Australian Government

Department of Health

Application Form

Targeted Intraoperative Radiotherapy For Early-Stage Breast Cancer

(New and / or Amended

Request for Public Funding)

(Version 2.4)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):
Corporation name: Regional Health Care Group Pty Limited
ABN: 65 137 382 159
Business trading name: Regional Health Care Group

Primary contact name:

Primary contact numbers
Business:
Mobile:
Email:

Alternative contact name:

Alternative contact numbers
Business:
Mobile:
Email:

2. (a) Are you a lobbyist acting on behalf of an Applicant?

☐ Yes
☒ No

(b) If yes, are you listed on the Register of Lobbyists?

☐ Yes
☐ No
Not Applicable

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Targeted Intraoperative Radiotherapy for Early-Stage Breast Cancer.

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Early stage breast cancer - which is the same population group already considered and approved as part of MSAC application 1189.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The administration of targeted intraoperative local radiotherapy to the tumour bed using the Xoft® Axxent® IORT treatment system following surgical removal of early stage breast cancer.

6. (a) Is this a request for MBS funding?

☒ Yes
☐ No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

☒ Amendment to existing MBS item(s)
☐ New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

15900 and 31516

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

i. ☐ An amendment to the way the service is clinically delivered under the existing item(s)
ii. ☐ An amendment to the patient population under the existing item(s)
iii. ☐ An amendment to the schedule fee of the existing item(s)
iv. ☐ An amendment to the time and complexity of an existing item(s)
v. ☐ Access to an existing item(s) by a different health practitioner group
vi. ☒ Minor amendments to the item descriptor that does not affect how the service is delivered
vii. ☐ An amendment to an existing specific single consultation item
viii. ☐ An amendment to an existing global consultation item(s)
ix. ☐ Other (please describe below):

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☐ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

Not Applicable

(f) Is the proposed service seeking public funding other than the MBS?

☐ Yes
☒ No

(g) If yes, please advise:

Not Applicable

7. What is the type of service:

- [x] Therapeutic medical service
- [ ] Investigative medical service
- [ ] Single consultation medical service
- [ ] Global consultation medical service
- [ ] Allied health service
- [ ] Co-dependent technology
- [ ] Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

i. [ ] To be used as a screening tool in asymptomatic populations
ii. [ ] Assists in establishing a diagnosis in symptomatic patients
iii. [ ] Provides information about prognosis
iv. [ ] Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. [ ] Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

Not Applicable

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- [ ] Pharmaceutical / Biological
- [ ] Prosthesis or device
- [x] No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

- [ ] Yes
- [x] No

(b) If yes, please list the relevant PBS item code(s):

Not Applicable

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

- [ ] Yes (please provide PBAC submission item number below)
- [x] No

Not Applicable

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name: Not Applicable
Generic name: Not Applicable

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

- [ ] Yes
- [x] No

(b) If yes, please provide the following information (where relevant):

Billing code(s): Not Applicable
Trade name of prostheses: Not Applicable
Clinical name of prostheses: Not Applicable
Other device components delivered as part of the service: Not Applicable

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

☐ Yes
☒ No

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

☐ Yes
☒ No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Not Applicable

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: Balloon Applicators
Multi-use consumables: Not Applicable

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: Balloon Dissector, Surgical
Manufacturer's name: Xoft (a subsidiary of iCad)
Sponsor's name: Regional Health Care Group Pty Limited

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

☐ Class III
☐ AIMD
☒ N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

☒ Yes (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: ARTG Identifier 231953
TGA approved indication(s), if applicable: Not Applicable
TGA approved purpose(s), if applicable: Insertion into the breast to create a cavity and conduit for the Xoft Axxent brachytherapy source

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

☐ Yes (please provide details below)
☒ No

Date of submission to TGA: Not Applicable
Estimated date by which TGA approval can be expected: Not Applicable
TGA Application ID: Not Applicable
TGA approved indication(s), if applicable: Not Applicable
TGA approved purpose(s), if applicable: Not Applicable

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

☐ Yes (please provide details below)
☒ No

Estimated date of submission to TGA: Not Applicable
Proposed indication(s), if applicable: Not Applicable
Proposed purpose(s), if applicable: Not Applicable

PART 4 – SUMMARY OF EVIDENCE

17. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

	Type of study design*	**Title of journal article or research project (including any trial identifier or study lead if relevant)**	**Short description of research (max 50 words)****	**Website link to journal article or research (if available)**	**Date of publication*****
1.	Observational study	Intraoperative Radiation Therapy (IORT): A Series of 1000 Tumours – Melvin J. Silverstein *et al*	Recurrence rates observed in this trial were comparable to those of the prospective randomized TARGIT-A trial. The low complication and recurrence rates reported in this study support the cautious use and continued study of X-ray IORT in women with low-risk breast cancer. A study of 984 patients	Annals of Surgical Oncology 2018; Volume 25: 2987-2993 https://doi.org/10.1245/s10434-018-6614-3	2nd July 2018

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
2.	Non-Inferiority Randomized Trial	Targeted intraoperative radiotherapy vs. whole breast radiotherapy: an international, prospective, randomized, non-inferiority phase 3 trial – Prof Jayant S. Vaidya *et al* This trial is registered with ClinicalTrials.gov, number NCT00983684.	Comparison of targeted intraoperative radiotherapy with the conventional policy of whole breast external beam radiotherapy. A study of 2232 patients	Lancet 2010; 376: 91–102 http://dx.doi.org/10.1016/S0140-6736(10)60837-9	5th June 2010
3.	Non-Inferiority Randomized Trial	Risk-adapted targeted intraoperative radiotherapy vs whole-breast therapy for breast cancer. 5-year results for local control and overall survival from the TARGIT-A randomized trial – Prof Jayant S. Vaidya *et al* This trial is registered with ClinicalTrials.gov, number NCT00983684.	Comparison of risk-adapted radiotherapy using single-dose targeted intraoperative radiotherapy (TARGIT) versus fractionated external beam radiotherapy (EBRT) for breast cancer. 5-year results for local recurrence and the first analysis of overall survival A study of 3451 patients	Lancet 2014; 383: 603–613 http://dx.doi.org/10.1016/S0140-6736(13)61950-9	15th February 2014

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise.*

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	Non-Inferiority Non-Randomized Trial	A Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft® Axxent® eBx™ System at the Time of Breast Conservation Surgery for Early Stage Breast Cancer – Helena Chang and Nisar Syed *et al* This trial is registered with ClinicalTrials.gov, number NCT01644669.	To demonstrate that the safety and efficacy of IORT using the Xoft Axxent eBx System is no worse (non-inferior) than whole breast irradiation (WBI) when used as stand-alone radiation treatment in breast conserving therapy in women with early stage breast cancer. A study of 1200 patients	https://clinicaltrials.gov/ct2/show/NCT01644669	TBA

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Faculty of Radiation Oncology - Royal Australia and New Zealand College of Radiologists

    Refer Faculty Position Paper on Techniques and Technologies included as part of our submission.

20. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    Faculty of Radiation Oncology - Royal Australia and New Zealand College of Radiologists

21. **List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    Breast Cancer Network Australia (BCNA)

    Breast Cancer Aotearoa Coalition (BCAC)

    Refer joint submission from the Breast Cancer Network Australia (BCNA) and Breast Cancer Aotearoa Coalition (BCAC) included as part of our submission.

22. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    Zeiss

23. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    Name of expert 1:

    Telephone number(s):

    Email address:

    Justification of expertise:

    Name of expert 2:

    Telephone number(s):

    Email address:

    Justification of expertise:

    Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Early Stage Breast Cancer

It is estimated that breast cancer will be the most commonly diagnosed cancer in 2018 and there were approximately 18,000 new cases of breast cancer diagnosed which accounts for approximately 13% of all new cancers diagnosed that year.

The estimated number of deaths from breast cancer was around 3,000 in 2018 so approximately 17% of the number of new breast cancer cases diagnosed.

The estimated number of deaths from all cancers in 2018 was approximately 6.5% of the number of all new cancer cases diagnosed so the mortality rate for breast cancer is significantly higher.

Patients diagnosed with breast cancer had around a 90% chance of surviving for 5 years.

References: Australian Institute of Health and Welfare
Australian Government – Cancer Australia

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Patient suitability for IORT delivered using the Xoft® Axxent® treatment device is the same existing MBS item number 15900, namely:

- is 45 years of age or more; and
- has a T1 or small T2 (less than or equal to 3cm in diameter) primary tumour; and
- has an histologic Grade 1 or 2 tumour; and
- has an oestrogen-receptor positive tumour; and
- has a node negative malignancy; and
- is suitable for wide local excision of a primary invasive ductal carcinoma that was diagnosed as unifocal on conventional examination and imaging; and
- has no contra-indications to breast irradiation

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

Detection of early stage breast cancer in asymptomatic patients is most likely to occur at the time of routine mammography screening as provided for by BreastScreen Australia

For symptomatic patients, finding a lump or some other physical symptom may indicate the possibility of early stage breast cancer.

In either case, the clinical management pathway before the patient would be eligible for the proposed medical service is the same

- Diagnostic mammography
- Supplementary diagnostic imaging using ultrasound, MRI or Molecular Breast Imaging

- Biopsy performed under stereotactic guidance. Alternatively, ultrasound or MRI guidance
- Diagnosis of early stage breast cancer limited to breast and/or regional lymph node confirmed
- Patient referred on for specialist appointments with Breast Surgeon and Oncologist
- Patient opts for Mastectomy or Breast Conserving Surgery
- If breast conserving surgery is the chosen path, the patient may undergo prophylactic Radiotherapy post-surgery

A clinical management algorithm is provided as an attachment

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

Patients have only one treatment which is delivered to the tumour bed in a single fraction of targeted radiotherapy immediately following the surgical removal of early stage breast cancer as part of breast-conserving surgery, partial mastectomy or lumpectomy surgical procedures.

Following lesion excision, the balloon applicator of the Xoft®Axxent® system is inserted into the surgical cavity and inflated with saline to the cavity volume determined using a cavity evaluation device. To prevent skin burns, an Ultrasound unit is used to verify that the distance from the skin surface to the balloon applicator surface is greater than 1cm. Shielding of critical structures is achieved by the placement of stainless-steel shields into the surgical site.

The x-ray source is then inserted into the applicator for delivery of a 20Gy single fraction prophylactic treatment. The treatment time is dependent on the size of the applicator but ranges between 8-15 minutes.

Following radiation delivery, the balloon applicator is deflated and withdrawn and the wound is closed in the usual fashion to achieve a good cosmetic result.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

The proposed medical service includes the use of a registered trademarked device, Axxent® Electronic Brachytherapy (eBx®) System® by Xoft®. Xoft® is a subsidiary of iCAD Inc.

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Not Applicable

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

No limitations as the delivery of the proposed medical service (IORT) is a once-off treatment delivered at the same time, and as part of breast conserving surgery.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

Breast Conserving Surgery

32. If applicable, advise which health professionals will primarily deliver the proposed service:

Breast Surgeons and Radiation Oncologists

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Not Applicable. Current Radiation Licencing laws restrict delivery of the proposed medical service to Radiation Oncologists.

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

The proposed Medical Service can only be delivered by a licenced Radiation Oncologist who has received appropriate training and accreditation for delivery of the proposed medical service.

Only the Breast Surgeon and Radiation Oncologist are in a position to determine if the patient is an eligible candidate for the proposed medical service so referrals should be restricted accordingly.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

Prior to the first T-IORT treatment delivery, all service providers must undertake appropriate training and achieve certification in treatment delivery and radiation safety. Service providers include:

(i) Breast surgeons
(ii) Radiation oncologists
(iii) Medical physicists

IORT is delivered by a radiation oncologist. A medical physicist is also required in order to calibrate the device.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- [x] Inpatient private hospital (admitted patient)
- [x] Inpatient public hospital (admitted patient)
- [ ] Private outpatient clinic
- [ ] Public outpatient clinic
- [ ] Emergency Department
- [ ] Private consulting rooms - GP
- [ ] Private consulting rooms – specialist
- [ ] Private consulting rooms – other health practitioner (nurse or allied health)
- [ ] Private day surgery clinic (admitted patient)
- [ ] Private day surgery clinic (non-admitted patient)
- [ ] Public day surgery clinic (admitted patient)
- [ ] Public day surgery clinic (non-admitted patient)
- [ ] Residential aged care facility
- [ ] Patient's home
- [ ] Laboratory
- [ ] Other – please specify below

Specify further details here

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

It is likely that both public and private hospitals will offer the proposed medical service going forward. There is no difference in the delivery of the proposed medical service between public and private entities.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- [x] Yes
- [ ] No – please specify below

Specify further details here

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

External Beam Whole Breast Radiotherapy (EB-WBRT) is the appropriate comparator.

Unlike the proposed medical service (IORT) which is delivered at the same time as breast conserving surgery, External Beam Whole Breast Radiotherapy (the comparator) is delivered some-time after surgery in an out-patient environment.

External Beam Whole Breast Radiotherapy is typically delivered over 5-7 weeks of daily radiotherapy treatments.

Recent advances in the provision of Hypofractionated External Beam Whole Breast Radiotherapy have cut overall treatment time to around three weeks.

In both cases, patients are required to attend a Radiotherapy facility on a daily basis to receive treatment which results in a high incidence of non-compliance for a number of reasons including, but not limited to:

- Patient lives in a remote geographic location a considerable distance away from a Radiotherapy treatment facility.
- Patient cannot afford to take time off work to attend a Radiotherapy treatment facility on a daily basis.
- Family commitments such as looking after children prevent daily attendance at a Radiotherapy treatment facility.

In many cases, due to the above restrictions, many patients diagnosed with early stage breast cancer opt for a mastectomy instead of breast conserving surgery.

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

☒ Yes (please list all relevant MBS item numbers below)
☐ No

15221, 15236, 15251, 15266, 15550, 15562 and 15705

40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

NBCC Recommended follow-up schedule

	1-2 Years	3-5 Years	After 5 Years
History & Exam	Every 3 months	Every 6 months	Every year
Mammography (& adjunctive imaging if indicated)	At 6-12 months after radiotherapy for conserved breast	Every year	Every year

- Chest X-ray: Only if clinically indicated
- Bone Scan, blood count & biochemistry: Only if clinically indicated

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

☐ In addition to (i.e. it is an add-on service)
☒ Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

The inclusion criteria for the proposed medical service (IORT) suggests that only around 20% of patients undergoing breast conserving surgery would be eligible for prophylactic IORT treatment at the time of breast conserving surgery and this percentage is unlikely to change in the foreseeable future.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

The clinical management pathway remains the same for the proposed medical service (IORT) and External Beam Whole Breast Radiotherapy (the comparator)

NBCC Recommended follow-up schedule

	1-2 Years	3-5 Years	After 5 Years
History & Exam	Every 3 months	Every 6 months	Every year
Mammography (& adjunctive imaging if indicated)	At 6-12 months after radiotherapy for conserved breast	Every year	Every year

- Chest X-ray: Only if clinically indicated
- Bone Scan, blood count & biochemistry: Only if clinically indicated

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

The results of recent randomised and non-randomised clinical trials indicate that the proposed medical service (IORT) has been proven to be non-inferior to External Beam Whole Breast Radiotherapy (the comparator) in terms of safety and clinical effectiveness for the defined patient group specified in Part 6a, section 25.

44. Please advise if the overall clinical claim is for:

☐ Superiority
☒ Non-inferiority

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

MSAC has already assessed and accepted the comparative efficacy and safety of the proposed medical service (IORT) as compared to External Beam Whole Breast Radiotherapy (the comparator) in a previous application by Zeiss, refer Application No. 1189

Furthermore, the Relative Biological Effectiveness (RBE) for comparable applicator sizes has been conclusively demonstrated to be in the order of less than 1% between the XOFT and Zeiss IORT systems, and MSAC has already accepted the evidence of technical equivalence between the two systems in a previous application, refer Application No. 1429

A summary of the health outcomes for the proposed medical service (IORT) is as follows:

- The primary health outcome (effect) is the prevention of the local recurrence of breast cancer.
- Secondary health outcomes are:
    - comparable overall survival rates,
    - improved cosmesis
    - reduced toxicity.
- Other outcomes include:
    - a reduced time spent in the hospital setting by the patient
    - a more rapid return to daily activities

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

There were approximately 18,000 new cases of breast cancer diagnosed in 2018 which accounts for approximately 13% of all new cancers diagnosed that year.

The estimated number of deaths from breast cancer was around 3,000 in 2018 so approximately 17% of the number of new breast cancer cases diagnosed.

The estimated number of deaths from all cancers in 2018 was approximately 6.5% of the number of all new cancer cases diagnosed so the mortality rate for breast cancer is significantly higher.

Patients diagnosed with breast cancer had around a 90% chance of surviving for 5 years.

References: Australian Institute of Health and Welfare
Australian Government – Cancer Australia

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The proposed medical service is delivered as a one-off treatment at the time of breast conserving surgery so is only delivered once.

48. How many years would the proposed medical service(s) be required for the patient?

Not applicable, the proposed medical service is a one-off treatment

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

200-300

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

2000

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

A rough estimate of the current funding for a typical course of EB-WBRT (the comparator) delivered using dual photon 3D-CRT linear accelerator is as follows:

MBS Item	Description	MBS per attendance*	HPG per attendance	Number of attendances	Total
MBS15550	Simulation	$658.60	$101.94	1	$760.54
MBS15562	Dosimetry	$1,120.75	$107.44	1	$1,228.19
MBS15251	Treatment	$59.65	$55.97	25	$2,890.50
MBS15266	Treatment (additional fields)	$173.50		25	$4,337.50
MBS15705	Verification	$76.60		8	$612.80
Total					**$9,830**

On the assumption that around 15% of patients undergoing IORT at the time of BCS will receive a supplemental booster course of EB-WBRT (the comparator) based on pathology at the time of surgery, the following estimated cost savings per patient could be achievable when using the proposed medical service (IORT) as opposed to EB-WBRT (the comparator).

Treatment	T-IORT	EB-WBRT	Incremental
Targeted Intraoperative Radiotherapy (T-IORT) in conjunction with BCS	$1,117	$0	+$1,117
Additional OR and Physicist time – 30min	$1,500	$0	+$1,500
Supplemental EB-WBRT following Pathology for 15% of patients	$1,280	$0	+$1,280
External Beam Whole Breast Radiotherapy (EB-WBRT)	$0	$9,830	-$9,830
Total	$3,897	$9,830	**-$5,933**

52. Specify how long the proposed medical service typically takes to perform:

The actual treatment time is dependent on the size of the applicator but ranges between 8-15 minutes. Overall additional breast conserving surgery operating theatre time is around 30 minutes.

By comparison, a course of EB-WBRT (the comparator) requires the patient to attend a treatment centre on a daily basis for around 5-6 weeks (typical treatment regime - 50Gy in 25 fractions).

Hypofractionated EB-WBRT can cut treatment time down to about three weeks (typical treatment regime - 40Gy in 15 fractions).

However, whilst the actual treatment time for each fraction of EB-WBRT is relative short, the fact remains that the patient has to attend a treatment facility on a daily basis for several weeks so in many cases, women who need to travel significant distances to receive their Radiotherapy treatment may choose not access radiotherapy, and as a consequence, suffer poorer outcomes.

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

MSAC has already accepted the evidence of technical equivalence between the Intrabeam® and Xoft® Axxent® devices in a previous application No. 1429 so rather than adding new MBS item numbers, the applicant is seeking a simple amendment to existing MBS item numbers 15900 and 31516. The requested amendments to MBS item numbers 15900 and 31516 are as follows:

15900	BREAST, MALIGNANT TUMOUR, targeted intraoperative radiotherapy, using an Intrabeam® or Xoft® Axxent® device, delivered at the time of breast-conserving surgery (partial mastectomy or lumpectomy) for a patient who: a) is 45 years of age or more; and b) has a T1 or small T2 (less than or equal to 3cm in diameter) primary tumour; and c) has an histologic Grade 1 or 2 tumour; and d) has an oestrogen-receptor positive tumour; and e) has a node negative malignancy; and f) is suitable for wide local excision of a primary invasive ductal carcinoma that was diagnosed as unifocal on conventional examination and imaging; and g) has no contra-indications to breast irradiation Fee: $250.00 Benefit: 75% = $187.50
31516	BREAST, MALIGNANT TUMOUR, complete local excision of, with or without frozen section histology when targeted intraoperative radiotherapy (using an Intrabeam® or Xoft® Axxent® device) is performed concurrently, if the requirements of item 15900 are met for the patient (Anaes.) (Assist.) Fee: $867.00 Benefit: 75% = $650.25