Optum Rx®

## Hercessi™ (trastuzumab-strf) – New biosimilar approval

- On April 29, 2024, Accord BioPharma announced the FDA approval of Hercessi (trastuzumab-strf), biosimilar to Genentech's Herceptin® (trastuzumab).
    - Hercessi is the sixth FDA-approved biosimilar to Herceptin. Kanjinti™ (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Trazimera™ (trastuzumab-qyyp), Herzuma® (trastuzumab-pkrb) and Ontruzant® (trastuzumab-dttb) have all previously launched.
- Hercessi, Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma and Ontruzant share the following indications:
    - Adjuvant treatment of human epidermal growth factor receptor 2 (HER2) overexpressing node positive or node negative (ER/PR negative or with one high risk feature breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; as part of a treatment regimen with docetaxel and carboplatin; and as a single agent following multi-modality anthracycline based therapy
    - In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, or as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.
    - In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.
- Herceptin is also available as brand Herceptin Hycleta™ (trastuzumab/ hyaluronidase-oysk) indicated for adjuvant breast cancer treatment and metastatic breast cancer.
- The approval of Hercessi is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Herceptin.
- Like Herceptin and the other biosimilars, Hercessi carries a boxed warning for cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity.
- A warning and precaution for Hercessi is exacerbation of chemotherapy-induced neutropenia.
- The most common adverse reactions (≥ 5%) with Hercessi use in adjuvant breast cancer treatment were headache, diarrhea, nausea and chills.
- The most common adverse reactions (≥ 10%) with Hercessi use in metastatic breast cancer treatment were fever, chills, headache, infection, congestive heart failure, insomnia, cough and rash.
- The most common adverse reactions (≥ 10%) with Hercessi use in metastatic gastric cancer treatment were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.
- The recommended dosage of Hercessi for adjuvant treatment of breast cancer is given as a mg/kg intravenous (IV) infusion based on recommended schedules for 52-weeks of therapy.
- The recommended dosage of Hercessi for metastatic treatment of breast cancer is given as a mg/kg IV infusion once weekly until disease progression.

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- The recommended dosage of Hercessi for metastatic treatment of gastric cancer is given as a mg/kg IV infusion every three weeks until disease progression.
- Patients should be selected for therapy with Hercessi based on HER2 protein overexpression or HER2 gene amplification in tumor specimens. Information on the FDA-approved tests for the detection of HER2 protein overexpression and HER2 gene amplification is available at: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools.
- Hercessi should not be substituted for or with ado-trastuzumab emtansine.
- Refer to Hercessi's drug label for further administration and dosing recommendations.
- Accord BioPharma's launch plans for Hercessi are pending. Hercessi will be available as a 150 mg lyophilized powder in a single dose vial.

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