International Cancer Patient Coalition

ADVANCING HER2-POSITIVE BREAST CANCER CARE IN RUSSIA

Moving Toward Consistency & Personalization in a Developing System

EXECUTIVE SUMMARY

Russia has expanded public healthcare coverage for cancer diagnostics and treatment over the past decade, including access to HER2 testing and first-line HER2-targeted therapies. HER2 testing is performed in regional cancer centers, and trastuzumab is included in the state benefit program. However, significant barriers persist: access to newer treatments remains limited, regional disparities in care delivery are prominent, and HER2-low classification has yet to be introduced into clinical practice. As a country at Maturity **Level 3 – Intermediate**, Russia is developing the infrastructure and policies needed for effective personalized breast cancer care but must now focus on ensuring national uniformity, innovation uptake, and outcome transparency.

INTRODUCTION

Breast cancer is the most common cancer among women in Russia, with over **70,000 new cases diagnosed annually**, and **approximately 15–20% identified as HER2-positive**. While HER2 testing is now routine in major oncology centers, disparities in test quality, access to second-line HER2 therapies (such as T-DM1 and trastuzumab deruxtecan), and survivorship care persist. National protocols provide a basis for HER2+ care, but implementation varies widely between urban and rural regions.

Russia's oncology strategy aims to modernize cancer care infrastructure, and recent federal programs have expanded diagnostic capacity. Yet slow drug registration timelines, limited real-world data systems, and underfunded survivorship care limit progress. Bridging these gaps will be essential for Russia to evolve from a developing HER2+ care system to one that provides consistent, timely, and personalized treatment nationwide.

CURRENT SITUATION

Russia's public health system provides basic cancer diagnostics and treatment through regional cancer centers and the **Federal Compulsory Medical Insurance Fund**. HER2 testing (IHC and FISH) is reimbursed, and trastuzumab is included in the **List of Vital and Essential Drugs (VED list)**, but availability is inconsistent in some regions. Access to pertuzumab, T-DM1, and T-DXd is limited to select urban centers and often delayed due to regulatory or budgetary constraints.

National screening for breast cancer is offered for women aged 40+ under preventive check-ups, but participation remains low. HER2-low classification is not yet part of routine diagnostics, and HER2-specific survival data is not reported. Survivorship services, including psychological support and long-term monitoring, are poorly integrated into routine care. Russia, at **Maturity Level 3 – Intermediate**, needs to align infrastructure, access, and policy to meet the demands of modern HER2-positive breast cancer care.

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HER2 BREAST CANCER IN RUSSIA

Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	HER2 testing is available in leading cancer centers...	...but smaller regional hospitals often lack pathology equipment or trained personnel.	Invest in regional lab infrastructure and telepathology networks to ensure access beyond major cities.
Access to Treatment	Trastuzumab is publicly funded via the VED list...	...but access to pertuzumab, T-DM1, and T-DXd is limited or delayed outside of major cities.	Expand the reimbursement list to include all EMA-approved HER2 therapies and fast-track regional distribution.
Research & Innovation	Russia participates in some international trials and has growing oncology research centers...	...but HER2-specific and HER2-low research is minimal and rarely published.	Create a national HER2 research consortium and encourage registries to include HER2 subtypes.
Awareness & Education	Public cancer awareness efforts exist, including Pink October campaigns...	...but HER2-specific information and education are lacking, especially in rural communities.	Develop HER2-focused educational materials and incorporate them into regional awareness programs.
Survival Rates	Breast cancer 5-year survival has improved with earlier diagnosis...	...but HER2-stratified outcomes are not available to inform care quality.	Mandate HER2-specific survival tracking in federal cancer statistics and link it with treatment databases.
Early Detection & Palliative Care	Breast cancer screening is part of the federal preventive care program...	...but participation is low, and palliative care access varies greatly by region.	Improve outreach for mammography participation and scale palliative service funding in under-resourced areas.
Biomarker	HER2 testing is reimbursed under state oncology programs...	...but HER2-low classification lacks national guidelines and consistency.	Develop and disseminate HER2-low testing standards with quality assurance programs through national labs.
Clinical Guidelines	National clinical protocols exist and reference international HER2 standards...	...but HER2 re-testing at relapse and HER2-low pathways are not integrated.	Update national oncology guidelines to include HER2 re-testing and incorporate HER2-low recommendations.
Reimbursement	Trastuzumab is reimbursed and widely available...	...but later-line HER2 therapies face long delays in registration and public funding.	Simplify approval pathways and create early access schemes for life-extending HER2 treatments.
Screening	Breast screening is included in preventive care services for women 40+...	...but participation is low due to lack of public awareness and rural barriers.	Launch targeted campaigns and mobile mammography outreach in low-participation regions.

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CONCLUSION

Russia has taken crucial steps toward advancing HER2-positive breast cancer care by including key diagnostics and therapies in the public system. However, the journey toward precision, equity, and timeliness remains incomplete. Regional disparities, lack of access to later-line HER2 therapies, and limited HER2 data infrastructure hinder progress. As an **Intermediate-level system**, Russia must now focus on refining and scaling its cancer care strategy—ensuring that innovation reaches all patients, regardless of geography or socioeconomic status.

KEY POLICY MESSAGES

1. HER2 testing and trastuzumab are included in Russia's public health system, but access to next-generation therapies is still limited.
2. HER2-low classification and HER2-specific survival data are not yet integrated into policy or practice.
3. Regional disparities in diagnostics, treatment, and palliative care remain a major challenge.
4. Personalized HER2 care requires national-level coordination, rapid innovation adoption, and consistent implementation.

CALL TO ACTION

- **Expand the VED list** to include pertuzumab, T-DM1, T-DXd, and future HER2 therapies with survival benefit.
- **Develop HER2-low guidelines** and implement HER2 re-testing at recurrence in national protocols.
- **Strengthen regional testing infrastructure** and introduce HER2 QA programs across pathology labs.
- **Disaggregate breast cancer outcomes by HER2 status** in national cancer statistics and registries.
- **Boost early detection efforts** with mobile screening programs and targeted campaigns for underserved populations.