Title:	**Advanced Breast Biopsy Instrumentation (ABBI) System for non-palpable breast lesions July 2001**
Agency:	Medicare Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia **http://www.msac.gov.au**
Reference:	**MSAC application 1037. Assessment report ISSN 1443-7120**

Aim

To assess the safety and effectiveness of the service and under what circumstances public funding should be supported for the service.

Conclusions and results

Safety Safety data differ widely. Adverse events associated with ABBI often relate to technical or equipment failure. Most other adverse events reported in case series and comparative studies are of low incidence and health significance.

More common adverse event	# studies/12	% of patients
hematoma	11	1-12.5%
wound infection	6	0-3%
dehiscence/wound problems	3	1-3%
bleeding	3	0.4-4.2%

Effectiveness In the absence of randomised controlled trials evaluation was based on comparative studies and case series. These show:

- discordant biopsy rates were lower for ABBI compared to core needle biopsy and Mammotome;
- technical success was slightly lower for ABBI compared to core needle biopsy, Mammotone and open wire localized biopsy;
- mean blood loss was considerably less than for needle localization with excisional breast biopsy; and
- margins for ABBI were generally positive.

Cost-effectiveness There is insufficient evidence for cost-benefit analysis. There may be some cost savings from using ABBI, but this may not necessarily translate into a better cost-benefit ratio.

Recommendations

1. Public funding of ABBI diagnosis be supported where fees do not exceed existing comparators.
2. There is insufficient evidence to assess a therapeutic role for ABBI against breast cancer.
3. The use of ABBI equipment is to be limited to surgeons and radiologists with training and expertise in the procedure.
4. A costing study should be carried out to assess the appropriate Medicare Rebate.

Method

MSAC expanded on the existing review (MSAC 1999). The current review included a systematic review of the biomedical literature from 1999 to March 2001 by accessing biomedical electronic databases, the Internet and international health technology agency websites . Relevant data from the manufacturer (subject to independent confirmation), textbooks and conference proceedings were also considered.

Produced by the Centre for Clinical Effectiveness, Australia