GSK Final Response 19th May 2014

Single Technology Appraisal (STA)

Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane [ID603]

Appraisal consultation document

- **GSK Response**
  No comments

- Error/Inconsistency
  In section 7.4.9 page 203 of the manufacturer's submission it states:

  "The response rates for trastuzumab and capecitabine and capecitabine monotherapy are estimated indirectly versus trastuzumab emtansine through using the response rates from the EGF100151 and GBG26 trials respectively."

  Section 3.28, page 20 of the ACD states.

  "For trastuzumab emtansine and lapatinib plus capecitabine, the manufacturer obtained response rates from EMILIA, estimating utility values of 0.78 and 0.74 respectively. Similarly, it estimated a utility value of 0.72 for capecitabine based on response rates from GBG26 and a utility value of 0.73 for trastuzumab plus capecitabine based on response rates from EGF100151."

  The EGF100151 trial compared lapatinib plus capecitabine with capecitabine monotherapy and the GBG26 trial compared trastuzumab plus capecitabine with capecitabine monotherapy. It therefore seems likely that the ACD is incorrect and that the utility value for capecitabine was based on response rates from the EGF100151 trial and the utility values for trastuzumab plus capecitabine are based on the response rates from the GBG26 trial.