

# **Herceptin Market Size, Share & Trends Analysis Report By Product (Biosimilar, Biologic) By Application (Breast Cancer, Stomach/Gastric Cancer), By Payer (Commercial/Private, Public), By Distribution Channel, By Region, And Segment Forecasts, 2025 - 2030**

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## **Abstracts**

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### **Herceptin Market Growth & Trends**

The global herceptin market size is anticipated to reach USD 4.10 billion by 2030 and is projected to grow at a CAGR of 5.5% from 2025 to 2030, according to a new report by Grand View Research, Inc. The key driver of the Herceptin market is its established efficacy in treating HER2-positive cancers, particularly breast and gastric cancers. As one of the earliest and most successful targeted therapies, Herceptin revolutionized the treatment paradigm by directly inhibiting the HER2 receptor, halting tumor growth, and activating immune-mediated cytotoxicity. Its inclusion as a standard-of-care therapy in both early-stage and metastatic settings continues to anchor its global demand. Herceptin's role in combination regimens-especially with chemotherapy and newer HER2-targeted agents like pertuzumab-further boosts its therapeutic relevance. Approvals in neoadjuvant and adjuvant contexts have expanded its patient base, while real-world evidence continues to support its long-term survival benefits.

However, Herceptin's market has undergone significant transformation due to the expiration of key patents-in the U.S. (2019) and Europe (2014)-which has opened the door to a wave of biosimilar competition. This shift has led to intense pricing pressures and

reduced exclusivity for the originator product, especially in price-sensitive markets. In response, Roche has implemented lifecycle management strategies, including the development of a subcutaneous (SC) formulation and the co-formulated fixed-dose combination Phesg(pertuzumab + trastuzumab SC), aimed at improving convenience, reducing administration time, and maintaining patient loyalty. These innovations not only enhance healthcare efficiency but also offer a competitive edge against biosimilars in clinical practice.

The biosimilar landscape for trastuzumab is robust and rapidly expanding, with multiple players such as Pfizer, Amgen, Biocon Biologics, Samsung Bioepis, and Celltrion securing approvals across global markets. The growing adoption of trastuzumab biosimilars in both high-income and emerging regions has democratized access to HER2-targeted therapy, significantly lowering treatment costs. While this benefits healthcare systems and patients, it also presents market share erosion risks for Roche's branded Herceptin. Regulatory authorities worldwide have supported biosimilar adoption through clear interchangeability guidelines and incentivized procurement models, further accelerating their uptake. The increasing number of country-specific biosimilars in regions like India, China, and Latin America is intensifying competition, especially where cost containment is a priority.

Despite these headwinds, opportunities remain strong in the Herceptin market through expanding indications, strategic partnerships, and regional growth. The uptake of SC Herceptin and Phesgin outpatient and community settings is poised to grow, particularly as healthcare systems seek more efficient delivery options. Additionally, the inclusion of trastuzumab in combination regimens with immune checkpoint inhibitors, such as pembrolizumab in HER2-positive gastric cancer, is opening new frontiers for its use. These novel combinations are being evaluated in clinical trials and could expand Herceptin's role beyond traditional HER2-positive indications. Furthermore, rising awareness, increasing screening rates, and improving access to diagnostics in low-to-middle-income countries are expected to fuel volume growth, even if unit prices decline due to biosimilar competition.

Looking ahead, the Herceptin market will likely stabilize at a new equilibrium, where originator and biosimilar coexistence is the norm. Roche's strategic pivot toward value-added products and real-world outcomes data will be critical in retaining market presence. Meanwhile, biosimilar manufacturers are poised to benefit from scale, cost leadership, and local partnerships, which will help them penetrate underserved markets. Emerging delivery innovations and digital treatment monitoring tools may also enhance trastuzumab's utility in evolving care models. Overall, while Herceptin may no longer

dominate in terms of exclusivity or pricing power, it will continue to play a pivotal role in HER2-targeted oncology, especially as part of broader combination strategies and integrated care solutions.

### Herceptin Market Report Highlights

Based on product, biosimilars dominated the Herceptin market in 2024, accounting for the largest share of 50.93%, driven by widespread adoption across both developed and emerging markets following the expiration of Herceptin's key patents in the U.S. and Europe. The availability of cost-effective trastuzumab biosimilars from multiple manufacturers has significantly improved access to HER2-targeted therapy, especially in regions with high cancer burden and cost-sensitive healthcare systems. Competitive pricing, local manufacturing, and supportive regulatory frameworks have further fueled biosimilar uptake. In contrast, the biologic/originator segment (Roche's Herceptin) holds the second-largest share but is witnessing a declining trend, as it continues to lose market exclusivity and volume to biosimilars.

Based on application, breast cancer dominated the Herceptin market in 2024 with a share of 57.68%, driven by its established use as a first-line and adjuvant therapy in HER2-positive breast cancer. The drug's long-standing role in both early-stage and metastatic breast cancer, combined with strong clinical evidence and guideline support, has ensured continued demand. Stomach/gastric cancer is projected to grow at the fastest CAGR over the forecast period, supported by expanded approvals for HER2-positive gastric and gastroesophageal cancers and growing use in combination with checkpoint inhibitors like pembrolizumab.

Based on payer, the commercial/private insurance segment accounted for the largest share at 91.03% in 2024, due to broad reimbursement for branded and biosimilar trastuzumab across developed markets. Access to HER2-targeted therapy

is typically covered under comprehensive oncology benefit plans. The public insurance segment is expected to experience faster growth, particularly in emerging economies where national health programs are expanding access to biosimilars as cost-effective alternatives to originator biologics.

Based on distribution channel, hospital pharmacies remained the leading segment with a 51.77% market share in 2024, reflecting the need for infusion-based administration and monitoring within oncology centers. Herceptin's IV formulation and the complexity of oncology regimens reinforce its delivery through hospital-based systems. Specialty pharmacies are projected to register the fastest CAGR, as the subcutaneous formulation of Herceptin and the combination product Phesgo (trastuzumab + pertuzumab) become more widely adopted in outpatient and home-care settings, offering greater flexibility and improved patient convenience.

In April 2024, the FDA granted accelerated approval to Enhertu (fam-trastuzumab deruxtecan-nxki) for the treatment of HER2-positive solid tumors that are unresectable or metastatic and have progressed following prior systemic treatment. This marks the first tumor-agnostic approval for a HER2-targeted therapy, expanding its use beyond traditional indications like breast and gastric cancers. The approval was based on results from the DESTINY-PanTumor02 trial, where Enhertu demonstrated meaningful response rates across multiple cancer types, including biliary tract, bladder, and endometrial cancers. This development significantly broadens the clinical utility of HER2-targeted therapies and positions Enhertu as a major player in the evolving landscape of precision oncology.

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