LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DKST (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB-DKST	OGIVRI	44673		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
   - The request is for adjuvant therapy
   - The patient meets **ONE** of the following:
     - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
     - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
     - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

   If yes, **approve for 12 months by HICL.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - Requested medication is being used in combination with paclitaxel for first-line treatment
     - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

   If yes, **approve for 12 months by HICL.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
   - Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.

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TRASTUZUMAB-DKST (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **TRASTUZUMAB-DKST (Ogivri)** requires a diagnosis of breast cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. In addition, the following criteria must be met:

For the diagnosis of breast cancer, approval requires:

- The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
- The request is for adjuvant therapy
- The patient meets **ONE** of the following:
  - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
  - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

For the diagnosis of metastatic breast cancer, approval requires:

- The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
- The patient meets **ONE** of the following:
  - Requested medication is being used in combination with paclitaxel for first-line treatment
  - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

For the diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:

- The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
- Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
- The patient has not received prior treatment for metastatic disease

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogivri.

REFERENCES

Ogivri [Prescribing Information]. Steinhausen, Switzerland: Mylan GmbH; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 11/16/19
Created: 11/19
Client Approval: 1/18
P&T Approval: 1/18