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# Injectable and Health Care Administered Oncology Medical Drug Program Summary

For BCBS KS, this program only targets the following non-preferred trastuzumab containing agents: Herceptin, Herceptin Hylecta, Herzuma, Ontruzant, Trazimera

For BCBS KS, the following preferred trastuzumab containing agents are **not** subject to prior authorization: Kanjinti, Ogivri

**FDA APPROVED INDICATIONS AND DOSAGE[1-70]**

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| **Herceptin®** (trastuzumab)<br><br>Injection for intravenous use | • Adjuvant treatment of HER2-overexpressing breast cancer:<br>○ As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel<br>○ As part of a treatment regimen with docetaxel and carboplatin<br>○ As a single agent following multi-modality anthracycline based therapy | **Adjuvant treatment of breast cancer:**<br>During and following paclitaxel, docetaxel, or docetaxel/carboplatin:<br>Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks pf paclitaxel or docetaxel or the first 18 weeks of docetaxel/carboplatin therapy. One week following the last weekly dose of Herceptin, administer Herceptin at 6 mg/kg as an intravenous infusion over 30-90 minutes every three weeks<br><br>As a single agent within three weeks following completion of multi-modality anthracycline-based chemotherapy regimens:<br>Initial dosing:<br>8 mg/kg as an intravenous infusion over 90 minutes<br><br>Subsequent dosing:<br>6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks |
| | • Metastatic breast cancer:<br>○ In combination with paclitaxel for first-line | **Metastatic breast cancer treatment:** |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | treatment of HER2-overexpressing metastatic breast cancer<br>○ As a single agent for treatment of HER-2 overexpressing breast cancer in patient who have received one or more chemotherapy regimens for metastatic disease | Administer Herceptin, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression |
| | ● The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil in patients who have not received prior treatment for metastatic disease | **Metastatic gastric cancer:** Administer Herceptin at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks until disease progression |
| **Herceptin Hylecta™** (trastuzumab and hyaluronidase-oysk)<br><br>Injection for subcutaneous use | ● The treatment of HER-2-overexpressing breast cancer | **Breast cancer:** 600mg/10,000 units subcutaneously over approximately 2-5 minutes once every 3 weeks.<br><br>Patients with adjuvant breast cancer should be treated for 52 weeks or until disease recurrence, whichever occurs first; extending treatment in adjuvant breast cancer beyond one year is not recommended<br><br>Patients with metastatic breast cancer should be treated until progression of disease |
| **Herzuma®** (trastuzumab-pkrb)<br><br>Injection for subcutaneous use | ● Adjuvant treatment of HER2-overexpressing breast cancer:<br>○ As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel | **Adjuvant treatment of breast cancer:** During and following paclitaxel, docetaxel, or docetaxel/carboplatin: Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then 2 mg/kg as an intravenous infusion over 30 |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | ○ As part of a treatment regimen with docetaxel and carboplatin<br>○ As a single agent following multi-modality anthracycline based therapy | minutes weekly during chemotherapy for the first 12 weeks pf paclitaxel or docetaxel or the first 18 weeks of docetaxel/carboplatin therapy. One week following the last weekly dose of Herceptin, administer Herceptin at 6 mg/kg as an intravenous infusion over 30-90 minutes every three weeks<br><br>As a single agent within three weeks following completion of multi-modality anthracycline-based chemotherapy regimens:<br>Initial dosing:<br>8 mg/kg as an intravenous infusion over 90 minutes<br><br>Subsequent dosing:<br>6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks |
| | ● Metastatic breast cancer:<br>○ In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer<br>○ As a single agent for treatment of HER-2 overexpressing breast cancer in patient who have received one or more chemotherapy regimens for metastatic disease | **Metastatic breast cancer treatment:**<br>Administer Herceptin, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression |
| | ● The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil in patients who have not received prior | **Metastatic gastric cancer:**<br>Administer Herceptin at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks until disease progression |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | treatment for metastatic disease | |
| **Kanjinti™** (trastuzumab-anns)<br><br>Injection for intravenous use | ● Adjuvant treatment of HER2 overexpressing breast cancer<br>○ As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel<br>○ As part of a treatment regimen with docetaxel and carboplatin<br>○ As a single agent following multi-modality anthracycline based therapy | **Adjuvant treatment during and following paclitaxel, docetaxel, or docetaxel and carboplatin total of 52 weeks of therapy:**<br>Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks of paclitaxel or docetaxel or the first 18 weeks of docetaxel and carboplatin<br><br>One week following the last weekly dose of Kanjinti, administer Kanjinti at 6 mg/kg as an intravenous infusion over 30-90 minutes every three weeks<br><br>**As a single agent within three weeks following completion of multi-modality, anthracycline-based chemotherapy regimens for 52 weeks total therapy:**<br>Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes<br><br>Subsequent doses at 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks |
| | Metastatic breast cancer<br>● In combination with paclitaxel for first-line treatment of HER2 overexpressing metastatic breast cancer<br><br>● As a single agent for treatment in patients who | **Metastatic treatment, breast cancer alone or in combination with paclitaxel:**<br>Initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as a 30- |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | have received one or more chemotherapy regimens for metastatic disease | minute intravenous infusion until disease progression |
| | ● Treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil, in patients who have not received prior treatment for metastatic disease | **Metastatic gastric or gastroesophageal cancer:** Administer Kanjinti at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks until disease progression |
| **Ogivri®** (trastuzumab-dkst)<br><br>Injection for intravenous use | ● Adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer<br>○ As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel<br>○ As part of a treatment regimen with docetaxel and carboplatin<br>○ As a single agent following multi-modality anthracycline based therapy | **During and following paclitaxel, docetaxel, or docetaxel and carboplatin total of 52 weeks of therapy:**<br>Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks of paclitaxel or docetaxel or the first 18 weeks of docetaxel and carboplatin<br><br>One week following the last weekly dose of Ogivri, administer Ogivri at 6 mg/kg as an intravenous infusion over 30-90 minutes every three weeks<br><br>**As a single agent within three weeks following completion of multi-modality, anthracycline-based chemotherapy regimens for 52 weeks total therapy:**<br>Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes<br><br>Subsequent doses at 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks |


 

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | ● Metastatic breast cancer<br>○ In combination with paclitaxel for first-line treatment for metastatic disease<br>○ As a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease | **Metastatic treatment, breast cancer:**<br>Administer Ogivri, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as a 30-minute intravenous infusion until disease progression |
| | ● Treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil, in patients who have not received prior treatment for metastatic disease | **Metastatic gastric or gastroesophageal cancer:**<br>Administer Ogivri at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks until disease progression |
| **Ontruzant®** (trastuzumab-dttb)<br><br>Injection for intravenous use | ● Adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer<br>○ As part of a treatment regimen, consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel<br>○ As part of a treatment regimen with docetaxel and carboplatin<br>○ As a single agent following multi-modality anthracycline based therapy | **During and following paclitaxel, docetaxel, or docetaxel and carboplatin total of 52 weeks of therapy:**<br>Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks of paclitaxel or docetaxel or the first 18 weeks of docetaxel and carboplatin<br><br>One week following the last weekly dose of Ogivri, administer Ogivri at 6 mg/kg as an intravenous infusion over 30-90 minutes every three weeks<br><br>**As a single agent within three weeks following completion of multi-modality, anthracycline-based chemotherapy** |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | | **regimens for 52 weeks total therapy:**<br>Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes<br><br>Subsequent doses at 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks |
| | ● In combination with paclitaxel for first-line treatment for metastatic breast cancer<br><br>● As a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic breast cancer | **Metastatic treatment, breast cancer:**<br>Administer Ogivri, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as a 30-minute intravenous infusion until disease progression |
| | ● Treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil, in patients who have not received prior treatment for metastatic disease | **Metastatic gastric or gastroesophageal cancer:**<br>Administer Ogivri at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30-90 minutes every 3 weeks until disease progression |
| **Trazimera™** (trastuzumab-qyyp)<br><br>Injection for intravenous use | ● Adjuvant treatment of HER2-overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer<br>o As a part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and wither paclitaxel or docetaxel<br>o As a part of a treatment regimen with docetaxel and carboplatin<br>o As a single agent following multi- | **Adjuvant treatment of breast cancer:**<br>Administer according to one of the following doses and schedules for a total of 522 weeks of Trazimera therapy:<br><br>During and following paclitaxel, docetaxel, or docetaxel and carboplatin:<br><br>● Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/k as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 (paclitaxel or |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | modality anthracycline based therapy | docetaxel) or 18 weeks (docetaxel and carboplatin)<br><br>● One week following the last weekly dose of Trazimera, administer Trazimera at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks<br><br>As a single agent within three weeks following completion of multi-modality, anthracycline-based chemotherapy regimens:<br>● Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes<br><br>● Subsequent doses at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks<br><br>● Extending adjuvant treatment beyond one year is not recommended |
| | ● In combination with paclitaxel for first-line treatment he treatment of HER2-overexpressing metastatic breast cancer<br><br>● As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease | **Metastatic treatment of breast cancer:**<br>Administer Trazimera, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression |
| | ● 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 | **Metastatic gastric cancer:**<br>Administer Trazimera at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks until disease progression |

| Agent(s) | Indication(s) | Dosage |
|---|---|---|
| | treatment for metastatic disease | |

**CLINICAL RATIONALE**
For the purposes of the Injectable Oncology Agents criteria, indications deemed appropriate are those approved in FDA labeling and/or supported by NCCN Drugs & Biologics compendia with a category 1 or 2A recommendation.

**Safety[1-7]**

| Agent(s) | Contraindication(s) |
|---|---|
| **Herceptin** (trastuzumab) | • None |
| **Herceptin Hylecta** (trastuzumab and hyaluronidase) | • None |
| **Herzuma** (trastuzumab-pkrb) | • None |
| **Kanjinti** (trastuzumab-anns) | • None |
| **Ogivri** (trastuzumab-dkst) | • None |
| **Ontruzant** (trastuzumab-dttb) | • None |
| **Trazimera** (trastuzumab-qyyp) | • None |

**References**

1. Herceptin Prescribing Information. Genetech, Inc. November 2019.
2. Herceptin Hylecta Prescribing Information. Genentech, Inc. February 2019.
3. Herzuma Prescribing Information. Celltrion Inc. May 2019.
4. Kanjinti Prescribing Information. Amgen Inc. June 2019.
5. Ogivri Prescribing Information. Mylan. April 2019.
6. Ontruzant Prescribing Information. Merck Sharp & Dohme Corp. March 2020.
7. Trazimera Prescribing Information. Pfizer Biosimilars. March 2019.



 

## Injectable and Health Care Administered Oncology Medical Drug Criteria Through Preferred

**TARGET AGENT(S)**
**Trastuzumab containing agents (excluding Kadcyla [ado-trastuzumab])**
**Herceptin®** (trastuzumab)
**Herceptin Hylecta™** (trastuzumab and hyaluronidase-oysk)
**Herzuma®** (trastuzumab-pkrb)
**Ontruzant®** (trastuzumab-dttb)
**Trazimera™** (trastuzumab-qyyp)

| Preferred Trastuzumab Containing Agent(s) | Non-Preferred Trastuzumab Containing Agent(s) |
|---|---|
| Kanjinti (trastuzumab-anns)<br>Ogivri (trastuzumab-dkst) | Herceptin (trastuzumab)<br>Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)<br>Herzuma (trastuzumab-pkrb)<br>Ontruzant (trastuzumab-dttb)<br>Trazimera (trastuzumab-qyyp) |

| Brand (generic) | GPI | Multisource Code | HCPCS/J Code |
|---|---|---|---|
| **Herceptin (trastuzumab)** | | | |
| 150 mg single use vial | 21170070002110 | M, N, O, or Y | J9355 |
| 440 mg multiple-dose vial | 21170070002120 | M, N, O, or Y | J9355 |
| **Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)** | | | |
| 600-10000 mg-unit/5 mL | 21990002722020 | M, N, O, or Y | J9356 |
| **Herzuma (trastuzumab-pkrb)** | | | |
| 150 mg single-dose vial | 21170070602110 | M, N, O, or Y | Q5113 |
| 420 mg multiple-dose vial | 21170070602120 | M, N, O, or Y | Q5113 |
| **Ontruzant (trastuzumab-dttb)** | | | |
| 150 mg single use vial | 21170070342120 | M, N, O, or Y | Q5112 |
| 420 mg multiple-dose vial | 21170070342140 | M, N, O, or Y | Q5112 |
| **Trazimera (trastuzumab-qyyp)** | | | |
| 150 mg single dose vial | 21170070652110 | M, N, O, or Y | Q5116 |
| 420 mg single dose vial | 21170070652120 | M, N, O, or Y | Q5116 |

**CRITERIA FOR APPROVAL**
**Target Agent(s)** will be approved when ALL of the following are met:
1. ONE of the following:
    A. The patient has an FDA labeled or compendia supported indication for the requested agent AND ALL of the following:
        i. ONE of the following:
            1. The requested indication does NOT require genetic/specific diagnostic testing (e.g., ALK, EGFR, HER2, KRAS) in FDA labeling or compendia support
            **OR**


 

2. The requested indication requires genetic/specific diagnostic testing in FDA labeling AND BOTH of the following:
    a. Genetic/specific diagnostic testing has been performed
    **AND**
    b. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate in FDA labeling or compendia support

**AND**

ii. ONE of the following:
    1. The requested agent will be used as a first-line agent AND is FDA labeled or compendia supported as a first-line agent for the requested indication
    **OR**
    2. The patient has used the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia support for the requested indication
    **OR**
    3. The patient has an intolerance or hypersensitivity to ALL of the required prerequisite agent(s) listed in the FDA labeling or compendia support for the requested indication
    **OR**
    4. The patient has an FDA labeled contraindication to ALL of the required prerequisite agent(s) listed in the FDA labeling or compendia for the requested indication

**AND**

iii. ONE of the following:
    1. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or compendia supported for the requested indication
    **OR**
    2. The requested agent will be used with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia support for the requested indication

**AND**

iv. ONE of the following:
    1. The FDA label or compendia does NOT include a performance status requirement
    **OR**
    2. The patient meets the performance status requirement in the FDA labeling or compendia support

**AND**

v. ONE of the following:
    1. The requested agent is a preferred trastuzumab containing agent
    **OR**
    2. The patient has tried and had an inadequate response to TWO preferred trastuzumab containing agents (medical records required)
    **OR**
    3. The patient has an intolerance or hypersensitivity to TWO preferred trastuzumab containing agents that is NOT expected to occur with the requested agent (medical records required)


 

**OR**

4. The patient has an FDA labeled contraindication to ALL preferred trastuzumab containing agents that is NOT expected to occur with the requested agent (medical records required)

| Preferred trastuzumab containing agents |
|---|
| Kanjinti (trastuzumab-anns)<br>Ogivri (trastuzumab-dkst) |

**AND**

2. ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent
      **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age

**AND**

3. The patient does NOT have any FDA labeled contraindications to the requested agent

**AND**

4. The requested quantity (dose) and duration is within FDA labeled dosing for the requested indication or compendia supported dosing for the requested indication

**Length of Approval:** 12 months or for duration of treatment as supported in FDA labeling or in NCCN 1 or 2a recommendations for the requested indication, whichever is shorter

**Compendia Allowed:** NCCN 1 or 2A recommended use



 