alphaXRT Submission to the 2016 Review of the Radiation Oncology Health Program Grants (ROHPG) Scheme

April 2016

Introduction

alphaXRT welcomes the Australian Government's review of the ROHPG Scheme as part of the current wider Healthier Medicare initiative. We endorse the goals of the ROHPG Scheme in endeavouring to ensure the availability and equitable access to radiotherapy services. The review of the scheme is timely as the current scheme is likely to benefit from reforms that take into account the technological advances that underpin current radiotherapy practice.

About alphaXRT

alphaXRT Ltd specialises in the marketing, sales, service and support of software and equipment for the treatment of cancer. This includes medical devices that are used in training hospital staff and in the routine treatment of patients, quality assurance and test tools that are used to check and monitor the clinical energies delivered, and patient positioning and immobilisation equipment.

alphaXRT is dedicated to improving the lives of cancer patients in Australia and New Zealand by providing excellence in radiotherapy technology. We aim to partner with hospitals, doctors, nurses and other health care professionals to deliver the best available radiotherapy treatment to cancer patients.

alphaXRT Radiotherapy Technologies in Australia

TomoTherapy® Systems

The TomoTherapy® System provides a type of Intensity Modulated Radiotherapy (IMRT) via a linear accelerator mounted on a computed tomography (CT) scanner. The radiation is delivered in slices (hence the use of the Greek prefix 'tomo' which means 'slice'). It is also known as 'helical' tomotherapy. The TomoTherapy® machine allows treatment to be delivered continually from all angles around the patient allowing physicians more control in targeting the tumour and more assurance that the dose will be confined to the tumour and minimise dose to normal tissues and organs.

Reimbursement Status

The distributors of TomoTherapy® were informed in 2014 that the system was eligible to be considered for the Scheme as a Single Photon Linear Accelerator.

IMRT and IGRT were included on the Commonwealth Medical Benefits Schedule in January 2016. The following MBS item numbers are now available:

15555

SIMULATION FOR INTENSITY-MODULATED RADIATION THERAPY (IMRT), with or without intravenous contrast medium if:

1. Treatment set-up and technique specifications are in preparation for three-dimensional conformal radiotherapy dose planning; and
2. Patient set-up and immobilisation techniques are suitable for reliable CT-image volume data acquisition and three-dimensional conformal radiotherapy; and
3. A high quality CT-image volume dataset is acquired for the relevant region of interest to be planned and treated; and
4. The image set is suitable for the generation of quality digitally-reconstructed radiographic images.

Fee: $710.55 **Benefit:** 75% = $532.95 85% = $631.05

15565

Preparation of an IMRT DOSIMETRY PLAN, which uses one or more CT image volume sets, if:

(a) in preparing the IMRT dosimetry plan:

(i) the differential between target dose and normal tissue dose is maximised, based on a review and assessment by a radiation oncologist; and

(ii) all gross tumour targets, clinical targets, planning targets and organs at risk are rendered as volumes as defined in the prescription; and

(iii) organs at risk are nominated as planning dose goals or constraints and the prescription specifies the organs at risk as dose goals or constraints; and

(iv) dose calculations and dose volume histograms are generated in an inverse planned process, using a specialised calculation algorithm, with prescription and plan details approved and recorded in the plan; and

(v) a CT image volume dataset is used for the relevant region to be planned and treated; and

(vi) the CT images are suitable for the generation of quality digitally reconstructed radiographic images; and

(b) the final IMRT dosimetry plan is validated by the radiation therapist and the medical physicist, using robust quality assurance processes that include:

(i) determination of the accuracy of the dose fluence delivered by the multi-leaf collimator and gantryposition (static or dynamic); and

(ii) ensuring that the plan is deliverable, data transfer is acceptable and validation checks are

(iii) completed on a linear accelerator; and

(iv) validating the accuracy of the derived IMRT dosimetry plan in a known dosimetric phantom; and

(v) determining the accuracy of planned doses in comparison to delivered doses to designated points within the phantom or dosimetry device; and

(c) the final IMRT dosimetry plan is approved by the radiation oncologist prior to delivery.

Fee: $3,313.85 **Benefit:** 75% = $2,485.40 85% = $3,234.35

15715
RADIATION ONCOLOGY TREATMENT VERIFICATION of planar or volumetric IGRT for IMRT, involving the use of at least 2 planar image views or projections or 1 volumetric image set to facilitate a 3-dimensional adjustment to radiation treatment field positioning, if: (a) the treatment technique is classified as IMRT; and (b) the margins applied to volumes (clinical target volume or planning target volume) are tailored or reduced to minimise treatment related exposure of healthy or normal tissues; and (c) the decisions made using acquired images are based on action algorithms and are given effect immediately prior to or during treatment delivery by qualified and trained staff considering complex competing factors and using software driven modelling programs; and (d) the radiation treatment field positioning requires accuracy levels of less than 5mm (curative cases) or up to 10mm (palliative cases) to ensure accurate dose delivery to the target; and (e) the image decisions and actions are documented in the patient's record; and (f) the radiation oncologist is responsible for supervising the process, including specifying the type and frequency of imaging, tolerance and action levels to be incorporated in the process, reviewing the trend analysis and any reports and relevant images during the treatment course and specifying action protocols as required; and (g) when treatment adjustments are inadequate to satisfy treatment protocol requirements, replanning is required; and (h) the imaging infrastructure (hardware and software) is linked to the treatment unit and networked to an image database, enabling both on line and off line reviews.
Fee: $76.60 **Benefit:** 75% = $57.45 85% = $65.15

Existing MBS item numbers which can be used in IMRT include:

15215
RADIATION ONCOLOGY TREATMENT, using a single photon energy linear accelerator with or without electron facilities - each attendance at which treatment is given - 1 field - treatment delivered to primary site (lung)
Fee: $59.65 **Benefit:** 75% = $44.75 85% = $50.75

15230
RADIATION ONCOLOGY TREATMENT, using a single photon energy linear accelerator with or without electron facilities - each attendance at which treatment is given - 2 or more fields up to a maximum of 5 additional fields (rotational therapy being 3 fields) - treatment delivered to primary site (lung)
The fee for item 15215 plus for each field in excess of 1, an amount of $37.95

15224
RADIATION ONCOLOGY TREATMENT, using a single photon energy linear accelerator with or without electron facilities - each attendance at which treatment is given - 1 field - treatment delivered to primary site for diseases and conditions not covered by items 15215, 15218 and 15221
Fee: $59.65 **Benefit:** 75% = $44.75 85% = $50.75

Other item numbers are available for breast and prostate lesions.

CyberKnife® Systems

The CyberKnife®System is a robotic stereotactic radiosurgery system and is also a stereotactic radiotherapy system. It uses image guidance software to track and continually adjust treatment for any patient or tumour movement. It allows patients to breathe normally and be more relaxed during treatment. It is able to direct radiotherapy to a tumour with sub-millimetre accuracy, sparing surrounding healthy tissue.

Reimbursement Status

The Medical Services Advisory Committee (MSAC) has advised that they consider CyberKnife® to be a variant of Image Guided Radiotherapy (IGRT) and is eligible for consideration of the ROHPG scheme in association with the following MBS item numbers:

15559
DOSIMETRY FOR THREE DIMENSIONAL CONFORMAL RADIOTHERAPY OF LEVEL 2 COMPLEXITY where: (a) dosimetry for a two phase three dimensional conformal treatment plan using CT image volume dataset(s) with at least one gross tumour volume, two planning target volumes and one organ at risk defined in the prescription; or (b) dosimetry for a one phase three dimensional conformal treatment plan using CT image volume datasets with at least one gross tumour volume, one planning target volume and two organ at risk dose goals or constraints defined in the prescription; or (c) image fusion with a secondary image (CT, MRI or PET) volume dataset used to define target and organ at risk volumes in conjunction with and as specified in dosimetry for three dimensional conformal radiotherapy of level 1 complexity. All gross tumour targets, clinical targets, planning targets and organs at risk as defined in the prescription must be rendered as volumes. The organ at risk must be nominated as planning dose goals or constraints and the prescription must specify the organs at risk as dose goals or constraints. Dose volume histograms must be generated, approved and recorded with the plan. A CT image volume dataset must be used for the relevant region to be planned and treated. The CT images must be suitable for the generation of quality digitally reconstructed radiographic images
Fee: $866.55 **Benefit:** 75% = $649.95 85% = $787.05

15562
DOSIMETRY FOR THREE DIMENSIONAL CONFORMAL RADIOTHERAPY OF LEVEL 3 COMPLEXITY - where: (a) dosimetry for a three or more phase three dimensional conformal treatment plan using CT image volume dataset(s) with at least one gross tumour volume, three planning target volumes and one organ at risk defined in the prescription; or (b) dosimetry for a two phase three dimensional conformal treatment plan using CT image volume datasets with at least one gross tumour volume, and (i) two planning target volumes; or (ii) two organ at risk dose goals or constraints defined in the prescription. or (c) dosimetry for a one phase three dimensional conformal treatment plan using CT image volumedatasets with at least one gross tumour volume, one planning target volume and three organ at risk dose goals or constraints defined in the prescription; or (d) image fusion with a secondary image (CT, MRI or PET) volume dataset used to define target and organ at risk volumes in conjunction with and as specified in dosimetry for three dimensional conformal radiotherapy of level 2 complexity. All gross tumour targets, clinical targets, planning targets and organs at risk as defined in the prescription must be rendered as volumes. The organ at risk must be nominated as planning dose goals or constraints and the prescription must specify the organs at risk as dose goals or constraints. Dose volume histograms must be generated, approved and recorded with the plan. A CT image volume dataset must be used for the relevant region to be planned and treated. The CT images must be suitable for the generation of quality digitally reconstructed radiographic images
Fee: $1,120.75 **Benefit:** 75% = $840.60 85% = $1,041.25

In addition, External Beam Radiotherapy (EBRT) item numbers are available as for IMRT

This item number relating to Stereotactic Radiotherapy is also available for CyberKnife® treatment but is not eligible to be considered for ROHPG payments

15600
STEREOTACTIC RADIOSURGERY, including all radiation oncology consultations, planning, simulation, dosimetry and treatment
Fee: $1,702.30 **Benefit:** 75% = $1,276.75 85% = $1,622.80

Response to the Review

alphaXRT would like to address the following key areas of the review

- Benefits and limitations of the Scheme
- Potential alternative funding methods
- Determining eligible equipment

Benefits of the Scheme

The ROHPG Scheme is a valuable mechanism to ensure the appropriate placement of radiotherapy facilities and the equitable distribution of radiotherapy capital equipment in Australia. A significant advantage of the Scheme is that funds in the public sector are quarantined for the purchase of equipment and not consumed in the ongoing costs of administering a radiotherapy practice. We understand that the Department of Health may be considering combining ROHPG payments and CMBS payments. alphaXRT believes that if this was introduced then one of the major benefits of the scheme would be lost.

Limitations of the Scheme

Definitions:

The current definitions of eligible equipment in the ROHPG Scheme are clearly anachronistic and an overhaul of the definitions to take into account current technologies would be very welcome. The current definitions of linear accelerators (Linacs) are:

- Single Photon Linear Accelerator (SPLA) with Electronic Portal Imaging and Multi Leaf Collimator (MLC)
- Dual Modality Linear Accelerator (DMLA) with Electronic Portal Imaging and Multi Leaf Collimator (MLC)

These definitions do not take into account the current methods by which therapy is provided. DMLAs are funded at a premium to SPLAs. This funding differentiation is at odds with current practice. This results in older DMLAs which are not capable of delivering sophisticated services such as Intensity Modulated Radiotherapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT) receiving higher funding than SPLAs that are equipped to deliver these services.

In addition, portal imaging is essentially two-dimensional but assessment is more accurate with current three-dimensional imaging technologies such as fan beam megavoltage computed tomography (MVCT) or cone beam kilovoltage imaging. It should also be noted that SBRT and hypofractionated treatments require fewer therapy sessions and therefore the requirement for Electronic Portal Imaging is redundant when a patient is treated with this modality. As the treatment is delivered over three to five treatment sessions, changes in the patient (weight loss etc) are not significant enough to warrant off-line assessment.

The current definitions of ‘Eligible Treatment Planning Computer Systems’ are

- CT Interfacing Planning Computer System with 3 or less workstations
- CT Interfacing Planning Computer System with 4 or more workstations

As with the definitions for the Linacs, these definitions are not in alignment with the needs of a contemporary radiotherapy practice. Contemporary treatment planning is not necessarily related to the number of workstations and is not limited to CT. Contemporary practice requires not just CT but multimodality imaging including 3D dose calculations algorithms, IMRT and rotational IMRT treatment planning.

alphaXRT recommends that the review consider the classification of radiotherapy technologies included in The Royal Australian and New Zealand College of Radiologists' Position Paper[1] The Faculty of Radiation Oncology (FRO) position is that the following techniques of delivering radiation therapy are essential for some Australian patients.

- Image Guided Radiation Therapy (IGRT)
- Intensity Modulated Radiation Therapy (IMRT)
- Stereotactic Radiation Treatments (including SRS, SRT and SBRT)
- Advanced Imaging for Treatment Planning (4DCT, PET-CT, MRI)
- Brachytherapy
- Particle Therapy

Incorporating the FRO's classification into the definitions of radiotherapy technologies included in the ROHPG scheme would better reflect current practice and result in a more fit for purpose scheme.

Potential Alternative Funding Mechanisms

Attendance Based Payment Model – As noted above modern SBRT and Stereotactic Radiation Surgery (SRS) are delivered in one to five treatment sessions. The treatment sessions however are longer but more intense. SBRT may take longer than an hour to deliver.

ROHPG payments do not take this into account and are geared to older modalities where 20-30 treatment sessions may be necessary but however only take 15 minutes to deliver. This table from the ROHPG guidelines highlights this issue:

Notional life and services of radiation oncology equipment[2]

Equipment	Notional Life (Years)	Notional Lifetime Services
Single Photon Linear Accelerators	10	82,800
Dual Modality Linear Accelerators	10	82,800
Simulators	10	15,000
High Dose Rate Brachytherapy (HDR)	10	1500
Low Dose Rate Brachytherapy (LDR)	5	200

[1] POSITION PAPER *'Techniques and Technologies in Radiation Oncology 2013 Horizon Scan Australia'* Faculty of Radiation Oncology

[2] http://www.health.gov.au/internet/main/publishing.nsf/Content/BF657EB28A5C5A6FCA257BF0001E02C7/$File/ROHPG%20Guidelines.pdf

If taken to its logical conclusion, SBRT equipment would exceed its notional life of 10 years long before the notional life services to which the ROHPG payments are linked are exhausted.

alphaXRT recommends that the Department of Health consider a course-based payment system where ROHPG payments are linked to the number of patients rather than the number of treatments.

Determining Eligible Equipment

The Medical Benefits Schedule (MBS) is linked to the ROPHG scheme in that ROHPG payments are paid per MBS item number. While alphaXRT understands and supports the Australian government's requirement for sound evidence based decisions, the Medical Benefits Advisory Committee (MSAC) assessment processes and requirements for randomised controlled clinical trials (RCTs) have proved an insurmountable barrier to most contemporary radiotherapy technologies.

As noted by the RANZCR in their commentary in the Public Summary Document of Application 1182 – Intensity Modulated Radiation Therapy (IMRT) in the treatment of cancer, '*conducting randomised controlled trials in radiotherapy is inherently difficult. All radiation therapy is delivered with the goal of minimising radiation to the surrounding tissue while delivering radiation to the tumour. Any RCT that randomised patients to a trial arm that would necessarily deliver more radiation to normal tissue would be unethical'*.[3] It would also be extremely difficult to recruit patients under such circumstances.

Australia lags behind other countries in the introduction of advanced radiotherapy technologies. For example, the CyberKnife® and TomoTherapy® Systems are available and supported by public funding in most European countries (including the United Kingdom), Japan and the USA. alphaXRT reiterates our support for strong evidence based decision making. However, we believe that in the field of radiotherapy that the Medical Services Advisory Committee (MSAC) in it's understandable zeal not to recommend funding for ineffective technologies, rejects technologies that are likely to offer benefits to the Australian population and have been adopted by similar advanced countries around the world.

alphaXRT welcomes the recent addition of new Item numbers for IGRT and IMRT although we note that there is no increase in overall MBS funding for these modalities. As stated above a revised classification scheme should be a priority for the ROHPG scheme. We also note that other contemporary therapies which have associated MBS item numbers are not supported by the ROHPG scheme.

MSAC has noted that the item number:

15600 STEREOTACTIC RADIOSURGERY, including all radiation oncology consultations, planning, simulation, dosimetry and treatment **Fee:** $1,702.30 **Benefit:** 75% = $1,276.75, 85% = $1,622.80

[3] http://msac.gov.au/internet/msac/publishing.nsf/Content/1182-public

[15600] Includes a component for capital equipment although this is not described in the item number. It is difficult to understand the rationale for some advanced equipment being excluded from the scheme.
As noted above the new item numbers are a welcome acknowledgement of contemporary radiotherapy practice, however unless these technologies receive corresponding support from the ROHPG scheme the addition of the item numbers will be of limited benefit in improving access to these technologies.

alphaXRT recommends that the classifications of eligible equipment take into account recent additions to the MBS such as IMRT, IGRT Intraoperative Breast Radiotherapy (IORT).

Conclusion

alphaXRT is wholly supportive of the ROHPG and believes it is a vital element in ensuring equitable access to radiotherapy for cancer patients in Australia. However, the scheme would benefit from the following measures.

1. A redesign of the classification system so that it accurately reflects the technologies that the RANZCR recommends as essential.
2. Moving from an attendance based funding model to one which is based on a course of treatment per patient.
3. It is imperative that MSAC acknowledges the real ethical difficulties in conducting randomised controlled clinical trials where patients may be randomised to a treatment arm that necessarily delivers more radiation to healthy tissues. Until this is acknowledged and accommodated there will be real barriers to the reasonable adoption of new radiotherapy technologies in Australia.

alphaXRT would like to thank the Department of Health for allowing us the opportunity to contribute to the review.