



Medical Services Advisory Committee

Public Summary Document

Application No. 1124

Cryotherapy for Recurrent Prostate Cancer and Renal Cancer

Applicant: Scanmedics Pty Ltd
Date of MSAC consideration: 46th MSAC meeting, 11 September 2009, Melbourne

Part B: Cryotherapy for renal cancer

1. Purpose of Application

Scanmedics Pty Ltd submitted an application to the MSAC for public funding of cryotherapy for the treatment of small localised renal cancer (<4cm) in patients with significant co-morbidities and/or renal impairment requiring a nephron-sparing approach.

Cryotherapy is a procedure that can be used for renal cancer. It has the potential to kill the cancer cells through a process of repeated freezing and thawing. The newer generations of cryotherapy use argon gas during the rapid freezing phase to form an ice ball around the top of the cryoprobe through the Joule-Thomson effect. Helium gas is then delivered to produce active thawing. Intra-operative ultrasound is required to monitor the cryoablative process. Multiple renal tumours may be treated in one cryotherapy procedure. Although renal cryotherapy can be performed using an open surgical approach, laparoscopic cryotherapy and percutaneous cryotherapy are more commonly used in current clinical practice.

2. Background

The applicant proposed that the new service be available in major hospitals or centres of excellence as a tertiary procedure following patient referral by other specialists. It was proposed that renal cryotherapy may replace some current surgery, particularly partial nephrectomy, but that renal cryotherapy would be a very low volume procedure until specialist expertise is more widely developed in Australia. Specialist urologists would perform renal cryotherapy with the vast majority of procedures being performed using the laparoscopic technique. The percutaneous procedures may be performed by procedural radiologists with special expertise in this area. However there are limitations on the use of this route due to tumour position.

The applicant also suggested that cryotherapy for renal cancer could replace the comparable procedure – Medicare Benefits Schedule (MBS) item 36522 (partial nephrectomy) and 36525 (partial nephrectomy complicated by previous surgery on the same kidney), with no anticipated change in the numbers of radical nephrectomy cases, or to staging investigations or follow up requirements.

3. Clinical need

Members noted the prognostic uncertainty of ‘incidentalomas’: the small renal lesions which are found on imaging, presumed to be renal cancers and may constitute the renal tumours proposed to be treated with cryotherapy. Current management options for patients requiring nephron-sparing treatment because they have a single functioning kidney fall into three main categories: surgery, ablative procedures including cryosurgery (laparoscopic or percutaneous) and radiofrequency ablation (RFA), and active surveillance.

4. Comparator

MSAC found that partial nephrectomy is an appropriate comparator. It is a more established procedure, with some supporting evidence in the current literature. By comparison, RFA is a less appropriate comparator. It is a procedure under investigation for clinical effectiveness without current long-term outcome data. Surveillance is also an appropriate comparator.

5. Safety

Cryotherapy is not proven to be safer than conservative treatment because of insufficient data but current evidence suggests an adequate safety profile for cryotherapy compared with partial nephrectomy and RFA.

6. Clinical effectiveness

There is currently inadequate evidence on clinical effectiveness due to a lack of long-term follow-up data with respect to control of disease and survival. This needs to be assessed in properly controlled trials of ablative therapies versus comparator interventions. In general, short term effectiveness appears promising, however the long-term follow up data are still not available.

7. Cost-effectiveness

A financial analysis (rather than a cost-effectiveness analysis) was performed as clinical effectiveness remained unproven (as there is not enough evidence to determine the clinical effectiveness and thus the cost-effectiveness of cryotherapy versus partial nephrectomy).

8. Financial/budget impacts

The volume of use/year is likely to increase because of an increase in scans and finding of 'incidentalomas'. On the financial analysis performed, cryotherapy is likely to cost more than either partial nephrectomy or RFA. Without proven clinical effectiveness, and the potential increased cost to the Australian healthcare system, MSAC concluded that there is no basis to support public funding for this procedure at this stage.

MSAC further agreed that, even if evidence were obtained to show that cryotherapy is as safe and as effective as currently available treatment (partial nephrectomy, RFA), the analysis of the financial implications indicates that publicly funding the procedure would mean that both the Australian Government and the Australian health care system would incur additional costs.

9. Summary of Consideration and Rationale for MSAC's Advice

MSAC found that little is known about the natural history of renal 'incidentalomas'; there is uncertainty over the comparative effectiveness of any option in this patient setting due to the low strength of evidence and the underlying uncertainty over the natural history; and cryotherapy is the most expensive of the alternative options.

MSAC also noted that there may be a greater incidence of bleeding after cryotherapy than after RFA, but there may also be some patients for whom there might be clinical reasons to indicate that the other alternatives are unsuitable.

10. MSAC's Advice to the Minister

Due to the lack of evidence that cryotherapy is as safe and as effective as currently available treatment, and the financial analysis indicating that public funding for this procedure would incur additional costs to the Australian Government and healthcare system, MSAC advises that it does not support public funding for cryotherapy for renal cancer.

11. Context for Decision

This advice was made under the MSAC Terms of Reference:

- Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported.
- Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness.
- Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures.
- Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

12. 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

<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/MSACCompletedAssessments1120-1140>