MSAC application 1794

Irreversible Electroporation (IRE) for Prostate Tumour Tissue in Patients with Prostate Cancer

Application for MBS eligible service or health technology

HPP Application number:

HPP200241

Application title:

Irreversible Electroporation (IRE) for Prostate Tumour Tissue

Submitting organisation:

GETZ HEALTHCARE PTY LTD

Submitting organisation ABN:

72076530946

Application description

Succinct description of the medical condition/s:

Prostate cancer is a tumour that arises in the prostate gland. As with any cancer, if it is advanced or left untreated in early stages, it can eventually spread throughout the blood. It is estimated that by age 65, about 60% of men exhibit some evidence of prostate cancer. Standard, invasive therapies for the treatment of prostate cancer such as prostatectomy where the prostate is surgically removed or radiation therapy often may lead to complications such as urinary incontinence and erectile dysfunction, affecting quality of life. This has led to an increased interest in focal irreversible electroporation for treating low to intermediate risk prostate cancer or patients that have had a recurrence post radiation therapy. This technology will treat prostate tumours while preserving functional outcomes.

Succinct description of the service or health technology:

Irreversible Electroporation (IRE) is an ablation procedure that uses the NanoKnife system to destroy soft tissue tumours. The system applies electrical pulses using electrodes placed around the tumour. This creates holes in the cell membranes, resulting cell death. IRE is non-thermal technology and can be used to treat tumours that are near critical structures such as nerves and blood vessels and urethras. This leads to successful treatment of the tumour with decreased risk of side effects such as incontinence and impotence.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Applicant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

GETZ HEALTHCARE PTY LTD

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO sets:

Irreversible Electroporation (IRE) for Prostate Tumour Tissue

Population

Describe the population in which the proposed health technology is intended to be used:

Ablation via irreversible electroporation (IRE) is proposed to be used in patients with intermediate risk prostate cancer as well as a salvage option for patients who have previously undergone radiation therapy unsuccessfully, have a recurrence and are not candidates for radical prostatectomy.

Australia has one of the highest incidence rates of prostate cancer. The population treated are men, most often between the ages of 55-75. Prostate cancer could be identified through initial prostate examination or investigations of PSA (prostate specific antigen) level initiated by a primary physician. Should prostate cancer be suspected, the patient would be referred to a urologist for additional investigations. The cancer is confirmed and graded by biopsy and imaging, and subsequently a treatment plan is developed. All newly diagnosed patients should be discussed by a multidisciplinary team (MDT) before beginning treatment.

Advances in imaging, have led to an increase in early detection and management of prostate cancer with and a focus on minimising harm and reducing overdiagnosis and overtreatment (Williams et al. 2022)

Irreversible electroporation can be used as a treatment option for two groups of prostate cancer patients-

As a primary, focal treatment for patients with a localised low to intermediate grade prostate cancer ISUP 2 or 3 (Gleason score 3+4=7 or 4+3=7) or a high-risk, low-grade cancer (Gleason 3+3=6) as assessed by an MDT.

As a salvage treatment option for prostate cancer patients who have previously undergone radiation therapy and have had a recurrence. These patients may not be suitable for surgery and have limited other treatment options.

The tumor in these patients should be localised and should be thoroughly evaluated with high quality transperineal targeted and mapping biopsies as well as visible on imaging. There should be good co-registration between the imaging and the tissue biopsy, and the patient must have a life expectancy greater than 10 years.

Within the Australian system, most prostate cancers are suspected based on routine informed PSA (prostate specific antigen) test. When results are elevated or abnormal, the patient is referred to a specialist urologist who evaluate the patient and investigate further, if appropriate using multiparametric MRI. At this stage, if there is abnormality on the MRI, patients would undergo a transperineal biopsy of the prostate to confirm if cancer is present and graded using the biopsy findings. Then, a full discussion with the urologist as well as a multidisciplinary medical team occurs to discuss potential treatment options, including radical prostatectomy, radiotherapy, brachytherapy and focal therapy including irreversible electroporation. In discussion of irreversible electroporation, the clinical and psychosocial needs of the patient are discussed, as well as the potential to preserve genitourinary and sexual function.

Select the most applicable Medical condition terminology (SNOMED CT):

Primary carcinoma of prostate

Intervention

Name of the proposed health technology:

Irreversible Electroporation (IRE) for Prostate Tumour Tissue

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

The appropriate comparator for Irreversible electroporation is radical therapy for localised prostate cancer. This includes radical prostatectomy and radiation therapy (radiotherapy and brachytherapy). These treatment options target the whole prostate gland through surgical removal or radiation treatment, unlike Irreversible electroporation which is considered focal therapy, targeting the segment of the prostate incorporating the prostate cancer lesion (Flegar et al. 2022).

Healthcare resources that need to be employed with the comparator services include: Radical prostatectomy requires inpatient hospital stay, a DaVinci Robot and its related disposable/rental/acquisition costs, a minimum of 4 nursing and surgical support staff and much longer recovery post procedure.

Radiotherapy requires a linear accelerator as part of an MR LINAC machine that includes MRI capabilities. In requires a large number of staff including physicists and radiation technicians to set up and run the device. The 10 to 20 fractions are provided over a period of 2-4 weeks of regular visits to the radiotherapy department. In addition, prior to radiation therapy, there is often need for placement of fiducial marker seeds and spacing gel between the rectum and prostate to prepare the patient for treatment. Additionally, there is often a need to down-regulate hormones before radiotherapy can begin. Finally, disposal of radioactive waste is required.

Brachytherapy (low-dose) requires an initial day surgery for treatment planning, an overnight stay for implantation of the radioactive material, the cost of the expensive radioiodine seeds, radiation planning and the combination of a radiation oncologist and urologist to be present in theatre and using theatre facilities while the patient is treated. Finally, disposal of radiation waste is a cost.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The key outcomes in comparing focal IRE to radical therapy include:
1. Genitourinary side effects
2. Sexual function
3. Resource Utilisation
4. Recurrence Rate for Cancer

Please refer PICO set document for details.

Proposed MBS items

Proposed item:

AAAAA

Proposed category:

THERAPEUTIC PROCEDURES

Proposed group:

SURGICAL OPERATIONS

Proposed item descriptor:

Prostate, Irreversible electroporation, using transrectal ultrasound guidance:
for a patient with:
(i) Confirmed histopathological localised prostatic malignancy
(ii) a Gleason score of less than or equal to 7 (Grade Group 1 to Grade Group 3)
(iii) a multidisciplinary team has reviewed treatment options for the patient and assessed that focal therapy is suitable
(b) performed by a urologist at an approved site

Proposed MBS fee:

$1,815.35

Indicate the overall cost per patient of providing the proposed health technology:

$23,000.00

Please specify any anticipated out of pocket expenses:

$12,000.00

Provide any further details and explain:

Cost breakdown includes Urologist fee, anaesthesia, Hospital fee including consumables and NanoKnife IRE generator and electrodes This treatment could be performed a second time in case of a recurrence.

Proposed item:

BBBBB

Proposed category:

THERAPEUTIC PROCEDURES

Proposed group:

SURGICAL OPERATIONS

Proposed item descriptor:

Prostate, Irreversible electroporation, using transrectal ultrasound guidance:
for a patient with:
(i) Confirmed imaged and/or histopathological recurrent prostatic malignancy
(ii) previous radiation therapy (including brachytherapy) on the prostate
(iii) a multidisciplinary team has reviewed treatment options for the patient and

assessed that salvage irreversible electroporation is suitable
(b) performed by a urologist at an approved site in association

Proposed MBS fee:

$1,815.35

Indicate the overall cost per patient of providing the proposed health technology:

$23,000.00

Please specify any anticipated out of pocket expenses:

$12,000.00

Provide any further details and explain:

Cost breakdown includes Urologist fee, anaesthesia, Hospital fee including consumables and NanoKnife IRE electrodes

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Self-funded by patients

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

Claim: IRE has a lower risk of genitourinary side effects, and a similar oncological outcomes along with lower treatment related morbidity and cost, in comparison to the comparators

Rationale: the comparator, radical therapies for treatment of intermediate risk prostate cancer ISUP 2 or 3 (Gleason 3+4=7 or 4+3=7), has higher resource utilization, higher morbidity, similar recurrence and a worse side effect profile for genitourinary and sexual function outcomes.

Said differently, in the intermediate risk prostate cancer population ISUP 2 or 3 (Gleason 3+4=7 or 4+3=7) focal IRE has lower resource utilisation and recovery time, lower morbidity, similar recurrence and a better side effect profile for genitourinary and sexual function outcomes.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

According to the Australian Institute of Health and Welfare, in 2022, it is estimated that a male has a 1 in 6 (or 17%) risk of being diagnosed with prostate cancer by the age of 85, and it was predicted that for 2023, 25,487 prostate cancer cases were expected to be diagnosed at a rate of 154.6 cases per 100,000 males (PCFA 2022). Of this population, approximately 40% are graded as ISUP 2 or 3 (Victorian Cancer Registry 2024) that may be suitable for IRE.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

5

Year 2 estimated uptake (%):

10

Year 3 estimated uptake (%):

15

Year 4 estimated uptake (%):

20

Estimate the number of patients who will utilise the proposed technology for the first full year:

450 patients

Optionally, provide details:

450 patients is an approximation derived from the estimated prevalence of prostate cancer, and predicted uptake of the technology. We approximate that of 25487 patients treated with prostate cancer, 40% of this group will have Intermediate risk prostate cancer. Of this 40%, we estimate that in the first year of uptake, approximately 5% of patients will opt for IRE treatment.

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service

THE UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

Patient and consumer advocacy organisations relevant to the proposed service/health technology

The trustee for Prostate Cancer Foundation of Australia

Entity who produces similar products

None

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
205431	Electrode, electrosurgical, active, foot-controlled, single use
205432	Electrosurgical system generator, general-purpose

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes