SUMMARY

neratinib

NERLYNX 40 mg,

film-coated tablets

Inclusion

Original French opinion adopted by the Transparency Committee on 24 May 2023

The legally binding text is the original French opinion version

Key points

Unfavourable opinion for reimbursement “in the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago”.

Role in the care pathway?

The Committee considers that NERLYNX (neratinib) has no role in the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.

Transparency Committee's conclusions

Clinical Benefit

- RH+/HER2+ early breast cancer is a serious, life-threatening disease.
- This is a specific curative treatment for breast cancer with HER2 receptor amplification or over-expression.
- The efficacy/adverse effects ratio remains uncertain due to the inadequate level of evidence to demonstrate the efficacy of neratinib in the MA indication and its poor safety profile, marked by significant gastrointestinal toxicity and hepatotoxicity.
- Considering the new efficacy and safety data available, the Committee considers that neratinib has no role in the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago (see 2.2 Current management).

Public health benefit

Considering:

- the seriousness of the disease and the incidence of RH+/HER2+ breast cancer,
- the medical need, which is considered to be partially met,
- the lack of response to the identified need in the absence of any demonstrated additional impact on morbidity and mortality or on quality of life in the Extenet pivotal phase-3 study,
- the lack of evidence to support an absence of deterioration in the care and/or life pathway,

NERLYNX (neratinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NERLYNX (neratinib) is insufficient in the marketing authorisation indication to justify public funding.

The Committee issues an unfavourable opinion for inclusion of NERLYNX (neratinib) 40 mg tablets in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.