GRHTA
Glob Reg Health Technol Assess 2026; 13: 309-312
ISSN 2283-5733 | DOI: 10.33393/grhta.2026.3970
SHORT COMMUNICATION

Oncology drug expenditure governance in an antineoplastic drug unit: comparative economic analysis 2023–2025 and the stratified recovery rate

Filomena D'Amico[1], Francesco Colasuonno[1], Loredana Brandi[1], Viviana Bruno[1], Alessandro Maggi[2], Antonio Ungaro[2], Tiziana Guarino[2], Vito Gregorio Colacicco[3], Salvatore Pisconti[2]

[1]Pharmaceutical Department, ASL Taranto, Taranto - Italy
[2]Onco-Haematology Department, ASL Taranto, Taranto - Italy
[3]General Directorate, ASL Taranto, Taranto - Italy

ABSTRACT

Introduction: Direct hospital pharmaceutical expenditure in Italy grew by +6.0% in 2025. Antineoplastic Drug Units (ADUs) play a key governance role through AIFA registry management, managed entry agreement (MEA) recovery, and prescribing appropriateness monitoring. No standardized indicator distinguishes recoveries dependent on local activity from those determined nationally.

Methods: Retrospective three-year comparative economic analysis, 2023-2025, at the ADU of a local health authority in southern Italy (~540,000 inhabitants). Expenditure, patient volumes, preparation counts, and recoveries were extracted from the AIFA registry platform and ADU management system. Recoveries were stratified into Tier 1 (national: AIFA MEA rebates, Innovative Drug Fund receipts) and Tier 2 (local: Law 648/96 recoveries, trial and compassionate use cost avoidance). Gross (all recoveries over net expenditure) and Local (Tier 2 over net expenditure) Recovery Rates were calculated.

Results: Net expenditure grew +8.0% in 2023, +19.0% in 2024 and +3.86% in 2025, below the +6.0% national growth, despite a +19.2% increase in treated patients (3,341 vs 2,804) and +21.8% in preparations. Cost per patient decreased from €11,286 to €9,837 (−12.8%). Total recoveries were €5,261,136, €5,291,062, and €8,918,159. The Gross Recovery Rate was 19.8%, 16.7%, and 27.1%; the Local Recovery Rate was 6.7%, 4.7%, and 6.5%.

Conclusions: The ADU governance model was associated with simultaneous expansion of patient access and reduction of per-patient cost. The stratified Recovery Rate separates recoveries dependent on local activity from those determined nationally, offering a transparent, reproducible indicator for benchmarking ADU governance across Italian NHS settings and European health systems with national MEA frameworks.

Keywords: Antineoplastic agents, Drug costs, Health technology assessment, Pharmaceutical services, Reimbursement mechanisms, Value-based health care

Introduction

Hospital pharmaceutical expenditure in Italy has been growing at a structurally sustained pace, with the OsMed 2024 National Report documenting a +7.7% increase in total public pharmaceutical expenditure for 2024, with antineoplastic agents representing the largest single category acquired by public health structures (1). More specifically, the AIFA Monitoring Report for January-December 2025 documents a +6.0% increase in direct hospital pharmaceutical expenditure (direct purchasing, class A+H) for 2025 vs 2024; this figure refers to overall hospital drug spending rather than to oncology alone (2).

Within the Italian NHS, Antineoplastic Drug Units (ADUs - Unità Farmaci Antiblastici, UFA) serve as both operational preparation hubs and strategic governance nodes for clinical-pharmaceutical expenditure. Their governance function encompasses prescribing appropriateness monitoring, AIFA registry management for conditional reimbursement, commercial negotiation, and drug waste minimization. Italy applies performance-based managed entry agreements (MEAs) more extensively than any other European country (3,4), creating significant recovery opportunities that can only be captured through precise, timely alignment between procurement and dispensation records.

Received: July 2, 2026
Accepted: October 20, 2026
Published online: November 17, 2026

This article includes supplementary materials

Corresponding author:
Filomena D'Amico
email: filomena.damico@asl.taranto.it

© 2026 The Authors. This article is published by AboutScience and licensed under Creative Commons Attribution-NonCommercial 4.0 International (CC BY-NC 4.0).
Commercial use is not permitted and is subject to Publisher's permissions. Full information is available at www.aboutscience.eu

Despite the recognized strategic relevance of ADUs, no standardized indicator exists to quantify their governance performance in terms of economic value generated. Existing measures aggregate all recoveries into a single figure, without separating those that follow from local organizational activity and those determined by national regulatory decisions such as price renegotiation or allocation of the Innovative Drug Fund. This study introduces a stratified Recovery Rate (RR) that distinguishes the two components, and illustrates its application through a three-year comparative analysis (2023-2025) at an ADU in southern Italy.

Methods

Three-year retrospective comparative economic analysis at the ADU of a local health authority in southern Italy (~540,000 inhabitants), covering the calendar years 2023, 2024 and 2025. The analysis adopts the local health authority payer perspective. In keeping with established practice for descriptive economic analyses, no inferential statistical testing was applied (5); results are presented as absolute values and year-on-year percentage changes.

Data were extracted from: (i) the AIFA national registry platform for MEA rebates; (ii) the ADU management system (FarmaSafe/regional UFA program) for expenditure, volumes, and preparations; and (iii) administrative records for Law 648/96, clinical trial and compassionate use drugs. Net expenditure is recorded at invoiced price, net of negotiated discounts, and gross of MEA rebates and Innovative Drug Fund receipts. The latter are credited to the health authority through separate accounting channels and are never deducted from drug expenditure, so that no recovery component is subtracted from the denominator and simultaneously added to the numerator.

Recoveries were stratified into two tiers. Tier 1 comprises AIFA MEA registry rebates and Innovative Drug Fund receipts, both of which follow from national regulatory decisions and from the epidemiological case mix. Tier 2 comprises Law 648/96 recoveries and the cost of drugs supplied free of charge within sponsored clinical trials or compassionate use programs, all of which require local patient identification, protocol management and registry alignment. Cash inflows and cost avoidance are reported separately: Tier 1 consists entirely of cash inflows, while Tier 2 combines a cash inflow (Law 648/96) with cost avoidance (trials and compassionate use), the latter being borne by the sponsor. Recovery of residual drug volumes after compounding, although the activity most directly dependent on local organization, is not recorded as a separate accounting item and could not be quantified in monetary terms; it is therefore excluded from both indicators. The Local RR is accordingly a conservative estimate of the true organizational impact, since the component most directly attributable to the unit is not captured.

Two indicators are defined:

$$\text{Gross RR (\%)} = (\text{Tier 1} + \text{Tier 2})/\text{Net Expenditure (€)} \times 100$$
$$\text{Local RR (\%)} = \text{Tier 2}/\text{Net Expenditure (€)} \times 100$$

The Gross RR expresses the overall economic return on total deployed resources and enables year-on-year and cross-institutional comparison. The Local RR isolates the component that depends on activity carried out within the unit. A one-way sensitivity analysis was performed on each Tier 2 component separately, varying it by ±20%. This range reflects the year-on-year variability observed for these components over the three years, whose coefficient of variation lies between 18% and 22%.

Results

In 2025, the ADU prepared 53,300 therapies for 3,341 patients (+4.2% preparations; +19.2% patients vs 2024). Net drug expenditure grew only +3.86% (€32,866,918 vs €31,646,276), below the +6.0% national growth in overall direct hospital pharmaceutical expenditure (2). Over the three years, preparations rose from 43,757 to 53,300 (+21.8%), while expenditure grew by +8.0% in 2023 and +19.0% in 2024, the latter a year in which several high-cost molecules and label extensions entered routine use. The number of treated patients was the same in 2023 and 2024 (2,804), while preparations increased by 16.9%, so that the 2024 expenditure growth reflects greater treatment intensity per patient (cost per patient €9,483 to €11,286). In 2025, cost per patient decreased to €9,837 (-12.8% vs 2024), with cost per preparation essentially unchanged (€617 vs €619).

Detailed expenditure data by active compound are reported in Supplementary Table 1. Among the ten principal compounds, patient numbers grew +30.4% while per-patient cost fell -2.1%. Pembrolizumab recorded a +12.4% patient increase accompanied by a net expenditure decrease of €12,304 (-0.8%); this follows the AIFA price renegotiation that accompanied approval of new indications, together with prescribing within registered indications as required for reimbursement, and is therefore classified as a Tier 1 effect.

Activities carried out within the unit included centralized dose banding, recovery of residual drug volumes after compounding, systematic use of subcutaneous daratumumab and protocol-driven review of treatment duration in adjuvant immunotherapy. For daratumumab, the acquisition cost of the subcutaneous formulation does not differ from the intravenous one, and the subcutaneous route is the only one authorized for several indications; the benefit lies in reduced chair time and nursing workload rather than in drug cost. CAR-T management generated €1,449,719 in Innovative Drug Fund receipts on €2,247,707 expenditure.

The three-year comparative analysis is reported in Supplementary Table 2. Total recoveries amounted to €5,261,136 in 2023, €5,291,062 in 2024 and €8,918,159 in 2025. Tier 1 recoveries rose from €3,474,193 to €6,785,757, driven by a +103.8% increase in Innovative Drug Fund receipts (€6,486,972 vs €3,182,463). Tier 2 recoveries fell from €1,786,943 in 2023 to €1,472,385 in 2024, mainly because Law 648/96 recoveries contracted from €500,802 to €132,141, and rose to €2,132,402 in 2025 (+385.8% in Law 648/96; +11.2% in trial and compassionate use cost avoidance). The Gross RR was 19.8%, 16.7%, and 27.1%; the Local RR was 6.7%, 4.7%, and 6.5%. Both indicators fell in 2024, when expenditure growth outpaced recovery capture, and rose again in 2025, with the Gross RR well above its 2023 value and the Local RR close to it. In the sensitivity analysis, trial and

© 2026 The Authors. Global & Regional Health Technology Assessment - ISSN 2283-5733 - www.aboutscience.eu/grhta

compassionate use cost avoidance was the dominant parameter, moving the 2025 Local RR between 5.58% and 7.39% against a base case of 6.49%, while Law 648/96 recoveries moved it between 6.10% and 6.88% (Supplementary Fig. 1).

Discussion

In this three-year analysis, the multidisciplinary ADU governance model was associated with a simultaneous expansion of patient access (+19.2%) and a reduction of per-patient cost (-12.8%), with expenditure growth remaining below the national average. Both recovery indicators fell in 2024 and rose again in 2025, showing that recoveries do not scale proportionally with expenditure when a large number of new molecules enter routine use within a single year.

The stratified Recovery Rate as a governance indicator: Aggregating all recoveries into a single figure attributes to local activity a result that also depends on MEA rebates, AIFA price renegotiations and Innovative Drug Fund allocations, all of which are decided nationally. The Local RR offers a more specific measure of what happens within the unit, while the Gross RR remains informative about the overall return on the drug budget. The Local RR moved from 4.7% in 2024 to 6.5% in 2025, driven by expanded Law 648/96 access and trial enrolment, both requiring intensive professional registry oversight to capture. Its 2023 value of 6.7% indicates that the 2025 figure represents the restoration of a previous level rather than a new one. Standardization of this indicator as a routine ADU reporting metric, potentially under SIFO or AIFA auspices, would enable evidence-based governance benchmarking across the Italian NHS.

European applicability: The stratified RR is transferable to any European NHS with a national MEA or conditional reimbursement system. NHS England's Cancer Drugs Fund (6), France's Autorisation d'Accès Précoce (4) and Spain's CIPM conditional pricing (7) all generate pharmacy-managed financial flows structurally analogous to AIFA MEA recoveries. Cross-national validation would require country-specific mapping of which flows follow from national decisions and which depend on local activity, a feasible adaptation given the indicator's transparent formula.

Limitations: Single-center design. Patient and preparation counts serve as activity proxies: days of therapy and defined daily doses were not available, so a change in treatment persistence cannot be ruled out as a contributor to the lower cost per patient, although cost per preparation remained stable over the same interval. Recovery of residual drug volumes could not be quantified in monetary terms, which makes the Local RR a conservative estimate of the true organizational impact; prospective recording of this component is planned. Compounding technology (semi-automated) and its associated costs were not included. Neither indicator captures clinical outcomes. Cross-year comparability of AIFA MEA rebates may be affected by registry reconciliation timing. The comparison with the +6.0% national figure should also be interpreted with caution, since it refers to overall direct hospital pharmaceutical expenditure, whereas this study concerns the activity of a single oncology drug unit. Three years remains a short horizon for structural conclusions, and extension to five years is planned.

Conclusions

Between 2023 and 2025, the ADU of this Italian local health authority recorded a +19.2% patient expansion and a -12.8% per-patient cost reduction, while expenditure growth was contained at +3.86%, against a +6.0% national growth in overall direct hospital pharmaceutical expenditure (2). The Gross RR moved from 19.8 to 27.1% and the Local RR from 6.7 to 6.5%, both falling in 2024 and recovering in 2025. Separating recoveries determined nationally from those that depend on local activity provides a transparent, auditable governance performance indicator calculable from routinely available administrative data in any ADU operating within a national registry and MEA framework.

Acknowledgements

The authors thank the Technical and Nursing Staff of the ADU and all clinical teams of the Onco-Haematology Department of ASL Taranto for their contribution. The authors thank Dr. Rosa Moscogiuri, who directed the Pharmaceutical Department of ASL Taranto until August 2024, for her institutional role during the study period. The authors acknowledge the ASL Taranto Strategic Management for supporting research activities. Artificial intelligence tools (Claude Sonnet 4.6, Anthropic, May 2026; NotebookLM, Google, May 2026) were used to support manuscript drafting and data tabulation. All intellectual content, data analysis, and clinical interpretation were performed and verified by the authors.

Disclosures

Conflicts of interest: All authors declare no conflicts of interest.

Financial support: No external funding received. Conducted as part of routine pharmacoeconomic governance activity.

Ethics: Exclusively anonymized aggregated administrative data; no patient-level identifiable data accessed. Ethics committee approval not required (D.Lgs. 196/2003; GDPR EU 679/2016).

Data availability: Aggregated data available from the corresponding author on reasonable request.

Author contributions: FDA: Conceptualization, Data curation, Formal analysis, Writing – original draft, Writing – review & editing. FC: Conceptualization, Supervision, Writing – review & editing. LB: Data curation, Validation, Writing – review & editing. VB: Data curation, Investigation, Writing – review & editing. AM: Validation (hematology data), Writing – review & editing. AU: Validation (oncology clinical data), Writing – review & editing. TG: Data curation (clinical trial and compassionate use data, AIFA registry coordination), Writing – review & editing. VGC: Supervision, Funding acquisition, Final approval. SP: Validation (oncology data), Supervision, Writing – review & editing. All authors approved the submitted version.

References

1. AIFA – OsMed. L'uso dei farmaci in Italia. Rapporto Nazionale Anno 2024. Italian Medicines Agency; 2025.
2. AIFA – Ufficio Monitoraggio della Spesa Farmaceutica. Monitoraggio della Spesa Farmaceutica Nazionale e Regionale Gennaio–Dicembre 2025. Rome: Italian Medicines Agency; Online (Accessed June 2026)
3. Ferrario A, Kanavos P. Managed entry agreements for pharmaceuticals: the European experience. EMiNET; 2013. Online

© 2026 The Authors. Published by AboutScience - www.aboutscience.eu

4. Pauwels K, Huys I, Vogler S, et al. Managed entry agreements for oncology drugs: lessons from the European experience to inform the future. Front Pharmacol. 2017;8:171. CrossRef PubMed
5. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014;17(1):5-14. CrossRef PubMed
6. NHS England. Cancer Drugs Fund: appraisal and funding process. Online (Accessed July 2026)
7. Espín J, Rovira J, García L. Experiences and impact of European risk-sharing schemes focusing on oncology medicines. EMINET; 2011.

© 2026 The Authors. Global & Regional Health Technology Assessment - ISSN 2283-5733 - www.aboutscience.eu/grhta