

Statement of advice SMC2854

trastuzumab deruxtecan powder for concentrate for solution for infusion (Enhertu®)

Daiichi Sankyo UK Limited

4 July 2025

ADVICE: in the absence of a submission from the holder of the marketing authorisation:

trastuzumab deruxtecan (Enhertu®) is not recommended for use within NHSScotland.

Indication under review: for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment or who have no satisfactory alternative treatment options.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result, we cannot recommend its use within NHSScotland.

The holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Co-Vice Chair Scottish Medicines Consortium