BlueCross BlueShield
Federal Employee Program

TRASTUZUMAB

Herceptin (trastuzumab), Hercessi* (trastuzumab-strf), Herzuma (trastuzumab-pkrb), **Kanjinti** (trastuzumab-anns), **Ogivri** (trastuzumab-dkst), **Ontruzant** (trastuzumab-dttb), Trazimera (trastuzumab-qyyp)

Preferred products: Kanjinti, Ogivri, Ontruzant
*Product covered on the medical benefit only

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Herceptin and its biosimilars are monoclonal antibodies that selectively binds with high affinity to the Human Epidermal Growth Factor Receptor – 2 (HER2) protein. Herceptin and its biosimilars are mediators of antibody-dependent cellular cytotoxicity (ADCC). Herceptin and its biosimilars effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not over-express HER2. Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera are biosimilars which means that the biological products are approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product (1-7).

Regulatory Status

FDA-approved indications: Herceptin and its biosimilars are indicated: (1-8)

- For the treatment of HER2-overexpressing breast cancer.
- For the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma.
- In combination with tucatinib for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

Herceptin and its biosimilars carry a boxed warning regarding possible risks for cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Trastuzumab 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 or its biosimilars during pregnancy can result in oligohydramnios, in some

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cases complicated by pulmonary hypoplasia and neonatal death. Female patients of reproductive potential should be advised to use effective contraception during treatment and for 7 months following the last dose of Herceptin or its biosimilars (1).

Safety and effectiveness in pediatric patients have not been established (1).

Summary

Herceptin and its biosimilars are monoclonal antibodies that selectively bind with high affinity to the HER2 protein. Herceptin and its biosimilars are mediators of antibody-dependent cellular cytotoxicity (ADCC). Herceptin and its biosimilars effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not overexpress HER2 (1-7).

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

References

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3. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2024.
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