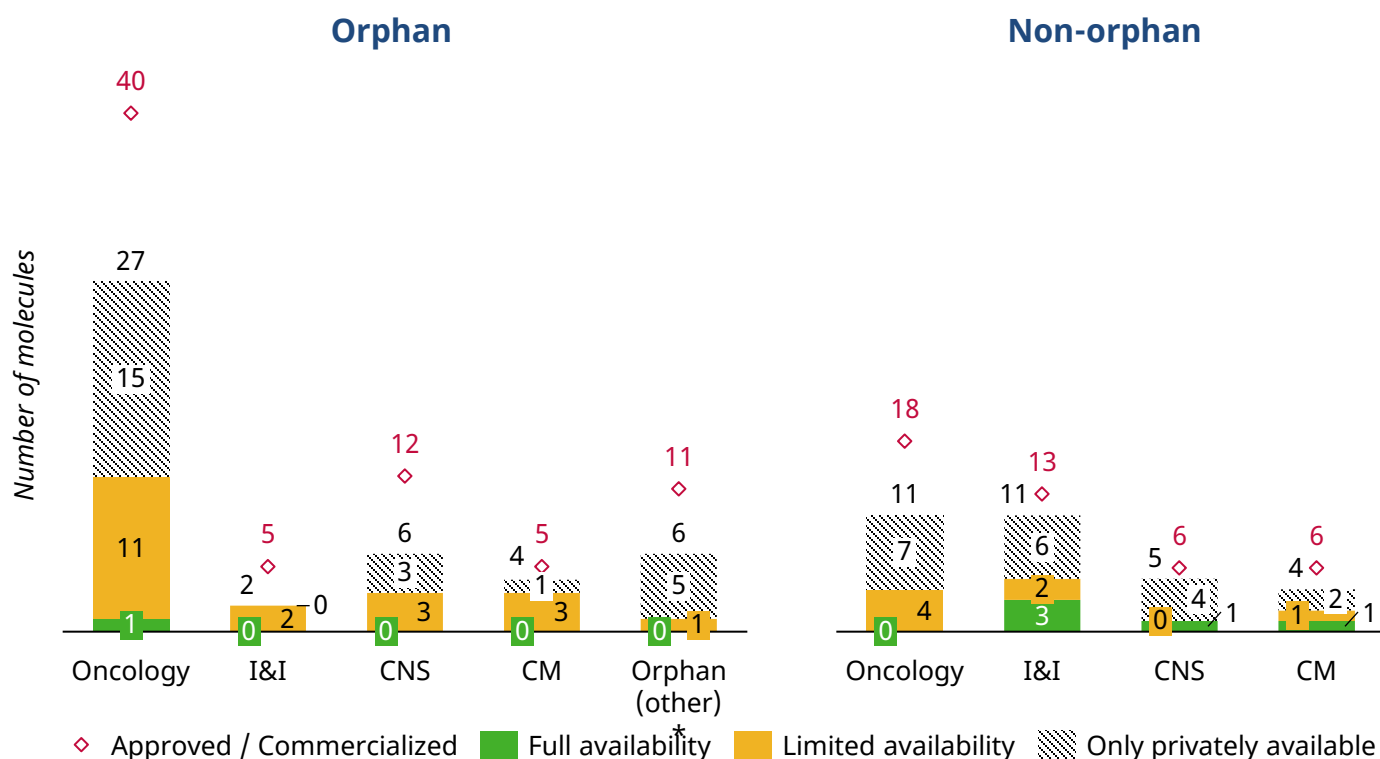
The largest access gaps in Chile are driven by high shares of therapies that are either not available or restricted to private channels, highlighting that public system access, not regulatory approval, is the primary bottleneck

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; OOP: Out-of-pocket

Orphan therapies show higher availability in Chile

Orphan therapies rely more on private access, while non-orphan therapies face stronger system constraints, limiting public availability across most TAs

Breakdown of local availability (2025) – Orphan vs. Non-orphan by TA



- Orphan therapies represent the largest share of the approved treatments, particularly in oncology (40 approved orphan molecules vs. 18 non-orphan), but very few achieve full availability

- Orphan availability is heavily driven by private-sector access, with a significant portion of therapies classified as private-only, indicating that access to rare disease treatments relies on non-public pathways

- Across therapeutic areas, even where orphan therapies are present, public system uptake remains minimal, highlighting constraints in integrating these treatments into broader coverage schemes

- In contrast, non-orphan therapies show lower reliance on private access but still face notable availability gaps, particularly in CNS and Oncology where full availability is absent or minimal

- Higher-budget, high-volume areas such as CM and CNS exhibit stronger system constraints, limiting both innovation uptake and expansion of public access

In Chile, orphan therapies benefit from relatively greater private-sector access, while non-orphan therapies face stronger system constraints, yet both segments ultimately show limited levels of full public availability

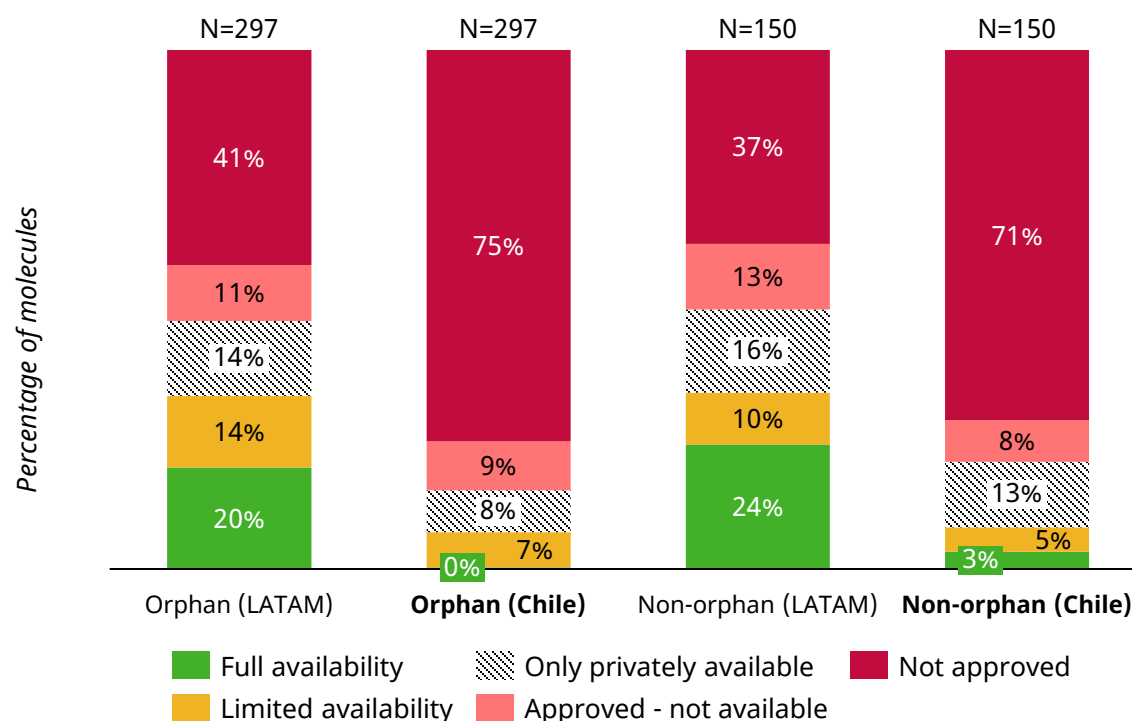
* Orphan (other) category considers orphan molecules that are not also part of any of the other TAs

Acronyms: I&I: Inflammatory and Immunology; CNS: Central Nervous System; CM: Cardiometabolic; TA: Therapeutic Area

Availability varies by therapeutic area

Non-orphan therapies show relatively better availability than orphan therapies in Chile, although both remain constrained with limited conversion into full public access

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



- Chile exhibits consistently low full availability across both orphan and non-orphan therapies, with 0% (orphan) and 3% (non-orphan) achieving full access, significantly below LATAM benchmarks (20% and 24%, respectively)
- The largest gap vs. LATAM is in approval, with a significantly higher share of therapies not approved in Chile (75% orphan; 71% non-orphan), indicating barriers at the entry stage
- Non-orphan therapies in Chile show slightly better performance than orphan in availability terms limited (~5%) or private-only (~13%) availability, resulting in extended availability difference of 21% vs. 15% respectively likely due to budget prioritization favoring higher-volume therapies

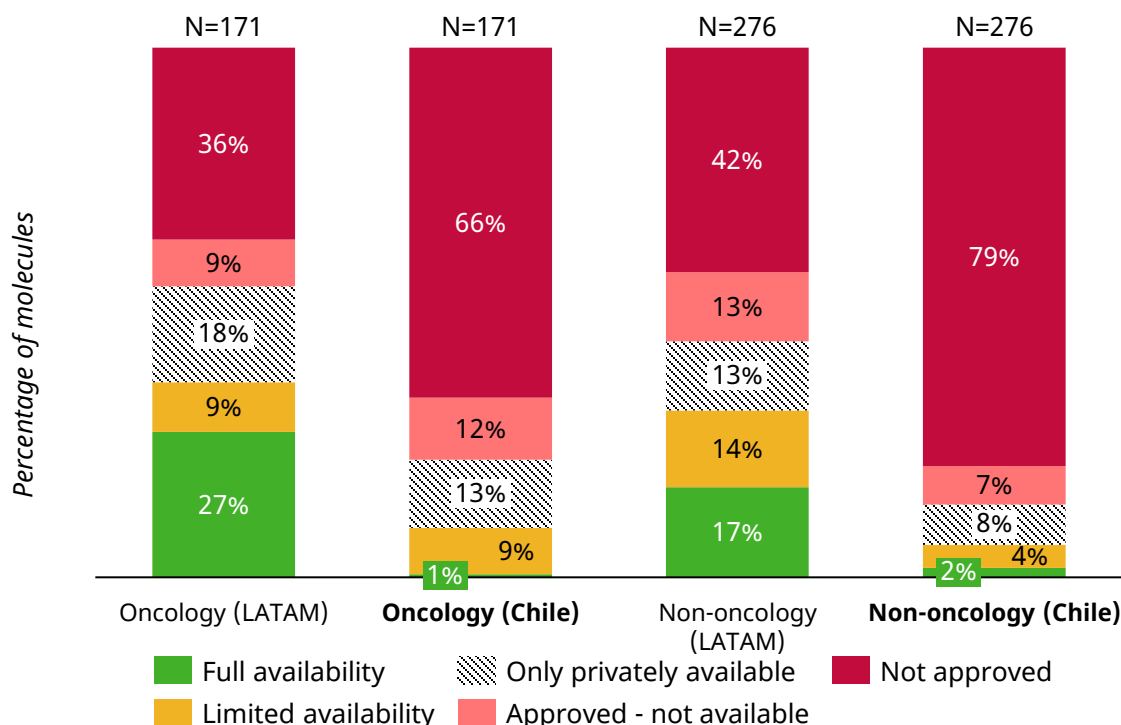
- Across both categories, the distribution of availability reflects system-wide limitations in expanding access beyond approval, particularly for innovative therapies
- High shares of not approved and not available treatments suggest compounded barriers, from regulatory entry to funding and implementation

Chile underperforms across both orphan and non-orphan therapies, with access challenges driven not only by system capacity constraints but also by limited approval and slow translation into availability

Non-oncology lags behind oncology in Chile in availability

Although oncology shows lower full availability, it has higher shares of therapies in limited, private, and approved-not-available stages compared to non-oncology

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



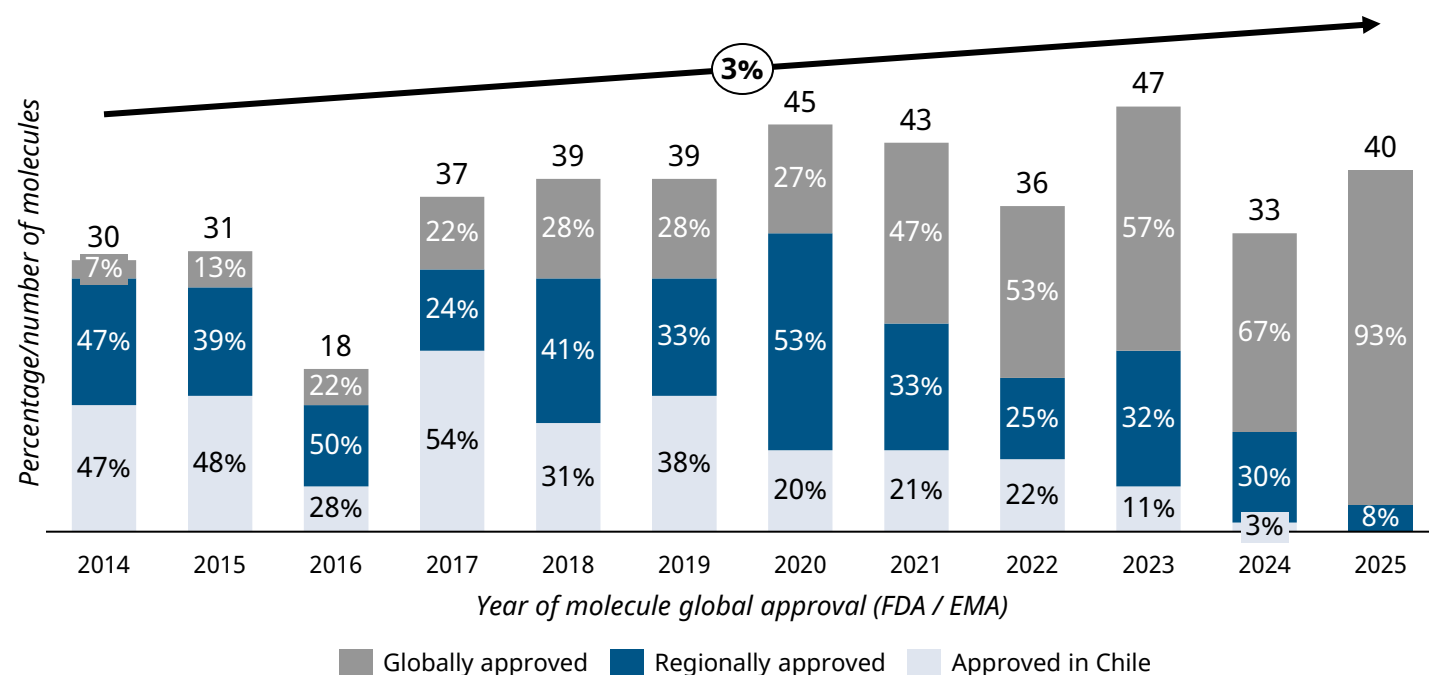
- Oncology in Chile shows lower full availability (1% vs. 2% in non-oncology), indicating weaker conversion into fully accessible treatments
- However, oncology has a higher concentration of therapies in intermediate access stages, including limited (9% vs. 4%), private-only (13% vs. 8%), and approved but not available (12% vs. 7%), suggesting greater presence but limited system integration
- This profile indicates that oncology innovation is more frequently approved or partially accessible, yet struggles to translate into full public availability, remaining fragmented across access channels
- In contrast, non-oncology therapies show slightly better full availability, but a higher share of not approved treatments (79% vs. 66%), indicating stronger barriers at the entry stage
- Across both areas, the data highlights different bottlenecks:
 - a. Oncology: post-approval access and funding constraints
 - b. Non-oncology: earlier regulatory and approval limitations

In Chile, oncology therapies are more frequently approved and partially available but face significant barriers to full access, while non-oncology therapies encounter stronger constraints at the approval stage

New medicines increase, approvals are lagging behind

Rising global innovation is not translating into Chile approvals, with widening gaps in recent years

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

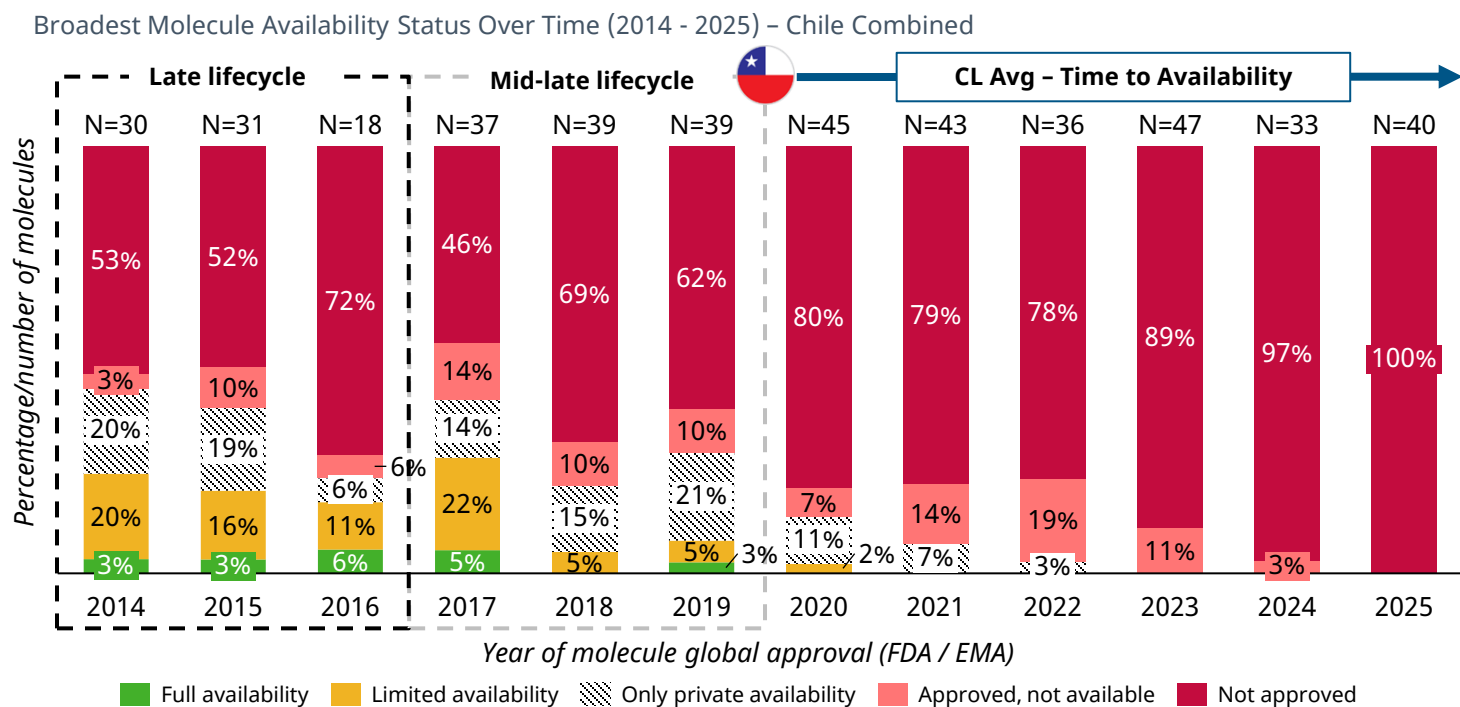


- Regional approval rates remain consistently high for older cohorts but show a pronounced decline for more recent approvals, falling from a strong range of 72–93% between 2014 and 2020 to just 33% in 2024 and 8% in 2025
- Chile follows a similar downward trajectory in approvals, consistently mirroring the regional trend, though with discrepancies ranging from 33% difference in 2020
- The proportion of therapies that remain exclusively at the global approval stage has increased markedly over time, rising from 7% in 2014 and 13% in 2015 to 57% in 2023, 67% in 2024, and 93% in 2025, reflecting a widening gap between global approvals and their translation into downstream approval
- A clear time-lag effect is evident, as therapies approved in earlier years have had sufficient time to expand into regional markets, but not necessarily Chile, reaching 93% regional but only 47% Chile availability for 2014 cohorts, this also impacts more recent approvals showing substantially lower penetration due to shorter time since launch
- Furthermore, over time the “ceiling”, that is the peak level of approvals in the region for globally approved medicines, is lowering with a very clear downward trend over time, even for the medicines in mid-late lifecycle, indicating compounding challenges to launching in the region

Approval rates are declining in the region, whilst global approvals are increasing; the gap will continue to widen without concerted action

Even for older technologies, public access is highly challenging

Older therapies rarely achieve full availability, while newer cohorts are increasingly concentrated in not approved categories, reflecting growing backlog and limited system uptake



- Full availability remains consistently low or nonexistent across all cohorts and declines even further, dropping from 6% in 2016 to 0% from 2020 onwards, indicating persistent challenges in achieving access
- The share of not approved molecules increases sharply for newer cohorts, rising from ~52% in 2014–2015 to 69% in 2018, 80% in 2020, and 100% in 2025, highlighting the challenges in reaching consensus on both submission and approval
- In mid-life cohorts 2017–2019 there is no clear progression towards full availability; the share of not approved therapies fluctuates significantly ~46–69% while limited and private access remain the main drives for availability

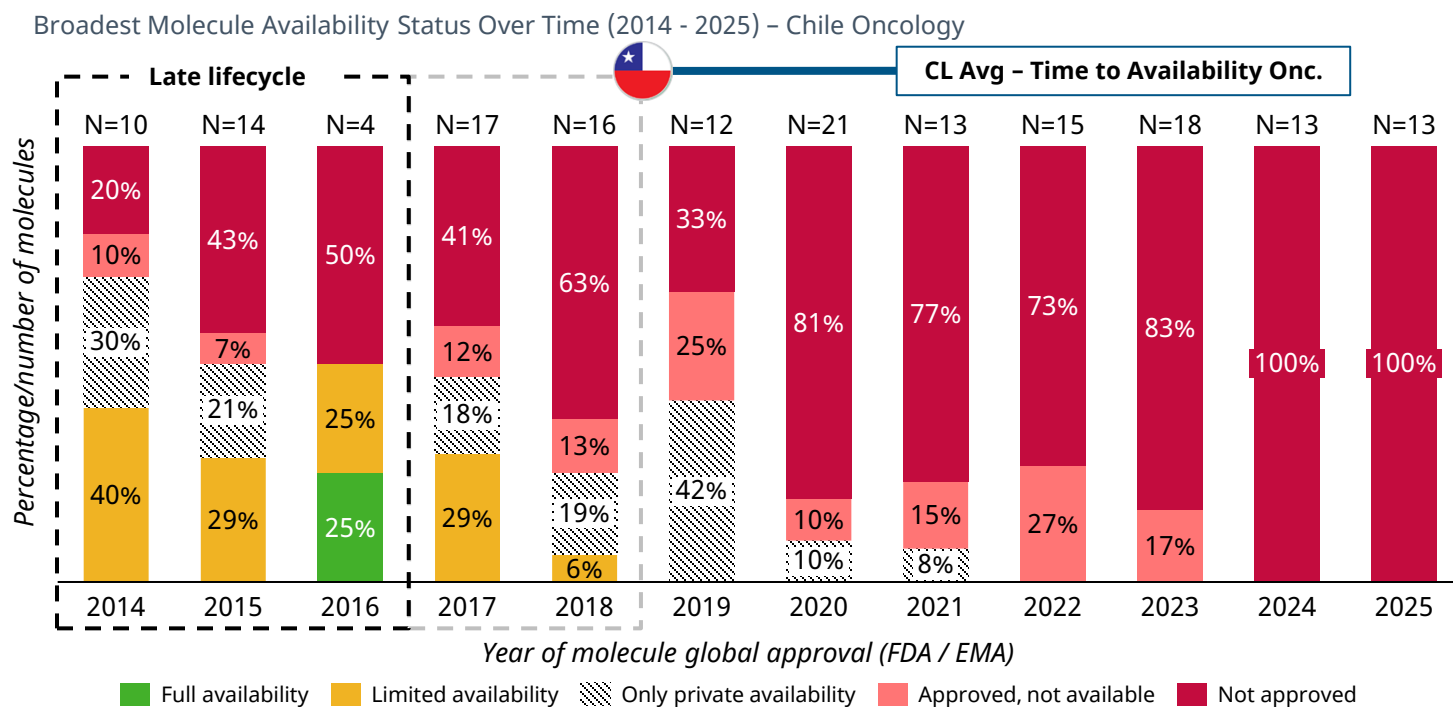
- However, there has been a decline in limited and private access in recent cohorts suggesting the limited ability of the system to provide even partial access
- The overall distribution shifts toward lower access over time, with recent cohorts increasingly concentrated in not approved and unavailable categories, pointing to a growing backlog and widening access gap despite ongoing innovation

“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

Oncology private sector access is strong, but public is very slow

Earlier cohorts show meaningful access through private and limited pathways, but recent oncology therapies are increasingly concentrated in not approved categories, with minimal system uptake



- Full availability of oncology molecules in Chile remains very limited, with only the 2016 outlier with 25% of full availability the rest of cohorts lack molecules with full availability; access is largely confined to older therapies, indicating long and selective incorporation cycles, with newer treatments facing increasing hurdles to enter the system
- The share of oncology molecules that are not approved rises sharply in recent years, increasing from 20% in 2014 to 77% in 2021, 83% in 2023 and 100% in 2024 and 2025, highlighting major barriers for newer oncology therapies
- Private-only availability represents an important access pathway, accounting for 30% in 2014, ~18-19% in 2017 and 2018, and 42% in 2019, suggesting that many products reach patients only through private channels rather than broad public availability

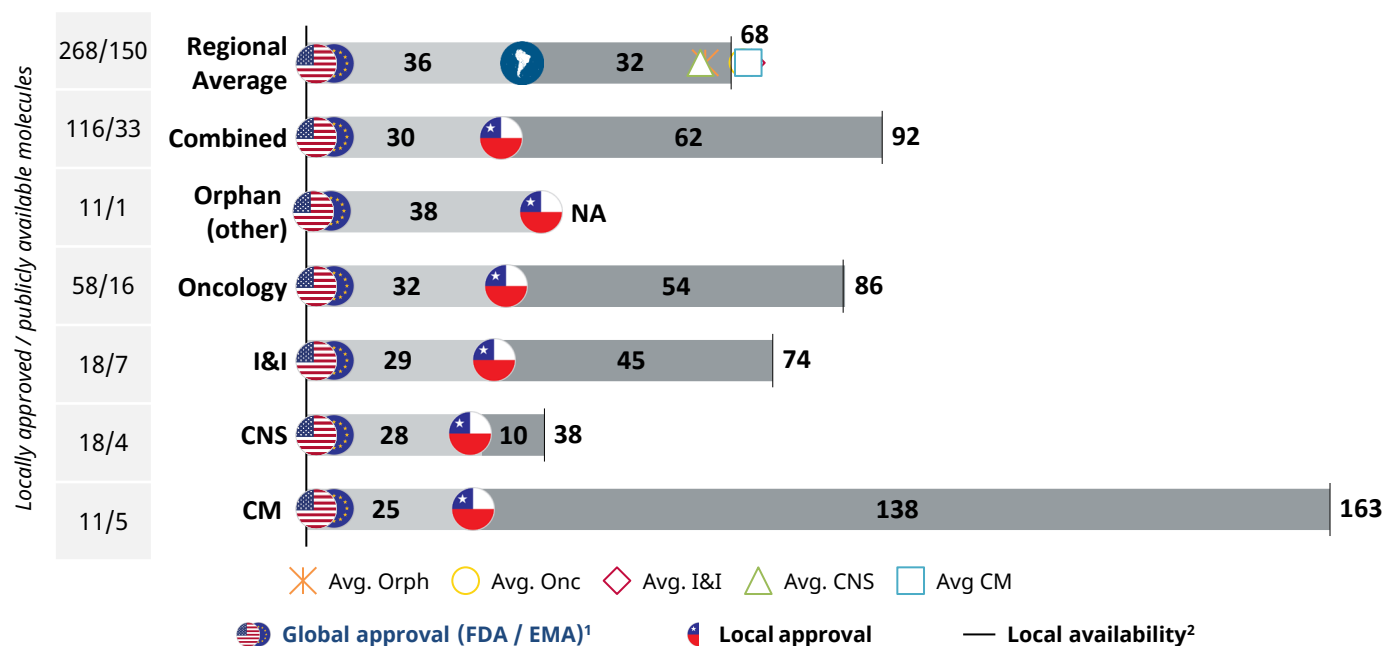
- Approved but not available molecules remain a meaningful share of the oncology pipeline, especially in later cohorts, reaching 27% in 2022, 25% in 2019, 17% in 2023; the gap is likely driven by orals or injectables which face additional hurdles to reach even the private sector vs. IV
- Access to oncology innovation in Chile has shifted away from limited availability toward restricted or absent access, with recent years showing minimal progression to full availability and a growing concentration of molecules that have not yet reached patients through the healthcare system

Access to oncology molecules in Chile has worsened over time, with newer cohorts increasingly concentrated in the not approved category

Access is a long and fragmented process

The time to availability in Chile averages 7.7 years, with a time to approval of 2.5 years and a time to availability of 5.1 years

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



¹ Global approval date considered the earliest date between FDA or EMA

² Considering molecules with Full and/or Limited Availability

- Total time to availability in Chile reaches ~92 months (~7.7 years), widely surpassing the regional average (68 months), confirming that Chile's waiting time is very significant and limited patient access remains significantly delayed
- Despite Chile's slightly faster regulatory approval timelines (30 months vs. 36 months regional), general time to local availability is greatly increased, skewed by some therapeutic areas that drive the time longer
- This slight advantage is completely offset by prolonged post-approval delays (62 months vs. 32 months regional), indicating that most access delays occur after approval, driven by reimbursement, pricing, and implementation barriers
- The most significant delays post approval correspond to the CM medicines, despite having a quick local approval time, the total time to availability exceeds the regional average by ~7.7 years
- In contrast other therapeutic areas, CNS (38 months), is strikingly quicker to availability, with lower approval and availability times

In Chile, access delays are driven primarily by prolonged post-approval processes, with therapies taking over five years on average to move from approval to availability

Timelines lengthened in 2026, driven by post-approval delays

While regulatory timelines remain stable, delays in availability are increasing in Chile, particularly in high-budget-impact therapeutic areas, reinforcing system strain beyond approval

Time to Availability from Global Approval vs. 2025 – By TA in Chile

		Approved	Available	Total
	Regional average	-5.6%	+9.4%	+1.5%
	Combined	+3.3%	+45.2%	+31.5%
	Orphan (other)	-5.3%	-	-
	Oncology	+3.2%	+22.2%	+15.3%
	I&I	-10.3%	-	-
	CNS	-	-	-
	CM	+4.0%	-	-

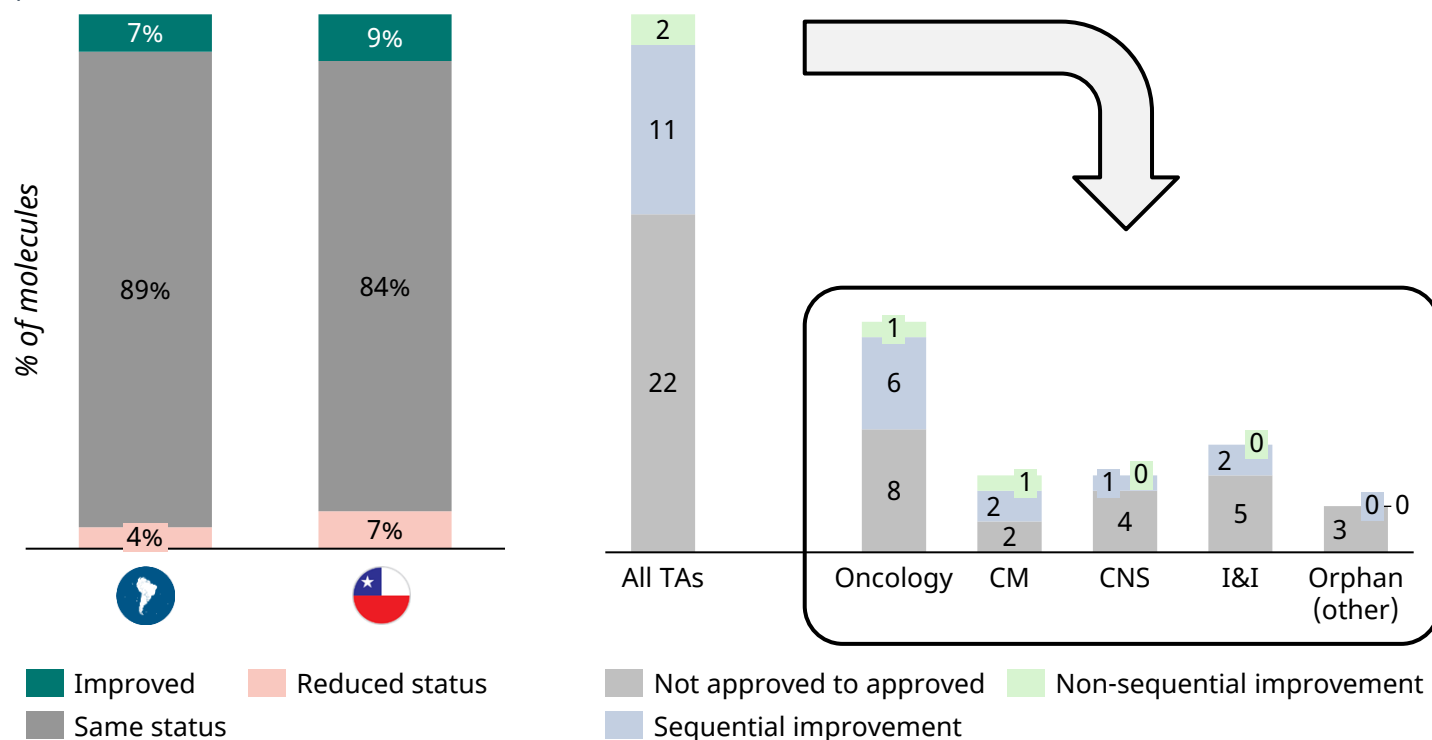
- Chile shows a +45.2% increase in time to availability vs. 2025, resulting in a +31.5% overall delay, which equates to approx. 20 months of additional wait time for patients to access treatments compared to the year prior, driven by prolonged access decisions
- There are isolated improvements but the overall trend indicates that system capacity is not keeping pace with innovation inflow, resulting in slower transitions from approval to availability
- This pattern is more deficient than the regional trend, where approval timelines improved (reduced by 5.6%) but availability timelines worsened (increased by 9.4%), highlighting a greater gap in access for Chile than its LATAM peers
- Delays are centered, but not limited to oncology (+15.3%) showing a large increase, reflecting the system inability to provide access to high complexity molecules

In Chile, access timelines are worsening significantly, driven primarily by accelerating post-approval delays, with high-impact therapies such as oncology particularly affected.

Access improvements in Chile are modest.

Only a small proportion of therapies show improvement, primarily driven by initial approvals rather than progression to broader availability, with most remaining unchanged

Improvement Index Chile (2026 vs 2025)



- Chile follows the regional trend in access progression, with 9% of molecules improving vs. 7% in LATAM; continuing a slow incremental progress of improvement
- Despite these gains, most molecules (~84%) remain in the same access status, with many remaining in the private sector only, highlighting a structure where most molecules are not scaling to the broader population, but can quickly reach approval and/or private sector access
- A portion of molecules (~7%) experienced reduced status, consistent with the regional benchmark (~4%); this can represent molecules that have become obsolete due to clinically superior options becoming available, competitive dynamics, etc.

- Across the therapeutic areas, more improvements are made in oncology, the least in Orphan, and relatively consistent patterns in other disease areas

Chile shows modest improvement in access, but gains are limited and concentrated at the approval stage, with most therapies remaining static and little progression toward broader availability

Structured access mechanisms are strengthening governance

Prioritization frameworks, high-cost funding mechanisms, and centralized procurement are reinforcing a more structured access system, but limit the speed and breadth of innovation uptake

Recent Health Reforms in Chile



Chile has built a structured access system based on prioritization and dedicated funding mechanisms

- GES (AUGE) prioritized coverage with explicit guarantees
- Ricarte Soto Law for high-cost and rare therapies
- Centralized procurement through CENABAST
- Budget-driven inclusion decisions through formal policy cycles

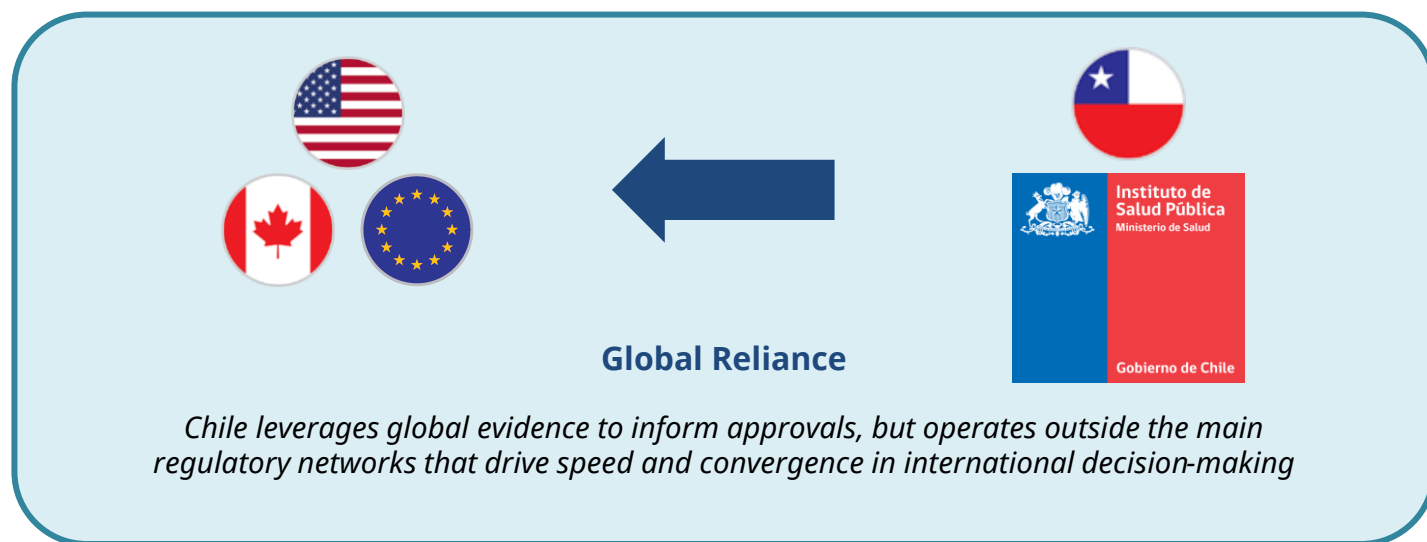
- Chile's healthcare system relies on mechanisms such as GES, which define guaranteed access for a limited set of prioritized conditions, including timing and financial protection; while this ensures predictability and baseline coverage, inclusion is restricted to predefined diseases and updated periodically, resulting in controlled but slow expansion of access to new therapies
- The Ricarte Soto Law provides dedicated funding for high-cost and rare treatments, enabling access to therapies that would otherwise be unaffordable; but the mechanism is highly selective and limited in scope, meaning that while it expands access for specific cases, it does not support broad system-wide uptake of innovation
- Public-sector access is supported by centralized purchasing through CENABAST, which improves negotiation capacity and supply coordination. however, this model links access to procurement cycles and cost-containment priorities, which can delay the incorporation of newer therapies, particularly those with high budget impact
- Access evolves through explicit policy-driven decisions rather than market-driven adoption, reinforcing selectivity across therapeutic areas

Chile has established a structured and predictable access system through prioritization and funding mechanisms, but its reliance on selective inclusion and policy cycles limits the speed and scale of innovation adoption

Chile's regulatory framework is aligned with global standards

Chile's regulatory system follows international standards and leverages external reference agencies, supporting approval processes, but remains less integrated in formal global reliance and collaboration frameworks

Global Reliance of Chile's Health Agencies



- Chile's regulatory authority incorporates decisions and evidence from established foreign regulators such as FDA and EMA, enabling the use of globally validated clinical and safety data; this approach strengthens technical rigor and reduces duplication of scientific assessment
- Chile is recognized as an NRA reflecting strong technical capability, and participates in NRAR collaboration mechanisms coordinated by PAHO, contributing to regional regulatory strengthening and convergence of efforts
- Although international evidence is leveraged, regulatory decision-making follows local procedures and sequential review pathways; this structure ensures control and rigor but differs from models where agencies engage in parallel or collaborative assessments, limiting the ability to fully capture efficiency gains from global processes

- Chile's inclusion in the PAHO NRAR group reflects its standing as a mature and capable regional regulator; however, it is not a core participant in global collaboration initiatives such as ICH or Project Orbis, where agencies coordinate evaluations and accelerate approvals

Chile's regulatory system combines strong technical alignment and regional reference recognition, but limited integration in global collaboration frameworks shapes a more independent and less accelerated approval model

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Oscar graduated with a Bachelor of Commerce in Marketing and Bachelor of Science in Psychology from the University of New South Wales, Australia.

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Yaneth Giha is an economist from the Universidad de los Andes, with Master's degrees in Political Sciences from the Javeriana University and War Studies from King's College, London. She has held several positions in the Colombian public sector such as Minister of Education, Vice Minister of Defense, Director of Science and she served as Executive President of AFIDRO, prior to joining FIFARMA in May 2022 as Executive Director.



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Dr. Diego Guarín is the Regional Market Access Lead for LATAM and is a founding member of the ISPOR Colombia chapter, also having served as chair of the ISPOR Latin American Consortium Industry Committees and Advisory Board. Dr. Guarín graduated as Medical Doctor from Universidad del Rosario-1653 (Colombia) and holds various master's degrees.



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

AMIIF, MX

FEDEFARMA, CAC

CAEME, AR

INTERFARMA, BR

AFIDRO, CO

ALAFARPE, PE

CIF, CL

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		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, Cibinco, 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 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

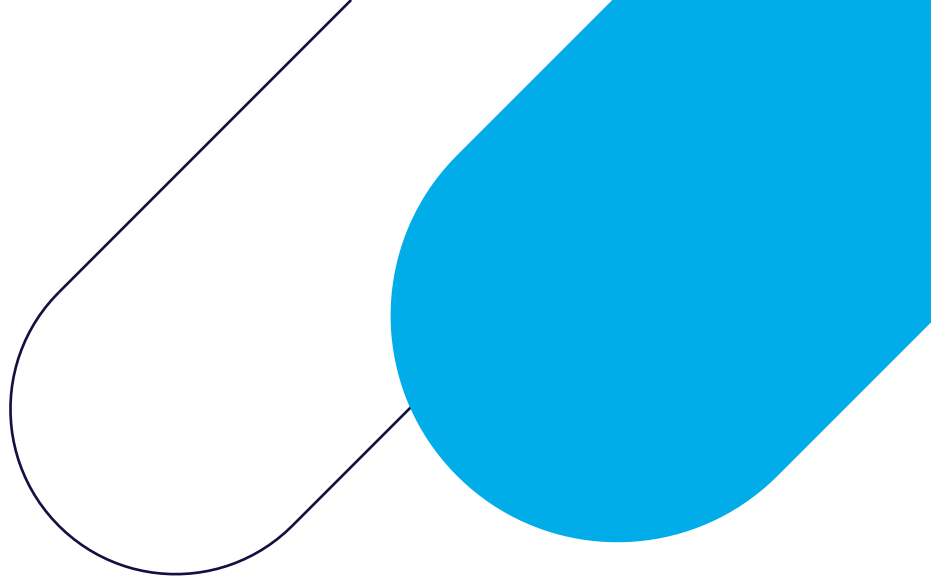
The approval/availability data is then gathered by IQVIA local consulting teams leveraging the data sources outlined (to the left)

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



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