



ADVANCING HER2-POSITIVE BREAST CANCER CARE IN SERBIA

Strengthening Access, Data, and Precision Pathways

EXECUTIVE SUMMARY

Serbia has made notable strides in expanding breast cancer diagnostics and treatment services within its universal healthcare system. HER2 testing is now available in major oncology centers, and key therapies such as trastuzumab are reimbursed. However, access to later-line HER2 treatments, consistent HER2 re-testing, and integration of HER2-low classification remain limited. Significant disparities exist between urban and rural care quality, and national data systems do not yet disaggregate HER2-specific outcomes. As a country at **Maturity Level 3 – Intermediate**, Serbia has laid the groundwork for more advanced HER2-positive breast cancer care but requires policy focus on innovation access, guideline updates, and rural equity.

CURRENT SITUATION

Serbia offers universal healthcare through the **Republic Health Insurance Fund (RFZO)**, covering cancer diagnostics and treatment. HER2 testing is widely available in national and university-level centers. Trastuzumab is included in the national formulary, while access to pertuzumab, T-DM1, and T-DXd is more limited and dependent on institutional capacity or special approvals.

Breast cancer screening is organized and offered biennially for women aged 50–69, but participation is below 50%, especially in rural regions. HER2-specific survival data is not collected nationally, and HER2-low classification is not reflected in clinical practice. As an **Intermediate-level** system, Serbia has foundational elements in place and now needs to ensure consistency, equity, and data-driven HER2 cancer care delivery.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer among women in Serbia, with approximately **4,600 new cases each year**, of which an estimated **15–20% are HER2-positive**. HER2 testing via immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) is offered in tertiary care institutions, and trastuzumab is included on the national reimbursement list. Yet access to second- and third-line HER2-targeted therapies—such as T-DM1 and trastuzumab deruxtecan (T-DXd)—remains limited or delayed.

The **National Cancer Control Plan (NCCP)** recognizes breast cancer as a strategic priority, but implementation has been uneven across regions. Screening participation is improving but remains below EU targets, and survivorship services are underdeveloped. As Serbia continues aligning its cancer care with European standards, HER2-positive care should be a focal point for expanding precision medicine and closing care gaps.

HER2 BREAST CANCER IN SERBIA

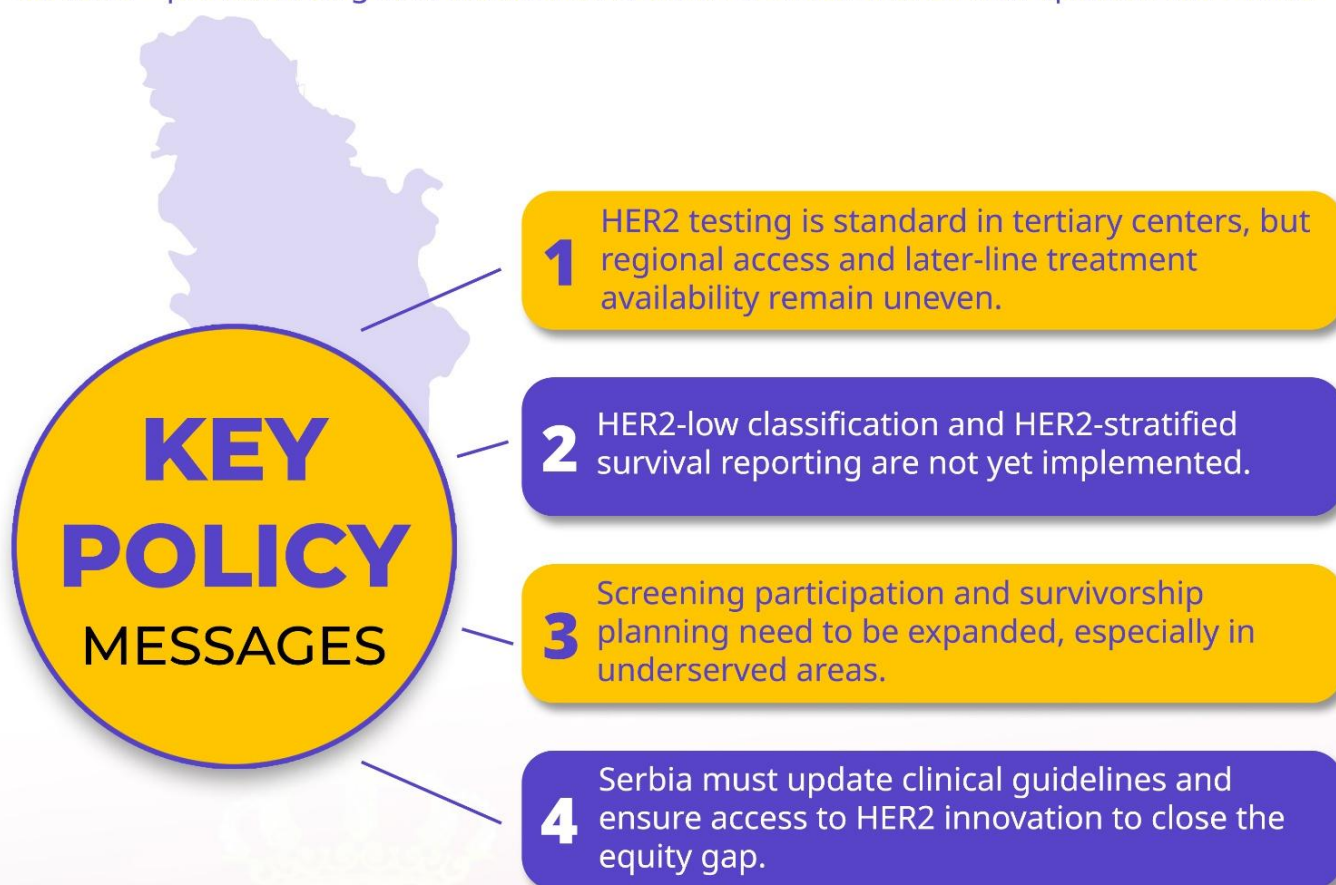
Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	HER2 testing is available in most tertiary and university hospitals...	...but regional hospitals lack testing equipment and trained staff.	Establish regional HER2 testing centers and invest in laboratory infrastructure across districts.
Access to Treatment	Trastuzumab is reimbursed by the RFZO...	...but access to T-DM1 and T-DXd is limited and dependent on institutional budgets or case-by-case approval.	Expand national reimbursement for all approved HER2 therapies and establish fast-track approval for life-extending drugs.
Research & Innovation	Serbia participates in some EU and regional oncology trials...	...but HER2-specific research and HER2-low data are limited.	Launch national HER2-positive breast cancer registries and incentivize participation in HER2-focused research.
Awareness & Education	National campaigns promote breast cancer awareness...	...but HER2 and subtype knowledge among the public and providers is low.	Integrate HER2 education into awareness programs and continuing medical education (CME) for primary care providers.
Survival Rates	Breast cancer outcomes are improving...	...but HER2-stratified survival data is not collected or reported.	Include HER2 status in national cancer registries and publish disaggregated outcome data for quality monitoring.
Early Detection & Palliative Care	Organized screening exists for women aged 50–69...	...but participation is suboptimal and rural outreach is limited.	Strengthen GP-based referral systems and introduce mobile screening units in underserved municipalities.
Biomarker	HER2 testing is standard in urban hospitals...	...but HER2-low is not yet recognized or standardized.	Develop HER2-low testing guidelines and quality control procedures through national oncology bodies.
Clinical Guidelines	Serbia's breast cancer guidelines are aligned with ESMO...	...but HER2 re-testing and HER2-low classification are not yet incorporated.	Update national clinical protocols to mandate HER2 re-testing at recurrence and integrate HER2-low pathways.
Reimbursement	Basic HER2 therapies like trastuzumab are covered...	...but delays in approval and limited budgets hinder access to newer therapies.	Create reimbursement fast lanes for HER2 drugs with proven survival benefit and use risk-sharing models.
Screening	Mammography is offered as part of the national screening program...	...but participation remains low, especially among rural women.	Increase community outreach, screening reminders, and awareness efforts tailored to rural populations.



CONCLUSION

Serbia has established critical components of HER2-positive breast cancer care, including routine HER2 testing and reimbursement of first-line therapies. However, to reach a more advanced level, the country must ensure timely access to all HER2 therapies, enhance equity between regions, and integrate emerging HER2 classifications into care protocols. As an **Intermediate-level system**, Serbia has strong potential to move forward—provided targeted investments, data reforms, and clinical updates are made.



CALL TO ACTION

- **Expand reimbursement** to include all EMA-approved HER2 therapies, including T-DM1 and T-DXd.
- **Update clinical guidelines** to mandate HER2 re-testing at recurrence and adopt HER2-low classification protocols.
- **Strengthen regional HER2 diagnostics** through investment in lab infrastructure and workforce development.
- **Improve screening coverage** via mobile outreach and GP-led awareness initiatives in rural areas.
- **Include HER2-specific data** in the national cancer registry to inform targeted policy and monitor treatment equity.