Innovation on Hold: A 2020-2025 Analysis of the Conditional Drug Reimbursement Framework in Romania

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Background

Romania's reimbursement system for innovative medicines is based on health technology assessments (HTAs) performed by the National Drug Agency (NDA) after approval from the European Medicines Agency (EMA). Using a scorecard approach, decisions rely mainly on HTA evaluations from other countries, local budget impact, and availability of therapeutic alternatives[1]. The HTA may result in either denial of reimbursement, or positive unconditional or conditional reimbursement decisions.

The only route for drugs with conditional decisions to obtain reimbursement is through cost-volume(-result) agreements managed by the National Health Insurance House, based on a pool of eligible patients issued by the Ministry of Health Advisory Committees. New agreements, as well as annual renewals, operate within a common budget limit set by Parliament through law. After signing a new agreement, the drug must be included by the Government in the national reimbursement list.

With minor exceptions, the conditional reimbursement framework has remained unchanged since it was introduced in 2015[2]. Limited to only two managed entry agreement models—the most common one (cost-volume) operates as a simple discount grid based on the percentage of eligible population being treated—this multi-step, multi-stakeholder, reimbursement pathway has struggled to keep up with the demand for innovative medicines.

Due to a growing backlog, in September 2024 the authorities changed the prioritization criteria for conditional decisions pending reimbursement[3]. The new criteria place budget savings above addressing unmet medical needs. Consequently, only a few new cost-volume agreements were signed in December 2024, awaiting further inclusion in the reimbursement list.

With delays in conditional reimbursement accumulating in recent years, we aim to quantify the current backlog, measure durations between key milestones, identify bottlenecks, and propose solutions to enable faster access for patients.

Prioritization criteria for conditional decisions pending reimbursement

Before September 2024

1 - no therapeutic alternative reimbursed
2 - EMA accelerated assessment
3 - major public health impact

After September 2024

1 - budget savings of 3% or more
2 - orphan, rare disease designation, or no reimbursed therapeutic alternative
3 - budget savings less than 3%

Methods

We analyzed public data from the National Drug Agency (HTA dossiers), National Health Insurance House (eligible populations, negotiation budget, prioritization list), and state budget laws. Reimbursement statuses were confirmed through the national reimbursement list and list of therapeutic protocols. Mean durations with 95% confidence intervals were calculated in days for conditional HTA dossiers submitted from January 1, 2020, until June 15, 2025 cut-off. Automated data extraction and statistical analysis were performed using Python and R.

Results

A total of 207 conditional HTA decisions were identified, accounting for 53.8% of all positive (conditional + unconditional) HTA decisions in the study period. The annual number of indications with conditional decisions increased from 29 in 2020 to 48 in 2024 (Figure 1). Among these annual cohorts of indications, a decreasing percentage became reimbursed: from 86% in 2020 to 6% in 2024. For some indications with conditional decisions, HTA dossiers were resubmitted and unconditional decisions obtained (n=16), thus being excluded from the "Waiting" category.

Figure 1: Indications with conditional HTA decisions
by reimbursement status and HTA submission year

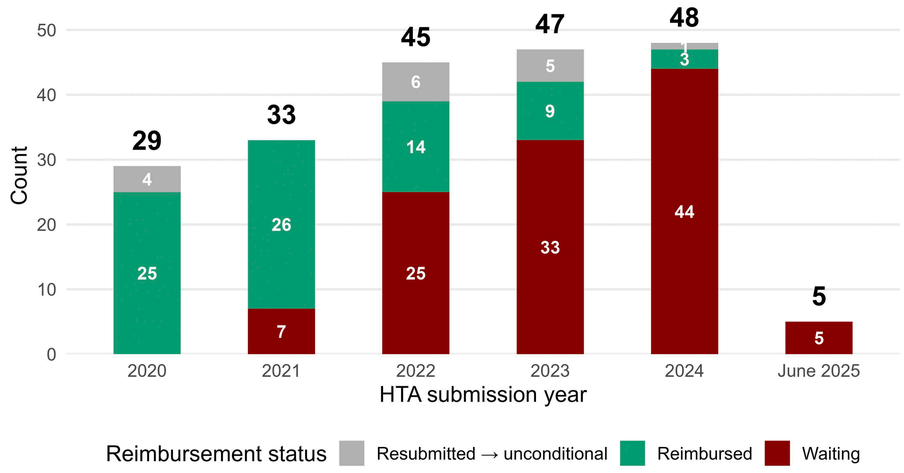
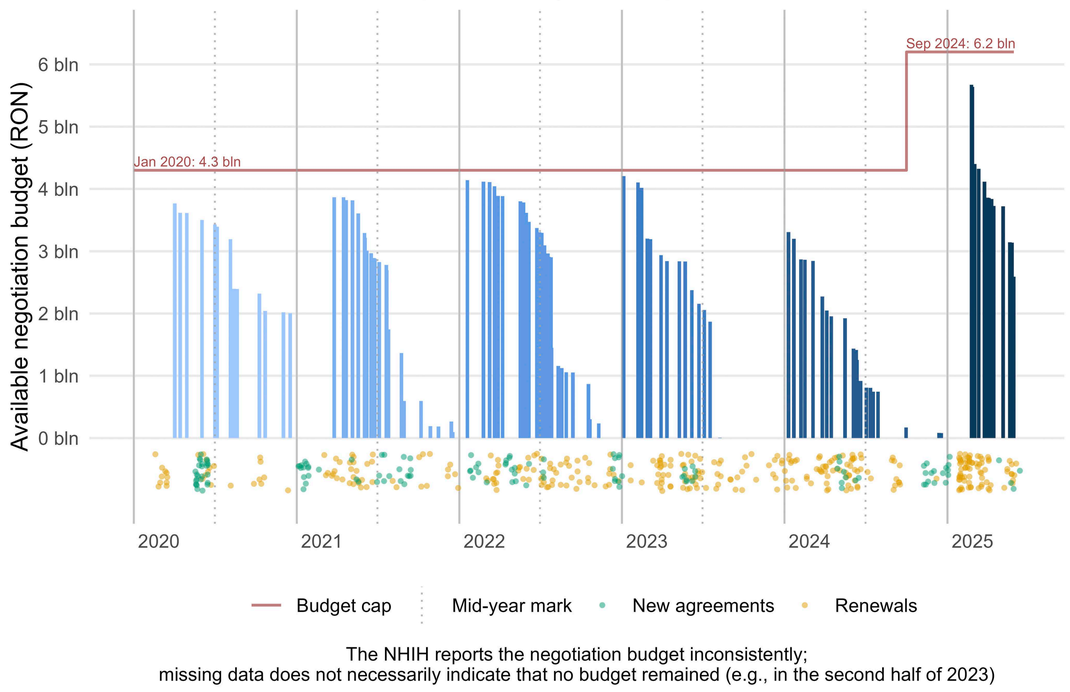


Figure 3: Budget dynamics for conditional reimbursements
use of annual negotiation budget: new agreements vs. renewals

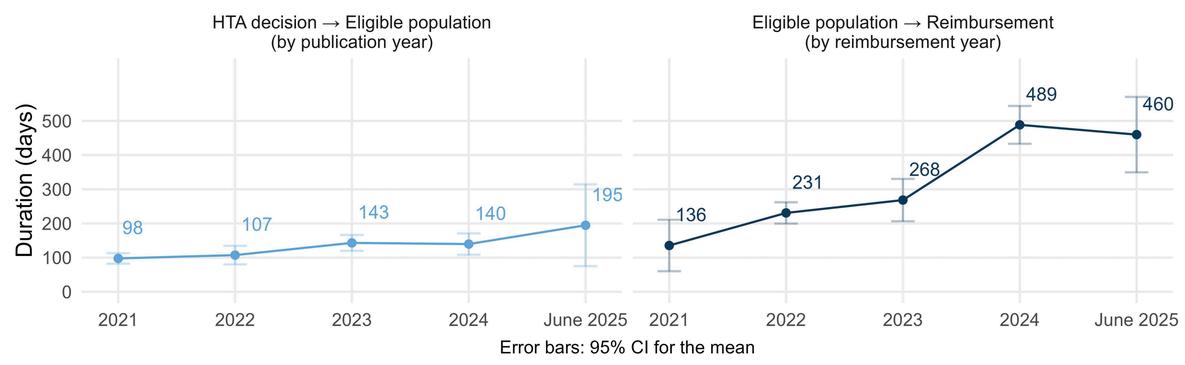


The NHIH reports the negotiation budget inconsistently;
missing data does not necessarily indicate that no budget remained (e.g., in the second half of 2023)

The annual NHIH negotiation budget cap has been maintained around 4.3 billion RON between 2020–2023 (Figure 3). As over 80% of the negotiation cap had been used mid-year, in September 2024 the cap was increased to 6.2 billion RON through budget rectification. By June 2025, 58% of the newly increased budget had already been depleted. The number of indications renewing an existing cost-volume agreement each year increased from 27 in 2020 to 70 in 2024.

Overall, the lag time from HTA decision to reimbursement for conditional indications increased from 205 days (95% CI: 140-270) in 2021 to 627 days (95% CI: 590-663) in 2024. The first phase of the process, from HTA decision to the issuing of the eligible population, increased by 42 days between 2021 and 2024 (Figure 2). However, the time from publication of the eligible population to reimbursement grew dramatically, from 136 days (95% CI: 60-211) in 2021 to 489 days (95% CI: 433-544) in 2024.

Figure 2: Durations between key milestones
for conditional indications



Error bars: 95% CI for the mean

As of June 15, 2025, 114 conditional decisions (55.1%) remained pending reimbursement, with 58 of them (50.8%) lacking therapeutic alternatives. The therapeutic areas with the most indications pending reimbursement are oncology (37.7%) and autoimmune diseases (17.5%). Among the few indications prioritized under the new set of criteria for conditional decisions (those for which cost–volume agreements were concluded in late 2024), none were reimbursed, although they would generate cost savings compared to existing alternatives.

Conclusions

Romania's conditional reimbursement system cannot adequately accommodate the growing number of conditional HTA decisions. The backlog of indications waiting for reimbursement is growing rapidly, while the duration from HTA decision to reimbursement has tripled over a time span of four years. The prolonged delays are mainly caused by the constrained budget that is not adjusted through horizon scanning and is used primarily for renewing existing agreements. The increasing burden placed on the Ministry of Health Advisory Committees in issuing more eligible populations has also added to the delays. Focusing on budget impact hinders reimbursement of drugs with no alternatives, and there is no other dedicated funding stream for drugs covering unmet medical needs. Solving this complex issue requires not only a technical solution, such as prioritization criteria, novel managed entry agreement models, or cost-effectiveness analysis, but also financial instruments for forecasting and adjusting the negotiation budget in accordance with patients' needs and the pace of medical innovation.

1. Radu CP, Chiriac ND, Pravat AM. The Development of the Romanian Scorecard HTA System. Value Health Reg Issues. 2016;10:41-47. doi:10.1016/j.vhri.2016.07.006
2. Radu, C. P., Drăgoi, L., Udroiu, M. A., Pană, B. C., & Iliescu, M. C. (2023). The outcomes of managed entry agreements in Romania from 2015 to 2022. Farmacia, 71(6), 1316–1323. doi:10.31925/farmacia.2023.6.23
3. Guvernul României. (2024, September 4). Ordonanță de urgență nr. 106/2024 [Emergency Ordinance No. 106/2024]. Monitorul Oficial al României

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