Injectable and Health Care Administered Oncology Medical Drug Criteria Program Summary

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

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

POLICY REVIEW CYCLE

Effective Date 12-30-2024 **Date of Origin**

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Herceptin® (trastuzumab) Lyophilized powder for reconstitution for intravenous infusion	• Adjuvant treatment of 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 • As a single agent following multi-modality anthracycline based therapy • Metastatic breast cancer: • In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer • 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 • 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		1
Herceptin Hylecta™ (trastuzumab and hyaluronidase -oysk)	• Adjuvant treatment of 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 • As a single agent following multi-modality anthracycline based therapy		2

Agent(s)	FDA Indication(s)	Notes	Ref#
Injection for subcutaneous use	• Metastatic breast cancer: • In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer • 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		
Hercessi™ (trastuzumab-strf) Lyophilized powder for reconstitution for intravenous infusion	• Adjuvant treatment of 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 • As a single agent following multi-modality anthracycline based therapy • Metastatic breast cancer: • In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer • 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 • 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		8
Herzuma ® (trastuzumab-pkrb) Lyophilized powder for reconstitution for intravenous infusion	• Adjuvant treatment of 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 • As a single agent following multi-modality anthracycline based therapy • Metastatic breast cancer: • In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer • 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 • The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with		3

Agent(s)	FDA Indication(s)	Notes	Ref#
	cisplatin and capecitabine or 5-fluorouracil in patients who have not received prior treatment for metastatic disease		
Kanjinti™ (trastuzumab-anns) Lyophilized powder for reconstitution for intravenous infusion	● Adjuvant treatment of 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 • As a single agent following multi-modality anthracycline based therapy ● Metastatic breast cancer • In combination with paclitaxel for first-line treatment of HER2 overexpressing metastatic breast cancer • As a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease ● 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		4
Ogivri® (trastuzumab-dkst) Lyophilized powder for reconstitution for intravenous infusion	● Adjuvant treatment of 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 • As a single agent following multi-modality anthracycline based therapy ● Metastatic breast cancer • In combination with paclitaxel for first-line treatment for metastatic disease • As a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease ● 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		5
Ontruzant®	● Adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer		6

Agent(s)	FDA Indication(s)	Notes	Ref#
(trastuzumab-dttb) Lyophilized powder for reconstitution for intravenous infusion	• 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 • As a single agent following multi-modality anthracycline based therapy • In combination with paclitaxel for first-line treatment for metastatic breast cancer • As a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic breast cancer • 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		
Trazimera™ (trastuzumab-qyyp) Lyophilized powder for reconstitution for intravenous infusion	• Adjuvant treatment of HER2-overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer • As a part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and wither paclitaxel or docetaxel • As a part of a treatment regimen with docetaxel and carboplatin • As a single agent following multi-modality anthracycline based therapy • In combination with paclitaxel for first-line treatment he treatment of HER2-overexpressing metastatic breast cancer • 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		7

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Indications deemed appropriate	For the purposes of the Injectable and Health Care Administered 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 (1-8)	

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

REFERENCES

Number	Reference
1	Herceptin Prescribing Information. Genentech, Inc. June 2024.
2	Herceptin Hylecta Prescribing Information. Genentech, Inc. June 2024.
3	Herzuma Prescribing Information. Cephalon Inc. May 2019.
4	Kanjinti Prescribing Information. Amgen Inc. October 2022.
5	Ogivri Prescribing Information. Mylan Institutional LLC. July 2023.
6	Ontruzant Prescribing Information. Organon LLC. June 2021.
7	Trazimera Prescribing Information. Pfizer Labs, Div Pfizer Inc. November 2020.
8	Hercessi prescribing information. Accord Biopharma, Inc. September 2024.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

HCPC Codes	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
J9355	Herceptin	trastuzumab for iv soln	150 MG	M ; N ; O ; Y	N		
J9356	Herceptin hylecta	trastuzumab-hyaluronidase-oysk inj	600-10000 MG-UNT/5ML	M ; N ; O ; Y	N		
Q5146	Hercessi	trastuzumab-strf for iv soln	150 MG ; 420 MG	M ; N ; O ; Y	N		
Q5113	Herzuma	trastuzumab-pkrb for iv soln	150 MG ; 420 MG	M ; N ; O ; Y	N		
Q5112	Ontruzant	trastuzumab-dttb for iv soln	150 MG ; 420 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Herceptin	trastuzumab for iv soln	150 MG	Commercial ; HIM ; ResultsRx
Herceptin hylecta	trastuzumab-hyaluronidase-oysk inj	600-10000 MG-UNT/5ML	Commercial ; HIM ; ResultsRx
Hercessi	trastuzumab-strf for iv soln	150 MG ; 420 MG	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Herzuma	trastuzumab-pkrb for iv soln	150 MG ; 420 MG	Commercial ; HIM ; ResultsRx
Ontruzant	trastuzumab-dttb for iv soln	150 MG ; 420 MG	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

CRITERIA FOR APPROVAL

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

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 indication for the requested agent and route of administration **OR**
   B. The patient has an indication that is supported by NCCN 1 or 2A recommended use (i.e., NCCN indication must be supported by ALL requirements in the compendia [e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.]) for the requested agent and route of administration **AND**
2. ALL of the following:
   A. 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 or compendia support 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**
   B. 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**

Module	Clinical Criteria for Approval

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**

C. 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 support 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**

D. 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**

E. ONE of the following:
1. The requested agent is a preferred trastuzumab containing agent (listed below) **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) **AND**

Preferred Trastuzumab Containing Agents
Kanjinti (trastuzumab-anns)
Ogivri (trastuzumab-dkst)
Trazimera (trastuzumab-qyyp)

3. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. The requested quantity (dose) and duration are within FDA labeled dosing (or supported in compendia) for the requested indication

Length of Approval: 12 months or for duration of treatment as supported in FDA labeling (or supported in compendia) for the requested indication, whichever is shorter

Compendia Allowed: NCCN 1 or 2A recommended use

