Medical Services Advisory Committee

Public Summary Document

Reference No. 1089.1 – Review of interim funded service: brachytherapy for the treatment of prostate cancer

Sponsors:	**The Australian and New Zealand Association of Urological Surgeons**
	Oncura Pty Ltd
	Department of Health and Ageing
Date of MSAC consideration:	**51st MSAC meeting, 2 December 2010**

1. Purpose of Application

On 28 November 2005, the Minister for Health and Ageing approved the MSAC recommendation to support interim public funding for Brachytherapy for the treatment of Prostate Cancer. This recommendation has now been reviewed to ascertain whether longer term safety, effectiveness and cost-effectiveness has been proven. The review considered evidence published since 2005 and updates the findings of the previous two MSAC assessments (1029 and 1089) for the patient cohort described prior to the change in reimbursement criteria (i.e. Gleason score ≤ 6). In addition, this review also considered all evidence from 2000 for the sub-population that was excluded from previous MSAC assessments and is now included on the MBS (i.e. Gleason score = 7).

In 2006, an application was submitted to the Department of Health and Ageing by the Australian and New Zealand Association of Urological Surgeons (ANZAUS) citing studies supporting the expansion of the eligibility criteria for LDR brachytherapy to include patients with a Gleason score of 7. The previous criteria restricted eligibility to patients with a Gleason score (Appendix B) ≤ 6. No other alteration to the eligibility criteria was sought. Primarily, the argument for including patients with Gleason scores of 7 on biopsy relates to the upward migration of Gleason scores in recent times, such that a proportion of Gleason 6 patients considered in the previous MSAC assessments would, were they re-graded today, be classified as Gleason 7.

Oncura Pty Ltd and the Department of Health and Ageing are co-sponsors for this review.

Brachytherapy is the implantation of radioactive sources in or near tumours. When used in the treatment of prostate cancer, radioisotopes are inserted directly into the prostate gland guided by a transrectal ultrasound probe as a single day-patient or overnight stay procedure. The radioactive sources have a localised effect and, when the placement and dosage are planned appropriately, destroy tumour cells of the prostate gland without significantly irradiating adjacent normal tissue. Brachytherapy has been proposed to offer a more efficient treatment (shorter treatment, in-hospital and recovery time) for localised prostate cancer with the additional advantages of limiting the side-effects to adjacent tissues that occur with EBRT and the surgical risks associated with radical prostatectomy (RP).

As outlined above, MSAC reconsidered the strength of the evidence relating to the safety, effectiveness and cost-effectiveness of low dose rate brachytherapy (BT) for men with localised prostate cancer. This consideration followed two previous appraisals of BT by MSAC in 2000 and 2005. On both occasions, MSAC recommended that BT receive interim funding through the MBS for the treatment of men with localised prostate cancer with a Gleason Score ≤ 6, and a prostate specific antigen (PSA) level ≤10ng/ml. In 2007, the MBS eligibility criteria were expanded to include men diagnosed with a Gleason score of 7, although the current MBS listing does not differentiate between Gleason scores of 3+4=7 and 4+3=7.

2. Current arrangements for public reimbursement

BT is performed in public and private hospital settings, with some of the services prior to the procedure occurring in an outpatient setting. MSAC estimated 70% of BT procedures are performed in private hospitals, and would therefore incur a cost to the MBS. The 'seeds' used in BT are currently recognised by the Prostheses List and therefore attract reimbursement for patients with relevant private health insurance.

In November 2001, the Government acted on MSAC's advice and listed BT for prostate cancer on the MBS under item numbers 15338 and 37220. The item descriptors were updated in 2006 to allow BT to be used for patients with a Gleason score ≤7.

The fee for MBS items 15338 is $900.15. The descriptor is:

> *PROSTATE, radioactive seed implantation of, radiation oncology component, using transrectal ultrasound guidance, for localised prostatic malignancy at clinical stages T1 (clinically inapparent tumour not palpable or visible by imaging) or T2 (tumour confined within prostate), with a Gleason score of less than or equal to 7 and a prostate specific antigen (PSA) of less than 10ng/ml at the time of diagnosis. The procedure must be performed at an approved site in association with a urologist.*

The fee from MBS item 37220 is $1,004.65. The descriptor is:

> *PROSTATE, radioactive seed implantation of, urological component, using transrectal ultrasound guidance, for localised prostatic malignancy at clinical stages T1 (clinically inapparent tumour not palpable or visible by imaging) or T2 (tumour confined within prostate), with a Gleason score of less than or equal to 7 and a prostate specific antigen (PSA) of less than or equal to 10ng/ml at the time of diagnosis. The procedure must be performed by a urologist at an approved site in association with a radiation oncologist, and be associated with a service to which item 55603 applies.*

BT was first assessed by MSAC on 15 November 2000 and at that time MSAC recommended BT should receive interim funding with a review in not less than three years. BT was subsequently introduced onto the MBS in November 2001 and reviewed on 18 May 2005, receiving continued interim funding due to the procedure being of benefit but without conclusive evidence. No end date for interim funding was suggested as part of this second recommendation.

As BT has been reviewed as part of the normal interim funding process, no MBS descriptor or fee has been proposed by the original applicant.

MSAC agreed that Radical Prostatectomy (RP) and External Beam Radiation Therapy (EBRT) were appropriate comparators for BT. It also agreed that Active Surveillance (AS) could be an alternative patient management strategy.

Both RP and EBRT are listed on the MBS under items 37210, 15248 and 15263. Active Surveillance involves a combination of MBS items, with item 66656 (PSA test) being the primary item.

3. Background

Prostate cancer is the most commonly diagnosed cancer in Australian men (excluding non-melanocytic skin cancer). Prostate cancer is the second leading cause of cancer deaths in men after lung cancer.

Following a decline from its peak in 1994 of 184.3 per 100,000 males, the incidence rate of prostate cancer has been steadily rising in Australia since 2000. The sudden increase of diagnoses in Australia in the early to mid 1990s most likely reflects the introduction of prostate specific antigen (PSA) testing and mirrors a trend that occurred in the US about three years prior. In 2006, the age standardised incidence rate for prostate cancer in Australian men reached 170.0 per 100,000 males.

The age standardised mortality rate has fallen steadily, from 43.7 per 100,000 in 1993 to 31.0 per 100,000 in 2007. Despite a decline in mortality rates, prostate cancer remains an important disease, responsible for more deaths than any other cancer in men with the exception of lung cancer.

Low dose rate brachytherapy (also known as permanent interstitial radiotherapy or seed brachytherapy) is the implantation of radioisotopes (iodine-125 or palladium-103) directly into the prostate gland. The implantation is carried out under trans-rectal ultrasound guidance and can be performed as a day-patient procedure, although it usually involves at least an overnight stay. The radioactive sources are distributed throughout the prostate either pre-operatively or intra-operatively to ensure adequate coverage of radiation (emitted as x-rays and gamma rays) for the ablation of tumour cells. Brachytherapy seeds have a local effect, with a sharp dose fall off governed by the inverse square law resulting in adjacent tissues receiving only very low doses of radiation.

In a typical BT procedure, the following MBS items are claimed:

- 104 – Urologist consultation
- 104 – Radiation oncologist consultation
- 61421 – Whole body bone scan (Gleason score 7 only)
- 56507 or 56409 – Computerised tomography scan (Gleason score 7 only)
- 11900 – Urine flow study
- 17610 – Pre-anaesthetic consultation
- 15539 – Planning and simulation of procedure
- 37220 – Procedure (urologist)
- 15338 – Procedure (radiation oncologist)
- 21973 – Anaesthesia
- 23063 – Anaesthesia
- 55603 – Prostate ultrasound
- 15513 – Radiation source localisation by x-ray or CT
- 60509 or 60506 – Fluoroscopy

The following AR-DRGs are used in the public hospital setting:

- AR-DRG L08B – Urethral procedures – CC(private)

The following PBS item is claimed:

- 8093Y – Goserelin Acetate

The following item from the Prostheses List is reimbursed by private health insurers:

- ON003 – Pre-loaded, stranded ^{125}I brachytherapy seeds

The LDR procedure involves a urologist, radiation oncologist, medical physicist, radiation therapist and anaesthetist. MSAC did not recommend restriction to any specialist groups through the MBS item descriptor.

As BT is already publicly funded, there will be no augmentation or substitution for existing MBS items. As other forms of treatment are available for prostate cancer, MSAC agreed that BT is not addressing an unmet need. As each form of treatment has advantages and disadvantages, BT offers additional patient choice.

BT is used as a first-line treatment for prostate cancer and is performed after staging of the disease has confirmed the patient is eligible for the procedure.

Initial grading of the tumour must be undertaken by a pathologist following a biopsy procedure performed by a urologist. Many men with prostate cancer also undergo imaging procedures (such as CT scans of the prostate and/or whole body bone scans as staging procedures.

4. Clinical need

BT does not address an area of unmet clinical need as RP and EBRT are currently available treatments for the same indication; AS may also be appropriate for some patients. MSAC considered that BT improves patient choice, offers a different side effect profile, and may be preferable for rural and remote patients with private health insurance as it requires less treatment time than RP and EBRT.

MSAC agreed that BT should remain restricted to patients with localised prostate cancer (clinical stage T1 or T2) with a prostate specific antigen (PSA) level of 10 ng/ml or less and a Gleason score of 7 or less.

It is expected that 5000 men will have been treated for prostate cancer in 2010. BT is one of the available modalities used for the treatment of prostate cancer, although the actual percentage of men with prostate cancer who receive BT is unknown. MSAC noted that the current trend of increased detection of early and possibly indolent disease means the eligible population for this procedure may increase over time.

MSAC noted uncertainty around the future utilisation of BT, EBRT and RP, as treatment choices are made taking into account the patient's individual circumstances and preferences, after considering the different side-effects and other factors such as time required to attend treatment (seven weeks for EBRT); travel; ability to pay for BT seeds (insurance status); fitness for surgery; access to operating theatres; access to inpatient beds; and waiting times for EBRT.

5. Comparator

BT, RP and EBRT are all used as first-line treatments for prostate cancer and are performed after staging of the disease has confirmed the patient is eligible for the procedures. EBRT may also be used as an adjunct to BT in patients with Gleason (4+3=7) disease, and RP may be used as a second-line treatment following failed BT or EBRT; these uses of EBRT and RP were not assessed by MSAC.

BT is currently funded through the MBS and is used as a first-line treatment for prostate cancer. Other treatments used in the same setting include RP and EBRT, which is why they were used as comparators for this assessment. MSAC also considered that AS was an appropriate comparator as it is an alternative management option that increases patients' morbidity-free time compared to the side-effects resulting from any of the available active therapeutic interventions.

MSAC considered that RP, EBRT and AS were appropriate comparators for BT.

6. Scientific basis of comparison

The primary source of evidence for MSAC's advice was an Assessment Report produced by contracted evaluators. The Assessment Report was a critical review of the available scientific literature review, informed by an Advisory Panel of clinical experts and consumers who ensured that the assessment considered relevant issues and appropriately reflected the Australian setting.

A total of 36 studies was included in the evidence base for this review, including three comparative studies. MSAC noted that the literature base for this review was of moderate quality.

The Advisory Panel suggested that results should be evaluated separately for patients with Gleason score ≤6 and Gleason score 7. MSAC noted that the literature reported mixed populations of patients with both Gleason score 6 (or less) and Gleason score 7 and results were not presented in such a manner that they could be distinguished as distinct subgroups. For this review, therefore, these groups were combined. MSAC noted that while Gleason score is likely to be a strong prognostic marker for oncological and survival outcomes, it is less likely to affect safety outcomes.

Based on data of limited quality, MSAC agreed that BT is likely to be at least as safe and effective as External Beam Radiotherapy (EBRT) or Radical Prostatectomy (RP) for early-stage prostate cancer. MSAC noted that each of these treatments has a different side-effect profile; for example BT and EBRT are associated with less erectile dysfunction than RP. MSAC also noted that many of the side-effects associated with these treatments improve over time.

MSAC noted that the inclusion criteria for effectiveness were developed *a priori*, but have been slightly adjusted to reflect the data available. Given that none of the eligible literature could meet the requirement for comparative data with a minimum of 10 year patient health outcomes, this criterion was changed to allow studies with a minimum of five year outcomes for inclusion. The inclusion criteria separated patients into groups based on Gleason score ≤6, Gleason score 7 with a primary score of 3 and a secondary score of 4 (3+4), and Gleason score 7 with a primary score of 4 and a secondary score of 3 (4+3). Analysis of these Gleason score groups has been combined given that no included studies on effectiveness separated results by Gleason score according to these criteria. MSAC noted that while Gleason score is less likely to affect safety outcomes, it is a strong prognostic marker for oncological and survival outcomes and this assessment is therefore limited by lack of data which differentiates effectiveness outcomes for patients on the basis of Gleason score.

MSAC noted that there were very few data on the clinical effectiveness of BT despite its interim listing on the MBS for 10 years.

Based on the evidence that is currently available, MSAC found that there was unlikely to be a significant difference in prostate cancer related mortality or biochemical recurrence between BT, EBRT and RP. No literature could be found that compares BT with active surveillance; MSAC was therefore unable to quantify the benefit of active surveillance due to this lack of data.

7. Safety

MSAC agreed that BT is likely to be as safe as EBRT and RP. Comparatively, MSAC noted evidence that patients receiving BT are likely to experience: less incontinence than RP; more irritative or obstructive urinary symptoms; more early urinary retention than RP; more rectal bleeding and faecal incontinence than RP; Less bowel dysfunction than EBRT; and less erectile dysfunction than RP. MSAC noted that many of these complications are likely to improve with time after surgery.

Based on data of limited quality, MSAC agreed that BT is likely to be at least as safe as EBRT or RP for early-stage prostate cancer, albeit with a different side-effect profile to those treatments.

In addition to safety issues, MSAC noted other associated factors such as time required to attend treatment (seven weeks for EBRT); travel; ability to pay for BT seeds (insurance status); fitness for radical surgery; access to operating theatres; access to inpatient beds; and waiting times for EBRT would also need to be considered.

8. Clinical effectiveness

Overall survival after treatment was assessed in two studies. The highest quality study did not directly compare BT with the other treatment modalities (EBRT and RP), but rather indirectly via comparison with a 'no treatment' group. Overall survival results suggest that BT patients are not likely to fare any worse than EBRT patients and have similar overall survival to RP patients. The other study was of poor quality and presented data on primary effectiveness for three out of four eligible treatments - RP, BT and EBRT. With no testing for statistical significance and questionable conclusions on the part of the authors, the point estimates provided inadequate evidence for either a difference or similarity between the treatments.

A third study (Pickles et al 2010) reported on prostate cancer specific death and death from all causes, however this represented a small number of deaths amongst the total number of patients after a follow-up of less than 10 years. This similarly provides no conclusive evidence about the superiority of either treatment used (BT or EBRT).

A total of five comparative studies reported on secondary effectiveness outcomes for low dose rate brachytherapy. All but one of these presented results for five-year freedom from biochemical recurrence ('biochemical non-evidence of disease' – bNED). Studies that presented bNED were all of moderate quality and the majority found no differences in outcomes for BT or EBRT (RP was not assessed in these studies). One study found that freedom from recurrence was 10 per cent greater among BT patients than among EBRT patients, while the final poor quality study was inadequate to affect the weight of evidence indicating that there is no difference in bNED for BT or EBRT.

Based on the evidence that is currently available, MSAC found that there was unlikely to be a significant difference in prostate cancer related mortality or biochemical recurrence between BT, EBRT and RP.

No literature could be found that compares BT with active surveillance; MSAC was therefore unable to quantify the benefit of active surveillance due to this lack of data.

Based on data of limited quality, MSAC agreed that BT is likely to be at least as effective as External Beam Radiotherapy (EBRT) or Radical Prostatectomy (RP) for the treatment of early-stage prostate cancer.

MSAC noted that their assessment of the evidence was based on limited data, with only one relevant randomised control trial found for the assessment. Furthermore, all studies identified for the review had <10 years follow-up time.

MSAC noted that men receiving EBRT may be more likely to have co-morbidities than patients receiving other treatment, which could impact the effectiveness data.

MSAC also noted that the definition of biochemical recurrence differs between studies of RP compared to EBRT and BT, which may impact secondary effectiveness data.

MSAC noted the literature was unable to support a comparison of BT with active surveillance which may have been useful.

9. Economic evaluation

Due to the limited comparative evidence, it was not possible to definitively conclude whether low dose rate brachytherapy for localised prostate cancer is as effective as, or more effective than, RP, EBRT or active surveillance. Therefore, only a cost analysis of the expenditures associated with the new procedure relative to the comparative procedures was conducted.

MSAC noted that the cost analysis found that the average unit cost per BT procedure for men with Gleason ≤6 was $12,297.75, compared with $12.070.20 and $13,995.45 for EBRT and RP (in a public setting) respectively. For men with Gleason 7 the cost per BT procedure was $13,142.58, compared with $13,654.20 and $14,840.28 for EBRT and RP (in a public setting) respectively.

MSAC noted that the $7,000 cost for brachytherapy seeds is covered by relevant private health insurance through the inclusion of these seeds on the Prostheses List. Patients receiving BT in a private setting without private health insurance would be liable for this cost themselves.

MSAC noted that the single largest expenditure for brachytherapy is the implanted radioactive seeds. In the public healthcare sector, this cost is borne by some State or Territory governments by arrangement with individual hospitals which may limit the provision of brachytherapy in the public system.

10. Financial/budgetary impacts

It is expected that 5000 men will be treated for prostate cancer in 2010. BT is one of the available modalities used for the treatment of prostate cancer, although the actual percentage of men with prostate cancer who receive BT is unknown. MSAC noted that the current trend of increased detection of early and possibly indolent prostate cancer means the eligible population for this procedure may increase over time.

MSAC noted that the total cost of BT to the MBS was calculated to be $5,828,622 over 10 years. RP was estimated to cost $3,930,815 over the same period while the cost of EBRT was estimated at $18,602,239. This represents a saving of $12,773,617 compared with EBRT and an additional cost of $1,897,807 compared with RP. These figures were based on an estimate that 55 per cent of men will present with Gleason score ≤6 prostate cancer; and that 70 per cent of men with prostate cancer will be treated in a private hospital; and further assumed that BT, RP and EBRT are all used equally.

MSAC noted that treating men with Gleason 7 disease increases the cost to the MBS by approximately $720 per patient, which is more than one fifth of the total MBS cost for either BT or RP. This added cost is made up by an increased use of staging scans (whole body bone scan and computerised tomography scan). This increased cost is across all treatments. MSAC noted that as treatment practices vary between centres, it is likely that a proportion of men with Gleason ≤ 6 prostate cancer will also receive staging scans, resulting in an increased cost to the MBS.

MSAC noted that the total cost to the Australian healthcare system using the above assumptions was $66.7 million over 10 years. They noted that if 20% of all men elected to proceed to active surveillance instead of active treatment, the total cost to the Australian health system was $65.7 million over 10 years. However, MSAC agreed that the costs in the active surveillance model contain considerable uncertainty due to the lack of explicit guidelines on the frequency and nature of appropriate surveillance activities, the appropriate patient groups and the thresholds for active intervention.

MSAC noted that whilst the total cost of BT, EBRT and RP are equivalent, costs are not distributed equally among payers (ie the Australian Government; State and Territory governments; private health insurance; and patient co-payments). However, MSAC agreed that the overall healthcare costs of continued public funding for BT are unlikely to differ significantly from EBRT or RP.

11. Other significant factors

MSAC noted that men with a Gleason score of 4+3=7 are at a higher risk of poor outcomes compared with Gleason score of 3+4=7. MSAC had reservations about endorsing the use of BT as a monotherapy for Gleason scores of 4+3=7 disease due to higher likelihood of extracapsular extension. MSAC also noted that international guidelines, and the Advisory Panel for this assessment, shared this concern. MSAC agreed not to amend the current item descriptor but recommended inclusion of comments in relation to Gleason score 7 in the MBS Explanatory Notes.

MSAC concluded that given the paucity of new evidence since BT's introduction to Australia over a decade ago, it is unlikely that a better evidence base will become available in the foreseeable future.

MSAC found that BT is likely to have particular advantages over EBRT and RP for men from rural/remote locations, primarily due to the significantly shorter length of time away from home. However, MSAC noted equity issues with the availability of BT, as remote patients are less likely to have private health insurance to pay for the seeds (approximately $7,000 per treatment) and would also incur travel costs to access BT.

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

MSAC reconsidered the strength of the evidence relating to the safety, effectiveness and cost-effectiveness of low dose rate brachytherapy (BT) for men with localised prostate cancer. This consideration followed two previous appraisals of BT by MSAC in 2000 and 2005. On both occasions, MSAC recommended that BT receive interim funding on the MBS for the treatment of men with localised prostate cancer meeting specific clinical requirements including a Gleason Score ≤ 6, and a prostate specific antigen (PSA) level ≤ 10ng/ml. In 2007, the MBS eligibility criteria were expanded to include men diagnosed with a Gleason score of 7, although the current MBS listing does not differentiate between Gleason scores of 3+4=7 versus 4+3=7.

MSAC noted that the limited studies available for this review did not differentiate between Gleason scores of 3+4=7 versus 4+3=7, and that all studies identified for the review had short follow-up times (under 10 years).

It is expected that 5000 men will be treated for prostate cancer in 2010. BT is one of the available modalities used for the treatment of prostate cancer, although the actual percentage of men with prostate cancer who receive BT is unknown. MSAC noted that the current trend of increased detection of early prostate cancer means the eligible population for this procedure may increase over time.

Based on data of limited quality, MSAC agreed that BT is likely to be at least as safe and effective as External Beam Radiotherapy (EBRT) or Radical Prostatectomy (RP) for early-stage prostate cancer.

MSAC found that there were very few data on the clinical effectiveness of BT despite its interim listing on the MBS for 10 years. Based on the evidence that is currently available, MSAC found that there was unlikely to be a significant difference in prostate cancer related mortality or biochemical recurrence between BT, EBRT and RP. MSAC noted that as BT is indicated for patients with indolent disease (expected survival ≥10 years), active surveillance could be appropriate alternative management as active surveillance increases patients'

morbidity-free time compared to the side-effects resulting from any of the available active therapeutic intervention. MSAC noted that the different side effect profile of each form of treatment is likely to influence which treatment is preferred by an individual patient. No literature could be found that compares BT with active surveillance. MSAC was therefore unable to quantify the benefit of active surveillance due to this lack of data.

MSAC concluded that given the paucity of new evidence since BT's introduction to Australia over a decade ago, it is unlikely that a better evidence base will become available in the foreseeable future.

MSAC noted uncertainty around the future utilisation of BT, EBRT and RP, as treatment choices are made taking into account the patient's individual circumstances and preferences, after considering the different side-effects and other factors such as time required off work (seven weeks for EBRT); fitness for surgery; access to operating theatres; access to inpatient beds; and waiting times for EBRT.

MSAC noted that whilst the total cost of BT, EBRT and RP are equivalent, costs are not distributed equally among payers (ie the Australian Government; State and Territory governments; private health insurance; and patient co-payments). However, MSAC agreed that the overall healthcare costs of continued public funding for BT are unlikely to differ significantly from EBRT or RP. It was noted that active surveillance would incur some costs due to surveillance procedures, although these costs could not be accurately determined due to the lack of explicit guidelines on the frequency and nature of appropriate surveillance activities, the appropriate patient groups and the thresholds for active intervention.

MSAC found that BT is likely to have particular advantages over EBRT and RP for men from rural/remote locations, primarily due to the significantly shorter length of time away from home. However, MSAC noted equity issues with the availability of BT, as remote patients are less likely to have private health insurance to pay for the seeds (approximately $7,000 per treatment) and would also incur travel costs to access BT.

MSAC noted that men with a Gleason score of 4+3=7 are at a higher risk of poor outcomes compared with Gleason score of 3+4=7. MSAC had reservations about endorsing the use of BT as a monotherapy for Gleason scores of 4+3=7 disease due to higher likelihood of extracapsular extension. MSAC also noted that international guidelines, and the Advisory Panel for this assessment, shared this concern. MSAC agreed not to amend the current item descriptor but recommended inclusion of comments in relation to Gleason score 7 in the MBS Explanatory Notes.

Given the equivalent safety, effectiveness and cost-effectiveness of BT, the likely attractiveness for patients from non-urban areas compared with RP and EBRT, and taking into account that better quality data on this procedure are unlikely to become available in the foreseeable future, MSAC agreed that BT should be given full listing on the MBS and hence continue to receive public funding.

MSAC agreed to retain the current MBS item descriptor regarding the Gleason scores, so as not to exclude access to BT in combination with EBRT where it was deemed appropriate by the clinician in consultation with the pathologist.

13. MSAC's advice to the Minister

MSAC supports public funding for low dose-rate ^{125}I brachytherapy for localised prostate cancer (clinical stage T1 or T2) with a prostate specific antigen (PSA) level of 10 ng/ml or less and a Gleason score of 7 or less.

MSAC agreed that BT is appropriate as a first-line monotherapy where the Gleason score is $\leq$(3+4) = 7, and if used for Gleason (4+3) = 7, should be part of combined modality treatment; such advice could form part of the MBS Explanatory Notes.

14. 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 including those 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 Minister's 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 such sub-committees."

15. Linkages to Other Documents

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

The MSAC Assessment Report is available at www.msac.gov.au/internet/msac/publishing.nsf/Content/1089.1