



PRECISION, ACCESS, & PROGRESS

in HER2-Positive Breast Cancer Care in Japan

EXECUTIVE SUMMARY

Japan offers one of the most comprehensive and equitable models for HER2-positive breast cancer care worldwide. From universal health coverage to the rapid integration of therapies like trastuzumab deruxtecan, Japanese patients benefit from timely, evidence-based treatment and high survival rates.

However, gaps remain in screening uptake, HER2 testing consistency, and access to care in rural regions.

INTRODUCTION

Japan's robust healthcare infrastructure, universal insurance, and emphasis on cancer research have made it a global leader in breast cancer care. HER2-positive breast cancer accounts for approximately 13% of Japan's ~95,000 annual breast cancer cases. The country was among the first to approve trastuzumab deruxtecan, reflecting both domestic innovation and rapid regulatory pathways.

Yet while Japan's system is among the most mature, issues like low screening participation, HER2-low diagnostic variability, and uneven access to supportive care indicate that policy attention is still needed to ensure truly equitable outcomes.

CURRENT FRAMEWORK/SITUATION

Japan's Cancer Control Act created a tiered system of over 400 designated cancer hospitals, ensuring access to oncology care across all regions. HER2 testing, imaging, and multidisciplinary care are standard in these facilities. HER2-targeted therapies—from trastuzumab to T-DXd—are reimbursed under national health insurance, with cost caps protecting patients. Five-year breast cancer survival now exceeds 92%. However, screening participation remains below 50%, and HER2 IHC scoring shows inter-laboratory variation, especially as HER2-low classification grows in importance. Addressing these gaps through quality assurance, outreach, and education will determine whether Japan can fully realize the promise of personalized care.

According to the Maturity Framework for Cancer Care, Japan is ranked in the **"Advanced"** category, but continued progress depends on addressing disparities in early detection and biomarker interpretation



HER2 BREAST CANCER IN JAPAN

Key Issues Table and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	Yes, Japan has 400+ designated cancer hospitals with HER2 testing and comprehensive treatment...	...but patients in rural areas still travel long distances for complex diagnostics and therapies.	Expand telemedicine networks and regional cancer alliances to decentralize care.
Access to Treatment	Yes, HER2-targeted therapies including T-DXd are reimbursed under universal health coverage...	...but frail elderly or rural patients may have less access to later-line or complex regimens.	Monitor treatment equity across demographics and regions using HER2+ registry data.
Research & Innovation	Yes, Japan co-developed T-DXd and funds extensive HER2 research through AMED and MHLW...	...but translational research on survivorship and HER2-low implementation is underfunded.	Prioritize HER2 subtype-specific research and invest in survivorship-focused studies.
Awareness & Education	Yes, national and corporate Pink Ribbon campaigns are widespread...	...but screening participation is only 47.4%, and HER2 subtype knowledge remains limited.	Launch HER2-focused public education campaigns and reinforce primary care reminders.
Survival Rates	Yes, 5-year breast cancer survival exceeds 92.9% overall...	...but HER2-subtype-specific real-world survival data are scarce.	Disaggregate national survival data by HER2 status to guide targeted policy updates.
Early Detection & Palliative Care	Yes, designated hospitals offer early detection and palliative care from diagnosis...	...but specialist availability varies, and rural patients face access delays.	Strengthen palliative care teams in non-designated hospitals and support mobile screening.
Biomarker	Yes, HER2 testing is universal and reimbursed, with IHC/FISH used nationwide...	...but HER2-low scoring reproducibility is a challenge for clinical decision-making.	Standardize HER2-low classification and invest in digital pathology QA programs.
Clinical Guidelines	Yes, Japan's guidelines align with NCCN/ESMO and are updated regularly...	...but awareness and adherence vary in non-specialist settings.	Expand national education initiatives to reinforce HER2+ guideline implementation.
Reimbursement	Yes, all HER2 drugs and diagnostics are covered with out-of-pocket caps...	...but patients may be unaware of benefits and delay initiating high-cost treatments.	Introduce patient navigation and financial counseling services in all cancer hospitals.
Screening	Yes, biennial mammography is available for women aged 40–74...	...but participation remains below 50%, with regional variation and cultural barriers.	Implement nationwide reminder systems and community-based outreach to raise uptake.



CONCLUSION

Japan exemplifies excellence in HER2-positive breast cancer care—yet even advanced systems must evolve. As new therapies, subtypes, and survivorship challenges emerge, the focus must shift from access alone to ensuring consistency, equity, and readiness across all prefectures and populations. The opportunity is clear: by reinforcing quality assurance, investing in outreach, and embracing real-world data, Japan can continue leading globally in the next generation of personalized breast cancer care.



KEY POLICY MESSAGES

- 1 Japan provides world-class HER2+ care—but rural access and diagnostic variability remain challenges.
- 2 Screening rates are too low for an “Advanced” system; early detection must be strengthened.
- 3 HER2-low classification demands urgent standardization and provider training.
- 4 Real-world data and survivorship policies must be modernized to reflect evolving patient needs.

CALL TO ACTION

- **Invest in HER2-low pathology training and quality assurance tools** across all pathology labs.
- **Improve breast cancer screening participation** with reminders, incentives, and primary care integration.
- **Disaggregate HER2+ outcomes in national cancer registries** to identify equity gaps and track innovation impact.
- **Launch HER2-positive patient education campaigns** and integrate HER2 content in school health curricula.
- **Ensure survivorship programs address long-term HER2 therapy effects**, especially cardiac health and treatment toxicity.