Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1157 – Cell enrichment liquid-based cytology in routine screening for the prevention of cervical cancer

Sponsor/Applicant/s: **Becton Dickinson Pty Ltd**

Date of MSAC consideration: **1 August 2013**

Please note: This item was also discussed by MSAC at its 5 April 2013 meeting.

1. Purpose of application

An application for Medical Benefits Schedule (MBS) listing of liquid-based cytology (LBC) for cervical cancer screening (SurePath™ LBC System), a cell enrichment testing methodology, was received from Becton Dickinson Pty Ltd by the Department of Health and Ageing in April 2011.

At the 59th meeting, MSAC noted that the renewal of the National Cervical Screening Program (NCSP) is currently underway. This has no bearing on consideration of another MSAC application in terms of assessing safety, clinical effectiveness and cost-effectiveness. However, the outcomes of the NCSP renewal may be a factor for Government to take into account when considering MSAC's advice for Application 1157.

MSAC noted that no application for ThinPrep® Pap system (Hologic [Australia] Pty Ltd) was received.

2. Background

MSAC reviewed LBC for cervical screening most recently at its 58th meeting on 5 April 2013. A previous review of LBC (MSAC 1122 assessment report March 2009) found that LBC was "safe, at least as effective, but not cost effective at the price requested". The 2009 review was not based on randomised controlled trial evidence, but rather the best evidence available at the time. The detailed conclusion drawn in the review was that LBC compared with conventional cytology was not statistically significantly different with the exception of reduced specificity for the detection of CIN 2+ at a threshold of possible low-grade squamous intraepithelial lesion (pLSIL), more slides classified as positive for LSIL and reduced rates of unsatisfactory tests. The cost-effectiveness ratio was high and unfavourable at the price requested.

The 58th MSAC meeting on 5 April 2013 advice to Minister was that after considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of cell enrichment liquid based cytology (BD SurePath™) for cervical cancer screening, MSAC does not support public funding at this time.

3. Summary of consideration and rationale for MSAC's advice

MSAC reaffirmed its April 2013 advice that, as found by MSAC in 2009 for application 1122, cell enrichment liquid-based cytology (CE LBC) is as safe as conventional cytology (CC) and there is no basis to conclude a significant clinical difference between CE LBC, cell filtration (CF) LBC and CC. MSAC's previous advice regarding the strength of the supporting evidence for CE LBC remain.

MSAC also reaffirmed its 5 April 2013 concern about the likely increased charge by laboratories beyond current bulk-billing practice, which could potentially result in a cost shift to patients and that this in turn may result in reduced screening participation rates. From a clinical perspective, MSAC retained the view that it would be a net harmful result if the consequence of listing CE LBC resulted in a reduction in screening participation rates.

MSAC noted the correspondence dated 13 June 2013 from the applicant to the Department. MSAC also noted the information provided on MBS pathology bulk-billing rates and patient out-of-pocket costs for total out-of-hospital pathology services (97.7% bulk billing in 2012-13), for out-of-hospital cytopathology services (91.6% in 2012-13) and for out-of-hospital CC services (95% in 2012-13).

MSAC also reviewed the direct input costs for CE LBC as estimated in Table 83 of the submission-based assessment considered in April 2013. Of this, only the cost of consumables (reagent) was in the direct control of the applicant. MSAC questioned the other identified cost estimates which were favourable to CE LBC because they assumed optimal economies of scale in the rates of processing slides, that all relevant personnel used in costing the service are at the lowest possible wage classification and rate, and that reporting costs are negligible. However, MSAC also noted that these other costs were only estimated to contribute an extra 26% beyond the reagent cost, so even if they were doubled, they should not sufficiently change the overall input costs (when overhead and re-screening costs are also included) to exceed the total MBS rebate of $23.55 for private laboratories and $18.60 for public laboratories. Therefore, overall MSAC accepted cost equivalence between CE LBC and CC.

MSAC considered likely bulk-billing practices for two populations. For those patients who currently agree to pay out-of-pocket fee about double the proposed MBS rebate as well as receiving CC, MSAC considered it likely that charging rates for LBC could remain high and bulk-billing rates could therefore be low. This is because this market has been established for 6 to 7 years and with screening every two years patients would have already paid the extra charge two or three times. For these patients, MBS listing of CE LBC would result in reduced cost because CC would no longer be conducted resulting in a lesser charge for CE LBC which would be reduced by the overall MBS rebate.

For those patients who currently only receive CC, the bulk-billing rates are high, so MSAC considered that there would be consumer resistance to paying a new charge for LBC in place of CC. MSAC considered that established laboratory charging practice for CC would again influence the likely charging practice for CE LBC, especially over the long term, and so bulk-billing rates should remain high. This reflects more conventional pathology experience, where laboratories which choose to bulk bill for CE LBC would likely retain a competitive advantage over laboratories which choose to charge patients for CE LBC rather than bulk bill.

MSAC noted that the majority of the screened population only receive CC, so bulk-billing rates should remain high overall, screening participation rates should also remain high and costs to society as a whole should not increase. For this reason, MSAC decided to amend its

5 April 2013 advice to the Minister. However, given the uncertainty of this prediction and the consequential issues at stake, MSAC advised the Department to closely monitor the relevant bulk-billing rates and screening participation rates, particularly in the period between implementing MBS listing for CE LBC and any subsequent MBS listing change as a consequence of the National Cervical Screening Program Renewal. Such monitoring would also usefully inform future MSAC considerations where applicants propose the same MBS fee for a new item that is only shown to be clinically non-inferior to an existing MBS item.

MSAC did not consider cell filtration liquid-based cytology (CF LBC) as part of this application as no further information (particularly a corresponding MBS fee) had been submitted. However, MSAC would welcome a minor application (directly to MSAC) from the sponsors of CF LBC.

4. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of cell enrichment liquid-based cytology (CE LBC) in routine screening for the prevention of cervical cancer, MSAC supports public funding via new MBS items, at the same MBS fee as conventional cytology (CC), acknowledging that some patients may still incur out-of-pocket costs as bulk billing may not occur to the same extent as for CC. In relation to the MBS item descriptor, MSAC reiterated its April 2013 advice that the new MBS item descriptors would:

- exclude cell filtration liquid-based cytology (CF LBC);
- not apply to the small volume MBS item relating to vaginal (rather than cervical) smears on the grounds that there was insufficient evidentiary basis to support this request; and
- allow CC or CE LBC to be funded on any one occasion, but not both.

MSAC also advises that the relevant bulk-billing rates and screening participation rates be closely monitored as part of implementing the supported listing.

5. Applicant's comments on MSAC's Public Summary Document

BD applauds the decision by the Medical Services Advisory Committee (MSAC) to support public funding for cell enrichment liquid-based cytology (CE LBC) in routine screening for the prevention of cervical cancer. In Australia, BD supports a comprehensive approach to the prevention of cervical cancer through education, participation in the National Cervical Screening Program, proper test follow-up, and treatment based on established clinical guidelines.

The advice provided by MSAC to the Minister for Health, the Hon Peter Dutton MP, supporting public funding for CE LBC via new Medical Benefit Schedule (MBS) items is a significant advance for women who undergo routine screening for the prevention of cervical cancer.

Note: The applicant has noted and agreed to release this public summary document noting that the Minister is yet to note the MSACs advice. This public summary document is not indicative of any Government decision regarding this MSAC application.

6. Context for decision

This advice was made under the MSAC Terms of Reference.

MSAC is to:

Advise the Minister for Health and Ageing on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:

- the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
- the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
- the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
- other matters related to the public funding of health services referred by the Minister.

Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

7. Linkages to other documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.