



ADVANCING HER2-POSITIVE BREAST CANCER CARE IN ITALY

Harmonizing Access in an Advanced, Decentralized System

EXECUTIVE SUMMARY

Italy has long been recognized for its strong performance in breast cancer care, with universal healthcare access, early adoption of HER2-targeted therapies, and alignment with international clinical guidelines. HER2 testing is widely available and reimbursed, and survival rates are among the highest in Europe. However, Italy's highly decentralized regional health system results in variation in access to diagnostics, treatment timelines, and follow-up services. Emerging challenges include HER2-low classification, equitable access to next-generation therapies, and survivorship care integration. Italy is currently at Maturity **Level 4 – Advanced**, indicating a high-functioning system with opportunities to optimize consistency and precision across regions.

CURRENT SITUATION

Italy's National Health Service ensures universal access to diagnostics, treatment, and follow-up care through a mix of public hospitals and accredited private providers. HER2 testing is standard practice and reimbursed under national oncology pathways.

Treatments including trastuzumab, pertuzumab, and T-DM1 are listed on the national formulary, and newer therapies like T-DXd are available through managed entry agreements. Screening is organized at the regional level, targeting women aged 50–69 through biennial mammography, though participation varies significantly. Breast cancer survival is among the best in Europe, with 5-year survival exceeding 88%, but HER2-specific outcomes are not reported nationally. Guidelines align with global standards but do not yet mandate HER2 re-testing at relapse or address HER2-low classification consistently.

Italy is classified at Maturity **Level 4 – Advanced**, supported by strong infrastructure and equity in principle, but challenged by regional fragmentation and lagging precision care integration.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among women in Italy, with over **55,000** new cases annually, of which **15–20% are HER2-positive**. Italy was an early adopter of HER2-targeted therapies such as trastuzumab, pertuzumab, and T-DM1, and recently introduced trastuzumab deruxtecan (T-DXd). HER2 testing is routine and standardized across public hospitals and private centers, and treatments are reimbursed under the **Servizio Sanitario Nazionale (SSN)**. Italy participates in major clinical trials and maintains strong alignment with ESMO guidelines.

Despite this, Italy's **regionally governed health system** introduces disparities in service delivery and timing. Some regions have faster access to newly approved drugs and better integration of survivorship care than others. National registries lack HER2-stratified outcomes, and HER2-low classification is not uniformly applied. To maintain its position as a European leader in breast cancer care, Italy must strengthen coordination across regions, accelerate innovation adoption, and collect HER2-specific data to guide policy.



HER2 BREAST CANCER IN ITALY

Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	HER2 testing and treatment are widely available through public hospitals...	...but turnaround times and service quality vary across regions.	Standardize diagnostic pathways and digital pathology networks to ensure consistency across all regions.
Access to Treatment	HER2 therapies (trastuzumab, pertuzumab, T-DM1, T-DXd) are reimbursed under SSN...	...but regional approval and distribution timelines delay access in some areas.	Harmonize therapy introduction timelines across regions and expand access to HER2 drugs via national-level fast-track agreements.
Research & Innovation	Italy contributes to major EU trials and translational research via centers like IEO and IRCCS...	...but HER2-low subtypes and survivorship cohorts are underrepresented in current research agendas.	Support national HER2-low research initiatives and create long-term outcome studies through AIFA or the Italian Cancer Network.
Awareness & Education	Awareness campaigns and screening reminders are issued at national and regional levels...	...but HER2 subtypes are not emphasized, and primary care awareness varies.	Include HER2 subtype information in public health materials and strengthen GP education on HER2 pathways.
Survival Rates	Italy's 5-year survival exceeds 88% for breast cancer...	...but HER2-disaggregated survival data is not publicly reported, limiting policy planning.	Mandate HER2-specific outcome data in cancer registries and promote regional performance benchmarking.
Early Detection & Palliative Care	Screening is free for women aged 50–69 and coordinated by regional health authorities...	...but participation varies (from 40% to 70%) and palliative care services remain fragmented.	Incentivize screening participation in low-uptake regions and expand integrated palliative care models nationally.
Biomarker	HER2 IHC and FISH testing are standard and quality controlled...	...but HER2-low reproducibility is not yet ensured across all pathology labs.	Develop national HER2-low pathology interpretation protocols and fund lab QA programs.
Clinical Guidelines	Guidelines follow ESMO and are adopted nationally via AIOM...	...but HER2 re-testing and HER2-low inclusion are inconsistently implemented in practice.	Update AIOM guidelines to include HER2 re-testing at relapse and clear HER2-low management pathways.
Reimbursement	HER2 therapies are reimbursed through SSN with no direct cost to patients...	...but EMA-approved drugs can face months of delay before regional access.	Streamline EMA-to-regional access with unified procurement and early national reimbursement mechanisms.
Screening	Public breast cancer screening is offered every two years to women aged 50–69...	...but participation remains below EU targets in several southern regions.	Introduce personalized screening reminders and community outreach in low-uptake areas.

CONCLUSION

Italy has laid a strong foundation for HER2-positive breast cancer care, ensuring access to testing and reimbursed therapy for all patients. However, its decentralized structure creates delivery inconsistencies that could hinder advances in personalized care. To consolidate its **Advanced maturity status**, Italy must address regional variation in HER2 care implementation, integrate HER2-low into practice, and improve HER2-stratified data collection. With robust infrastructure and clinical expertise already in place, the next step is national coordination and precision execution.



KEY POLICY MESSAGES

- 1 Italy ensures broad access to HER2 testing and therapy, but regional variation slows innovation uptake.
- 2 HER2-low classification and relapse re-testing are not yet fully integrated into clinical practice.
- 3 HER2-stratified survival data is lacking, limiting targeted planning and monitoring.
- 4 Italy's next frontier is harmonizing HER2 care delivery across all regions, not just leading centers.

CALL TO ACTION

- **Update AIOM national guidelines** to include HER2 re-testing and HER2-low protocols.
- **Accelerate regional adoption** of new HER2 therapies through centralized approval pathways and shared procurement.
- **Expand HER2 testing infrastructure and quality controls** across all regions, especially in the south and islands.
- **Disaggregate survival and treatment data by HER2 status** and publish registry-based benchmarks.
- **Strengthen survivorship and palliative care frameworks** with HER2-specific pathways in national and regional cancer plans.