HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
24 MARCH 2021

The legally binding text is the original French opinion version

pertuzumab/trastuzumab
PHESGO 1,200 mg/600 mg solution for injection
PHESGO 600 mg/600 mg solution for injection

First assessment

Key points

Favourable opinion for reimbursement in combination with docetaxel only in the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

Unfavourable opinion for reimbursement in the two indications in combination with chemotherapy in:

- the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence
- the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence.

What therapeutic improvement?

No clinical added value compared to the free combination of PERJETA (pertuzumab) and HERCEPTIN (trastuzumab) in the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease

In the other indications: not applicable.

Role in the care pathway?

Early breast cancer

The treatment of early breast cancer may be based on surgery, radiotherapy, chemotherapy (neoadjuvant and/or adjuvant) and endocrine therapy, depending on the tumour type and grade, axillary lymph node involvement and the existence of hormone receptors.

In both the neoadjuvant and adjuvant situation, the most widely used protocol for HER2-positive early breast cancer is based on anthracycline-based chemotherapy followed by taxane-based chemotherapy combined with targeted therapy with trastuzumab.

It is highlighted that the Committee considered that the clinical benefit of PERJETA (pertuzumab), in combination with trastuzumab and chemotherapy, was insufficient in the neoadjuvant and adjuvant treatment of early breast cancer. Consequently, PERJETA (pertuzumab) has no role in the care pathway for these two indications.

Role of the medicinal product in the care pathway

Considering the absence of a role in the care pathway for the free active substance PERJETA (pertuzumab) in its two early breast cancer indications, the Committee considers that PHESGO (pertuzumab/trastuzumab) has no role in the care pathway, in combination with chemotherapy, in the neoadjuvant or adjuvant treatment of early breast cancer.

Metastatic breast cancer

In HER2-positive metastatic breast cancer, it is essential to maintain an anti-HER2 action, irrespective of the treatment line. In the first-line treatment of metastatic breast cancer, in the event of over-expression of HER2, treatment is based on taxane-based chemotherapy in combination with trastuzumab (HERCEPTIN) and pertuzumab (PERJETA)

Role of the medicinal product in the care pathway

The proprietary medicinal product PHESGO (pertuzumab/trastuzumab), administered subcutaneously, is an alternative to the free combination of the two active substances already available individually: PERJETA (pertuzumab) and HERCEPTIN (trastuzumab), in the first-line treatment of HER2-positive metastatic breast cancer.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

Early breast cancer

◗ HER2-positive early breast cancer is a serious, life-threatening disease.

◗ The proprietary medicinal product PHESGO (pertuzumab/trastuzumab) is a curative medicinal product.

◗ The efficacy/adverse effects ratio of the PHESGO (pertuzumab/trastuzumab) fixed dose combination is identical to that of the free combination of PERJETA (pertuzumab) and HERCEPTIN (trastuzumab): low in the two early breast cancer indications, as neoadjuvant and adjuvant treatment.

◗ There are medicinal alternatives.

◗ PHESGO has no role in the care pathway, in combination with chemotherapy, in the neoadjuvant or adjuvant treatment of early breast cancer.

Public health impact

Considering:

- the seriousness of the disease and its incidence,
- the partially met medical need,
- the lack of additional response to the identified partially met need due to the absence of benefit of the active substance PERJETA (pertuzumab) in the neoadjuvant and adjuvant treatment of HER2-positive early breast cancer,
- the lack of additional impact on the care and/or life pathway,
- the absence of an additional impact on the organisation of care,

PHESGO (pertuzumab/trastuzumab) is unlikely to have an additional impact on public health.

Metastatic breast cancer

◗ HER2-positive metastatic or locally recurrent unresectable breast cancer is a serious, life-threatening disease.

◗ The proprietary medicinal product PHESGO (pertuzumab/trastuzumab) is a curative medicinal product.

◗ The efficacy/adverse effects ratio of the PHESGO (pertuzumab/trastuzumab) fixed dose combination is identical to that of the free combination of PERJETA (pertuzumab) and HERCEPTIN (trastuzumab): high in combination with docetaxel treatment.

◗ There are medicinal alternatives.

◗ It is a first-line treatment.

Public health impact

Considering:

- the seriousness of the disease and its incidence,
- the partially met medical need,
- the lack of response to the identified partially met need due to a non-inferiority demonstrated on pharmacokinetic parameters and the absence of robust quality of life data,
- the absence of data enabling assessment of a potential impact of PHESGO (pertuzumab/trastuzumab) on the care and/or life pathway, and on the organisation of care, in locally recurrent or metastatic breast cancer,

PHESGO (pertuzumab/trastuzumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of PHESGO (pertuzumab/trastuzumab) is:

- **substantial in combination with docetaxel in the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease;**
- **insufficient in other situations to justify public funding cover.**

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the indication "in combination with docetaxel in the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease" and at the MA dosages.

The Committee issues an unfavourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the other situations.

Clinical Added Value

Within the reimbursement scope:

The proprietary medicinal product PHESGO (pertuzumab/trastuzumab), administered subcutaneously, is a fixed dose combination of two active substances already available individually: PERJETA (pertuzumab) and HERCEPTIN (trastuzumab).
Consequently, PHESGO (pertuzumab/trastuzumab) provides no clinical added value (CAV V) compared to the free combination of PERJETA (pertuzumab) and HERCEPTIN (trastuzumab).

Within the scope included in the MA but not retained for reimbursement:
Not applicable.