BlueCross BlueShield
Federal Employee Program

HERCEPTIN HYLECTA
(trastuzumab and hyaluronidase-oysk)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Herceptin Hylecta contains trastuzumab and hyaluronidase. Trastuzumab has been shown to inhibit the proliferation of human tumor cells that overexpress HER2. In vitro, trastuzumab-mediated antibody-dependent cellular cytotoxicity (ADCC) has been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2. Hyaluronidase has been shown to increase the absorption rate of a trastuzumab product into the systemic circulation (1).

Regulatory Status

FDA-approved indication: Herceptin Hylecta is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, indicated in adults for: (1)

1. The treatment of HER2-overexpressing breast cancer

Herceptin Hylecta carries a boxed warning regarding possible risks for cardiomyopathy, pulmonary toxicity, and embryo-fetal toxicity. Herceptin Hylecta use can result in cardiac failure that manifests as congestive heart failure (CHF) or decreased left ventricular ejection fraction (LVEF), with greatest risk when administered concurrently with anthracyclines (1).

Exposure to Herceptin Hylecta during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death (1).

The safety and effectiveness of Herceptin Hylecta in pediatric patients less than 18 years of age have not been established (1).

Summary

Herceptin Hylecta contains trastuzumab and hyaluronidase. Trastuzumab has been shown to inhibit the proliferation of human tumor cells that overexpress HER2. In vitro, trastuzumab-mediated antibody-dependent cellular cytotoxicity (ADCC) has been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2. Hyaluronidase has been shown to increase the absorption rate of a trastuzumab product into the systemic circulation. The safety and effectiveness of Herceptin Hylecta in pediatric patients

less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Herceptin Hylecta while maintaining optimal therapeutic outcomes.

References

1. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. NCCN Drugs & Biologics Compendium® Trastuzumab and hyaluronidase-oysk 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.