BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

HERCEPTIN (trastuzumab), monoclonal antibody

Insufficient clinical benefit as a third-line monotherapy in HER2+ metastatic breast cancer

Main points

- HERCEPTIN has marketing authorisation as a monotherapy in the treatment of HER2+ metastatic breast cancer in patients who have already been treated by at least two chemotherapy protocols.
- This indication relies on data of very poor methodological quality which does not permit quantifying its contribution in this indication.
- Patients currently treated for HER2+ metastatic breast cancer have all received trastuzumab as a first-line treatment, so this indication is now obsolete. Trastuzumab as a monotherapy is no longer part of the recommended therapeutic options at this stage of the disease, although it could be recommended to maintain an anti-HER2 blockade.

Pre-existing indications

- HERCEPTIN also has marketing authorisation in the treatment of early HER2+ breast cancer, in metastatic HER2+ breast cancer not previously treated and in metastatic gastric cancer.

Therapeutic use

- For this second line treatment of HER2 positive metastatic breast cancer, monotherapy with trastuzumab emtansine (KADCYLA) should be preferred.
- If disease progression is observed during or after second-line treatment and beyond, maintaining an anti-HER2 treatment is recommended. Monotherapy with trastuzumab emtansine should be proposed if the patient has not received it as a second-line treatment. In other cases, several therapeutic options can be considered, which cannot always be prioritised: the lapatinib/capecitabine combination, the lapatinib/trastuzumab combination or the trastuzumab/capecitabine combination.

Role of the medicinal product in the therapeutic strategy

HERCEPTIN as a third-line monotherapy no longer has a role in the current therapeutic strategy, given the therapeutic alternatives currently available.

Clinical data

- The initial assessment of trastuzumab as a monotherapy in patients already treated by at least two chemotherapy protocols for their metastatic disease relied on data from a non-comparative study conducted in 222 patients. In this study, after a median follow-up of 2.8 years, the overall response rate was 15% with a median response duration of 9.1 months.
- For this new assessment, the manufacturer submitted the results of a descriptive non-interventional study conducted in 70 patients. In this study, after a median treatment duration of 12 weeks, the overall response rate was 19%. The median time to progression after a follow-up of more than 4 years was 12 weeks and the median overall survival was 68 weeks.

---

1 This summary does not cover these indications.

© Haute Autorité de Santé 2016
Special prescribing conditions

- Medicine for hospital prescription.
- Prescription restricted to cancer treatment and oncology specialists and departments.

Benefit of the medicinal product

- The actual benefit* of HERCEPTIN is insufficient in this indication to justify reimbursement by National Health Insurance.
- Does not recommend inclusion on the list of reimbursable products for hospital use.

---

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.

© Haute Autorité de Santé 2016