

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**Single Technology Appraisal****Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy****Final scope****Remit/appraisal objective**

To appraise the clinical and cost effectiveness of ramucirumab within its marketing authorisation for advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy.

Background

Gastric cancer is a malignant tumour arising from cells in the stomach. The most common type of gastric cancer is gastric or gastro-oesophageal junction adenocarcinoma, which affects about 95% of people with the disease. In 2011, 5681 people in England were diagnosed with gastric cancer and there were 3921 deaths from gastric cancer in England. About 80% of people have metastatic disease at diagnosis.

The aim of treatment in advanced gastric or gastro-oesophageal junction adenocarcinoma (that is, locally advanced unresectable or metastatic disease) is to prevent progression, extend survival and relieve symptoms with minimal adverse effects. There is no standard treatment for previously treated advanced disease: treatment options include chemotherapy, palliative radiotherapy and palliative surgery.

The technology

Ramucirumab (Cyramza, Eli Lilly and Company) is a fully human IgG1 monoclonal antibody, which acts as a vascular endothelial growth factor receptor-2 (VEGFR-2) antagonist. It prevents activating ligands from interacting with VEGFR-2 receptors, which may prevent the formation of new blood vessels and thereby limit nutrient supply to the tumour causing death of tumour cells. Ramucirumab is administered intravenously.

Ramucirumab has a marketing authorisation in the UK for use alone or in combination with paclitaxel:

- Ramucirumab in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy.

- Ramucirumab monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate.

Intervention(s)	Ramucirumab alone or in combination with paclitaxel
Population(s)	<ul style="list-style-type: none"> • Adults with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy
Comparators	<p>Chemotherapy including but not limited to:</p> <ul style="list-style-type: none"> • Docetaxel monotherapy • Irinotecan monotherapy • Irinotecan and fluorouracil-based therapy (FOLFIRI) • Paclitaxel monotherapy (only for people for whom treatment in combination with paclitaxel is appropriate) <p>Best supportive care (including but not limited to antiemetics, blood transfusions, oesophageal stents, palliative radiotherapy and palliative surgery)</p>
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.
Economic analysis	<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>

Other considerations	Guidance will only be issued in accordance with the marketing authorisation (or CE marking if it is a device). 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.
Related NICE recommendations and NICE Pathways	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No 208, Jul 2010, 'Trastuzumab for the treatment of HER2-positive metastatic gastric cancer'. Guidance on static list</p> <p>Technology Appraisal No 191, Jul 2010, 'Capecitabine for the treatment of advanced gastric cancer'. Guidance on static list</p> <p>Related NICE Pathways:</p> <p>NICE Pathway: Gastrointestinal Cancers, Pathway created: Nov 2013.</p>
Related national policy	<p>NHS Commissioning Board (2012) Manual for prescribed specialist services: 105 Specialist cancer services (adults)</p> <p>NHS England (May 2013) B11. Upper GI Surgery</p> <p>NHS England Cancer and Blood – Group B</p> <p>National Service Frameworks: Cancer</p> <p>Department of Health (2012) NHS Outcomes Framework 2013-2014</p> <p>Department of Health (2011) Improving outcomes: a strategy for cancer</p> <p>Department of Health (2009) Cancer commissioning guidance</p> <p>Department of Health (2007) Cancer reform strategy</p>