**Title: Intravascular brachytherapy -November 2001**

**Agency:** Medicare Services Advisory Committee (MSAC) Commonwealth Department of Health and Aged Care

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**Reference: MSAC application 1041. Assessment report**

**Aim**

To assess the safety and effectiveness of intravascular brachytherapy (IVB) and under what circumstances such services should be supported with public funding.

**Conclusions and results**

*Safety* The following safety conclusions were made:

 IVB should be conducted by an appropriate multidisciplinary clinical team.

 Catheter-based IVB exposes staff to radiation that is considered to be at an acceptable level.

 Patients are exposed to very low levels of radiation, as only a small local area of vessel wall is irradiated. Consequently, adverse events are more likely to be associated with vessel wall

damage, rather than the development of malignancy.

 IVB may be associated with late thrombosis, however long-term antiplatelet therapy with new stent avoidance appears to reduce the likelihood of late thrombosis.

 Edge restenosis appears to be more pronounced with the use of beta based IVB (either radioactive stents or catheter-based IVB).

*Effectiveness* The effectiveness conclusions were based on level II and III-3 evidence:

 In the short-term, catheter-based IVB appears to be significantly associated with a reduction in angiographic restenosis and clinical revascularisation. It does not significantly reduce the rate

of MI or death, it is possible that current trials are insufficiently powered to detect differences

in these relatively rare outcomes;

 Long term follow-up is limited and it is unclear whether IVB defers rather than prevents the onset of restenosis following intervention.

 Significant technological and radiological differences between gamma and beta catheter-based

IVB systems prevent direct comparison of the evidence pertaining to each system.

 Results suggest that the Guidant Intravascular Radiotherapy System and the Novoste Beta- CathM Intracoronary Radiation System show comparable effectiveness; however these systems have not been directly compared in the same group of patients.

*Cost-effectiveness* Using published randomised controlled evidence, the baseline cost per target lesion

revascularisation (TLR) prevented from the use of IVB is estimated to be approximately

$31,500 per TLR prevented. Sensitivity analyses suggest that the estimate of cost- effectiveness of IVB is sensitive to estimates of IVB treatment effect, baseline risk of TLR

and, to a certain extent, cost of the provision of IVB. Therefore, based on an annual incidence

of between 500 – 1,000 cases, the total incremental cost will be in the order of $2.2 – 4.4 million.

**Recommendations**

MSAC recommended that on the strength of evidence pertaining to IVB public funding should be

supported for this procedure. However, as there is a strong likelihood that IVB could be replaced by drug-eluting stents in three to four years time, the supporting committee recommends only interim funding, pending review in three years.

**Method**

The National Health and Medical Research Council (NHMRC) Clinical Trials Centre at the University of

Sydney conducted a systematic review of the literature (with eligibility criteria defined *a priori*) on the role of IVB. The following sources were searched from commencement to November 2001: Medline, PreMedline, National Library of Medicine Health Services Research Databases, Biological Abstracts, Best

Evidence, Current Contents, EmBase, the Cochrane Library, ISTAHC, and the NHS Databases, DARE, EED

and HTA. Internet and health technology assessment agency sources were searched and studies were also identified from MSAC applications and members of the Supporting Committee.

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