RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Herceptin (trastuzumab) is a monoclonal antibody that selectively binds with high affinity to the Human Epidermal Growth Factor Receptor – 2 (HER2) protein. Trastuzumab is a mediator of antibody-dependent cellular cytotoxicity (ADCC). Trastuzumab’s effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not over-express HER2 (1).

Regulatory Status
FDA-approved indication: Herceptin indicated for the adjuvant treatment of HER 2 overexpressing breast cancer and the treatment of HER 2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (1).

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

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

Summary
Herceptin (trastuzumab) is a monoclonal antibody that selectively binds with high affinity to the HER2 protein. Trastuzumab is a mediator of antibody-dependent cellular cytotoxicity (ADCC). Trastuzumab’s effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not overexpress HER2 (1).

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

References