SAUDI ARABIA

International Cancer Patient Coalition

ADVANCING HER2-POSITIVE BREAST CANCER CARE IN SAUDI ARABIA

Bridging Access and Equity Gaps in a Transforming System

EXECUTIVE SUMMARY

Saudi Arabia has made considerable progress in expanding access to cancer care, with HER2 testing and trastuzumab-based therapies available in major oncology centers across the kingdom. National cancer strategies, centralized care systems, and a growing oncology workforce support advancements in early detection and treatment. However, disparities persist between urban and rural regions, delays occur in the approval of next-generation therapies, and HER2-low classification is not yet part of national clinical practice. As a country at **Maturity Level 3 – Intermediate**, Saudi Arabia has a strong healthcare foundation but must focus on harmonizing access, accelerating innovation uptake, and embedding HER2 precision into standard cancer care pathways.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among women in Saudi Arabia, accounting for over **4,000 new cases annually**, with approximately **15–20% classified as HER2-positive.** HER2 testing is widely performed in tertiary care centers, and trastuzumab is included in public formularies. Yet access to second-line HER2 therapies like **T-DM1 and trastuzumab deruxtecan (T-DXd)** is variable and often limited to major hospitals in Riyadh, Jeddah, or Dammam.

Saudi Arabia has launched several national health initiatives under **Vision 2030**, including cancer control and digital health reforms. These offer opportunities to close remaining care gaps. However, awareness of HER2 subtypes among patients and providers is low, and national screening participation remains modest. Real-world HER2 outcome data is sparse, and survivorship services are inconsistently delivered. To strengthen its precision oncology capabilities, Saudi Arabia must ensure nationwide, equitable, and timely access to diagnostics, advanced therapies, and HER2-personalized care.

CURRENT SITUATION

The Kingdom's healthcare system is primarily state-funded through the **Ministry of Health (MoH)**, alongside other public providers (e.g., National Guard Health Affairs, King Faisal Specialist Hospital, and the Ministry of Defense). HER2 testing (IHC/FISH) is routinely available in tertiary centers and is funded by public insurance schemes. Trastuzumab and pertuzumab are listed on institutional formularies, while T-DM1 and T-DXd are available in select facilities under limited access.

The **Saudi Cancer Registry** tracks national cancer trends, but HER2-specific survival data is not published. Breast cancer screening is recommended every 2 years for women aged 40+, yet uptake is low due to stigma, low health literacy, and limited outreach in rural regions. Saudi Arabia, at Maturity **Level 3 – Intermediate**, is well-positioned to evolve toward an advanced system with targeted policy and delivery reforms.

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HER2 BREAST CANCER IN SAUDI ARABIA

Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	HER2 testing is available in most tertiary and academic centers...	...but rural and peripheral hospitals lack molecular pathology resources.	Expand HER2 testing through national lab networking and telepathology to cover remote areas.
Access to Treatment	Trastuzumab and pertuzumab are covered in the public sector...	...but T-DM1 and T-DXd access is restricted and slow to reach all institutions.	Include all EMA/FDA-approved HER2 therapies in MoH formularies with streamlined procurement.
Research & Innovation	Saudi Arabia hosts academic trials and contributes to GCC cancer research networks...	...but HER2-low research and real-world HER2 data are lacking.	Launch HER2-low registries and fund HER2-focused clinical trials through Vision 2030 research programs.
Awareness & Education	Breast cancer awareness campaigns run through MoH and foundations...	...but HER2 education is limited and early detection lags, especially in conservative regions.	Add HER2 subtyping to national awareness campaigns and increase culturally sensitive screening education.
Survival Rates	Breast cancer survival has improved, especially for early-stage cases...	...but HER2-stratified outcomes are not available in public data.	Mandate HER2-specific data reporting through the Saudi Cancer Registry and national oncology audits.
Early Detection & Palliative Care	Screening is available through MoH facilities and mobile clinics...	...but uptake is low due to stigma, fear, and gaps in follow-up services.	Expand mobile screening in underserved regions and build patient navigation for diagnostic follow-up.
Biomarker	HER2 testing is standard in MoH tertiary hospitals...	...but HER2-low classification is not routinely applied or validated.	Develop HER2-low testing protocols and train pathologists through national QA programs.
Clinical Guidelines	National guidelines are aligned with ESMO and adapted to Saudi context...	...but HER2 re-testing and HER2-low are not yet reflected.	Update national guidelines to include HER2-low categories and mandate HER2 re-testing at progression.
Reimbursement	First-line HER2 therapies are reimbursed in public and military sectors...	...but newer drugs face regulatory delays and inconsistent inclusion.	Implement fast-track approval and price negotiation pathways for life-extending HER2 therapies.
Screening	Free breast cancer screening is available for women aged 40+...	...but participation is estimated below 25%, particularly outside major cities.	Strengthen screening incentives, employer partnerships, and digital reminders to improve uptake.

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CONCLUSION

Saudi Arabia has built strong foundations for HER2-positive breast cancer care, with widespread testing and access to first-line therapies in major cities. Yet the challenge lies in reaching all populations equitably, ensuring access to newer therapies, and integrating HER2 subtyping into clinical decision-making. As an **Intermediate-level system**, Saudi Arabia can move toward leadership in precision oncology by advancing national guideline updates, accelerating drug availability, and embedding HER2 personalization into awareness and survivorship strategies.

KEY POLICY MESSAGES

1. HER2 testing and first-line therapies are well-established in urban centers but must be scaled to peripheral regions.
2. T-DM1, T-DXd, and HER2-low pathways are not yet universally available or integrated into practice.
3. Screening participation is low, especially in rural or conservative communities, despite national availability.
4. Survival and outcomes are improving, but HER2-specific monitoring is needed to drive quality and innovation.

CALL TO ACTION

- **Expand HER2 testing and pathology capacity** across regional hospitals through digital solutions and MoH investment.
- **List T-DM1, T-DXd, and HER2-low therapies** in national formularies and accelerate access via regulatory reform.
- **Integrate HER2-specific data collection** into the Saudi Cancer Registry and publish disaggregated survival statistics.
- **Enhance community awareness** by embedding HER2 and subtype education in culturally tailored campaigns.
- **Update national clinical guidelines** to include HER2-low definitions and HER2 re-testing at disease progression.