NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisals and Guidance Information Services

Static List Review (SLR)

Title and TA publication number of static topic:	Gemcitabine for the treatment of metastatic breast cancer (2007) NICE technology appraisal guidance 116.
Final decision:	The guidance will remain on the 'static guidance list'

1. Publication date:	January 2007.
2. Date added to static list:	May 2010.
3. Date the last searches were run:	21st December 2009.
4. Current guidance:	Gemcitabine in combination with paclitaxel, within its licensed indication, is recommended as an option for the treatment of metastatic breast cancer only when docetaxel monotherapy or docetaxel plus capecitabine are also considered appropriate.
5. Research recommendations from original guidance:	None.
6. Current cost of technology/ technologies (excluding VAT; British National Formulary, online	Powder for reconstitution and injection: Proprietary formulation (Eli Lilly): £32.55 for a 200 mg vial and £162.76 for a 1 g vial. Non-proprietary formulation: 200-mg vial = £29.80, 1-g vial = £154.62.

edition, August 2015):	Solution for infusion also available.
7. Cost information from the TA (if available):	Powder for reconstitution and injection: £32.55 for a 200 mg vial and £162.76 for a 1 g vial The TA notes that costs may vary in different settings because of negotiated procurement discounts.
8. Alternative company(ies):	Accord Actavis Hospira Sun Pharmaceuticals Medac Mylan
9. Changes to the original indication:	No change. Note that the licensed indications for gemcitabine covers use in unresectable, locally recurrent breast cancer, as well as metastatic breast cancer.
10. New, relevant trials:	NCT01287624: Gemcitabine plus cisplatin versus gemcitabine plus paclitaxel in triple negative breast cancer (TNBC). n = 240. Published in the Lancet Oncology. Hu et al., 2015; doi: 10.1016/S1470-2045(15)70064-1. NCT00236899: Phase III study of two different schedules (weekly and tri-weekly) of combination of gemcitabine and two taxanes in MBC. n = 241. Completed ~August 2010. Published in BMC Cancer. Del Mastro et al., 2013; doi: 10.1186/1471-2407-13-164.
11. Relevant NICE guidance (published or in progress):	Management of advanced breast cancer. (2015) NICE pathway. Advanced breast cancer (2009 updated 2014) NICE guideline CG81.

	Guidance on the use of trastuzumab for the treatment of advanced breast cancer (2002) NICE technology appraisal guidance 34. Bevacizumab in combination with a taxane for the first-line treatment of metastatic breast cancer (2011) NICE technology appraisal guidance 214. Eribulin for the treatment of locally advanced or metastatic breast cancer (2012) NICE technology appraisal guidance 250. Lapatinib or trastuzumab in combination with an aromatase inhibitor for the first-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses HER2 (2012) NICE technology appraisal guidance 257. Fulvestrant for the treatment of locally advanced or metastatic breast cancer (2011) NICE technology appraisal guidance 239. Bevacizumab in combination with capecitabine for the first-line treatment of metastatic breast cancer (2012) NICE technology appraisal guidance 263. Everolimus in combination with exemestane for treating advanced HER2-negative hormone-receptor-positive breast cancer after endocrine therapy (2013) NICE technology appraisal 295. Trastuzumab emtansine for treating unresectable metastatic HER2-positive breast cancer after treatment with trastuzumab and a taxane. NICE technology appraisal. Publication date to be confirmed. Pertuzumab in combination with trastuzumab and docetaxel for the treatment of HER2 positive metastatic or locally recurrent unresectable breast cancer, which has not been previously treated, or has relapsed after adjuvant therapy. NICE technology appraisal. Publication date to be confirmed. Breast Cancer Quality Standard (Update). NICE Quality Standard. Publication expected: June 2016.

12. Relevant safety issues:	None.
13. Any other additional relevant information or comments:	None.
14. Technical Lead comments and recommendation:	The wording of the marketing authorisation has not changed since the publication of technology appraisal 116. There are 6 generic versions of gemcitabine available but their introduction has not affected the price of branded gemcitabine. According to the BNF the price of the generic powder for reconstitution is slightly lower (200-mg vial = £29.80, 1-g vial = £154.62, 1.5-g vial = £213.93, 2-g vial = £324.00) than the price of the branded version but is unlikely to make a difference to the recommendations in technology appraisal 116 (gemcitabine plus paclitaxel will be more cost effective if the price of gemcitabine reduces). Two trials for gemcitabine plus paclitaxel for treating metastatic breast cancer have been published since the publication of technology appraisal 116. The Hu et al 2015 trial compared gemcitabine plus cisplatin with gemcitabine plus paclitaxel so does not provide direct data for the comparators in the guidance, which were docetaxel monotherapy or docetaxel plus capecitabine. Del Mastro et al., 2013 compared gemcitabine plus docetaxel with gemcitabine plus paclitaxel. Again this was not the correct comparator for the guidance. This trial also observed the treatment regimen (once a week compared with every 3 weeks) for gemcitabine plus paclitaxel and the results demonstrated that there were no differences between median time-to-progression or overall survival between the two regimens. There are no on-going trials comparing gemcitabine plus paclitaxel for treating metastatic breast cancer. A review of the guidance on the basis of the information above would not provide value for the NHS.

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Appendix 1 – explanation of options

Options	Consequence	Selected – 'Yes/No'
The guidance will remain on the 'static guidance list'	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The decision to review the guidance will be deferred to specify date or trial	NICE will consider whether a review is necessary at the specified date. NICE will actively monitor the evidence available to ascertain when a consideration of a review is more suitable.	No
A full consideration of a review will be carried out through the Review Proposal Process	There is evidence that could warrant a review of the guidance. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No
The guidance will be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No