

ADVANCING HER2-POSITIVE BREAST CANCER CARE IN AUSTRALIA

Closing Precision Gaps in an Advanced Health System

EXECUTIVE SUMMARY

Australia provides one of the world's most robust frameworks for HER2-positive breast cancer care, with universal access to HER2 testing, early adoption of HER2-targeted therapies, and strong national screening infrastructure. Public coverage through Medicare ensures diagnostic and treatment access, while the Pharmaceutical Benefits Scheme (PBS) supports timely reimbursement. Yet despite its Maturity **Level 4 – Advanced** status, Australia faces equity challenges for patients in rural and remote areas, delays in access to new HER2 therapies, and limited HER2-stratified outcome tracking. To maintain leadership in precision oncology, Australia must strengthen national coordination on HER2-low integration, survivorship programs, and timely therapy rollout.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among Australian women, with over 20,000 new cases each year. Around 15–20% are HER2-positive, a subtype that historically had poorer outcomes but now benefits from effective targeted treatments. Australia has long championed HER2 care, being among the first countries to adopt and reimburse trastuzumab, pertuzumab, T-DM1, and more recently trastuzumab deruxtecan. HER2 testing is universally available and quality-assured, with routine integration in pathology. However, delayed access to next-generation therapies, uneven survivorship services, and incomplete HER2-specific data collection suggest that gaps remain. To evolve from advanced delivery to world-leading personalization, Australia must enhance precision infrastructure beyond major metro centers.

CURRENT FRAMEWORK/SITUATION

Australia's publicly funded healthcare system—anchored by Medicare and the PBS—offers equitable access to diagnostics, therapies, and cancer services nationwide. HER2 testing is performed in certified laboratories across the country and is reimbursed as part of standard care. BreastScreen Australia provides free mammography to women aged 50–74, with optional screening from age 40. HER2 therapies are listed on the PBS and available at minimal cost for eligible patients.

However, geographic inequities persist: patients in remote and regional areas often face barriers in accessing specialist care, timely biopsies, and clinical trials. While national guidelines are aligned with international standards, HER2-low classification and HER2 re-testing at relapse are not yet fully adopted. Survivorship care also varies by jurisdiction, & HER2-stratified survival data is not systematically published, limiting efforts to target improvements for specific subgroups.

Australia sits at Maturity **Level 4 – Advanced**, with a highly capable system that now needs to harmonize delivery across regions, integrate HER2 innovations, and ensure data-driven improvement.



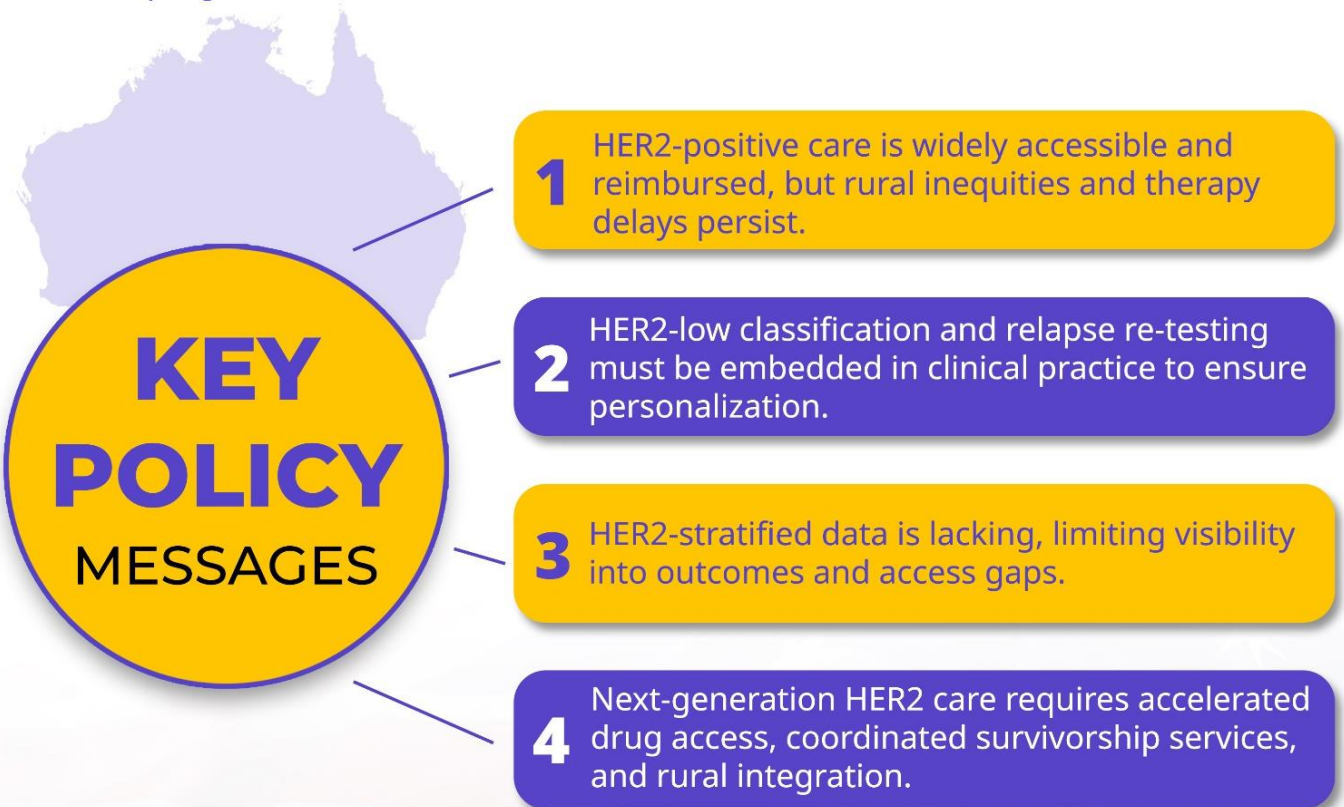
HER2 BREAST CANCER IN AUSTRALIA

Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	HER2 testing and treatment are available nationwide through public and private systems...	...but regional & rural areas have fewer oncology specialists & delayed diagnostic turnaround times.	Expand mobile diagnostic units and tele-oncology partnerships to improve access in remote communities.
Access to Treatment	Trastuzumab, pertuzumab, T-DM1, and T-DXd are reimbursed via PBS...	...but newer therapies can face 12–18 month delays from TGA approval to PBS listing.	Streamline Health Technology Assessment (HTA) pathways for HER2 therapies with proven survival benefit.
Research & Innovation	Australia leads global breast cancer research and trials, including HER2-positive subgroups...	...but HER2-low subtypes and long-term survivorship are under-studied.	Launch dedicated HER2-low research initiatives through the National Breast Cancer Foundation and MRFF.
Awareness & Education	National screening and awareness campaigns are well established...	...but HER2 biology is not widely understood by the public or all primary care providers.	Integrate HER2-specific messaging into BreastScreen outreach and CME for general practitioners.
Survival Rates	Five-year breast cancer survival exceeds 91%—among the highest globally...	...but survival data is not disaggregated by HER2 status, masking subgroup outcomes.	Mandate HER2-specific outcome reporting through state and national cancer registries.
Early Detection & Palliative Care	BreastScreen Australia offers free mammography and national coordination...	...but participation is lower among Indigenous, CALD, and remote communities.	Co-develop screening and palliative care programs with Indigenous leaders and local health services.
Biomarker	HER2 testing is standardized and quality-controlled nationwide...	...but HER2-low classification and IHC/FISH reproducibility in low-resource labs vary.	Adopt national HER2-low protocols and reinforce lab quality assurance under RCPA guidelines.
Clinical Guidelines	National guidelines align with NCCN and ESMO standards...	...but HER2-low integration and HER2 re-testing at relapse are not yet universally implemented.	Update guidelines to require HER2 re-testing at progression and incorporate HER2-low clinical pathways.
Reimbursement	HER2 therapies are subsidized by PBS with minimal patient cost...	...but access to off-label or new therapies may be restricted prior to PBS approval.	Introduce early-access programs for HER2 drugs pending reimbursement and improve compassionate use pathways.
Screening	BreastScreen Australia covers women aged 50–74 at no cost...	...but screening rates are below 55% and significantly lower in underserved populations.	Boost culturally tailored campaigns and implement mobile screening in rural and Indigenous areas.

CONCLUSION

Australia has achieved universal access to HER2 testing and has led early adoption of HER2-targeted therapies, backed by a high-functioning public health system. But maintaining leadership requires refining the final steps: equitable delivery, HER2 subtype integration, and consistent survivorship follow-up. While Australia is firmly in the **Advanced maturity tier**, precision oncology success depends on closing delivery gaps between urban and remote areas, speeding up access to next-generation drugs, and generating disaggregated outcomes for tailored policy. Australia is well-positioned to become a global model of equity in precision cancer care—if implementation matches scientific progress.



CALL TO ACTION

- **Mandate HER2 re-testing and HER2-low classification** in national guidelines and pathology protocols.
- **Improve rural access** through expanded tele-oncology, mobile diagnostics, and Indigenous partnerships.
- **Accelerate PBS inclusion** of new HER2 therapies with conditional reimbursement models or real-world evidence support.
- **Publish HER2-specific survival and access data** to drive policy accountability and investment.
- **Strengthen HER2-focused survivorship care** within national cancer plans, particularly in low-access populations.