



ADVANCING HER2-POSITIVE BREAST CANCER CARE IN CHINA

Aligning Scale with Precision in a Developing System

EXECUTIVE SUMMARY

China has made rapid progress in breast cancer care through national reforms, large-scale public insurance coverage, and growing investment in precision oncology. HER2 testing and access to trastuzumab are widely available in tertiary hospitals, and newer HER2-targeted therapies are increasingly reimbursed under national schemes. Yet disparities persist—particularly between urban and rural areas, and between eastern and western provinces. Testing reproducibility, out-of-pocket costs for newer agents, and underdeveloped survivorship programs continue to limit full realization of precision care. China currently sits at **Maturity Level 3 – Intermediate**, reflecting a system in transition: with strong infrastructure in major cities but uneven implementation, rising demand, and quality variability. Advancing HER2-positive breast cancer care will require a coordinated focus on equity, standardization, and outcome measurement.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among Chinese women, with more than 420,000 new cases reported in 2022. An estimated 15–20% are HER2-positive, a biologically aggressive subtype for which China has expanded access to targeted therapies. Trastuzumab was approved early in China and is now included in the National Reimbursement Drug List (NRDL), with subsequent inclusion of pertuzumab and trastuzumab deruxtecan. HER2 testing is routine in urban tertiary hospitals and comprehensive cancer centers, with national and provincial guidelines largely aligned with international standards. However, barriers remain in universal early detection, rural access to molecular diagnostics, quality assurance in HER2 testing, and timely access to newer therapies across all provinces. As survivorship grows and HER2-low subtypes emerge globally, China must align its growing scale with the next phase of personalized cancer care.

CURRENT FRAMEWORK/SITUATION

China's healthcare system is supported by cities, and public health insurance covers trastuzumab and other targeted therapies through price negotiations and bulk purchasing mechanisms. Yet access is unequal: rural and lower-income patients face delays or referral burdens for HER2 testing and treatment. There are also variations in pathology test reproducibility and a lack of external quality control systems for HER2-low classifications. Although screening guidelines exist (women aged 40–69), national adherence remains low, especially in remote areas. Moreover, HER2-stratified outcome data are not routinely published, limiting transparency and policy refinement.

China is currently at **Maturity Level 3 – Intermediate**, indicating a relatively mature infrastructure in many areas but with key gaps in equitable access, consistent biomarker testing, rural service delivery, and survivorship integration.



HER2 BREAST CANCER IN CHINA

Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	HER2 testing is available in tertiary hospitals across China...	...but community hospitals and county-level facilities often lack trained personnel and equipment.	Expand diagnostic capacity to lower-tier hospitals through regional partnerships, training, and telepathology.
Access to Treatment	Trastuzumab and newer HER2 therapies are covered under the NRDL...	...but patients in rural or western regions face higher out-of-pocket costs and logistical barriers.	Introduce patient navigation and co-payment protection programs for low-income and rural populations.
Research & Innovation	China is a global leader in oncology trials, with many HER2 therapies developed and trialed locally...	...but HER2-low subtypes and real-world data on treatment outcomes are underrepresented.	Launch national HER2-low research projects and link real-world data platforms to cancer registries.
Awareness & Education	National cancer campaigns and media coverage have increased breast cancer awareness...	...but HER2-specific knowledge is limited among the general public and primary care doctors.	Embed HER2 subtype information into national awareness campaigns and update continuing medical education (CME) modules.
Survival Rates	5-year survival for breast cancer exceeds 80% in cities like Shanghai and Beijing...	...but provincial disparities exist and HER2-stratified data are not routinely disclosed.	Require HER2-specific survival reporting in national and provincial cancer outcome registries.
Early Detection & Palliative Care	Screening programs are recommended nationally for women 40–69...	...but actual participation is low, and access is limited in rural areas.	Strengthen outreach screening programs in rural provinces and integrate follow-up with digital health platforms.
Biomarker	IHC and FISH for HER2 are standard in major hospitals...	...but test reproducibility and HER2-low classification lack standardized oversight.	Implement national external quality assessment (EQA) schemes and standardize HER2-low testing protocols.
Clinical Guidelines	China's breast cancer guidelines follow NCCN and ESMO recommendations...	...but HER2-low integration and mandatory re-testing upon relapse are inconsistently applied.	Update guidelines to include HER2-low pathways and mandatory retesting at disease progression.
Reimbursement	Trastuzumab, pertuzumab, and trastuzumab deruxtecan are reimbursed under public insurance...	...but price negotiations may delay access to newer drugs in lower-tier cities.	Streamline national-to-provincial rollout timelines and support patient access programs for new HER2 therapies.
Screening	National guidelines support biennial screening for middle-aged women...	...but rural uptake is poor and awareness is lower among older women.	Expand mobile mammography services and integrate breast screening into rural community health packages.



CONCLUSION

China has taken major steps toward becoming a global leader in precision cancer care, particularly in HER2-positive breast cancer. Its inclusion of key therapies in the national reimbursement list, expansion of testing capacity in urban centers, and growing oncology innovation sector mark major milestones. However, disparities between urban and rural populations, inconsistency in HER2 testing quality, and lack of survivorship and HER2-stratified outcomes hold the system back from reaching full potential. As a system at the **Intermediate level of maturity**, China's next challenge is to ensure national equity, testing standardization, and integration of emerging HER2 classifications. Aligning delivery with innovation will ensure every patient—regardless of geography or income—benefits from China's rapidly advancing cancer care ecosystem.



1 HER2-positive testing and therapy are broadly available, but rural and western provinces face access and affordability barriers.

2 HER2-low classification, relapse re-testing, and quality assurance protocols need to be more consistently applied.

3 HER2-stratified survival and treatment data should be integrated into national registries to inform policy.

4 National reforms must ensure timely delivery and consistent application of HER2 innovations across all provinces.

CALL TO ACTION

- **Expand HER2 testing to county hospitals** through training, regional labs, and telepathology networks.
- **Improve affordability and delivery** of HER2 therapies in rural and underserved provinces through navigation and subsidy programs.
- **Mandate HER2 re-testing and HER2-low integration** in updated national clinical guidelines.
- **Establish a national HER2-positive breast cancer registry** to track outcomes, access, and innovation uptake.
- **Enhance rural screening participation** through mobile programs and integration with digital health platforms.