



**National Institute for
Health and Clinical Excellence**

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PRESS RELEASE

**NICE guidance recommends a new treatment for
certain patients with metastatic gastric cancer**

NICE has recommended trastuzumab (Herceptin, Roche Products) in combination with cisplatin and either capecitabine or 5-fluorouracil as an option for certain patients with metastatic adenocarcinoma of the stomach and gastro-oesophageal junction who have high levels of human epidermal growth factor receptor 2 (HER2)¹.

HER2 is a protein found on the surface of some cancer cells. Trastuzumab attaches itself to the protein so that epidermal growth factor production is reduced in the cancer cells; this stops the cells from dividing and growing.

Dr Carole Longson, Health Technology Evaluation Centre Director at NICE

said: "We are very pleased to be able to recommend trastuzumab for patients with gastric cancer who have very high levels of HER2. This new guidance is good news for patients. The average life expectancy for people with metastatic gastric cancer is around one year. Although trastuzumab is not a cure, it has the potential to extend the lives of those patients with high levels of HER2 by more than three months."

During consultation on the first draft guidance, Roche Products, the manufacturer of trastuzumab, submitted a new analysis on a subgroup of patients with the highest levels of HER2. The Committee discussed this new information in the context of the supplementary advice to the Committee on appraising a life-extending, end-of-life treatment and concluded that trastuzumab was cost-effective in this patient group.

¹ In final guidance published today, NICE has recommended trastuzumab, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of people with HER2-positive, metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior treatment for their metastatic disease and whose tumours express high levels of HER2 as defined by a positive immunohistochemistry score of 3 (IHC3 positive).

Ends

Notes to Editors

About the appraisal

1. The guidance will be available from 24 November, 2010 at: www.nice.org.uk/guidance/TA208
2. Gastric cancer, which is also known as stomach cancer, including cancer of the gastro-oesophageal junction affects approximately 7700 people in the UK every year - of whom approximately 350 would be suitable for treatment with trastuzumab
3. Immunohistochemistry (IHC) is used to show whether or not the cancer cells have HER2 receptors and/or hormone receptors on their surface. If the cancer cells score 0 to 1+, it's HER2 negative. If it scores 2+, it may be HER2 positive, but requires confirmation via another test known as FISH (fluorescence in situ hybridisation). If it scores 3+ then it is HER2 positive, with no FISH confirmation test required.
4. A 150-mg vial of trastuzumab costs £407.40. In the regulatory clinical trial people received on average 8 infusions of trastuzumab. The total drug cost of trastuzumab is approximately £10,185 per patient based on a patient weight of 62 kg.
5. The most plausible estimates of cost effectiveness for the IHC3 positive subgroup were between £45,000 and £50,000, whilst those for the full licensed population were between £63,100 and £71,500 per QALY gained.
6. Trastuzumab is administered at an initial loading dose of 8 mg/kg body weight, followed by 6 mg/kg body weight 3 weeks later and then 6 mg/kg repeated at 3-weekly intervals. Providing treatment is tolerated, it can be given until disease progression.
7. Trastuzumab has been found to increase median overall survival by 5.6 months for the IHC3 subgroup

About NICE

8. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
9. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.