

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

### Trastuzumab deruxtecan for neoadjuvant treatment of HER2-positive early breast cancer

#### Final scope

#### Remit/evaluation objective

To appraise the clinical and cost effectiveness of trastuzumab deruxtecan within its marketing authorisation for neoadjuvant treatment of HER2-positive early breast cancer.

#### Background

Breast cancer arises from the tissues of the ducts or lobules of the breast. Breast cancer is described as 'early' if it is restricted to the breast, or the breast and nearby lymph nodes, and has not spread to other parts of the body. Human epidermal growth factor receptor 2 (HER2) is a receptor for a growth factor which occurs naturally in the body. When human epidermal growth factor attaches itself to HER2 receptors on breast cancer cells, it can stimulate the cells to divide and grow. Some breast cancer cells have more HER2 receptors than others. In this case, the tumour is described as being HER2-positive.

In 2023, there were 50,535 new diagnoses of breast cancer in England.<sup>1</sup> Of these, 35,618 were diagnoses of early breast cancer.<sup>1</sup> Around 15% of breast cancers are HER2-positive.<sup>2</sup>

Treatment may depend on genetic mutations, receptor status and the extent of the disease. Neoadjuvant therapy refers to treatment that is given before surgery. For people with HER2-positive, invasive breast cancer, NICE guideline NG101 ([Early and locally advanced breast cancer: diagnosis and management](#)) recommends neoadjuvant chemotherapy where indicated. [NICE technology appraisal 424](#) recommends pertuzumab with trastuzumab and chemotherapy as an option for neoadjuvant treatment of HER2-positive, locally advanced, inflammatory or early-stage breast cancer at high risk of recurrence in adults.

#### The technology

Trastuzumab deruxtecan (Enhertu, Daiichi Sankyo) does not currently have a marketing authorisation in the UK for neoadjuvant treatment of HER2-positive early breast cancer. It has been studied in a clinical trial as monotherapy or followed by paclitaxel, trastuzumab and pertuzumab, for neoadjuvant treatment of high-risk, HER2-positive early non-metastatic breast cancer. It has been compared with doxorubicin and cyclophosphamide followed by paclitaxel, trastuzumab and pertuzumab.

<b>Intervention</b>	Neoadjuvant trastuzumab deruxtecan followed by a taxane, trastuzumab and pertuzumab
<b>Population</b>	Adults with HER2-positive early breast cancer

Final scope for the evaluation of trastuzumab deruxtecan for neoadjuvant treatment of HER2-positive early breast cancer

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<b>Comparators</b>	<ul style="list-style-type: none"> <li>• Neoadjuvant pertuzumab with trastuzumab and chemotherapy</li> <li>• Neoadjuvant chemotherapy with trastuzumab</li> <li>• Neoadjuvant chemotherapy</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• overall survival</li> <li>• event-free survival</li> <li>• invasive disease-free survival</li> <li>• rate of pathologic complete response</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<b>Other considerations</b>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<b>Related NICE recommendations</b>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer</a> (2016) NICE technology appraisal guidance 424.</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Early and locally advanced breast cancer: diagnosis and management</a> (2018 updated 2025) NICE guideline NG101. Last reviewed April 2025. <a href="#">Several areas for update</a>.</p> <p><b>Related quality standards:</b></p>

## References

1. National Disease Registration Service (2025) [Cancer registration statistics](#). Accessed January 2026.
2. Cancer Research UK (2023) [Tests on your breast cancer cells](#). Accessed January 2026