Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/30/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®). Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description

The human epidermal growth factor receptor 2 (HER2) proto-oncogene encodes a transmembrane receptor protein of 185 kDa, which is structurally related to the epidermal growth factor receptor. Trastuzumab has been shown, in both in vitro assays and in animals, to inhibit the proliferation of human tumor cells that overexpress HER2. Trastuzumab is a mediator of antibody-dependent cellular cytotoxicity (ADCC). In vitro, trastuzumab-mediated ADCC has been shown to be preferentially exerted on HER2 overexpressing cancer cells compared with cancer cells that do not overexpress HER2. Hyaluronan is a polysaccharide found in the extracellular matrix of the subcutaneous tissue. It is depolymerized by the naturally occurring enzyme hyaluronidase. Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan.

FDA Indications

Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®) is FDA indicated for the following:

- The treatment of HER2-overexpressing breast cancer in adults

Coverage Determinations

Trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®) will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Breast cancer, HER2+

- The member has a diagnosis of breast cancer and HER2 positive disease and one of the following applies:
    - Member is receiving trastuzumab and hyaluronidase-oysk as adjuvant treatment **AND**
        - In combination with paclitaxel or docetaxel following doxorubicin and cyclophosphamide **OR**
        - In combination with docetaxel and carboplatin **OR**
        - As monotherapy following multimodality anthracycline based therapy **OR**
    - Member is receiving trastuzumab and hyaluronidase-oysk as treatment for metastatic disease **AND**
        - In combination with paclitaxel as first line treatment **OR**
        - As monotherapy following one or more combination chemotherapy treatments for metastatic disease

Recommended dosage: Trastuzumab 600 mg/hyaluronidase 10,000 units as subcutaneous injection once every 3 weeks.

Do not substitute Trastuzumab and hyaluronidase-oysk for or with ado-trastuzumab emtansine or fam-trastuzumab deruxtecan-nxki.

Duration of treatment:

Patients with adjuvant breast cancer should be treated with Trastuzumab and hyaluronidase-oysk for 52 weeks or until disease recurrence, whichever occurs first; extending treatment in adjuvant breast cancer beyond one year is not recommended.

Patients with metastatic breast cancer should be treated with Trastuzumab and hyaluronidase-oysk until progression of disease.

All indications:

- Trastuzumab and hyaluronidase-oysk will be approved through clinical review for up to a 12-month duration

Coverage Limitations

Treatment with Trastuzumab and hyaluronidase-oysk is not considered medically necessary for members with the following concomitant conditions:

- Member is receiving concomitant intravenous therapy
- Member has a diagnosis of gastric or gastroesophageal or esophageal carcinoma
- Member is using concomitantly with Kadcyla® (ado-trastuzumab emtansine)
- Member has a baseline left ventricular ejection fraction (LVEF) less than 55%
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
    - Cardiomyopathy (Boxed warning)
    - Pulmonary toxicity (Boxed warning)
    - Embryo-fetal toxicity (Boxed warning)
    - Exacerbation of chemotherapy-induced neutropenia
    - Hypersensitivity and administration-related reactions

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: injection, trastuzumab, 10 mg and hyaluronidase-oysk
    - J9356

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Herceptin Hylecta [package insert]. Genentech, Inc., South San Francisco, CA. Available at: https://www.gene.com/download/pdf/herceptin_hylecta_prescribing.pdf
2. Trastuzumab and hyaluronidase-oysk. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Ismael G, Hegg R, Muehlbauer S, et al. Subcutaneous versus intravenous administration of (neo)adjuvant trastuzumab in patients With HER2-positive, clinical stage I–III breast cancer (HannaH Study): a phase 3, open-label, multicentre, randomised trial. Lancet Oncol. 2012;13(9):869-878.
4. Gligorov J, Ataseven B, Verrill M, et al; SafeHer Study Group. Safety and tolerability of subcutaneous trastuzumab for the adjuvant treatment of human epidermal growth factor receptor 2–positive early breast cancer: SafeHer phase III study's primary analysis of 2573 patients. Eur J Cancer. 2017;82:237-246.