



ACCELERATING EQUITY & INNOVATION in HER2-Positive Breast Cancer Care in Spain

EXECUTIVE SUMMARY

Spain's national health system delivers broad access to breast cancer screening, diagnostics, and HER2-targeted therapies. Urban oncology centers provide world-class care, and new genomic tools such as HER2DX signal a growing leadership role in precision oncology. However, regional disparities remain in treatment timelines, biomarker access, and reimbursement for innovative therapies.

Spain stands at an inflection point: it has the scientific capital and clinical infrastructure to lead in HER2-positive care, but unlocking this potential requires faster adoption of innovations, better regional coordination, and a stronger policy push toward equity.

INTRODUCTION

Spain is one of Europe's most active breast cancer research hubs and has consistently improved outcomes through national screening and treatment programs. With ~36,400 new breast cancer cases annually and HER2-positive disease comprising 15–20% of them, Spain's health system faces a significant burden—but also a major opportunity. Trastuzumab, pertuzumab, and newer agents like trastuzumab deruxtecan are available, and projects like HER2DX are reshaping risk stratification. Yet reimbursement delays, regional fragmentation, and gaps in guideline implementation continue to affect patient outcomes.

According to the Maturity Framework for Cancer Care, Spain is classified as **"Advanced"**—but rising to a leadership tier will require targeted policy reform.

CURRENT FRAMEWORK/SITUATION

Spain's universal healthcare system guarantees core cancer services without out-of-pocket costs. HER2 testing is near-universal, and 85% of cases are detected early through organized screening. Large academic centers in cities like Madrid and Barcelona offer molecular diagnostics, multidisciplinary tumor boards, and access to clinical trials. However, rural patients often face longer wait times for specialized services, and decentralized healthcare management across autonomous communities leads to inequities in drug reimbursement.

Trastuzumab deruxtecan, for example, took over 17 months to be reimbursed for third-line treatment—delays that can measurably reduce survival. While Spain has world-class capabilities, access remains uneven and innovation uptake too slow.



HER2 BREAST CANCER IN SPAIN

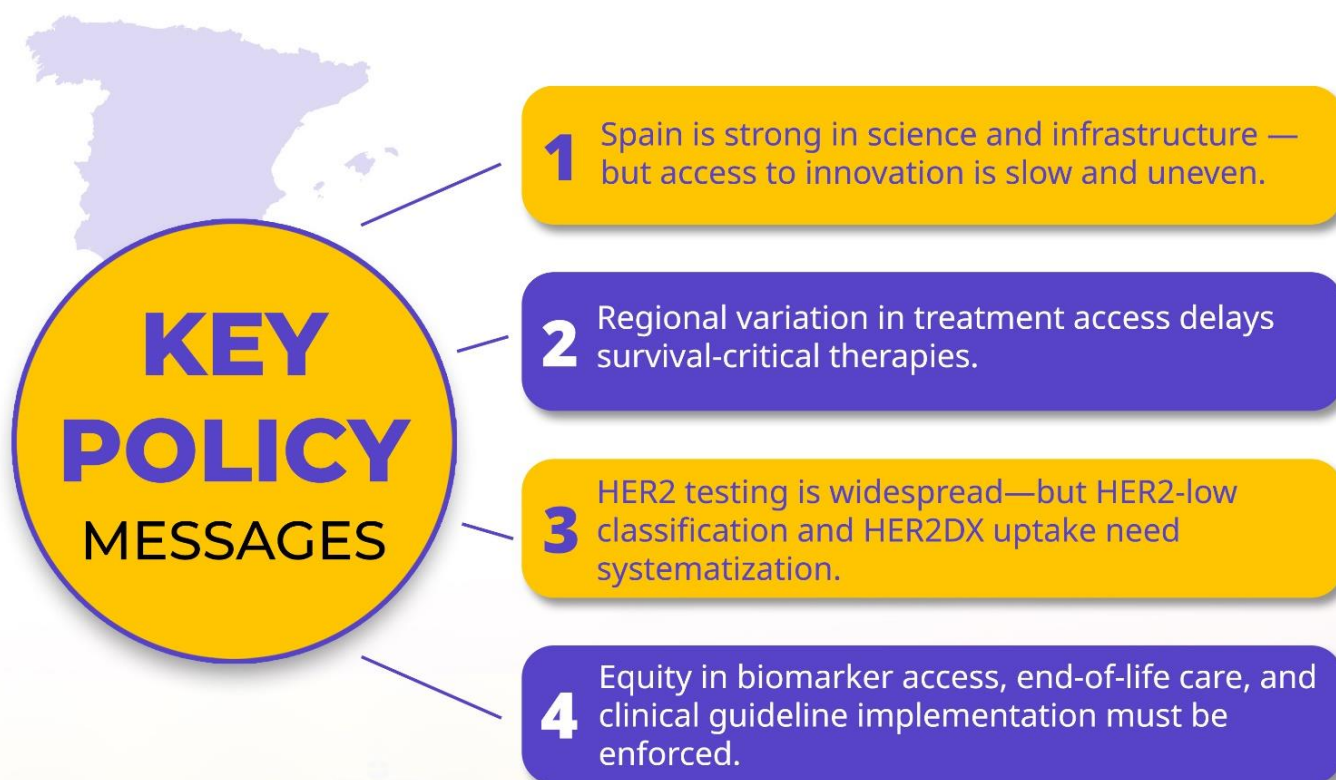
Key Issues Table and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	Yes, Spain has specialized cancer centers in major cities with advanced diagnostics and HER2 treatment...	...but rural regions still lack timely access to molecular testing and specialist consultations.	Expand mobile diagnostic units and tele-oncology to decentralize specialist access.
Access to Treatment	Yes, over 85% of patients receive HER2-targeted treatment within 3 months of diagnosis...	...but time to treatment and drug reimbursement varies significantly between autonomous communities.	Standardize national treatment timelines and create a HER2+ access equity mandate across regions.
Research & Innovation	Yes, Spain leads EU-funded HER2 research, including the €8M HER2DX DEFINITIVE trial...	...but new diagnostics and therapies face slow integration into clinical pathways.	Create fast-track reimbursement channels for validated HER2 diagnostics and treatments.
Awareness & Education	Yes, screening participation is ~75% nationwide and mobile units improve outreach...	...but few awareness campaigns focus specifically on HER2-positive disease or genomic testing.	Launch HER2-focused patient education campaigns and provider training programs.
Survival Rates	Yes, 5-year survival is ~85.5%, with >41,000 life-years gained from trastuzumab use since 2006..	...but HER2-specific survival data are limited, and regional gaps in late-stage care persist.	Require HER2-specific survival reporting in national cancer registries and expand late-stage care audits.
Early Detection & Palliative Care	Yes, 64% of breast cancers are diagnosed at stages I-II and palliative care is integrated into major hospitals...	...but access to end-of-life care in rural areas remains inconsistent.	Fund regional palliative care networks and track access via equity benchmarks.
Biomarker	Yes, nearly 100% of patients receive HER2, ER, and PR testing; HER2DX is in clinical validation...	...but uptake of NGS and HER2DX is limited by reimbursement and training gaps.	Fast-track HER2DX adoption upon validation and subsidize NGS access for regional centers.
Clinical Guidelines	Yes, Spain follows ESMO and NCCN guidelines and has national HER2+ treatment protocols (SEOM-GEICAM-SOLTI)...	...but implementation in smaller hospitals remains variable.	Link hospital funding to adherence with HER2+ clinical pathways and HER2DX integration.
Reimbursement	Yes, over 95% of treatments are covered by national health insurance...	...but delays of 9-17 months for new therapies like trastuzumab deruxtecan remain common.	Introduce centralized oncology drug evaluation to reduce inter-regional delays.
Screening	Yes, free biennial mammography is available to all women aged 50-69, with high participation...	...but coverage strategies differ across regions, and outreach to high-risk groups is uneven.	Harmonize screening protocols nationwide and integrate genetic risk stratification tools.



CONCLUSION

Spain's HER2-positive breast cancer system is scientifically strong but operationally fragmented. From HER2DX to trastuzumab deruxtecan, the country is at the forefront of research—but not yet in access or speed of implementation. To fully realize the survival and quality-of-life benefits of HER2 innovations, Spain must close regional gaps, accelerate drug and diagnostic reimbursement, and reinforce national accountability measures. Equity is not an aspiration—it's a responsibility. And with thousands of life-years at stake, the time to act is now.



CALL TO ACTION

- **Mandate equitable HER2+ treatment access** across all autonomous communities with national accountability targets.
- **Fast-track reimbursement** for HER2DX and next-generation HER2-targeted therapies.
- **Launch HER2-positive education campaigns** focused on both public awareness and clinical guideline updates.
- **Include HER2+ disaggregated outcomes** in national cancer registries and policy evaluations.
- **Fund palliative care equity programs** in underserved regions with dedicated monitoring of uptake.