Herceptin Hylecta

Description

Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)

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).

**Related policies**
Kadcyla, Nerlynx, Perjeta, Trastuzumab, Tykerb

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Herceptin Hylecta may be considered **medically necessary** for patients 18 years of age or older for the treatment of HER-2 overexpressing breast cancer and if the conditions indicated below are met.

Herceptin Hylecta may be considered **investigational** in patients under 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

HER-2 overexpressing breast cancer

**AND ALL** of the following:

1. HER2 protein overexpression or HER2 gene amplification as confirmed by an FDA-approved test
2. Prescriber agrees to monitor for cardiac function and pulmonary toxicity
3. Females of reproductive potential will be advised to use effective contraception during treatment and for 7 months following the last dose
4. Patient **MUST** have tried the preferred product (Kanjinti) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)
Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

HER-2 overexpressing breast cancer

AND ALL of the following:

1. Prescriber agrees to monitor for cardiac function and pulmonary toxicity
2. Females of reproductive potential will be advised to use effective contraception during treatment and for 7 months following the last dose
3. Patient MUST have tried the preferred product (Kanjinti) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre – PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

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


Policy History

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<td>March 2019</td>
<td>Addition to PA</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.